CHAPTER 04

LABEL CLAIMS / ADVERTISEMENTS

Makers of drugs, traditional foods, and dietary supplements can all expect more action from the feds these days. And when labeling and advertising claims are in issue, these product categories overlap as never before.

That's because for over a decade, legal professionals, regulatory officials, and industry have faced new challenges as drugs and foods, including dietary supplements (marketed as "nutraceuticals"), have begun to overlap in important ways due to changes in law, and changes in the marketing and product development habits of the industry.

Packagers and consumers alike see the evidence every day: dietary supplements that claim to help with one or another health condition, or traditional foods like orange juice or green tea that claim to prevent disease, sometimes based on their traditional formulations, and sometimes based on fortification. It was the supplements whose claims proliferated first, followed by more claims on labels of traditional foods.

Though you see it written and hear it said all the time, it's simply not true that "dietary supplements are not regulated." They are plenty regulated, with detailed labeling requirements, limits on the claims their labels can make for health effects, required manufacturing practices, and other requisites applicable to the companies who make them. While supplement labels can claim effects on the structure or function of the body, they cannot in most cases claim effect on a disease. Supplement companies must have substantiation for any such claim they make, and give the FDA written notice of the claim.

Dietary supplements are not, however, approved for marketing in advance by the FDA or any other agency, the way new drugs are, because, generally speaking, supplements tend to be safe to those who take them (or at least not unsafe enough as a class to merit a whole government approval apparatus). That's not a trivial matter, and it's probably why supplements are often perceived as unregulated.

Also emerging and sharing characteristics with foods and drugs is a whole category called "medical foods," which thus far is lightly regulated by the FDA, but includes foods that are intended for use under medical supervision to address a specific dietary need, though they are sold freely like other foods and labeled as foods.

In many cases, what makes something a "drug" under the law is its intended use, revealed most often by the claims on its label—if it's a product that claims to have an effect on a disease, usually the law says it's a drug, even if the manufacturer thinks it's a food or that special category of foods called dietary supplements.

So supplement products, or even traditional foods, compete directly in some cases with drugs when they claim to have effect on the structure of the body. Imagine you make such a drug product, which you spent years and millions of dollars in getting approved by the FDA, and have to compete with a supplement that does not require approval.

As a drug maker, you might be pleased to see the agency cracking down on supplements that make improper drug claims on their labels or in advertising.
The FDA will occasionally write a Warning Letter to a maker of supplements who makes a disease claim on its label or Web site or elsewhere, and will tell them that such claims make the products into drugs under the law. They will also warn makers of traditional foods who make improper disease claims, though some food types have been cleared to make specified disease prevention claims.

Recent FDA Warning Letters indicate that the agency is not reluctant to warn companies about alleged labeling violations even if the violations have a tenuous connection to health consequences.

A product is not always what a packager thinks it is, for legal purposes, and the claims made for the product's effect are a key determinant of its status. With foods, dietary supplements, and drugs able these days to make some similar types of claims, and a newly active FDA taking action against violations, packagers need to be vigilant and careful about their labeling and advertising content.


Drug labeling refers to all of the printed information that accompanies a drug, including the label, the wrapping and the package insert. Drug labeling is regulated by the Food and Drug Administration's Division of Drug Marketing, Advertising, and Communications. These regulations apply to prescription drugs, over-the-counter (nonprescription) drugs, and dietary supplements.

The Food and Drug Administration (FDA) requires that drug labeling be balanced and not misleading. The label must be scientifically accurate and provide clear instruction to health care practitioners for prescription drugs and to consumers for over-the-counter drugs and supplements. Labeling regulations require that the statement of ingredients must include all ingredients, in the order in which they are used in the drug. These ingredients must also be identified by their established name.

In evaluating prescription drug labels, the FDA looks at the overall usefulness of the information that accompanies the drug. The name of the medicine along with any critical warnings must be given top billing. The label must describe the uses of the medicine along with the conditions under which the medicine should not be used. The consumer must be given directions for the contraindications; for example, "Talk to your health care professional before taking this medication if any of these apply to you."

Under FDA regulations, the label must describe foods, drugs and activities that the patient should avoid while taking the medication, along with any related precautions. The drug manufacturer must spell out the symptoms of any adverse reactions to the drug. The FDA requires the manufacturer to collect this information. If the patient faces any risk of drug tolerance or dependency while taking the drug, the label must contain a warning.

The label must include instructions for correctly using the medicine, including the dosage and what to do if the patient misses a dose. This description should cover any special instructions such as taking the medicine with food or water. In addition, the label should spell out storage instructions and general instructions, such as discussing questions with a health professional, because the label is not intended to be all-inclusive. The label should warn of the danger of giving the drug to someone other than the patient. (http://www.faaqs.org/health/topics/89/Drug-labeling.html)

Pharmaceutical marketing, sometimes called medico-marketing, is the business of advertising or otherwise promoting the sale of pharmaceuticals or drugs. Evidences show that marketing practices can negatively affect both patients and the health care profession. Many countries have measures in place to limit advertising by pharmaceutical companies. Pharmaceutical company spending on marketing far exceeds that spent on research.
The marketing of medication has a long history. The sale of miracle cures, many with little real potency, has always been common. Marketing of legitimate non-prescription medications, such as pain relievers or allergy medicine, has also long been practiced, although, until recently, mass marketing of prescription medications has been rare. It was long believed that since doctors made the selection of drugs, mass marketing was a waste of resources; specific ads targeting the medical profession were thought to be cheaper and just as effective. This would involve ads in professional journals and visits by sales staff to doctor’s offices and hospitals. An important part of these efforts was marketing to medical students.

To health care providers: Marketing to health care providers takes four main forms: gifting, detailing, drug samples, and sponsoring continuing medical education (CME). In Britain, Canada, New Zealand, and the United States 80-90% of physicians see pharmaceutical representatives. Of statements made by pharmaceutical representatives 11% are false and of the false statements all are in favour of the representatives’ drugs. While very few physicians consider themselves susceptible to detailing, 84% of them believed that their colleagues are.

The Partners Healthcare, Massachusetts’ largest hospital and physician network, has adopted new guidelines prohibiting physicians and researchers from accepting gifts from pharmaceutical manufacturers. This will include meals or individual drug samples, and drug samples left by companies will be distributed through a centralized system, while educational programs and fellowships will be required to be centrally reviewed and approved.

Free samples: Free samples have been shown to affect physician prescribing behaviour. Physicians with access to free samples are more likely to prescribe brand name medication over equivalent OTC medications. Other studies found that free samples decreased the likelihood that physicians would follow standard of care practices.

Continuing medical education: Hours spent by physicians in industry-supported CME is greater than that from either medical schools or professional societies.

Pharmaceutical representatives: Currently, there are approximately 100,000 pharmaceutical sales reps in the United States pursuing some 830,000 pharmaceutical prescribers. A pharmaceutical representative will often try to see a given physician every few weeks. Representatives often have a call list of about 200 physicians with 120 targets that should be visited in 1-2 week cycles.

Because of the large size of the pharmaceutical sales force, the organization, management, and measurement of effectiveness of the sales force are significant business challenges. Management tasks are usually broken down into the areas of physician targeting, sales force size and structure, sales force optimization, call planning, and sales forces effectiveness. A few pharmaceutical companies have realized that training sales representatives on high science alone is not enough, especially when most products are similar in quality. Thus, training sales representatives on relationship selling techniques in addition to medical science and product knowledge, can make a difference in sales force effectiveness. Specialist physicians are relying more and more on specialty sales reps for product information, because they are more knowledgeable than primary care reps.

The United States has 90,000 pharmaceutical representatives or 1 for every 6.3 physicians. The number and persistence of pharmaceutical representatives has placed a burden on the time of physicians "As the number of reps went up, the amount of time an average rep spent with doctors went down—so far down, that tactical scaling has spawned a strategic crisis. Physicians no longer spend much time with sales reps, nor do they see this as a serious problem."
Marketers must decide on the appropriate size of a sales force needed to sell a particular portfolio of drugs to the target market. Factors influencing this decision are the optimal reach (how many physicians to see) and frequency (how often to see them) for each individual physician, how many sales representatives to devote to office and group practice and how many to devote to hospital accounts. To aid this decision, customers are broken down into different classes according to their prescription behavior and of course, their business potential.

Marketers attempt to identify the set of physicians most likely to prescribe a given drug. Historically, this was done by measuring the number of total prescriptions (TRx) and new prescriptions (NRx) per week that each physician writes. This information is collected by commercial vendors. The physicians are then "deciled" into ten groups based on their writing patterns. Higher deciles are more aggressively targeted. Some pharmaceutical companies use additional information such as:

- profitability of a prescription (scrip),
- accessibility of the physician,
- tendency of the physician to use the pharmaceutical company's drugs,
- effect of managed care formularies on the ability of the physician to prescribe a drug,
- the adoption sequence of the physician (that is, how readily the physician adopts new drugs in place of older, established treatments), and
- the tendency of the physician to use a wide palette of drugs
- influence that physicians have on their colleagues.

Data for drugs prescribed in a hospital are not usually available at the physician level. Advanced analytic techniques are used to value physicians in a hospital setting.

Physicians are perhaps the most important component in sales. They write the prescriptions that determine which drugs will be used by people. Influencing the physician is the key to pharmaceutical sales. Historically, this was done by a large pharmaceutical sales force. A medium-sized pharmaceutical company might have a sales force of 1000 representatives. The largest companies have tens of thousands of representatives around the world. Sales representatives called upon physicians regularly, providing advertising and free drug samples. This is still the approach today; however, economic pressures on the industry are causing pharmaceutical companies to rethink the traditional sales process to physicians.

4.1 UNITED STATES OF AMERICA

In 1912, Congress issued corrective legislation. The Sherley Amendment brought therapeutic claims within the jurisdiction of the Pure Food and Drugs Act, but required the Bureau to prove those claims to be false and fraudulent before they would be judged as illegal.
•Labels contained misleading FDA guarantee -1906* Label guarantee revoked -1918

•Food, Drug, and Cosmetic Act of 1938° Complete list of ingredients° Directions for safe use
•Improved consumer information° Over-the-counter (OTC)° Prescription (Rx)

1950 In Alberty Food Products Co. v. U.S., a court of appeals rules that the directions for use on a drug label must include the purpose for which the drug is offered. Therefore, a worthless remedy cannot escape the law by not stating the condition it is supposed to treat.

1960 Federal Hazardous Substances Labeling Act, enforced by FDA, requires prominent label warnings on hazardous household chemical products

1966 Fair Packaging and Labeling Act requires all consumer products in interstate commerce to be honestly and informatively labeled, with FDA enforcing provisions on foods, drugs, cosmetics, and medical devices.

1970 FDA requires the first patient package insert: oral contraceptives must contain information for the patient about specific risks and benefits

1972 Over-the-Counter Drug Review begun to enhance the safety, effectiveness and appropriate labeling of drugs sold without prescription

1973 THE U.S. Supreme Court upholds the 1962 drug effectiveness law and endorses FDA action to control entire classes of products by regulations rather than to rely only on time-consuming litigation.

1977 Saccharin Study and Labeling Act passed by Congress to stop FDA from banning the chemical sweetener but requiring a label warning that it has been found to cause cancer in laboratory animals

1982 Tamper-resistant Packing Regulations issued by FDA to prevent poisonings such as deaths from cyanide placed in Tylenol capsules. The Federal Anti-Tampering Act passed in 1983 makes it a crime to tamper with packaged consumer products

1988 The Prescription Drug Marketing Act bans the diversion of prescription drugs from legitimate commercial channels. Congress finds that the resale of such drugs leads to the distribution of mislabeled, adulterated, sub potent, and counterfeit drugs to the public. The new law requires drug wholesalers to be licensed by the states; restricts reimportation from other countries; and bans sale, trade or purchase of drug samples, and traffic or counterfeiting of redeemable drug coupons

1997 Food and Drug Administration Modernization Act reauthorizes the Prescription Drug User Fee Act of 1992 and mandates the most wide-ranging reforms in agency practices since 1938. Provisions include measures to accelerate review of devices, regulate advertising of unapproved uses of approved drugs and devices, and regulate health claims for foods.

Section 201 DEFINITIONS: The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.
The term "labeling" means all labels and other written, printed, or graphic matters (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

Under the Food, Drug and Cosmetic Act, a company must specify the intended uses of a product in its new drug application to the FDA. Before approving a drug, the FDA must determine that the drug is safe and effective for the use proposed by the company. Once approved, the drug may not be marketed or promoted for off-label uses.

The United States alleges that AstraZeneca illegally marketed Seroquel for uses never approved by the FDA. The United States alleges that AstraZeneca illegally marketed Seroquel for uses never approved by the FDA.

AstraZeneca LP and AstraZeneca Pharmaceuticals LP will pay $520 million to resolve allegations that AstraZeneca illegally marketed the anti-psychotic drug Seroquel for uses not approved as safe and effective by the Food and Drug Administration (FDA), the Departments of Justice and Health and Human Services' Health Care Fraud Enforcement Action Team (HEAT) announced today the Tuesday. April 27, 2010

Such unapproved uses are also known as "off-label" uses because they are not included in the drug's FDA approved product label.

On September 30, 2010, the U.S. Department of Justice announced that it had reached an agreement with Novartis Pharmaceuticals Corporation in which the company agreed to pay $237.5 million to settle four False Claims Act lawsuits alleging that Novartis engaged in an unlawful off-label marketing scheme in connection with its anti-epileptic drug Trileptal and wrongfully paid kickbacks to physicians to encourage them to prescribe Trileptal, as well as other Novartis drugs. The lawsuits asserted that Novartis knowingly promoted the sale of Trileptal for bipolar disorder and neuropathic pain—uses that were not approved by the Food and Drug Administration. The lawsuits also alleged that Novartis paid illegal kickbacks to physicians via speaker programs, advisory boards, entertainment, travel, and meals to induce them to prescribe Trileptal, Diovan, Zelnorm, Sandostatin, Exforge, and Tekturna.

The qui tam lawsuits were filed by former Novartis employees. As a reward for disclosing Novartis’s unlawful activity to the Government, the whistleblowers will share $25,675,035 of the federal recovery. (http://fraudfighters.wordpress.com/2010/10/05/pharmaceuticai-giant-novartis-to-pay-237-5-million-to-settle-false-claims-act-lawsuits-relating-to-off-label-marketing-and-kickbacks/)

In a decision that will have far-reaching implications in pharmaceutical product liability litigation and beyond, on March 4, 2009 the U.S. Supreme Court issued its highly anticipated ruling in Wyeth v. Levine, holding 6-3 that federal law does not bar a claim that a drug's warning label is inadequate, even though the label warnings were expressly approved by the FDA. The ruling is a defeat for the pharmaceutical industry and the FDA, which both argued that state-law failure to warn claims challenging the adequacy of an FDA-approved label should be pre-empted because Congress intended that the FDA, and not civil juries, should determine what warnings should be included on a drug's label.
While recognizing that drug manufacturers are generally required to use only the FDA-approved label, the Court found that FDA regulations do not prohibit a manufacturer from adding stronger warnings to a product’s label and then subsequently seeking FDA approval for the change. Thus, the Court reasoned, because the manufacturer could have included a stronger label warning without violating federal law, and there was no evidence that the FDA would not have approved such a change, then the injured plaintiff’s state-law failure to warn claim was not pre-empted.

(http://www.ralaw.com/resources/documents/Pharamaceutical.pdf)

SEC. 502. [21 USC 352] Misbranded Drugs and Devices: A drug or device shall be deemed to be misbranded--

(a) False or misleading label. If its labeling is false or misleading in any particular. Health care economic information provided to a formulary committee, or other similar entity, in the course of the committee or the entity carrying out its responsibilities for the selection of drugs for managed care or other similar organizations, shall not be considered to be false or misleading under this paragraph if the health care economic information directly relates to an indication approved under section 505 or under section 351(a) of the Public Health Service Act [42 USC § 262(a)] for such drug and is based on competent and reliable scientific evidence.

(b) Package form; Contents of label. If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: Provided, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established.

(c) Prominence of information on label. If any word statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

d) [Repealed]

(e) Designation of drugs by established names.: (1) (A) If it is a drug, unless its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula)

(i) the established name of the drug, if there is such a name;

(ii) the established name and quantity or, if determined to be appropriate by the Secretary, the proportion of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including whether active or not. and

(iii) the established name of each inactive ingredient listed in alphabetical order on the outside container of the retail package and, if determined to be appropriate by the Secretary, on the immediate container, as prescribed in regulation promulgated by the Secretary, except that nothing in this sub clause shall be deemed to require that any trade secret be divulged, and except that the requirements of this sub clause with respect to alphabetical order shall apply only to nonprescription drugs that are not also cosmetics and that this sub clause shall not apply to nonprescription drugs not intended for human use.
(B) For any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) shall be printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient, except that to the extent that compliance with the requirements of above or this clause is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

(f) Directions for use and warnings on label: Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users.

(g) Representations as recognized drug; packing and labeling; inconsistent requirements for designation of drug. If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein. The method of packing may be modified with the consent of the Secretary. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia with respect to packaging and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States, and not to those of the United States Pharmacopoeia, except that in the event of inconsistency between the requirements of this paragraph and those of paragraph (e) as to the name by which the drug or its ingredients shall be designated, the requirements of paragraph (e) shall prevail.

(h) Deteriorative drugs; packing and labeling: If it has been found by the Secretary to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the Secretary shall by regulations require as necessary for the protection of the public health. No such regulation shall be established for any drug recognized in an official compendium until the Secretary shall have informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.

(i) Drug; misleading container; imitation; offer for sale under another name. (1) If it is a drug and its container is so made, formed, or filled as to be misleading; or (2) if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug.

(j) Health-endangering when used as prescribed. If it is dangerous to health when used in the dosage or manner or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

(k), (l) [Repealed]

(m) Color additives; packing and labeling: If it is a color additive the intended use of which is for the purpose of coloring only, unless it's packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive, as may be contained in regulations.

(n) Prescription drug advertisements: established name; quantitative formula; side effects, contraindications, and effectiveness; prior approval; false advertising; labeling; construction of the Convention on Psychotropic Substances. In the case of any prescription drug distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of (1) the established name as defined in section...
502(e) [subsec. (e) of this section], printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under section 502(e) [subsec. (e) of this section], and (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary in accordance with the procedure specified in section 701(e) of this Act, except that (A) except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement.

(o) Drugs or devices from nonregistered establishments: If it was manufactured, prepared, propagated, compounded, or processed in an establishment in any State not duly registered under section 510, if it was not included in a list required by section 510(j), if a notice or other information respecting it was not provided as required by such section or section 510(k), or if it does not bear such symbols from the uniform system for identification of devices prescribed under section 510(e) as the Secretary by regulation requires.

(p) Packaging or labeling of drugs in violation of regulations: If it is a drug and its packaging or labeling is in violation of an applicable regulation issued pursuant to the Poison Prevention Packaging Act of 1970.

(q) Restricted devices: using false.................................prescribed under section 520(e).

(r) Restricted devices: not carrying requisite accompanying statements..............Secretary determines to be labeling as defined in section 201(m).

(s) Devices: subject to ......................performance standard.

(t) Devices: for which there has been...............................a requirement under section 522.

(u) Identification of manufacturer.: (*) Subject to paragraph (2), if it is a reprocessed single-use device,..................identifying such manufacturer.

(2) If the original device .........................to be affixed to the medical record of a patient.

(v) Reprocessed single-use device. If it is a reprocessed single-use device, .....................the person responsible for reprocessing.

(w) New animal drugs.

(x) If it is a nonprescription drug that is marketed in the United States, unless the label of such drug includes a domestic address or domestic phone number through which the responsible person may receive a report of a serious adverse event with such drug.

(y) Note: This subsection takes effect 180 days after enactment of Act Sept. 27, 2007, P.L. 110-85, as provided by sec. 909(a) of such Act, which appears as 21 USC sec. 331 note. If it is a drug subject to an approved risk evaluation and mitigation strategy pursuant to section 505(p) and the responsible person (as such term is used in section 505-1) fails to comply with a requirement of such strategy provided for under subsection (c), (e), or (f) of section 505-1.

(z) Note: This subsection takes effect 180 days after enactment of Act Sept. 27, 2007, P.L. 110-85, as provided by sec. 909(a) of such Act, which appears as 21 USC sec. 331 note. If it is a drug and the responsible person (as such term is used in section 505(o) ) is in violation of a requirement
established under paragraph (3) (relating to post market studies and clinical trials) or paragraph (4) (relating to labeling) of section 505(o) with respect to such drug.

(a) The Secretary is hereby directed to promulgate regulations exempting from any labeling or packaging requirement of this Act drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded, under the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

(b)(1) A drug intended for use by man which—

(A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(B) is limited by an approved application under section 505 to use under the professional supervision of a practitioner licensed by law to administer such drug; shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

(2) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 502, except paragraphs (a), (i), (2) and (3), (k), and (l), and the packaging requirements of paragraphs (g), (h), and (p), if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (1) of this subsection.

(3) The Secretary may by regulation remove drugs subject to section 505 from the requirements of paragraph (1) of this subsection when such requirements are not necessary for the protection of the public health.

(4)(A) A drug that is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing the label of the drug fails to bear, at a minimum, the symbol “Rx only”.

(B) A drug to which paragraph (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing the label of the drug bears the symbol described in subparagraph (A).

(5) Nothing in this subsection shall be construed to relieve any person from any requirement prescribed by or under authority of law with respect to drugs now included or which may hereafter be included within the classifications stated in section 3220 of the Internal Revenue Code (26 USC 3220), or to marihuana as defined in section 3238(b) of the Internal Revenue Code (26 USC 3238(b)).
(c)(1) No person may sell, purchase, or trade or offer to sell, purchase, or trade any drug sample. For purposes of this paragraph and subsection (d), the term "drug sample" means a unit of a drug, subject to subsection (b), which is not intended to be sold and is intended to promote the sale of the drug. Nothing in this paragraph shall subject an officer or executive of a drug manufacturer or distributor to criminal liability solely because of a sale, purchase, trade, or offer to sell, purchase, or trade in violation of this paragraph by other employees of the manufacturer or distributor.

(2) No person may sell, purchase, or trade, offer to sell, purchase, or trade, or counterfeit any coupon. For purposes of this paragraph, the term "coupon" means a form which may be redeemed, at no cost or at a reduced cost, for a drug which is prescribed in accordance with subsection (b).

(3)(A) No person may sell, purchase, or trade, or offer to sell, purchase, or trade, any drug—

(i) which is subject to subsection (b), and

(ii) which was purchased by a public or private hospital or other health care entity, or

(iii) which was donated or supplied at a reduced price to a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1954.

(B) Subparagraph (A) does not apply to—

(i) the purchase or other acquisition by a hospital or other health care entity which is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities which are members of such organization,

(ii) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by an organization described in subparagraph (A)(ii)(II) to a nonprofit affiliate of the organization to the extent otherwise permitted by law,

(iii) a sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities which are under common control,

(iv) a sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons, or

(v) a sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription executed in accordance with subsection (b).

For purposes of this paragraph, the term "entity" does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law and the term "emergency medical reasons" includes transfers of a drug between health care entities or from a health care entity to a retail pharmacy undertaken to alleviate temporary shortages of the drug arising from delays in or interruptions of regular distribution schedules.

(d)(1) Except as provided in paragraphs (2) and (3), no person may distribute any drug sample. For purposes of this subsection, the term "distribute" does not include the providing of a drug sample to a patient by a—

(A) practitioner licensed to prescribe such drug,

(B) health care professional acting at the direction and under the supervision of such a practitioner, or
(C) pharmacy of a hospital or of another health care entity that is acting at the direction of such a practitioner and that received such sample pursuant to paragraph (2) or (3).

(2) (A) The manufacturer or authorized distributor of record of a drug subject to subsection (b) may, in accordance with this paragraph, distribute drug samples by mail or common carrier to practitioners licensed to prescribe such drugs or, at the request of a licensed practitioner, to pharmacies of hospitals or other health care entities. Such a distribution of drug samples may only be made—

(i) in response to a written request for drug samples made on a form which meets the requirements of subparagraph (B), and

(ii) under a system which requires the recipient of the drug sample to execute a written receipt for the drug sample upon its delivery and the return of the receipt to the manufacturer or authorized distributor of record.

(B) A written request for a drug sample required by subparagraph (A)(i) shall contain—

(i) the name, address, professional designation, and signature of the practitioner making the request,

(ii) the identity of the drug sample requested and the quantity requested,

(iii) the name of the manufacturer of the drug sample requested, and

(iv) the date of the request.

(C) Each drug manufacturer or authorized distributor of record which makes distributions by mail or common carrier under this paragraph shall maintain, for a period of 3 years, the request forms submitted for such distributions and the receipts submitted for such distributions and shall maintain a record of distributions of drug samples which identifies the drugs distributed and the recipients of the distributions. Forms, receipts, and records required to be maintained under this subparagraph shall be made available by the drug manufacturer or authorized distributor of record to Federal and State officials engaged in the regulation of drugs and in the enforcement of laws applicable to drugs.

(3) The manufacturer or authorized distributor of record of a drug subject to subsection (b) may, by means other than mail or common carrier, distribute drug samples only if the manufacturer or authorized distributor of record makes the distributions in accordance with subparagraph (A) and carries out the activities described in subparagraphs (B) through (F) as follows:

(A) Drug samples may only be distributed—

(i) to practitioners licensed to prescribe such drugs if they make a written request for the drug samples, or

(ii) at the written request of such a licensed practitioner, to pharmacies of hospitals or other health care entities. A written request for drug samples shall be made on a form which contains the practitioner’s name, address, and professional designation, the identity of the drug sample requested, the quantity of drug samples requested, the name of the manufacturer or authorized distributor of record of the drug sample, the date of the request and signature of the practitioner making the request.
(B) Drug manufacturers or authorized distributors of record shall store drug samples under conditions that will maintain their stability, integrity, and effectiveness and will assure that the drug samples will be free of contamination, deterioration, and adulteration.

(C) Drug manufacturers or authorized distributors of record shall conduct, at least annually, a complete and accurate inventory of all drug samples in the possession of representatives of the manufacturer or authorized distributor of record. Drug manufacturers or authorized distributors of record shall maintain lists of the names and address of each of their representatives who distribute drug samples and of the sites where drug samples are stored. Drug manufacturers or authorized distributors of record shall maintain record for at least 3 years of all drug samples distributed, destroyed, or returned to the manufacturer or authorized distributor of record, of all inventories maintained under this subparagraph, of all thefts or significant losses of drug samples, and of all requests made under subparagraph (A) for drug samples. Records and lists maintained under this subparagraph shall be made available by the drug manufacturer or authorized distributor of record to the Secretary upon request.

(D) Drug manufacturers or authorized distributors of record shall notify the Secretary of any significant loss of drug samples and any known theft of drug samples.

(E) Drug manufacturers or authorized distributors of record shall report to the Secretary any conviction of their representatives for violations of subsection (c)(1) or a State law because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample.

(F) Drug manufacturers or authorized distributors of record shall provide to the Secretary the name and telephone number of the individual responsible for responding to a request for information respecting drug samples.

(e)(1)(A) Each person who is engaged in the wholesale distribution of a drug subject to subsection (b) and who is not the manufacturer or an authorized distributor of record of such drug shall, before each wholesale distribution of such drug (including each distribution to an authorized distributor of record or to a retail pharmacy), provide to the person who receives the drug a statement (in such form and containing such information as the Secretary may require) identifying each prior sale, purchase, or trade of such drug (including the date of the transaction and the names and addresses of all parties to the transaction).

(B) Each manufacturer of a drug subject to subsection (b) shall maintain at its corporate offices a current list of the authorized distributors of record of such drug.

(2)(A) No person may engage in the wholesale distribution in interstate commerce of drugs subject to subsection (b) in a State unless such person is licensed by the State in accordance with the guidelines issued under subparagraph (B).

(B) The Secretary shall by regulation issue guidelines establishing minimum standards, terms, and conditions for the licensing of persons to make wholesale distributions in interstate commerce of drugs subject to subsection (b). Such guidelines shall prescribe requirements for the storage and handling of such drugs and for the establishment and maintenance of records of the distributions of such drugs.

(3) For the purposes of this subsection and subsection (d)—

(A) the term "authorized distributors of record" means those distributors with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products, and

(B) the term "wholesale distribution" means distributor of drugs subject to subsection (b) to other than the consumer or patient but does not include intracompany sales and does not include distributions of
drugs described in subsection (c)(3)(B). (f)(1)(A) A drug intended for use by animals other than man, other than a veterinary feed directive drug intended for use in animal feed or an animal feed bearing or containing a veterinary feed directive drug, which—

(i) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary for its use, is not safe for animal use except under the professional supervision of a licensed veterinarian, or

(ii) is limited by an approved application under subsection (b) of section 512, a conditionally-approved application under section 571, or an index listing under section 572 to use under the professional supervision of a licensed veterinarian, shall be dispensed only by or upon the lawful written or oral order of a licensed veterinarian in the course of the veterinarian's professional practice.

(B) For purposes of subparagraph (A), an order is lawful if the order—

(i) is a prescription or other order authorized by law,

(ii) is, if an oral order, promptly reduced to writing by the person lawfully filling the order, and filed by that person, and

(iii) is refilled only if authorized in the original order or in a subsequent oral order promptly reduced to writing by the person lawfully filling the order, and filed by that person.

(C) The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

(2) Any drug when dispensed in accordance with paragraph (1) of this subsection—

(A) Shall be exempt from the requirements of section 502, except subsections (a), (g), (h), (i)(2), (i)(3), and (p) of such section, and

(B) shall be exempt from the packaging requirements of subsections (g), (h), and (p) of such section, if—

(i) when dispensed by a licensed veterinarian, the drug bears a label containing the name and address of the practitioner and any directions for use and cautionary statements specified by the practitioner, or

(ii) when dispensed by filling the lawful order of a licensed veterinarian, the drug bears a label containing the name and address of the dispenser, the serial number and date of the order or of its filing, the name of the licensed veterinarian, and the directions for use and cautionary statements, if any, contained in such order.

The preceding sentence shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail.

(3) The Secretary may by regulation exempt drugs for animals other than man subject to section 512, 571, or 572 from the requirements of paragraph (1) when such requirements are not necessary for the protection of the public health.

(4) A drug which is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian." A drug to which paragraph (1) does not apply shall be deemed to be
misbranded if at any time prior to dispensing its label bears the statement specified in the preceding sentence.

(g)(1) The Secretary shall in accordance with this subsection assign an agency center to regulate products that constitute a combination of a drug, device, or biological product. The Secretary shall determine the primary mode of action of the combination product. If the Secretary determines that the primary mode of action is that of—

(A) a drug (other than a biological product), the agency center charged with premarket review of drugs shall have primary jurisdiction,

(B) a device, the agency center charged with premarket review of devices shall have primary jurisdiction, or

(C) a biological product, the agency center charged with premarket review of biological products shall have primary jurisdiction.

(2) Nothing in this subsection shall prevent the Secretary from using any agency resources of the Food and Drug Administration necessary to ensure adequate review of the safety, effectiveness, or substantial equivalence of an article.

(3) The Secretary shall promulgate regulations to implement market clearance procedures in accordance with paragraphs (1) and (2) not later than 1 year after the date of enactment of this subsection. 11

(4) (A) Not later than 60 days after the date of the enactment of this paragraph 12, the Secretary shall establish within the Office of the Commissioner of Food and Drugs an office to ensure the prompt assignment of combination products to agency centers, the timely and effective premarket review of such products, and consistent and appropriate postmarket regulation of like products subject to the same statutory requirements to the extent permitted by law. Additionally, the office shall, in determining whether a product is to be designated a combination product, consult with the component within the Office of the Commissioner of Food and Drugs that is responsible for such determinations.

Such office (referred to in this paragraph as the ‘Office’) shall have appropriate scientific and medical expertise, and shall be headed by a director.

(B) In carrying out this subsection, the Office shall, for each combination product, promptly assign an agency center with primary jurisdiction in accordance with paragraph (1) for the premarket review of such product.

(C)(i) In carrying out this subsection, the Office shall ensure timely and effective premarket reviews by overseeing the timeliness of and coordinating reviews involving more than one agency center.

(ii) In order to ensure the timeliness of the premarket review of a combination product, the agency center with primary jurisdiction for the product, and the consulting agency center, shall be responsible to the Office with respect to the timeliness of the premarket review.

(D) In carrying out this subsection, the Office shall ensure the consistency and appropriateness of postmarket regulation of like products subject to the same statutory requirements to the extent permitted by law.

(E)(i) Any dispute regarding the timeliness of the premarket review of a combination product may be presented to the Office for resolution, unless the dispute is clearly premature.
During the review process, any dispute regarding the substance of the premarket review may be presented to the Commissioner of Food and Drugs after first being considered by the agency center with primary jurisdiction of the premarket review, under the scientific dispute resolution procedures for such center. The Commissioner of Food and Drugs shall consult with the Director of the Office in resolving the substantive dispute.

The Secretary, acting through the Office, shall review each agreement, guidance, or practice of the Secretary that is specific to the assignment of combination products to agency centers and shall determine whether the agreement, guidance, or practice is consistent with the requirements of this subsection. In carrying out such review, the Secretary shall consult with stakeholders and the directors of the agency centers. After such consultation, the Secretary shall determine whether to continue in effect, modify, revise, or eliminate such agreement, guidance, or practice, and shall publish in the Federal Register a notice of the availability of such modified or revised agreement, guidance or practice. Nothing in this paragraph shall be construed as preventing the Secretary from following each agreement, guidance, or practice until continued, modified, revised, or eliminated.

Not later than one year after the date of the enactment of this paragraph and annually thereafter, the Secretary shall report to the appropriate committees of Congress on the activities and impact of the Office. The report shall include provisions—

(i) describing the numbers and types of combination products under review and the timeliness in days of such assignments, reviews, and dispute resolutions;

(ii) identifying the number of premarket reviews of such products that involved a consulting agency center; and

(iii) describing improvements in the consistency of postmarket regulation of combination products.

Nothing in this paragraph shall be construed to limit the regulatory authority of any agency center.

As used in this subsection:

The term "agency center" means a center or alternative organizational component of the Food and Drug Administration.

The term "biological product" has the meaning given the term in section 351(i) of the Public Health Service Act (42 USC 262(i)).

The term "market clearance" includes—

(i) approval of an application under section 505, 507, 515, or 520(g),

(ii) a finding of substantial equivalence under this subchapter, and

(iii) approval of a biologics license application under subsection (a) of section 351 of the Public Health Service Act (42 USC 262).

SEC. 503A. [21 USC 353a] Pharmacy compounding: (a) IN GENERAL—
Sections 501(a)(2)(B), 502(f)(1), and 505 shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the unsolicited receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient, if the drug product meets the requirements of this section, and if the compounding—

(1) is by—

(A) a licensed pharmacist in a State licensed pharmacy or a Federal facility, or

(B) a licensed physician, on the prescription order for such individual patient made by a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or

(2) (A) is by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient; and

(B) is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between—

(i) the licensed pharmacist or licensed physician; and

(ii) (I) such individual patient for whom the prescription order will be provided; or

(II) the physician or other licensed practitioner who will write such prescription order.

(b) **Comproped Drugs.**—

(1) **Licenced Pharmacist And Licenced Physician**—A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician—

(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations—

(i) that—

(I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

(ii) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or

(iii) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (d);

(ii) that are manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i)); and

(iii) that are accompanied by valid certificates of analysis for each bulk drug substance;
(B) compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

(C) does not compound a drug product that appears on a list published by the Secretary in the Federal Register of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective; and

(D) does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product.

(2) Definition—For purposes of paragraph (1)(D), the term "essentially a copy of a commercially available drug product" does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product.

(3) Drug Product—A drug product may be compounded under subsection (a) only if—

(A) such drug product is not a drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product; and

(B) such drug product is compounded in a State—

(i) that has entered into a memorandum of understanding with the Secretary which addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State; or

(ii) that has not entered into the memorandum of understanding described in clause (i) and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician.

The Secretary shall, in consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of understanding for use by the States in complying with subparagraph (B)(i).

(C) Advertising And Promotion—A drug may be compounded under subsection (a) only if the pharmacy, licensed pharmacist, or licensed physician does not advertise or promote the compounding of any particular drug, class of drug, or type of drug. The pharmacy, licensed pharmacist, or licensed physician may advertise and promote the compounding service provided by the licensed pharmacist or licensed physician.

(D) Regulations—(1) In General—The Secretary shall issue regulations to implement this section. Before issuing regulations to implement subsections (b)(1)(A)(III), (b)(1)(C), or (b)(3)(A), the Secretary shall convene and consult an advisory committee on compounding unless the Secretary determines that the issuance of such regulations before consultation is necessary to protect the public health. The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopoeia, pharmacy, physician, and consumer organizations, and other experts selected by the Secretary.
(2) Limiting Compounding—The Secretary, in consultation with the United States Pharmacopoeia Convention, Incorporated, shall promulgate regulations identifying drug substances that may be used in compounding under subsection (b)(1)(A)(i)(III) for which a monograph does not exist or which are not components of drug products approved by the Secretary. The Secretary shall include in the regulation the criteria for such substances, which shall include historical use, reports in peer reviewed medical literature, or other criteria the Secretary may identify.

(E) Application—This section shall not apply to— (1) compounded positron emission tomography drugs as defined in section 201(ii); or

(2) radiopharmaceuticals.

(F) Definition—As used in this section, the term "compounding" does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.

SEC. 503B. [21 USC 353b] Prereview of television advertisements [Note: This section takes effect 180 days after enactment of Act Sept. 27, 2007, P.L. 110-85, as provided by § 909(a) of such Act, which appears as 21 USC § 331 note.]

(a) In general. The Secretary may require the submission of any television advertisement for a drug (including any script, story board, rough, or a completed video production of the television advertisement) to the Secretary for review under this section not later than 45 days before dissemination of the television advertisement.

(b) Review. In conducting a review of a television advertisement under this section, the Secretary may make recommendations with respect to information included in the label of the drug—

(1) on changes that are—

(A) necessary to protect the consumer good and well-being; or

(B) consistent with prescribing information for the product under review; and

(2) if appropriate and if information exists, on statements for inclusion in the advertisement to address the specific efficacy of the drug as it relates to specific population groups, including elderly populations, children, and racial and ethnic minorities

(c) No authority to require changes. Except as provided by subsection (e), this section does not authorize the Secretary to make or direct changes in any material submitted pursuant to subsection (a).

(d) Elderly populations, children, racially and ethnically diverse communities. In formulating recommendations under subsection (b), the Secretary shall take into consideration the impact of the advertised drug on elderly populations, children, and racially and ethnically diverse communities.

(e) Specific disclosures.

(1) Serious risk; safety protocol. In conducting a review of a television advertisement under this section, if the Secretary determines that the advertisement would be false or misleading without a specific
disclosure about a serious risk listed in the labeling of the drug involved, the Secretary may require inclusion of such disclosure in the advertisement.

(2) **Date of approval.** In conducting a review of a television advertisement under this section, the Secretary may require the advertisement to include, for a period not to exceed 2 years from the date of the approval of the drug under section 505 or section 351 of the Public Health Service Act [42 USC § 262], a specific disclosure of such date of approval if the Secretary determines that the advertisement would otherwise be false or misleading.

(f) **Rule of construction.** Nothing in this section may be construed as having any effect on requirements under section 502(n) or on the authority of the Secretary under section 314.550, 314.640, 601.45, or 601.94 of title 21, Code of Federal Regulations (or successor regulations).

SEC. 705. [21 U.S.C. 375] **Publicity:**

(a) The Secretary shall cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this Act, including the nature of the charge and the disposition thereof.

(b) The Secretary may also cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health, or gross deception of the consumer. Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department.

SEC. 736A. [21 USC § 379h-1] **Fees relating to advisory review of prescription-drug television advertising:**

(a) **Types of direct-to-consumer television advertisement review fees.** Beginning in fiscal year 2008, the Secretary shall assess and collect fees in accordance with this section.

(b) **Advisory review fee revenue amounts.** Fees under subsection (a)(1) shall be established to generate revenue amounts of $6,250,000 for each of fiscal years 2008 through 2012, as adjusted pursuant to subsections (c) and (g)(4).

(c) **Adjustments.**

(d) **Operating reserves.**

(e) **Effect of failure to pay fees.** Notwithstanding any other requirement, a submission for advisory review of a DTC advertisement submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for review by the Secretary until all fees owed by such person under this section have been paid.

(f) **Effect of inadequate funding of program.**

(g) **Crediting and availability of fees.**

(h) **Definitions.** For purposes of this section:
The term "advisory review" means reviewing and providing advisory comments on DTC advertisements regarding compliance of a proposed advertisement with the requirements of this Act [21 USC §§ 301 et seq.] prior to its initial public dissemination.

The term "advisory review fee" has the meaning indicated for such term in subsection (a)(1)(D).

The term "carry over submission" means a submission for an advisory review for which a fee was paid in one fiscal year that is submitted for review in the following fiscal year.

The term "direct-to-consumer television advertisement" means an advertisement for a prescription drug product (as defined in section 735(3) [21 USC sec. 379g(3)]) intended to be displayed on any television channel for less than 3 minutes.

The term "DTC advertisement" has the meaning indicated for such term in subsection (a)(1)(A).

The term "operating reserve fee" has the meaning indicated for such term in subsection (a)(2)(A).

The term "person" includes an individual, partnership, corporation, and association, and any affiliate thereof or successor in interest.

The term "process for the advisory review of prescription drug advertising" means the activities necessary to review and provide advisory comments on DTC advertisements prior to public dissemination and, to the extent the Secretary has additional staff resources available under the program under this section that are not necessary for the advisory review of DTC advertisements, the activities necessary to review and provide advisory comments on other proposed advertisements and promotional material prior to public dissemination.

The term "resources allocated for the process for the advisory review of prescription drug advertising" means the expenses incurred in connection with the process for the advisory review of prescription drug advertising for:

(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees, and costs related to such officers, employees, and committees, and to contracts with such contractors;

(B) management of information, and the acquisition, maintenance, and repair of computer resources;

(C) leasing, maintenance, renovation, and repair of fixtures and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies;

(D) collection of fees under this section and accounting for resources allocated for the advisory review of prescription drug advertising; and

(E) terminating the program under this section pursuant to subsection (f)(2) if that becomes necessary.

The term "resubmission" means a subsequent submission for advisory review of a direct-to-consumer television advertisement that has been revised in response to the Secretary's comments on an original submission. A resubmission may not introduce significant new concepts or creative themes into the television advertisement.
The "patent medicines" were a constant danger to millions who believed their false promises but had little else to rely on for serious ailments. Typical products claimed to "renovate" the stomach, liver, and kidneys, and to cure cancer, diabetes, gallstones, and weak hearts.

[11] The term "submission for advisory review" means an original submission of a direct-to-consumer television advertisement for which the sponsor voluntarily requests advisory comments before the advertisement is publicly disseminated.

1962 Drug Amendments

The trend toward preventive lawmaking continued. A drug tragedy in Europe, the births of thousands of deformed infants whose mothers had taken the new sedative thalidomide, focused public attention on pending U.S. legislation to further strengthen the Federal Food, Drug, and Cosmetic Act. The Drug Amendments of 1962, passed unanimously by the Congress, tightened control over prescription drugs, new drugs, and investigational drugs. It was recognized that no drug is truly safe unless it is also effective, and effectiveness was required to be established prior to marketing -- a milestone advance in medical history. Drug firms were required to send adverse reaction reports to FDA, and drug advertising in medical journals was required to provide complete information to the doctor -- the risks as well as the benefits. In the years since 1962 literally thousands of prescription drug items have been taken off the U.S. market because they lacked evidence of safety and/or effectiveness, or they have had their labeling changed to reflect the known medical facts.

Kinds Of Material Regulated:

FDA regulates advertisements and other promotional material, called "promotional labeling," disseminated by or on behalf of the advertised product's manufacturer, packer or distributor. Mostly, this means materials that the product's sponsor issues or places for publication, which are directed to consumers and patients, such as ads printed in magazines, journals and newspapers; ads broadcast over television, radio and telephone; brochures, letters and flyers sent through the mail; and videotapes, pharmacy counter displays, billboards, and patient compliance program materials. According to the October 2002 GAO report entitled, Prescription Drugs: FDA Oversight of Direct-to-Consumer Advertising Has Limitations, "Promotion to physicians accounted for more than 80 percent of all promotional spending"
by pharmaceutical companies in 2001." Therefore, the bulk of the Agency's time spent reviewing promotional material, is spent reviewing materials produced for promotion to health care professionals, such as detail aids used by manufacturer representatives, convention displays, file cards, booklets, and videotapes, which is distinct from advertising directed toward consumers.

Types Of Advertisements: Of the three different types of ads that product sponsors use to communicate with consumers, FDA regulates two of them; "product-claim" and "reminder" ads. The third type, "help-seeking" ads are not regulated by FDA.

"Product-claim" ads are regulated by FDA and are those ads which generally include both the name of a product and its use, or make a claim or representation about a prescription drug. Claims of drug benefits, such as safety and effectiveness, must be balanced with relevant disclosures of risks and limitations of efficacy. This balanced presentation of drug therapy is commonly referred to as "fair balance." In addition, when used in print ads, sponsors must provide a brief summary of risk information included in the product's FDA-approved labeling or, for broadcast "product-claim" ads, provide convenient access to the approved labeling. In our regulations, the phrase "adequate provision" is used to identify the convenient access option.

"Reminder" ads are regulated by FDA and are ads that may disclose the name of the product and certain specific descriptive information such as dosage form (i.e., tablet, capsule, or syrup) or price information, but they are not allowed to give the product's indication (use) or to make any claims or representations about the product. They specifically are not allowed for products with serious warnings (called "black box" warnings) in their labeling. The regulations specifically exempt "reminder" ads from the risk disclosure requirements because they were historically designed generally to remind health care professionals of a product's availability. Health care professionals presumably know both the name of a product and its use.

"Help-seeking" ads discuss a disease or condition and advise the audience to "see your doctor" for possible treatments. They need not include any risk information. Because no drug product is mentioned or implied, this type of ad is not considered to be a drug ad and is not regulated by FDA.

Statutory And Regulatory Authority:

FDA regulates the manufacture, sale, and distribution of drugs in the United States under authority of the Federal Food, Drug, and Cosmetic (FD&C) Act (or the Act), which includes approval of prescription drug labeling that provides information about the use of a drug. Section 502(n) of the Act provides the Agency with authority to regulate prescription drug advertisements and the implementing regulations (Title 21, Code of Federal Regulations [CFR] section 202.1) which provide specifics about the content of such advertisements. Nothing in the law or regulations prohibits DTC promotion in any advertising medium even if the drug being advertised is a controlled substance. Also, the advertising provisions of the Act do not address the issues of pharmaceutical coverage by insurance companies or drug product price.

The regulations specify, among other things, that prescription drug advertisements cannot be false or misleading, cannot omit material facts, and must present a "fair balance" between benefit and risk information. Further, for print advertisements, the regulations specify that every risk addressed in the product's approved labeling also must be disclosed in the brief summary. For broadcast advertisements, however, the regulations require ads to disclose the most significant risks that appear in the labeling. The regulations further require that broadcast advertisements either contain a brief summary of "all necessary
FDA generally cannot require that prescription drug advertisements be reviewed and approved prior to their use. Prior FDA review of advertisements occurs only in very narrow circumstances, primarily for products receiving accelerated approvals. In other words, FDA's review of promotional materials is intended to occur post hoc - once the materials have appeared in public. Enforcement actions for advertising violations are generally intended to be taken post hoc as well. Most of FDA's enforcement actions request that sponsors stop using the violative materials. In some cases, FDA asks sponsors to run corrective advertisements or issue corrective letters to correct product misimpressions created by false, misleading, or unbalanced materials. To avoid this, the majority of sponsors voluntarily seek prior comment from FDA on draft broadcast ads for their products thereby reducing the likelihood that sponsors may face an enforcement action.

Development Of Regulation For Consumer-Directed Ads:

Prior to the early 1980s, prescription products were not promoted directly to consumers and patients. At that time, FDA's regulation of promotional drug material was limited to that which manufacturers prepared to present to physicians and other health care professionals. In the early 1980s, a few companies began advertising products directly to patient audiences (specifically, older people concerned about pneumonia and people taking prescription ibuprofen to treat arthritis pain). As questions and concerns directed to the Agency about such DTC promotion began to grow, FDA issued a policy statement on September 2, 1983, requesting a voluntary moratorium on DTC ads. The Agency needed time to study whether the current regulations developed in the 1960s for prescription drug advertising directed toward health care professionals provided sufficient safeguards to protect consumers when applied to DTC promotion. In addition, the Agency wanted to allow time for a dialogue among consumers, health professionals, and industry, and for interested parties to conduct research on aspects of consumer-oriented advertising. The industry complied with the request. In 1984, the University of Illinois and Stanford Research Institute jointly sponsored a symposium to discuss consumer-directed prescription drug advertising from a broad research and policy perspective.

In a September 9, 1985, Federal Register (FR) Notice (50 FR 36677), FDA concluded that the "current regulations governing prescription drug advertising provide sufficient safeguards to protect consumers," which lifted the voluntary moratorium.

During the early 1990s, sponsors increasingly used consumer print material (magazines, etc.) to advertise their products. The ads typically included a promotional message together with the brief summary of adverse effects, similar to that used in physician-directed ads. The brief summary statement, which frequently appears in small print using medical jargon, is not very consumer friendly.

In the 1990s, product sponsors also started using television advertisements in a limited fashion. Television advertisements were limited because of the extensive disclosure needed to fulfill the brief summary requirement, and FDA and industry did not believe that it was feasible to disseminate the product's approved labeling in connection with the ad. Therefore, it was believed that the brief summary was required. For example, one way to satisfy the brief summary requirement would be to scroll the brief summary on the screen, which would take a minute or more at a barely readable scrolling rate. By the mid-1990s, sponsors were placing "reminder" ads on television because these ads are not required to include a brief summary. Some of these ads were confusing to consumers who were not knowledgeable about the name and use for these products.
In response to increasing consumer demand for information and clarity, FDA issued an FR Notice on August 16, 1995, announcing a public hearing to discuss several aspects of DTC advertising and a Notice for further comment on May 14, 1996, to clarify additional issues, including the brief summary requirement. Further, in light of changes in consumers' ability to get additional product information, FDA began to consider whether broadcast ads could be constructed to ensure access to product labeling information, the only alternative to including the brief summary requirement. FDA considered suggestions about providing access to multiple sources of product labeling as a means of satisfying the requirement that consumers have convenient access to FDA-approved labeling when manufacturers broadcast a "product-claim" ad.

In August 1997, FDA issued a draft guidance entitled, "Guidance for Industry: Consumer-Directed Broadcast Advertisements" (see Attachment A) that clarified the Agency's interpretation of the existing regulations. The Guidance described an approach for ensuring that audiences exposed to prescription drug advertisements on television and radio has convenient access to the advertised product's approved labeling. The proposed approach consisted of reference in the broadcast ad to four sources the consumer could use to obtain more detailed labeling information: a toll-free telephone number, a website address, a concurrently running print advertisement, and health care professionals. Following a comment period, and detailed review and consideration of the comments, FDA made only minor changes to the draft guidance, and issued it in final form in August 1999 (64 FR 43197, also found at: [www.fda.gov/cder/guidance/1804fnl.htm].)

In April 2001, FDA issued draft guidance for industry entitled, "Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements." The draft guidance describes how FDA did not intend to object to the use of certain FDA-approved patient labeling to fulfill the brief summary requirement for prescription drug and biological product print advertisements directed toward consumers. FDA said it would not object to the use of FDA-approved patient labeling if such labeling were reprinted in full and comprehensively discussed in consumer-friendly language the product's most serious and most common risks. FDA believed that this labeling contained the information patients would likely find helpful in deciding whether to discuss with their health care provider the possible usefulness of the product for their own health care.

Center for Drug Evaluation and Research (CDER's) Division of Drug Marketing, Advertising and Communications (DDMAC) Operations:

Since 1997, DDMAC has been staffed with about 28-30 staff members. This has recently been increased to 40 staff members. Of the 40 staff members, 20 are primary reviewers and 5 are secondary reviewers (team leaders). The review staff currently has six review groups. Four are Professional Review Groups, each with two review teams, who review materials prepared for health care professionals. In addition, there is one Direct-to-Consumer Review Group consisting of two review teams and one research team; one Evidence Review Group; and a Policy and Enforcement Team. All report to the Division Director.

With the transfer of the therapeutic products from the Center for Biologics Evaluation and Research (CBER), CDER has created a seventh review group within DDMAC to be officially transferred October 1, although the staff currently is at DDMAC in detail status. The Biologic Review Group, which consists of a team leader and three reviewers, will review the promotional materials for the products that are being transferred from CBER.

Under the post-marketing submission requirement, DDMAC received approximately 31,600 pieces of all categories of promotional material in 1999; 32,100 in 2000; 34,200 in 2001 and 36,700 in 2002. Although DDMAC is unable to thoroughly review every piece, certain materials are flagged for expedited review. These include materials that introduce newly approved products or products with new indications, which
we identify as launch. These go to the Professional Review Groups and to the Direct-to-Consumer Review Group if consumer materials are part of the "launch" campaign. Also flagged for expedited review are TV and radio advertisements, which go to the Direct-to-

Consumer Review Group. In addition to promotional materials that are submitted at the time of initial use, DDMAC reviews complaints about promotion from competitors, health care professionals, and consumers; promotional activities in the commercial exhibit halls of scientific meetings; promotional meetings; and evolving technology.

The total number of DTC broadcast advertisements (TV and radio) submitted to DDMAC in recent years was: 1999 - 293; 2000 - 443; 2001 - 376 and 2002 - 486. This includes both those advertisements that were proposed but not aired and those that were aired. Since January 1997, sponsors of 93 prescription drugs (see Attachment B) have aired "product-claim" and/or "reminder" advertisements on television or radio. A small number of prescription biological products also have been aired. It is important to note that DDMAC does not know how many different variations of the original advertisements have aired in broadcast media for these 93 drugs. Many of the products have been the subjects of multiple campaigns and many of the campaigns include different length "product-claim" commercials – variations of the initial commercial submitted to the Agency. It would be impossible for DDMAC to try to track the number of different broadcast advertisements that are aired. In addition, because "help-seeking" ads, if properly done, are not considered to be drug ads, most product sponsors do not send them to DDMAC. Thus, we have no measure of how many of them have been in the public domain.

DDMAC does not track the number of DTC print ads. Last year, however, DDMAC estimated the consumer pieces to be about one-sixth of the total, or about 6,000. It should be noted that these are not all DTC print and broadcast ads, but also consumer promotional pieces distributed by drug companies directly to consumers or through health care providers.

An Example of How the DTC Review Group Functions

DDMAC uses a group meeting to discuss proposed promotional pieces and decide on our response to the company. A typical meeting to review a new proposal for a drug that already has been advertised in a broadcast medium includes a DTC review team and group leader, someone from one of the professional review groups, a social scientist, and a regulatory counsel, also from DDMAC’s staff. Drugs that are new products, have new indications, are first in a class to have broadcast advertisements, or are being advertised in a broadcast medium for the first time have more extensive reviews.

Almost all companies send new proposed DTC broadcast concepts to DDMAC for comments in advance of use, although companies are under no obligation to follow DDMAC’s advice. Consequently, DDMAC generally does not see the final broadcast ad before the company submits it as part of its post-marketing requirements at the time the ad is first aired on TV or radio. DDMAC instituted the group review process for proposals in an effort to help ensure that DDMAC provide consistent advice to companies across product classes, and over time.

Current Regulatory Tools As stated previously, unless sponsors voluntarily submit their draft materials for comment before use, DDMAC sees the materials at the same time as the public. DDMAC’s options to address promotional materials that are false or misleading are:

Untitled letters – notices of violations issued to sponsors directing that they discontinue use of the violative false or misleading advertising materials
Warning Letters – issued to sponsors for more serious violations, such as those possibly posing serious health risks the public

Injunctions and consent decrees

Referrals for criminal investigation or prosecution

Seizures:

FDA has moved toward a risk-based enforcement strategy designed to achieve effective deterrence through use of Warning Letters and untitled letters that are more clearly designed to serve as a basis for further enforcement action. Under a directive issued to FDA by the Department of Health and Human Services in November 2001, all Warning Letters and untitled letters that originate within FDA, including DDMAC letters, must be reviewed and cleared by the Agency’s Office of the Chief Counsel (OCC) before issuance. OCC review focuses on ensuring that the correct legal violation has been cited, that the violation is substantiated by the facts, and that enforcement action is legally sustainable if the violation continues. Under this system, a firm that receives a DDMAC letter is on notice that OCC has already determined that enforcement action based on the cited violation stands a relatively high likelihood of succeeding in court. Put another way, FDA now uses Warning Letters to presage enforcement action, not substitute for it. Moreover, firms that commit repeated violations face a much stronger basis for further enforcement action. The Agency acknowledges that in some instances, this may result in longer review times, however, OCC and DDMAC work together to minimize delays and have agreed to expedite the review of certain letters by setting a goal of 15 working days for completing such reviews.

Criteria Used When Issuing an Untitled or Warning Letter:

Untitled letters are used for less serious violations than Warning Letters. Such violations may include overstating the effectiveness of the advertised drug product, suggesting a broader range of conditions than the drug was approved for, or making misleading claims because of inadequate context or lack of balancing risk information. Warning Letters address more serious violations including serious safety or health risks and/or repetitive violative conduct which, if not promptly and adequately corrected, could lead to additional enforcement actions without further notice from FDA. Warning Letters generally result in the company disseminating a remedial message to correct the violative ad.

Educational Programs for Industry:

DDMAC aims to increase voluntary compliance by industry through educational programs. These programs include outreach, website postings, guidances, and advisory comments.

Outreach Programs:

FDA staff participates in many panel discussions and presentations for groups including industry, law firms, consultants to industry, and marketing and advertising agencies. These programs are intended to increase these groups’ understanding of the regulations relating to promotion of prescription drugs so that industry can better comply.
Website Postings:

CDER posts on its website all Warning Letters and Untitled Letters and the cited promotional materials. Industry has noted that these letters serve as useful examples of violations that FDA has acted against and helps them understand what type of promotion is unacceptable.

Guidances: FDA publishes guidances in areas for which industry seeks clarification. An example is the guidance on broadcast advertisement published in August 1999, following on the draft guidance published in August 1997. Guidances help industry understand FDA’s current thinking and how to comply with the regulations.

Advisory Comments:

Although there is no requirement, for most drugs, that companies submit proposed promotional materials BEFORE their initial use, companies often request DDMAC’s review and comments on proposed materials. We provide this service so that companies can ensure that their materials are in compliance with the regulations.

Enforcement Related To DTC Promotion:

Since August 1997, for broadcast advertisements, FDA has issued:

45 untitled (or “Notice of Violation”) letters on “product-claim” broadcast ads. Such letters request that the violative promotion be stopped immediately. Product sponsors virtually always comply immediately with this request.

3 Warning Letters on broadcast ads. This is a higher-level enforcement action, and requests that a remedial campaign be conducted by the company to correct the misimpressions left by the ad. 13 untitled letters on purported reminder broadcast ads. 3 untitled letters on purported “help-seeking” broadcast ads.

Most of the violations cited were because the ad overstated or guaranteed the product’s efficacy, expanded the indication or the patient population approved for treatment, or minimized the risks of the product, through either inadequate presentation or omission of information.

Since August 1997, for print advertisements, the Agency has issued:

54 untitled letters that addressed DTC print ads or other promotional materials, including purported “reminder” and “help-seeking” materials.

2 Warning Letters: one for a specific DTC print ad and one that included a DTC print ad as part of an overall misleading campaign.

Generally, the violations for “product-claim” print ads were similar to those cited above. Nearly all “reminder” ad violations were the result of representations about the product that triggered the need for full disclosure of benefits and risks. “Help-seeking” ad violations were due to a particular product being suggested in the message. FDA cannot determine how many specific advertisements serve as the denominator for assessing how many have resulted in enforcement action compared with those that have not.
FDA's DTC Promotion Research:

A number of groups, including FDA, have been conducting research on DTC promotion to learn about its effects on consumers and physicians. As part of its commitment to examine the effect of DTC promotion on public health, FDA has conducted three national telephone surveys of U.S. adults to ask their views on DTC promotion of prescription drugs and its effects on the patient-physician relationship. One consumer survey was conducted in the spring of 1999 and again in the spring of 2002. FDA has only released the preliminary results of the 2002 consumer and physician surveys and is currently working on the final report which is expected to be released some time in the fall of 2003. FDA is planning a public meeting to present this information and to give other organizations and individuals an opportunity to present their research to FDA. Specifics about this meeting will be announced in the Federal Register at a later date.

Two FDA Consumer Surveys On DTC Promotion:

In the two consumer surveys, FDA gave special attention to surveying adults who had recently visited a physician (within the last three months). Participants were asked questions measuring the influence of DTC advertising on attitudes toward prescription drugs' health-related behavior, and on aspects of the doctor-patient relationship. The preliminary results from these two consumer studies show:

Among respondents who had seen a doctor with the past three months and remembered seeing an ad for a prescription drug, approximately half in 1999 and approximately 40 percent in 2002 said that an advertisement for a prescription drug had caused them to seek more information, for example, about the drug and their health.

Among those respondents who indicated that a DTC ad had caused them to search for more information in 2002, 61 percent reported they were searching for information about side effects.

More than a quarter (27 percent) of survey respondents in 1999 and 18 percent in 2002 who had seen a doctor in the last three months said that an ad for a prescription drug had caused them to ask a doctor about a medical condition or illness that they had not talked to a doctor about before.

In both 1999 and 2002, the most frequently reported reasons for visiting a doctor are the presence of a previous condition, the need for a checkup, or that the respondent had not been feeling well. Less than 7 percent of respondents report that they visited their doctor because of something they read or saw, or because of an ad for a prescription drug.

Forty-two percent of respondents in 2002 agreed strongly or somewhat agree that DTC ads make it seem as though the drug will work for everyone.

The results of the two consumer surveys need additional analysis but indicate that DTC may serve as stimulus for consumers to seek more information about their health and the drug product including the risks associated with the use of the drug.

Preliminary Results Of FDA's 2002 Survey Of Physicians:

Highlights of the preliminary results of FDA's survey of 500 physicians in the U.S. about DTC promotion include:
Many physicians believe that DTC advertising can play a positive role in their interactions with their patients. For example, most agreed that because their patients saw a DTC ad, he or she asked more thoughtful questions.

Some physicians thought the ads made their patients more aware of possible treatments.

Many physicians thought that DTC ads made their patients more involved in their health care. Physicians felt they had to provide additional information to patients beyond what the patients retained from the DTC ad. About 75 percent believed that DTC ads cause patients to think the drug works better than it did, and many physicians felt some pressure to prescribe something when patients mentioned DTC ads.

Forty percent of physicians believe that patients understood well the possible risks and negative effects of an advertised drug from the DTC ad alone.

Eight percent of physicians felt very pressured and 20 percent felt somewhat pressured to prescribe the specific brand name drug when the patient asked the physician to do so. Most physicians suggested alternative courses of action. The physician survey is an important tool to consider when doing the evaluation of the impact of DTC advertising on public health because of the role of the physician as the "learned intermediary." The patient does not select the drug for self-use but the decision is made by the physician in consultation with the patient. The results of the physician survey are preliminary but indicate that DTC advertising, when done correctly, can serve positive public health functions such as increasing patient awareness of diseases that can be treated, and prompting thoughtful discussions with physicians that result in needed treatments being prescribed. Often, the treatment that was prescribed was not the drug the patient saw advertised. Physicians in this survey indicate that they appeared comfortable in not necessarily prescribing the advertised drug for reasons including: that a different drug was more appropriate, the drug was not right for the patient, the drug has side effects of which the patient was not aware, and/or a less expensive drug was available. Two concerns that physicians expressed are that DTC advertising causes patients to think that the drug works better than it did and that patients did not understand very well the possible risks of the advertised drug.

Future Agency Activities Concerning DTC Advertising:

FDA is committed to ensuring that its DTC advertising policies promote truthful and non-misleading advertising that helps to better inform consumers about their health and health care choices and prevents potential misconceptions about benefits and risks of the advertised treatment. Two concerns expressed by some physicians in FDA's survey, relate to overstatement of the product's efficacy and inadequate conveyance of risk information, and are two of the most common violations cited in the letters that FDA issues to pharmaceutical companies about DTC ads. FDA will continue to review DTC ads closely to ensure that essential information is communicated as clearly as possible, as outlined in our current policies. In addition, FDA will continue its comprehensive evaluation of DTC advertising and its impact on public health and FDA's policies and guidances.

In sum, prescription drug advertising can provide consumers with important information about new prescriptions and new indications for existing prescription drugs, as well as information about symptoms of treatable illnesses and other conditions. Done properly, prescription drug advertising can assist consumers in taking a pro-active role in improving their health. However, to be of value, these advertisements must not be false and misleading. As a result, FDA continues to closely monitor DTC advertising to help ensure that this promotional activity is accurate and balanced. FDA will complete evaluation of its own research and that of other groups to help ensure that FDA's policies in regulating DTC advertising are optimal. To this end, the Agency is planning a public meeting in the fall for a full
discussion of the known research. This concludes my remarks, Mr. Chairman. I will be glad to answer any questions you may have.

(http://www.fda.gov/ola/2003/AdvertisingcIPrescriptionDrugs0722.htm)

GUIDANCE FOR INDUSTRY Consumer-Directed Broadcast Advertisement

Introduction: This guidance is intended to assist sponsors who are interested in advertising their prescription human and animal drugs, including biological products for humans, directly to consumers through broadcast media, such as television, radio, or telephone communications systems.

The purpose of this guidance is to describe an approach that FDA believes can fulfill the requirement for adequate provision in connection with consumer-directed broadcast advertisements for prescription drug and biological products. The approach presumes that such advertisements:

Are not false or misleading in any respect. For a prescription drug, this would include communicating that the advertised product is available only by prescription and that only a prescribing healthcare professional can decide whether the product is appropriate for a patient.

Present a fair balance between information about effectiveness and information about risk.

Include a thorough major statement conveying all of the product’s most important risk information in consumer-friendly language.

Communicate all information relevant to the product’s indication (including limitations to use) in consumer-friendly language.

Fulfilling The Adequate Provision Requirement: A sponsor wishing to use consumer-directed broadcast advertisements may meet the adequate provision requirement through an approach that will allow most of a potentially diverse audience to have reasonably convenient access to the advertised product’s approved labeling. This audience will include many persons with limited access to technologically sophisticated outlets (e.g., the Internet) and persons who are uncomfortable actively requesting additional product information or are concerned about being personally identified in their search for product information. One acceptable approach to disseminating the product’s approved labeling is described below. This approach includes the following components.

A. Disclosure in the advertisement of an operating toll-free telephone number for consumers to call for the approved package labeling. Upon calling, consumers should be given the choice of:

Having the labeling mailed to them in a timely manner (e.g., within 2 business days for receipt generally within 4-6 days); or Having the labeling read to them over the phone (e.g., by offering consumers a selection of prerecorded labeling topics).

B. Reference in the advertisement to a mechanism to provide package labeling to consumers with restricted access to sophisticated technology, such as the Internet and those who are uncomfortable actively requesting additional product information or are concerned about being personally identified in their search for product information. One acceptable mechanism would be to provide the additional product information in the form of print advertisements appearing concurrently in publications that reach the exposed audience. The location of at least one of these advertisements would be referenced in the
broadcast advertisement. If a print advertisement is part of an adequate provision procedure, it should supply a toll-free telephone number and an address for further consumer access to full package labeling. This mechanism of providing access to product labeling has the advantage of also providing considerable information in the form of the required brief summary and in the advertising text itself.

C. When a broadcast advertisement is broadly disseminated, FDA believes that ensuring that passive and privacy-sensitive information seekers have adequate access to detailed product information is critical to complying with the adequate provision regulatory requirement. Thus, print advertisements associated with broadly disseminated broadcast advertisements should be comparably broadly disseminated in terms of the targeted audiences.

An alternative mechanism for providing private access to product information would be to ensure the availability of sufficient numbers of brochures containing package labeling in a variety of publicly accessible sites (e.g., pharmacies, doctors' offices, grocery stores, public libraries). Brochures should be available at enough sites so that most consumers exposed to the broadcast advertisement can obtain the labeling without traveling beyond their normal range of activities. This alternative mechanism is likely to be logistically feasible only when the associated broadcast advertising campaign is relatively limited in audience reach.

D. Disclosure in the advertisement of an Internet web page (URL) address that provides access to the package labeling.

E. Disclosure in the advertisement that pharmacists, physicians (or other healthcare providers), or veterinarians (in the case of animal drugs) may provide additional product information to consumers. This statement should communicate clearly that the referenced professional is a source of additional product information.

Telephone advertisements that make a product claim (not reminder advertisements) occur when there is a telephone communication between an individual and a product's sponsor where both a product name and a representation or suggestion relating to a product (e.g., its indication) are disclosed by the sponsor. Under these circumstances, such advertisements are subject to the disclosure requirements of the Act and the regulations. However, telephone advertisements are different from advertisements broadcast through television and radio. By participating in the telephone communication, the consumer has already indicated his or her willingness to discuss the topic or receive additional information. Consequently, adequate provision for disseminating product labeling in connection with telephone advertisements may be achieved with fewer of the components listed above. For such advertisements, adequate provision could consist of the availability of the option of having product labeling mailed to the caller in a timely manner (e.g., within 2 business days for receipt generally within 4-6 days), or having the labeling read to them over the phone (e.g., by allowing consumers to select from prerecorded labeling topics), as well as disclosing that health care providers are a source of additional product information.

When a broadcast advertisement is presented in a foreign language, the information sources that are part of the advertisement's "adequate provision" mechanism (i.e., print advertisements or brochures, websites, toll-free telephone number recorded messages or operators) should be in the language of the broadcast ad. Regardless of the language used for the advertisement, current broadcast advertising regulations require the dissemination of approved product labeling, which, in most cases, must be in English, and is generally written in language directed to health care professionals. The Agency strongly encourages sponsors to consider the benefits of also providing consumers with nonpromotional, consumer-friendly product information in the language of the broadcast ad (e.g., FDA-approved patient labeling or accurate, consumer-friendly translations of product labeling information).
The FDA encourages sponsors who use this adequate provision mechanism to collect relevant data on consumer use and make their findings publicly known. FDA also encourages sponsors and other interested parties to make known their research relating to the overall effects of DTC promotion on the public health.

Footnotes

1. This guidance has been prepared by the intra-Agency Group on Advertising and Promotion at the Food and Drug Administration. This guidance represents the Agency’s current thinking on procedures to fulfill the requirements for disclosure of product information in connection with consumer-directed broadcast advertisements for prescription human and animal drugs, and human biological products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

2. This guidance is not intended to cover the advertising of restricted medical devices, which are subject to the requirements of section 502(r) of the Federal Food, Drug, and Cosmetic Act (http://www.fda.gov/ola/2003/AttachmentA0722.html)

Prescription Drug Product Ads Broadcast Directly to Consumers Since 8/97
By Drug Category Includes Product Claim Ads and Reminder Ads As of 7/17/03

<table>
<thead>
<tr>
<th>Category</th>
<th>Product</th>
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<tr>
<td>Cholesterol/Heart Disease</td>
<td>Altace, Lescol, Lipitor, Plavix, Pravachol, WelChol, Zocor</td>
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<tr>
<td>Osteoporosis/Menopause</td>
<td>Actonel, Evista, Fosamax, Premarin, Prempro</td>
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<tr>
<td>Mental-Health</td>
<td>Buspar (persistent anxiety), Paxil (social or generalized anxiety disorder), Prozac (depression), Sarafem (PMD), Wellbutrin SR (depression), Zoloft (depression, PTSD, Panic)</td>
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<tr>
<td>Smoking Cessation</td>
<td>Nicotrol Inhaler, Zyban</td>
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### Diabetes
- Avandia
- Glucophage XR (radio)

### Asthma
- Accolate
- Advair Diskus
- Flovent
- Singulair

### STDs
- Alcara (genital warts)
- Valtrex (genital herpes)

### Arthritis
- Celebrex
- Mobic
- Vioxx

### Contraception
- Depo-Provera
- Ortho Tri-Cyclen (and acne)
- Plan B
- Yasmin

### Allergies
- Allegra
- Clarinex
- Claritin Tablets
- Claritin Syrup
- Claritin D-24
- Flonase
- Nasacort/AQ
- Nasonex
- Patanol (ocular)
- Rhinocort AQ
- Singulair
- Zaditor (ocular)
- Zyrtec

### Acute Otitis Media
- Rocephin injection
- Zithromax oral suspension

### Influenza
- Relenza
- Tamiflu

### Overactive Bladder
- Detrol
- Ditropan XL

### Migraines
- Imitrex
- Zomig

### GERD-Related Heartburn
- Nexium
- (EE)
- Prevacid
Drug Enforcement Laws – Globalization, Vis-à-Vis, Indian Drug Laws

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<td>Insomnia</td>
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<td>Ambien</td>
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<td>Sonata</td>
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<td>Weight loss</td>
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<td>Meridia</td>
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<td>Xenical</td>
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<tr>
<td>Skin/Hair-Related</td>
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<tr>
<td>Denavir (cold sores)</td>
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<tr>
<td>Differin (acne)</td>
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<tr>
<td>Lamisil (nail fungus)</td>
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<td>Luxiq (scalp psoriasis/radio)</td>
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<td>MetroGel (rosacea)</td>
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<tr>
<td>Ortho Tri-Cyclen (acne/contraception)</td>
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<td>Propecia (male baldness)</td>
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<td>Prottopic (eczema)</td>
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<td>Retin-A Micro (acne)</td>
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<td>Valtrex (cold sores)</td>
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<td>Vaniqa (unwanted facial hair)</td>
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<td>Impotence (ED)</td>
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<td>MUSE</td>
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<td>Other</td>
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<td>Combitil (HIV/radio)</td>
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<td>Covera HS (hypertension)</td>
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<td>Diflucan (vaginal fungal infection)</td>
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<tr>
<td>Epi-Pen (anaphylaxis)</td>
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<td>Flomax (benign prostatic enlargement)</td>
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<td>Periostat (periodontitis aid)</td>
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<td>Plavix (acute coronary syndrome (ACS))</td>
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<tr>
<td>Serevent (COPD)</td>
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<tr>
<td>Zelnorm (irritable bowel syndrome (IBS) with constipation)</td>
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(http://www.fda.gov/ola/2003/AttachmentB0722.html)

GUIDANCE FOR INDUSTRY

Aerosol Steroid Product Safety Information in Prescription Drug Advertising and Promotional Labeling

I. Introduction: Aerosol steroid products (i.e., inhaled corticosteroid drug products) may be used after a course of therapy with systemic steroids. Labeling for all aerosol steroid products contains a prominent...
boxed warning that describes the importance of switching carefully from systemic to inhaled steroids to prevent the life-threatening occurrence of adrenal insufficiency.

II. Precautionary Statement in Advertisements and Labeling: Certain precautionary information addressing the life-threatening occurrence of adrenal insufficiency when patients switch from systemic to aerosol steroid products should be included in advertising and promotional labeling for the aerosol steroid products. Advertisements and promotional labeling that only contain a notice referring to the brief summary or full prescribing information for this precautionary information would not meet the fair balance requirements under § 202.1, ‘True Statement’ of information (21 CFR 202.1(e)(5)).

Therefore, all advertisements and labeling for aerosol steroid products should contain within the body of the advertisement or labeling piece a prominent note similar to the following:

CAUTION: Adrenal Inefficiency May Occur When

TRANSFERRING PATIENTS FROM SYSTEMIC STEROIDS (SEE WARNINGS)

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1 This guidance has been prepared by the Division of Drug Marketing, Advertising, and Communications in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration. This guidance document represents the Agency's current thinking on aerosol steroid safety information in prescription drug advertising and labeling. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. Additional copies of this draft guidance document are available from the Drug Information Branch, Division of Communications Management, HFD-210, 5600 Fishers Lane, Rockville, MD 20857, (Tel) 301-827-4573. 

(http://www.fda.gov/cder/guidance/1326fnl.pdf)

Guidance for Industry

Industry-Supported Scientific and Educational Activities

Food and Drug Administration Office of Policy November 1997

This guidance has been prepared by FDA’s Intra-Agency Working Group on Advertising and Promotion. This guidance represents the Agency’s current thinking on industry-supported scientific and educational activities. It does not create or confer any rights for or on any person and does not operate to bind FDA or the industry. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

I. Background: Promotion, Education, and Independence

Two important sources of information on therapeutic products (human and animal drugs, biological products, and medical devices regulated by the Food and Drug Administration (FDA)) for health care professionals are: (1) Activities (programs and materials) performed by, or on behalf of, the companies that market the products; and (2) activities, supported by companies, that are otherwise independent from the promotional influence of the supporting company. Although both provide valuable and sometimes vital information to health care professionals, the programs and materials performed and disseminated by
companies are subject to the labeling and advertising provisions of the Federal Food, Drug, and Cosmetic Act (the act), whereas the truly independent and nonpromotional industry-supported. In this context, the terms "independent" and "nonpromotional" are not mutually exclusive. The agency views independence as an indication of whether an activity is nonpromotional.

This jurisdictional line is important because the constraints on advertising and labeling, when applied to scientific and educational activities, can restrict the freedom of participants to discuss their data or express their views. In particular, discussions of unapproved uses, which can be an important component of scientific and educational activities, are not permissible in programs that are or can be (because the provider is not functionally independent) subject to substantive influence by companies that market products related to the discussion. Thus, the agency, has traditionally sought to avoid regulating activities that are produced independently from the influence of companies marketing the products. The agency recognizes that industry-supported activities can be both nonpromotional and educational.

These provisions require the company to ensure that the content does not promote unapproved uses, and that discussions of the company's products are not false or misleading and do not lack fair balance.

Demarcating the line between activities that are performed by or on behalf of the company, and thus, subject to regulation, and activities that are essentially independent of their influence has become more difficult due to the increasing role industry has played in supporting postgraduate and continuing education for health care professionals.

The agency traditionally has recognized the important public policy reasons not to regulate all industry-supported activities as advertising or labeling. To permit industry support for the full exchange of views in scientific and educational discussions, including discussions of unapproved uses, FDA has distinguished between those activities supported by companies that are nonpromotional and otherwise independent from the substantive influence of the supporting company and those that are not. Those activities that have been deemed by the agency to be independent from influence by the supporting company and nonpromotional have not been treated as advertising or labeling, and have not been subjected to the agency's regulatory scrutiny.

In determining whether an activity is independent of the substantive influence of a company, the agency examines whether and to what extent the company is in a position to influence the presentation of information related to its products or otherwise transform an ostensibly independent program into a promotional vehicle. FDA is concerned that companies may influence the content of educational programs both directly and indirectly. Directly, by being involved in the selection of speakers or in the treatment of topics. Indirectly, through the nature of the relationship between the company and the provider (e.g., if the provider has reason to believe that future financial support from the company depends upon producing programs that promote the company's products.)

FDA is responsible for seeing that scientific and educational activities that are not intended to be promotional are designed to be truly independent from substantive influence by the marketers of regulated products. The agency recognizes, however, that the primary responsibility for overseeing the process of postgraduate and continuing professional education and scientific exchange lies with the scientific and health care communities and accrediting organizations. Accordingly, FDA will work closely with scientific and professional health care communities and accrediting organizations to help ensure that provider activities are independent.
The agency is providing this guidance to describe the agency's enforcement policy with regard to scientific and educational activities supported by industry. The guidance seeks to clarify the distinction drawn by the agency between scientific and educational activities that FDA considers nonpromotional and those that the agency considers promotional, and to provide guidance on how industry may support such activities without subjecting them to regulation under the labeling and advertising provisions of the act.

This guidance applies only to those company-supported activities that relate to the supporting company’s products or to competing products. A company-supported educational activity or part thereof that does not relate to the company's products or a competing product, or suggest a use for the company's products, would not be considered a promotional activity under this guidance.

II. Guidance: Industry-Supported Scientific and Educational Activities

FDA has not regulated and does not intend to regulate, under the labeling and advertising provisions of the act, industry-supported scientific and educational activities that are independent of the influence of the supporting company. Companies and providers who wish to ensure that their activities will not be subject to regulation should design and carry out their activities free from the supporting company's influence and bias, based on the factors considered in evaluating activities and determining independence, as described below. These factors are provided to furnish guidance on the design and conduct of such activities, so that they will be educational and nonpromotional in nature. These factors will be considered as part of an overall evaluation of an activity; no individual factor is likely by itself to stimulate an action based on lack of independence.

A. Factors Considered in Evaluating Activities and Determining Independence

FDA will consider the following factors in evaluating programs and activities and determining independence:

(1) Control of Content and Selection of Presenters and Moderators

The agency will consider whether the provider has maintained full control over the content of the program, planning of the program's content, and over the selection of speakers and moderators. In so doing, the agency will look at whether the supporting company has engaged in scripting, targeting points for emphasis, or other actions designed to influence the program's content. In addition, the agency will consider if the company has suggested speakers who are or were actively involved in promoting the company's products or who have been the subject of complaints or objections with regard to presentations that were viewed as misleading or biased in favor of the company's products.

(2) Disclosures

The agency will consider whether there was meaningful disclosure, at the time of the program, to the audience of: (1) The company's funding of the program; (2) any significant relationship between the provider, presenters or moderators, and the supporting company (e.g., employee, grant recipient, owner of significant interest or stock); and (3) whether any unapproved uses of products will be discussed;

(3) The Focus of the Program
The agency will consider whether the intent of the company and the provider is to produce an independent and nonpromotional activity that is focussed on educational content and free from commercial influence or bias. The agency will also consider whether the title of the activity fairly and accurately represents the scope of the presentation.

The agency also will look at the focus of the activity to determine if the central theme is based on a single product marketed by the company or a competing product, except when existing treatment options are so limited as to preclude any meaningful discussion of alternative therapies. This is not to suggest that each treatment option must be discussed with precisely equal emphasis. However, emphasis on a newer or, in the view of the presenter, more beneficial treatment modality should be provided in the context of a discussion of all reasonable and relevant options.

(4) Relationship Between Provider and Supporting Company

The agency will consider whether there are legal, business, or other relationships between the company and the provider that could place the company in a position whereby it may exert influence over the content of the activity (e.g., a provider that is owned by, or is not viable without the support of, the company supporting the activity).

(5) Provider Involvement in Sales or Marketing

The agency will consider whether individuals employed by the provider and involved in designing or conducting scientific or educational activities are also involved in advising or otherwise assisting the company with respect to sales or marketing of the company's product.

(6) Provider’s Demonstrated Failure to Meet Standards

The agency will consider whether the provider has a history of conducting programs that fail to meet standards of independence, balance, objectivity, or scientific rigor when putting on ostensibly independent educational programs.

(7) Multiple Presentations

The agency will consider whether multiple presentations of the same program are held. (FOOTNOTE)

FDA recognizes that some repeat programs can serve public health interests. The Department of Health and Human Services sometimes actively encourages multiple presentations on selected urgent topics.

(8) Audience Selection

The agency will consider whether invitations or mailing lists for supported activities are generated by the sales or marketing departments of the supporting company, or are intended to reflect sales or marketing goals (e.g., to reward high prescribers of the company's products, or to influence "opinion leaders").

(9) Opportunities for Discussion

In the case of a live presentation, the agency will consider whether there was an opportunity for meaningful discussion or questioning provided during the program.
(10) Dissemination

The agency will consider whether information about the supporting company's product presented in the scientific or educational activity is further disseminated after the initial program, by or at the behest of the company, other than in response to an unsolicited request or through an independent provider as discussed herein.

(11) Ancillary Promotional Activities

The agency will consider whether there are promotional activities, such as presentations by sales representatives or promotional exhibits, taking place in the meeting room.

(12) Complaints

The agency will consider whether any complaints have been raised by the provider, presenters, or attendees regarding attempts by the supporting company to influence content.

B. Additional Considerations

The foregoing list of factors is not intended to be exhaustive and other factors may be appropriate for consideration in a particular case.

One means of documenting the measures taken to ensure independence of an activity is to have a written agreement between the provider and the supporting company. This document should reflect that the provider will be solely responsible for designing and conducting the activity, and that the activity will be educational, nonpromotional, and free from commercial bias. While not required, a written agreement, coupled with the factors described above, can provide valuable evidence as to whether an activity is independent and nonpromotional.

III. FDA'S Cooperation With Major Accrediting Organizations

FDA recognizes the important role accrediting organizations can play in ensuring that industry-sponsored educational activities are independent and nonpromotional. The agency also recognizes the importance of avoiding undue Government interference in postgraduate and continuing education for health care professionals, as the agency seeks to ensure that company-promotional activities meet applicable legal requirements. Thus, the agency will continue to work with major accrediting organizations to monitor company-supported educational activities conducted by their accredited providers.

Date created: December 4, 1997; last update: July 6, 2005 (http://www.fda.gov/cder/guidance/isse.htm)

Examples Of Recall Of Drugs Due To Incorrect Labelling: The FDA Enforcement Report is published weekly by the Food and Drug Administration, Department of Health and Human Services. It contains information on actions taken in connection with agency Regulatory activities.

September 1, 2010
Recalls And Field Corrections: DRUGS - CLASS III

Product
Acetaminophen Tablets, Acetaminophen 325 mg., 100 tablet bottles, OTC, sold under the following brand names: Good Neighbor Pharmacy Pain Relief, Good Neighbor Pharmacy, NDC 24385-403-78; Care One Pain Relief Care One, NDC 41520-403-78; H.E.B. Pain Relief, H.E.B, NDC 37808-403-78; HyVee Pain Relief, NDC 42507-403-78; Leader Pain Reliever, NDC 57205-031-78; CVS Pain Relief, NDC 59779-403-78; Sunmark Pain reliever, NDC 49348-009-10; Hannaford Pain Reliever, NDC 41268-403-78; Equaline pain relief, NDC 41163-403-78; TopCare Pain Relief, NDC 36800-0403-78; Goodsense Pain Relief, NDC 0113-0403-78. Recall # D-768-2010

Code
Lot numbers: 0BE2230, 0CE1359, 0CE1623, 0CE2533, 0DE1161, 0DE1610 and 0EE1594

Recalling, Firm / Manufacturer

Reason: The liver warning section of the product label warns that severe liver damage may occur if an adult takes more than 8 tablets in 24 hours. The warning should state that liver damage may occur if an adult takes more than 12 tablets in 24 hours

Volume Of Product In Commerce
60,594-bottles

DISTRIBUTION-Nationwide
(http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm)

August 25, 2010

Recalls And Field Corrections: Drugs- Class II

Product: Cephalexin for Oral Suspension USP, 125 mg/5 mL, 100 mL bottle, Rx only, NDC 0093-4175-73, Recall #, -774-2010


Reason: Subpotent (single ingredient) Drug: The product was found to be sub potent at the 12 month, stability-time-point.

Volume Of Product In Commerce: 12,776-bottles

DISTRIBUTION-Nationwide
(http://www.fda.gov/Safety/Recalls/EnforcementReports/ucm224125.htm)

August 18, 2010

Product: Losartan Potassium and Hydrochlorothiazide tablets, 100 mg/12.5 mg, Rx only 90 tablets, NDC,0781-5817-92, Recall #, D-767-2010
Code: Lot Number: Z1809, Exp. Date: 01-2013; Lot Number: Z1895, Exp. Date: 02-2013 and Lot-Number:E004934,Exp.Date:02-2013

Manufacturer: Merck Sharp & Dohme Ltd., Cramlington North D, UK. Firm initiated recall-is-ongoing.

Reason: Labeling error: The front portion of the bottle label correctly states the product strength as "100mg/12.5mg", while the text on the back portion of the bottle label incorrectly states "Each tablet contains 100 mg losartan potassium and 25 mg hydrochlorothiazide."

Volume Of Product In Commerce: 16,690,unit-packages

Distribution—CO

July 7, 2010

Product: Metronidazole Injection, USP, 500 mg/100 mL (5 mg/mL), Single Dose Premix Bag, Rx only, 24 bags per case; NDC 25021-131-82, UPC 3 25021 13182 4. Recall # D-667-2010


Reason: Non-Sterility: This product is being recalled because of two complaints of a white feathery substance floating inside the IV bag which was identified as Mucor spp. fungus.

Volume of Product In Commerce: 142,176,bags

Distribution- Nationwide

June 30, 2010

Product: LITTLE TUMMYS Stimulant Laxative Drops (Sennosides 8.8mg/mL), 1 fl oz (30 mL) dropper bottle. OTC. UPC Code: 7 56184 12071 2; Product Code: 10756184123222. There are 24 packages in each case. Recall # D-615-2010

Code: Lots: 08288 (exp. 07/28/10), 08518 (exp. 12/18/10), 09415 (exp. 10/16/11), 09478 (exp. 12/03/11)

Recalling Firm / Manufacturer: Recalling Firm: Medtech Products, Inc., Irvington, NY, by e-mail, telephone or visit on April 19, 2010 and by letters on April 20, 2010. Manufacturer: Altaire Pharmaceuticals, Inc., Aquebogue, NY. Firm initiated recall is ongoing.

Reason: Defective Container: seal breach on tamper evident foil seal.

Volume Of Product In Commerce: 193,992,bottles,(8083-cases-of-24-each)

Distribution: Nationwide
June 23, 2010

**Product:** Paroxetine Tablets, USP, 40 mg, 30-count bottles, Rx only; NDC 65862-157-30. Recall # D-559-2010

**Code:** Lot # PEP410005-A, Exp 12/11


**Reason:** Labeling: Label Mix-Up: some bottles labeled as Paroxetine 40 mg tablets actually contain Citalopram 20 mg tablets.

**Volume Of Product In Commerce:** 20,424 bottles

**Distribution:** Nationwide

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**Product:** Tretinoin Cream, 0.025% Tretinoin topical cream, 20 gram tubes Rx only, NDC 4580218202. Recall # D-598-2010

**Code:** Lot & Exp 9AM459 JAN 2011 , 9DM626 April 2011, and 9EM634 May 2011


**Reason:** Labeling: Label Error on Declared Strength: Tretinoin Cream 0.025% was packaged in tubes labeled as Tretinoin Cream 0.1%.

**Volume Of Product In Commerce:** 82,866 tubes

**Distribution:** Nationwide

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**Product:** Sulfacetamide Sodium Topical Suspension USP, 10% (Lotion), 118mL (4 fl oz) Bottle, Rx only; NDC 51672-1346-8. Recall # D-602-2010

**Code:** Lots: G9101 expiration date July 2011, H9026 expiration date August 2011


**Reason:** Labeling: Label w/Wrong or Incorrect EXP. Date: The product is mislabeled with an incorrect (extended) expiration period of 24 months.

**Volume Of Product In Commerce:** 3,638 units

**Distribution:** Nationwide

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(http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm)
4.2 EUROPEAN UNION


(2) The essential aim of any rules governing the production, distribution and use of medicinal products must be to safeguard public health.

(3) However, this objective must be attained by means which will not hinder the development of the pharmaceutical industry or trade in medicinal products within the Community.

TITLE V: Labeling And Package Leaflet

Article 54: The following particulars shall appear on the outer packaging of medicinal products or, where there is no outer packaging, on the immediate packaging:

(a) the name of the medicinal product followed by its strength and pharmaceutical form, and, if appropriate, whether it is intended for babies, children or adults; where the product contains up to three active substances, the international non-proprietary name (INN) shall be included, or, if one does not exist, the common name;

(b) a statement of the active substances expressed qualitatively and quantitatively per dosage unit or according to the form of administration for a given volume or weight, using their common names;

(c) the pharmaceutical form and the contents by weight, by volume or by number of doses of the product;

(d) a list of those excipients known to have a recognized action or effect and included in the detailed guidance published pursuant to Article 65. However, if the product is injectable, or a topical or eye preparation, all excipients must be stated;

(e) the method of administration and, if necessary, the route of administration. Space shall be provided for the prescribed dose to be indicated;

(f) a special warning that the medicinal product must be stored out of the reach and sight of children;

(g) a special warning, if this is necessary for the medicinal product;

(h) the expiry date in clear terms (month/year);

(i) special storage precautions, if any;

(j) specific precautions relating to the disposal of unused medicinal products or waste derived from medicinal products, where appropriate, as well as reference to any appropriate collection system in place;
(k) the name and address of the marketing authorisation holder and, where applicable, the name of the representative appointed by the holder to represent him;

(l) the number of the authorization for placing the medicinal product on the market;

(m) the manufacturer's batch number;

(n) in the case of non-prescription medicinal products, instructions for use.

Article 55: 1. The particulars laid down in Article 54 shall appear on immediate packagings other than those referred to in paragraphs 2 and 3.

2. The following particulars at least shall appear on immediate packagings which take the form of blister packs and are placed in an outer packaging that complies with the requirements laid down in Articles 54 and 62.

— the name of the medicinal product as laid down in point (a) of Article 54,
— the name of the holder of the authorization for placing the product on the market,
— the expiry date,
— the batch number.

3. The following particulars at least shall appear on small immediate packaging units on which the particulars laid down in Articles 54 and 62 cannot be displayed:

— the name of the medicinal product as laid down in point (a) of Article 54 and, if necessary, the route of administration,
— the method of administration,
— the expiry date,
— the batch number,
— the contents by weight, by volume or by unit.

Article 56: The particulars referred to in Articles 54, 55 and 56 shall be easily legible, clearly comprehensible and indelible.

Article 56 a: The name of the medicinal product, as referred to in Article 54, point (a) must also be expressed in Braille format on the packaging. The marketing authorisation holder shall ensure that the package information leaflet is made available on request from patients' organisations in formats appropriate for the blind and partially-sighted.

Article 57: Notwithstanding Article 60, Member States may require the use of certain forms of labelling of the medicinal product making it possible to ascertain:

— the price of the medicinal product,
— the reimbursement conditions of social security organizations,
— the legal status for supply to the patient, in accordance with Title VI,
— identification and authenticity.

For medicinal products authorised under Regulation (EC) No 726/2004, Member States shall, when applying this Article, observe the detailed guidance referred to in Article 65 of this Directive.
Article 58: The inclusion in the packaging of all medicinal products of a package leaflet shall be obligatory unless all the information required by Articles 59 and 62 is directly conveyed on the outer packaging or on the immediate packaging.

Article 59: 1. The package leaflet shall be drawn up in accordance with the summary of the product characteristics; it shall include, in the following order:

(a) For the identification of the medicinal product:

(i) the name of the medicinal product followed by its strength and pharmaceutical form, and, if appropriate, whether it is intended for babies, children or adults. The common name shall be included where the product contains only one active substance and if its name is an invented name;
(ii) the pharmaco-therapeutic group or type of activity in terms easily comprehensible for the patient;

(b) The therapeutic indications;

(c) A list of information which is necessary before the medicinal product is taken:

(i) contra-indications;
(ii) appropriate precautions for use;
(iii) forms of interaction with other medicinal products and other forms of interaction (e.g. alcohol, tobacco, foodstuffs) which may affect the action of the medicinal product;
(iv) special warnings;

(d) The necessary and usual instructions for proper use, and in particular:

(i) the dosage,
(ii) the method and, if necessary, route of administration;
(iii) the frequency of administration, specifying if necessary the appropriate time at which the medicinal product may or must be administered; and, as appropriate, depending on the nature of the product:
(iv) the duration of treatment, where it should be limited;
(v) the action to be taken in case of an overdose (such as symptoms, emergency procedures);
(vi) what to do when one or more doses have not been taken;
(vii) indication, if necessary, of the risk of withdrawal effects;
(viii) a specific recommendation to consult the doctor or the pharmacist, as appropriate, for any clarification on the use of the product;

(e) A description of the adverse reactions which may occur under normal use of the medicinal product and, if necessary, the action to be taken in such a case; the patient should be expressly asked to communicate any adverse reaction which is not mentioned in the package leaflet to his doctor or pharmacist;

(f) A reference to the expiry date indicated on the label, with:

(i) a warning against using the product after that date;
(ii) where appropriate, special storage precautions;
(iii) if necessary, a warning concerning certain visible signs of deterioration;
(iv) the full qualitative composition (in active substances and excipients) and the quantitative composition in active substances, using common names, for each presentation of the medicinal product;

(v) for each presentation of the product, the pharmaceutical form and content in weight, volume or units of dosage;

(vi) the name and address of the marketing authorisation holder and, where applicable, the name of his appointed representatives in the Member States;

(vii) the name and address of the manufacturer;

(g) Where the medicinal product is authorised in accordance with Articles 28 to 39 under different names in the Member States concerned, a list of the names authorised in each Member State;

(h) The date on which the package leaflet was last revised.

2. The list set out in point (c) of paragraph 1 shall:

(a) take into account the particular condition of certain categories of users (children, pregnant or breastfeeding women, the elderly, persons with specific pathological conditions);

(b) mention, if appropriate, possible effects on the ability to drive vehicles or to operate machinery;

(c) list those excipients knowledge of which is important for the safe and effective use of the medicinal product and which are included in the detailed guidance published pursuant to Article 65.

3. The package leaflet shall reflect the results of consultations with target patient groups to ensure that it is legible, clear and easy to use.

Article 60: Member States may not prohibit or impede the placing on the market of medicinal products within their territory on grounds connected with labelling or the package leaflet where these comply with the requirements of this Title.

Article 61: 1. One or more mock-ups of the outer packaging and the immediate packaging of a medicinal product, together with the draft package leaflet, shall be submitted to the authorities competent for authorizing marketing when the marketing authorisation is requested. The results of assessments carried out in cooperation with target patient groups shall also be provided to the competent authority.

2. The competent authority shall refuse the marketing authorization if the labelling or the package leaflet do not comply with the provisions of this Title or if they are not in accordance with the particulars listed in the summary of product characteristics.

3. All proposed changes to an aspect of the labelling or the package leaflet covered by this Title and not connected with the summary of product characteristics shall be submitted to the authorities competent for authorizing marketing.

If the competent authorities have not opposed a proposed change within 90 days following the introduction of the request, the applicant may put the change into effect.

4. The fact that the competent authority do not refuse a marketing authorization pursuant to paragraph 2 or a change to the labelling or the package leaflet pursuant to paragraph 3 does not alter the general legal liability of the manufacturer and the marketing authorization holder.
Article 62: The outer packaging and the package leaflet may include symbols or pictograms designed to clarify certain information mentioned in Articles 54 and 59(1) and other information compatible with the summary of the product characteristics which is useful for the patient to the exclusion of any element of a promotional nature.

Article 63: 1. The particulars for labelling listed in Articles 54, 59 and 62 shall appear in the official language or languages of the Member State where the product is placed on the market.

The first subparagraph shall not prevent these particulars from being indicated in several languages, provided that the same particulars appear in all the languages used.

In the case of certain orphan medicinal products, the particulars listed in Article 54 may, on reasoned request, appear in only one of the official languages of the Community.

2. The package leaflet must be written and designed to be clear and understandable, enabling the users to act appropriately, when necessary with the help of health professionals. The package leaflet must be clearly legible in the official language or languages of the Member State in which the medicinal product is placed on the market. The first subparagraph shall not prevent the package leaflet from being printed in several languages, provided that the same information is given in all the languages used.

3. When the product is not intended to be delivered directly to the patient, the competent authorities may grant an exemption to the obligation that certain particulars should appear on the labelling and in the package leaflet and that the leaflet must be in the official language or languages of the Member State in which the product is placed on the market.

Article 64: Where the provisions of this Title are not complied with, and a notice served on the person concerned has remained without effect, the competent authorities of the Member States may suspend the marketing authorization, until the labelling and the package leaflet of the medicinal product in question have been made to comply with the requirements of this Title.

Article 65: In consultation with the Member States and the parties concerned, the Commission shall draw up and publish detailed guidance concerning in particular:

(a) the wording of certain special warnings for certain categories of medicinal products;
(b) the particular information needs relating to non-prescription medicinal products;
(c) the legibility of particulars on the labelling and package leaflet;
(d) the methods for the identification and authentication of medicinal products;
(e) the list of excipients which must feature on the labelling of medicinal products and the way in which these excipients must be indicated;
(f) harmonised provisions for the implementation of Article 57.

Article 66: The outer carton and the container of medicinal products containing radionuclides shall be labelled in accordance with the regulations for the safe transport of radioactive materials laid down by the International Atomic Energy Agency. Moreover, the labelling shall comply with the provisions.

Article 67: The competent authority shall ensure that a detailed instruction leaflet is enclosed with the packaging of radiopharmaceuticals, radionuclide generators, radionuclide kits or radionuclide precursors.

Article 68: Without prejudice to the provisions of Article 69, homeopathic medicinal products shall be labelled in accordance with the provisions of this title and shall be identified by a reference on their labels, in clear and legible form, to their homeopathic nature.
Article 69: 1. In addition to the clear mention of the words 'homoeopathic medicinal product', the labelling and, where appropriate, the package insert for the medicinal products shall bear the following, and no other, information:

— the scientific name of the stock or stocks followed by the degree of dilution, making use of the symbols of the pharmacopoeia used in accordance with Article 1(5); if the homeopathic medicinal product is composed of two or more stocks, the scientific names of the stocks on the labelling may be supplemented by an invented name,
— name and address of the registration holder and, where appropriate, of the manufacturer,
— method of administration and, if necessary, route,
— expiry date, in clear terms (month, year),
— pharmaceutical form,
— contents of the sales presentation,
— special storage precautions, if any,
— a special warning if necessary for the medicinal product,
— manufacturer's batch number,
— registration number,
— 'homoeopathic medicinal product without approved therapeutic indications',
— a warning advising the user to consult a doctor if the symptoms persist.

2. Notwithstanding paragraph 1, Member States may require the use of certain types of labelling in order to show:

— the price of the medicinal product,
— the conditions for refunds by social security bodies.

TITLE VIII: Advertising

Article 86: 1. For the purposes of this Title, 'advertising of medicinal products' shall include any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products; it shall include in particular:

— the advertising of medicinal products to the general public,
— advertising of medicinal products to persons qualified to prescribe or supply them,
— visits by medical sales representatives to persons qualified to prescribe medicinal products,
— the supply of samples,
— the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind, except when their intrinsic value is minimal,
— sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products,
— sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products and in particular payment of their travelling and accommodation expenses in connection therewith.

2. The following are not covered by this Title:

— the labelling and the accompanying package leaflets, which are subject to the provisions of Title V,
— correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product,
Article 87: 1. Member States shall prohibit any advertising of a medicinal product in respect of which a marketing authorization has not been granted in accordance with Community law.

2. All parts of the advertising of a medicinal product must comply with the particulars listed in the summary of product characteristics.

3. The advertising of a medicinal product:

— shall encourage the rational use of the medicinal product, by presenting it objectively and without exaggerating its properties,
— shall not be misleading.

Article 88: 1. Member States shall prohibit the advertising to the general public of medicinal products which:

(a) are available on medical prescription only,
(b) contain substances defined as psychotropic or narcotic by international convention, such as the United Nations Conventions of 1961 and 1971.

2. Medicinal products may be advertised to the general public which, by virtue of their composition and purpose, are intended and designed for use without the intervention of a medical practitioner for diagnostic purposes or for the prescription or monitoring of treatment, with the advice of the pharmacist, if necessary.

3. Member States shall be entitled to ban, on their territory, advertising to the general public of medicinal products the cost of which may be reimbursed.

4. The prohibition contained in paragraph 1 shall not apply to vaccination campaigns carried out by the industry and approved by the competent authorities of the Member States.

5. The prohibition referred to in paragraph 1 shall apply without prejudice to Article 14 of Directive 89/552/EEC.

6. Member States shall prohibit the direct distribution of medicinal products to the public by the industry for promotional purposes.

TITLE VIII Information And Advertising

Article 89: 1. All advertising to the general public of a medicinal product shall:

(a) be set out in such a way that it is clear that the message is an advertisement and that the product is clearly identified as a medicinal product;
(b) include the following minimum information:
— the name of the medicinal product, as well as the common name if the medicinal product contains only one active substance,
— the information necessary for correct use of the medicinal product,
— an express, legible invitation to read carefully the instructions on the package leaflet or on the outer packaging, as the case may be.

2. Member States may decide that the advertising of a medicinal product to the general public may, notwithstanding paragraph 1, include only the name of the medicinal product or its international non-proprietary name, where this exists, or the trademark if it is intended solely as a reminder.

Article 90: The advertising of a medicinal product to the general public shall not contain any material which:

(a) gives the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by mail;

(b) suggests that the effects of taking the medicine are guaranteed, are unaccompanied by adverse reactions or are better than, or equivalent to, those of another treatment or medicinal product;

(c) suggests that the health of the subject can be enhanced by taking the medicine;

(d) suggests that the health of the subject could be affected by not taking the medicine; this prohibition shall not apply to the vaccination campaigns referred to in Article 88(4);

(e) is directed exclusively or principally at children;

(f) refers to a recommendation by scientists, health professionals or persons who are neither of the foregoing but who, because of their celebrity, could encourage the consumption of medicinal products;

(g) suggests that the medicinal product is a foodstuff, cosmetic or other consumer product;

(h) suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural;

(i) could, by a description or detailed representation of a case history, lead to erroneous self-diagnosis;

(j) refers, in improper, alarming or misleading terms, to claims of recovery;

(k) uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts thereof.

Article 91: 1. Any advertising of a medicinal product to persons qualified to prescribe or supply such products shall include:

— essential information compatible with the summary of product characteristics;
— the supply classification of the medicinal product.

Member States may also require such advertising to include the selling price or indicative price of the various presentations and the conditions for reimbursement by social security bodies.
2. Member States may decide that the advertising of a medicinal product to persons qualified to prescribe or supply such products may, notwithstanding paragraph 1, include only the name of the medicinal product, or its international non-proprietary name, where this exists, or the trademark, if it is intended solely as a reminder.

Article 92: 1 Any documentation relating to a medicinal product which is transmitted as part of the promotion of that product to persons qualified to prescribe or supply it shall include, as a minimum, the particulars listed in Article 91(1) and shall state the date on which it was drawn up or last revised.

2. All the information contained in the documentation referred to in paragraph 1 shall be accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the medicinal product concerned.

3. Quotations as well as tables and other illustrative matter taken from medical journals or other scientific works for use in the documentation referred to in paragraph 1 shall be faithfully reproduced and the precise sources indicated.

Article 93: Medical sales representatives shall be given adequate training by the firm which employs them and shall have sufficient scientific knowledge to be able to provide information which is precise and as complete as possible about the medicinal products which they promote.

Article 94: 1. Where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy.

2. Hospitality at sales promotion events shall always be strictly limited to their main purpose and must not be extended to persons other than health-care professionals.

3. Persons qualified to prescribe or supply medicinal products shall not solicit or accept any inducement prohibited under paragraph 1 or contrary to paragraph 2.

4. Existing measures or trade practices in Member States relating to prices, margins and discounts shall not be affected by paragraphs 1, 2 and 3.

Article 95: The provisions of Article 94(1) shall not prevent hospitality being offered, directly or indirectly, at events for purely professional and scientific purposes; such hospitality shall always be strictly limited to the main scientific objective of the event; it must not be extended to persons other than health-care professionals.

Article 96: 1. Free samples shall be provided on an exceptional basis only to persons qualified to prescribe them and on the following conditions:

(a) the number of samples for each medicinal product each year on prescription shall be limited;
(b) any supply of samples shall be in response to a written request, signed and dated, from the prescribing agent;
(c) those supplying samples shall maintain an adequate system of control and accountability;
(d) each sample shall be no larger than the smallest presentation on the market;
(e) each sample shall be marked ‘free medical sample — not for sale’ or shall show some other wording having the same meaning;
(f) each sample shall be accompanied by a copy of the summary of product characteristics;
(g) no samples of medicinal products containing psychotropic or narcotic substances within the meaning of international conventions, such as the United Nations Conventions of 1961 and 1971, may be supplied.
2. Member States may also place further restrictions on the distribution of samples of certain medicinal products.

**Article 97**: 1. Member States shall ensure that there are adequate and effective methods to monitor the advertising of medicinal products. Such methods, which may be based on a system of prior vetting, shall in any event include legal provisions under which persons or organizations regarded under national law as having a legitimate interest in prohibiting any advertisement inconsistent with this Title, may take legal action against such advertisement, or bring such advertisement before an administrative authority competent either to decide on complaints or to initiate appropriate legal proceedings.

2. Under the legal provisions referred to in paragraph 1, Member States shall confer upon the courts or administrative authorities powers enabling them, in cases where they deem such measures to be necessary, taking into account all the interests involved, and in particular the public interest:

   — to order the cessation of, or to institute appropriate legal proceedings for an order for the cessation of, misleading advertising, or

   — if misleading advertising has not yet been published but publication is imminent, to order the prohibition of, or to institute appropriate legal proceedings for an order for the prohibition of, such publication, even without proof of actual loss or damage or of intention or negligence on the part of the advertiser.

3. Member States shall make provision for the measures referred to in the second subparagraph to be taken under an accelerated procedure, either with interim effect or with definitive effect. It shall be for each Member State to decide which of the two options set out in the first subparagraph to select.

4. Member States may confer upon the courts or administrative authorities powers enabling them, with a view to eliminating the continuing effects of misleading advertising for which order has been obtained by a final decision:

   — to require publication of that decision in full or in part and in such form as they deem adequate,

   — to require in addition the publication of a corrective statement.

5. Paragraphs 1 to 4 shall not exclude the voluntary control of advertising of medicinal products by self-regulatory bodies and recourse to such bodies, if proceedings before such bodies are possible in addition to the judicial or administrative proceedings referred to in paragraph 1.

**Article 98**: 1. The marketing authorization holder shall establish, within his undertaking, a scientific service in charge of information about the medicinal products which he places on the market.

2. The marketing authorization holder shall:

   — keep available for, or communicate to, the authorities or bodies responsible for monitoring advertising of medicinal products, a sample of all advertisements emanating from his undertaking together with a statement indicating the persons to whom it is addressed, the method of dissemination and the date of first dissemination,

   — ensure that advertising of medicinal products by his undertaking conforms to the requirements of this Title,
—verify that medical sales representatives employed by his undertaking have been adequately trained and fulfill the obligations imposed upon them by Article 93(2) and (3),

—supply the authorities or bodies responsible for monitoring advertising of medicinal products with the information and assistance they require to carry out their responsibilities

—ensure that the decisions taken by the authorities or bodies responsible for monitoring advertising of medicinal products are immediately and fully complied with.

3. The Member States shall not prohibit the co-promotion of a medicinal product by the holder of the marketing authorisation and one or more companies nominated by him.

**Article 99:** Member States shall take the appropriate measures to ensure that the provisions of this Title are applied and shall determine in particular what penalties shall be imposed should the provisions adopted in the execution of Title be infringed.

**Article 100:** Advertising of the homeopathic medicinal products referred to in Article 14(1) shall be subject to the provisions of this Title with the exception of Article 87(1). However, only the information specified in Article 69(1) may be used in the advertising of such medicinal products. ([www.emea.europa.eu](http://www.emea.europa.eu))

### 4.2.1 UNITED KINGDOM

The Medicines and Healthcare products Regulatory Agency (MHRA) is a government body which was set up in 2003 to bring together the functions of the Medicines Control Agency (MCA) and the Medical Devices Agency (MDA).

These include the regulation of medicines and medical devices and equipment used in healthcare and the investigation of harmful incidents. The MHRA now also looks after blood and blood products, working with UK blood services, healthcare providers, and other relevant organisations to improve blood quality and safety. The principal aim of the Agency is to safeguard the public’s health. It does this by making sure that medicines and medical devices—from painkillers to pacemakers—work properly and are acceptably safe; and by responding promptly when new concerns come to light. **No product is completely free of risk but sound evidence underpins all the MHRA’s decisions to ensure that these risks are minimized**

When is a product acceptably safe?: **No product is 100 per cent safe, because all products have side effects. These may be very minor, but they may also be serious.** For example, cancer treatments may make the difference between living and dying. They can also make patients feel very unwell and increase the chances of infections. Aspirin reduces inflammation and fever. But it can also irritate the lining of the stomach.

The Medicines Control Agency was created in 1989, and merged with the Medical Devices Agency to become the MHRA in 2003.

How does the MHRA work?: The Agency has the power to withdraw a product from the market, and in the case of medicines, to suspend production. The Agency can also prosecute a manufacturer or distributor if the law has been broken.
The regulations need to be robust enough to protect the public's health, and this costs money. The MHRA is funded largely by public monies from government for the regulation of devices, and by fees from the pharmaceutical industry for the regulation of medicines. **The Agency's regulatory decisions are impartial and based solely on the extensive evidence of quality, safety, and efficacy required for each product.** Different products are treated differently but the MHRA considers the particular characteristics, drawbacks and advantages of each one.

Monitoring new medicines and vaccines: New chemicals and vaccines are effectively put on probation for up to two years and labelled with a black triangle to ensure prescribers are aware of the need to monitor them carefully. The black triangle symbol accompanies new medicines and vaccines in prescribing manuals, product information and advertising material. It prompts healthcare professionals to report any potential side effects to the MHRA. This information helps to build up a broader picture of how the treatment works in the general population and enables the MHRA to act promptly, should a previously unrecognized and serious side effect come to light. The black triangle may also be assigned to a medicine that has already been licensed if it contains a new combination of active chemicals or if it is being used in a new way or for a different condition. The black triangle is not removed until the MHRA is satisfied that the medicine works safely in large numbers of people. Additionally, the MHRA also asks manufacturers to keep a close watch on side effects that may be associated with newly marketed products.

There are around 20,000 different medicines available in the UK.

The Traditional Herbal Medicines Registration Scheme sets out specific safety and quality standards for traditional herbal medicines that are mass produced and sold over the counter. Registered manufacturers are also legally obliged to monitor the safety of their products once they are on the market. Many herbal remedies used in the UK are not mass produced, but made up on an individual basis, and these are currently exempt from the need for a licence. The MHRA is working with herbal practitioners and the government to introduce safeguards for this type of treatment. Details of any herbal product found to contain potentially harmful ingredients, or which interacts with conventional medicines, are posted on the MHRA website. The Agency has also recently introduced a new scheme for regulating homeopathic remedies.

Advertising is highly used and well recognised in our consumer society. It comes in different forms, sizes and shapes, plays an important part in our daily life and affects the choices and decisions we make. Advertising, including that of medicines, is acceptable provided it is in line with legislation and agreed standards of good practice. Over and above the general legislation and controls on advertising, there is additional legislation that applies to the advertising of medicines. There are specific Regulations that strictly control the advertising and promotion of medicinal products in the UK. All advertising and promotion of medicines must be responsible and of the highest standard to ensure the safe use of medicines both in self-medication and where medical supervision is required. All means and methods used in the promotional marketing of medicines are subject to the legislation controlling advertising.

The Regulations prohibit advertising of prescription only medicines to the public. Prescription only medicines are generally potent drugs that must be taken under medical supervision.

**How to Complain**

2.1 Introduction: This chapter describes how to complain about an advertisement for a medicinal product, whether it is aimed at healthcare professionals or the public.
2.2 When to complain: The MHRA investigates complaints received from anyone who has seen an advertisement for a medicine that in his or her view is misleading or otherwise fails to comply with the legal requirements. To make a complaint, details of when and where the advertisement was seen should be provided, if possible with a copy of the advertisement, together with details of the concerns about the advertisement. The MHRA is particularly keen to receive complaints where the advertisement may have an adverse impact on public health.

2.3 What will happen next? The Agency acknowledges receipt of all complaints and will contact the advertiser concerned to investigate the case within 30 days. This time may be extended where there is detailed discussion between the Agency and the company, or when statutory action is taken. Should the investigation take longer, the complainant will be updated on progress. When closing the case the Agency will provide the complainant with details of the outcome and a summary report that will then be published on the website.

Note for pharmaceutical companies who have a complaint: The MHRA can and does use its powers to take immediate action where serious public health concerns are raised and, if urgent action is required, then the issue should be raised with MHRA. Normally, if an advertisement is identified that is believed to be in breach of the Advertising Regulations the first consideration and point of contact for companies should be the marketing authorisation holder or advertiser outlining the concerns regarding their advertising.

Legal Requirements for Medicines Advertising in the UK: The European and UK legislation regulating the advertising of medicines applies to all forms and means of advertising licensed medicines including branded and generic products for supply by prescription only and over-the-counter products for sale through pharmacies and on general sale.

There is also general legislation on advertising which extends to medicines advertising. Generally speaking, the labelling and package leaflet of a product which comply fully with the requirements of SI 1994/3144 and Title V of European Directive - 2001/83/EC, would not fail to be considered here. A ‘relevant medicinal product’ is defined at regulation 2(1) of the Advertising Regulations. The term ‘relevant medicinal product’ covers the vast majority of medicines. Products that typically fall outside the definition are homoeopathic medicines covered by product licences of right and unlicensed herbal medicines. Since October 2005, the definition of a ‘relevant medicinal product’ has also included traditional herbal medicinal products (THM) with a “traditional herbal registration” under the Traditional Herbal Medicines Registration Scheme (THMRS) which implements Directive 2004/24/EC (the Traditional Herbal Products Directive).

3.1 The Legislative Framework: This chapter describes the specific European and UK legislation that regulates the advertising of medicines and provides definitions of the terms used.


3.3 Scope of the Regulations: The Advertising Regulations apply to “advertisements” for “relevant medicinal products”.  

Devi Ahilya Vishwavidyalaya Indore
'Advertisement' has a broad definition under the Advertising Regulations. Advertisement has the meaning assigned to it by regulation Advertising Regulations of the Medicines Act 1968. The Regulations exclude from that definition reference material, factual informative statements or announcements, trade catalogues and price lists, provided that they do not make a product claim. The definition of advertising applied to medicines is not limited to specific media.

3.4 Other legislation relevant to medicines advertising: There are other regulations, as well, relevant in controlling medicines advertisements.


General Rules

4.1 Introduction: This chapter sets out the general rules for advertising medicines. Specific information on advertisements aimed at health professionals and the general public can be found in the following chapters.

4.2 Prohibition on advertising unlicensed medicines: By Regulation 3 of the Advertising Regulations, medicinal products which do not have a valid marketing authorisation may not be advertised for medicinal purposes (with the exception of products registered under the homoeopathic registration scheme). The Agency Borderline Section will offer advice on the status of products where it is not clear whether they should be licensed as medicines. It is in breach of the Regulations to issue any promotional material for a licensable medicine until the marketing authorisation has been granted.

4.3 Quality standards: By Regulation 3A of the Advertising Regulations, an advertisement must:

(1) comply with the particulars listed in the summary of product characteristics (SPC);
(2) encourage rational use by presenting the medicine objectively and without exaggerating its qualities; and
(3) Not misleading.

(1) Compliance with the Summary of Product Characteristics (SPC): An advertisement must not promote a medicine outside the therapeutic indications listed in the approved SPC for that medicine. This means an advertisement cannot promote a medicine for use in treating or preventing conditions or illness for which it has not been licensed. Nor can an advertisement promote a medicine for use by a patient group not indicated. For example, an advertisement which depicted a baby where the medicine was not indicated below the age of 2 years would be in breach of this provision. An advertisement may include statements not included in the SPC provided these can be substantiated.

(2) Encouraging rational use: An advertisement must encourage the correct and proper use of a medicine; this is a positive obligation. This might include when a medicine should be taken, how much should be taken, the route of administration, by whom it should be taken and special precautions. An advertisement must present information which is factually correct and those facts should not be exaggerated in any way by the presentation of the advertisement. The factual accuracy should be independently verifiable. For example, an advertisement for a product offering symptomatic relief should not imply that it cures the underlying condition.

(3) Not be misleading: This is a widely drawn prohibition. It will catch any advertisement which leads to an erroneous belief of any nature about the medicine. In particular it will catch advertisements which
mislead as to the potential benefits or possible risks of a medicine. Often advertisements which fall foul of this provision will already have breached Regulation 3A(1) or (2). A factually accurate advertisement may also be misleading due to the overall impression given. An example could be the use of a driving image in an advertisement for a medicine where caution is required over impairment of driving ability.

4.4 Who is responsible?: The primary responsibility for the content and dissemination of all advertising and promotion of a medicine lies with the marketing authorisation holder, who is also responsible for the training and conduct of medical representatives. Whilst the responsibility for ensuring that all advertising and promotional material for a medicine complies with the Regulations lies predominantly with the marketing authorisation holder, the Regulations provide that it is an offence for ‘any person’ to breach Regulations. This allows enforcement action to be taken against others involved in the promotion of medicines, such as publishers.

4.5 Keeping records: A Marketing Authorisation Holder (MAH) also has a duty under the Regulations to keep samples of advertising materials available, to respond to requests for information on advertising materials by providing such items as the MHRA may request for consideration and to comply with any decisions taken by the MHRA in respect of advertising and promotional material. Failure to do so is a criminal offence under the Regulations.

The MHRA also has powers to require copies of any published advertisement from any person appearing to be involved in its publication, and again failure to comply is an offence. All advertisers must therefore have arrangements to ensure that copies of all advertising material are retained, either by themselves or on their behalf. To comply with these legal requirements, the MHRA considers that the minimum time that materials should be kept for by MAHs and/or other parties is a period of three years after either the last use of the piece or the conclusion of any regulatory or self-regulatory action, whichever is later. Where pieces are likely to be in use by recipients for a period of time, the three years should start from the end of the expected normal period of use. Companies should consider the need to retain material for a longer time if there are other reasons, particularly if there has been a safety concern or a complaint about advertising for the product.

4.6 Special requirements for Traditional Herbal Medicinal Products (THMs): In addition to the requirements set out in Chapters 4 to 6, all advertisements for herbal medicinal products with a traditional herbal registration should include the following additional statement: ‘Traditional herbal medicinal product for use in [specify one or more indications for the product consistent with the terms of the registration] exclusively based upon long-standing use as a traditional remedy’. Care should be taken in devising advertising for these products to ensure that claims are in line with the approved indication for the product and do not mislead as to the efficacy of the product. Where the indication states ‘traditionally used for...’ or similar wording, this information should be stated in advertising materials. Claims such as ‘clinically proven’ or ‘effective in ...’ are not acceptable for THMs since the registration is based exclusively on long-standing use.

4.7 Special requirements for registered homoeopathic medicines: Only the information specified on the labelling may be used in the advertising of registered homoeopathic products. No mention of a specific indication may be made.

Advertising to the Public

5.1 Introduction: This chapter explains the legal requirements and restrictions on advertising aimed at the public. Advertisers have a responsibility to ensure that advertising of medicines available for self-medicating does not in any way put patient and consumer safety at risk.
5.2 Medicines suitable for advertising to the public: Advertising to the public is permitted for medicines legally classified pharmacy sale (P) or General Sale List (GSL), subject to compliance with Advertising Regulations. The Regulations prohibit the issue of any advertisement wholly or mainly directed to the general public which is likely to lead to the use of a prescription only medicine (POM) except Government controlled vaccination campaigns. The Cancer Act 1939 ("the Cancer Act") prohibits any advertisement to the public that contains an offer to treat any person for cancer.

5.3 Prohibition of certain material: Advertising to the general public should not suggest that one product is better than (or equivalent to) another identifiable treatment or product, or that the effects of taking it are guaranteed. Material which refers in improper, alarming or misleading terms to claims of recovery must not be included. Advertising should not give the impression that a medical consultation or surgical operation is unnecessary, for example by offering a diagnosis or suggesting treatment by post, FAX or telephone. Nor should it suggest that health can be enhanced by taking a medicine or that health could be affected by not taking the medicinal product.

5.4 Children: Advertising of medicines should not be directed exclusively or principally at children (under-16s). Nor should advertising material aimed at parents and carers be included in non-promotional material aimed at children.

5.5 Information necessary for the correct use of a medicine: Advertisements directed at the public should be presented in such a way that it is clear that the message or material is an advertisement and that the product being advertised is a medicine. Advertisements to the public must include the name of the medicine and the common name where the product contains only one active ingredient. They must also include the information necessary for correct use of the medicine, which is interpreted to mean one or more indications for use of the product. There should be a clear and legible invitation to read carefully the instructions on the leaflet contained within the package or on the label as the case may be.

A reference to the label alone should be made only where no leaflet is provided or where the label carries a clear and specific instruction to refer to the enclosed leaflet. Safe use of some medicines depends on compliance with certain conditions, which should be clearly indicated in advertising material. For example, where a medical diagnosis is necessary before self-treatment, or treatment is likely to be successful only if continuous, the advertising material should clearly reflect those conditions. In the area of self-medication particular care should be taken to ensure that vulnerable patient groups are not put at risk. One particular example is that it should not convey the message that it is usual for pregnant women to take medicines.

5.6 Advice on claims: Claims which suggest a product is as good as the best such as "Nothing acts faster than . . ." are not prohibited under the legislation but care should be taken that consumers are not misled as to the benefits of the medicine in comparison to other products in the category. Advertising should not suggest that a product does not have any side-effect or that its safety or efficacy is due to the fact that it is natural. Similarly, claims that a product has been manufactured in such a way as to make it purer or otherwise of better quality to a similar product should not be misleading regarding the benefits to the patient. Claims for fast action should be related to a condition where speed of onset is relevant and may not be appropriate for chronic conditions or those not requiring immediate relief. The time scale for which "fast" claims are appropriate will depend on the clinical indication and the speed of action of other products in the category. For a 24-hour relief claim, data must show clinical effect over the 24-hour period. The product should be for once daily dosing but a once daily dosing interval alone is insufficient to support a 24-hour claim. The MHRA discourages advertisements which promote more than one product with similar names, companies should be very careful to avoid causing confusion. For example where one product may be indicated for infants or children whilst the other is not. All messages conveyed to the audience should support safe use of the products concerned.
5.7 Recommendations and endorsements: Advertisements to the general public should not contain material which refers to recommendations by scientists or health professionals, or which refers to recommendations by celebrities or well known organisations who, because of their celebrity, could encourage consumption of products. Advertisers should not suggest that their product is “special” or different from or better than other medicines because it has been granted a marketing authorisation or registration. Nor should an advertisement state that a product has MHRA or Department of Health “approval”.

5.8 Sponsorship: Sponsorship linked to a brand of medicine would be acceptable in principle for products classified for over-the-counter sale. Any endorsement by individual celebrities would not be considered acceptable. Sponsorships by manufacturers or pharmaceutical companies should not include any promotion of prescription only medicines (POM), whether directly or indirectly. Schemes, charities or like activities cannot be sponsored in the name of a POM.

5.9 Samples for promotional purposes: The Advertising Regulations prohibit the sale or supply of samples of relevant medicinal products to any member of the public for promotional purposes by marketing authorisation holders and persons acting on their behalf (such as distributors), and commercial undertakings including registered pharmacies, general retailers and third parties acting on behalf of, or with the consent of, these persons. Supply via published media or by post, for example with magazines, is similarly unacceptable. The distribution of vouchers for free products or free coupons to potential consumers to enable them to obtain the pack for free or for an unreasonably low sum so as to be almost free is considered to fall within this prohibition. There is no prohibition under the Advertising Regulations on the sale of small-sized packs of medicines for supply through normal trade outlets on normal business terms provided the necessary authorisation has been obtained to market the product.

5.10 Advertising on the Internet: The Internet is used widely to provide information to both consumers and healthcare professionals. Website providers should ensure that materials posted on the Internet do not contravene the Advertising Regulations. Material posted on UK websites and/or aimed at the UK audience is subject to UK medicines advertising legislation. As for other media, the promotion of prescription only medicines to the public on the Internet is prohibited.

5.11 Disease awareness and health education campaigns: Campaigns relating to human health directed at the general public with a view to providing information, promoting awareness or educating the public about a particular condition or disease are encouraged. Care must be taken to ensure that the information provided does not make product claims for the material to remain outside the definition of an “advertisement” under the Regulations. In particular, use of brand names, restricting the range of treatments described in the campaign or drawing attention to the campaign by advertising which is likely to lead to the use of a specific prescription only medicine or medicines can all lead to a potential breach of the Regulations.

5.12 Promotion of services: Clinics and other organisations may promote the service they provide, e.g. medical services for those with a certain condition or travel immunisations. They may also provide information on the condition and its management, which may include a balanced overview of the range of therapeutic options available. Such material should not draw attention to specific prescription only medicines since this is likely to breach the Advertising Regulations by encouraging individuals to request a particular treatment. As an example, advertising for cosmetic clinics and beauty salons may promote the service provided, e.g. “treatment for lines and wrinkles”, as this is non-specific and may include various procedures. Advertising must not mention product names such as “Botox” or “botulinum toxin”.

5.13 Multiple purchase promotions for analgesics: When Resale Price Maintenance for medicines came to an end in 2001, the longstanding restrictions on price competition for OTC medicines were lifted. This meant multi-buy offers for medicines such as “3 for the price of 2”, “buy one get second half price”
and “buy one get one free” were possible. The Government introduced legal restrictions on pack sizes for aspirin and paracetamol in 1998 to reduce toxicity in overdose particularly related to impulsive gestures which may be associated with stocks of medicines in the home.

The MHRA discourages companies and retail suppliers of medicines from undertaking any volume-based promotion which includes any products containing analgesics (aspirin, paracetamol and ibuprofen in solid dose and other formulations) that could encourage unnecessary purchases of medicines and put consumer safety at risk. This is an area of voluntary action but the MHRA closely monitors price-related promotions involving analgesics. Guidelines issued by trade associations of the pharmaceutical industry such as the Proprietary Association of Great Britain (PAGB) aim to encourage “good practice” in this area and ensure that there is a level playing field across the industry.

5.14 Prescription only medicines: Press releases and other information to the media: Press releases e.g. at the time of launch should not be used as a mechanism to promote prescription only medicines. Information on prescription only medicines which is provided to the lay press, television or radio or by press releases must be factual and non-promotional, where appropriate putting the treatment in the context of the effects of the disease. It should not encourage the general public to ask their GP to prescribe the product. The MHRA considers that press releases should be genuinely newsworthy rather than having the intention of promoting a product. The use of brand names should be kept to a minimum and the tone and content of the press release must be factual and not sensationalised. Where statements from healthcare professional are included these should be balanced and informative. Particular care should be taken in providing information in response to direct approaches from the media where a company has little or no control over the final production, for example, with television programmes, and which could result in the promotion of prescription only medicines to the general public.

5.15 Prescription only medicines: Responses to enquiries from the public: Companies responding to enquiries from the public about prescription only medicines should ensure that such responses are factual, non-promotional and limited to the subject matter of the enquiry. Information provided must be appropriate to the enquiry, must be balanced and must not promote a prescription only medicine.

Advertising to Persons Qualified to Prescribe or Supply

6.1 Introduction: This chapter provides guidance on advertising of medicinal products, both prescription only and over-the-counter medicines, targeting health professionals who are “persons qualified to prescribe or supply” (POPS) medicines as defined in the Advertising Regulations. They include persons who in the course of their profession or in the course of a business sell or supply medicinal products.

6.2 Scope of “persons qualified to prescribe or supply” (POPS): The scope of “persons qualified to prescribe or supply” is interpreted as including persons (and their employees) who, under the current UK systems of control and supply of medicinal products, are legally entitled to choose which medicinal product is supplied, or to supply such a product even if it is chosen by the consumer or by another person legally entitled to make that choice on the consumer’s behalf. POPS will include all persons who are capable of influencing or determining which product is purchased by or supplied to an end consumer.

6.3 Advertising on the Internet: Internet advertising of medicines is acceptable provided it complies with the Advertising Regulations. The MHRA considers that advertisements for POMs are acceptable only on websites whose nature and content are directed at health professionals. Sections of a website aimed at health professionals and containing promotional material should ideally be access restricted. A journal which is published or posted on the Internet and which is expressly stated to be for health professionals is considered to be directed at persons qualified to prescribe or supply medicines and the advertising contained within the journal should comply with the Advertising Regulations. Each page of an
advertisement for a prescription only medicine (POM) should be clearly labelled as intended for health professionals.

6.4 Provision of information – full advertisements: Essential information compatible with the summary of product characteristics (SPC) of the product(s) must be given but the wording of this information can be adjusted to take account of the varying levels of technical knowledge of individuals falling within the class of POPS.

6.5 Provision of information - Abbreviated advertisements: Abbreviated advertisements, defined under regulations may only appear in professional publications as an integral part of the publication. They must be no larger than 420 sq. cm. and cannot be issued in the form of a loose insert. They must contain essential information compatible with the product SPC.

6.6 Messages given in advertising: Advertising which states or implies that a product is “safe” is unacceptable. All medicines have the potential for side-effects and no medicine is completely risk-free as individual patients respond differently to treatment. For example the term “placebo-like” in relation to safety or side-effects in general is considered to be misleading as it implies that there are no drug associated side-effects. By implication the medicine could be assumed to be 100% safe, when no medicine is completely risk-free.

6.7 Urgent safety restrictions or safety Variations: It is the responsibility of the marketing authorisation holder (MAH) to ensure that prescribes are made fully aware of important changes to product information in their promotional campaigns. Following an urgent safety restriction (USR) or similar safety variation advertisers should take care to ensure that subsequent advertising gives due prominence to important safety restrictions and should include a strap-line or equivalent highlighting the changes.

6.8 Trade advertisements: The Advertising Regulations provide that “reference material, a factual, informative statement or announcement, a trade catalogue or a price list shall not be taken to be an advertisement,” provided that it does not make product claims. Advertisements for medicines issued in trade publications in the form of an informative announcement, for example of a new introduction or notification of planned TV marketing spend would fall to be considered outside the definition of an advertisement under the Regulations provided they do not make product claims.

6.9 Promotional aids: A “promotional aid” is a non-monetary gift made for a promotional purpose by a commercially interested party (e.g. the supply of an item such as a pen, notepad or mug). Advertisements relating to products which are on a promotional aid and which consist solely of the name of the product are exempt from the need to include other essential information.

6.10 Advertising intended for international publication: International journals which are in English are subject to UK legislation if their primary affiliation and/or base is the UK and all journals with a European intended audience are subject to the requirements of Directive 2001/83/EC.

6.11 International meetings: Material relating to products that do not hold UK marketing authorisations which is displayed or available on request at international symposia, conferences and other meetings is permitted provided that a significant proportion of the attendees are from countries outside the UK where the product is licensed (this should include at least one major developed country).

6.12 Professional samples: Regulation applies to the supply of a free sample of a medicinal product to a person who receives it for the purpose of acquiring experience in dealing with it will be informed or reminded of the restriction to the licence on the basis of safety. Information on where to find further information on the changes, such as a link to the MHRA website, should be provided.
6.13 Medical sales representatives: Medical sales representatives must be given adequate training and have sufficient scientific knowledge to enable them to provide information which is as precise and complete as possible about the products they are promoting.

6.14 Gifts, inducements and other Benefits: Regulation provides that "where relevant medicinal products are being promoted to persons qualified to prescribe or supply relevant medicinal products, no person shall supply, offer or promise to such persons any gift, pecuniary advantage or benefit in kind, unless it is inexpensive and relevant to the practice of medicine or pharmacy".

6.15 Interpretation of "inexpensive" and "relevant to the practice of medicine or pharmacy": The item or benefit offered must be both inexpensive and relevant to the practice of medicine or pharmacy for it to fall outside the prohibition in Regulation 21(1) of the Advertising Regulations. That is, both conditions must be satisfied. Inexpensive items are considered to be those which do not cost a company more than £6 (excluding VAT) and represent a similar value to the recipient.

6.16 Hospitality: The restrictions of regulations do not prevent the offer of hospitality to POPS at events purely for professional or scientific purposes under the conditions laid down under regulation 21(2) which include the conditions that the hospitality should be strictly limited to the main objective of the meeting and should not be offered to persons who are not health professionals e.g. partners.

6.17 Provision of medical or pharmaceutical education, goods and services: Schemes which are launched by the pharmaceutical industry offering sponsorship of research posts, study visits and suchlike may well be acceptable provided that there is no element of promotion of individual products associated with them.

6.18 Co-promotion: Co-promotion of a medicinal product by the marketing authorisation holder and one or more companies nominated by him is not prohibited in the UK. The control of medicines advertising in the UK is based on a long-established system of self-regulation.

Regulation of Medicines Advertising in the UK: The control of medicines advertising in the UK is based on a long-established system of self-regulation. The statutory powers of the MHRA, acting on behalf of Health Ministers, underpin and support this system, which is permitted under European legislation on advertising, by providing a means of enforcement should self-regulation fail.

The Role of the MHRA: Where advertising material is assessed for vetting the opinion of the MHRA is based upon the information provided at the time and the current state of scientific knowledge. The MHRA has a statutory function to monitor advertisements on a continuing basis and to consider complaints made to it in the future. The above opinions will therefore be given without prejudice to the Agency’s ability to perform this function.

7.1 Introduction: This chapter outlines the various methods used to regulate the promotion of medicinal products, to ensure that advertising complies with the legislation and where necessary the sanctions that MHRA may use to ensure compliance with the legislation. A key function of the MHRA is to protect public health by promoting the safe use of medicines. On advertising, this statutory role, acting on behalf of Health Ministers, supports the system of self-regulation. The MHRA conducts a number of activities relevant to advertising control:

(i) checking advertising for compliance with the law prior to publication (vetting) in clearly defined circumstances,
(ii) monitoring of published advertising material for medicines,
(iii) handling of complaints about advertising, and

Devi Ahilya Vishwavidyalaya Indore
- 309 -
(iv) enforcement in relation to materials not compliant with the Regulations

Each of the above four activities is described in more detail below.

7.2 Vetting of advertising material: In order to perform its supervisory functions under the Regulations, the MHRA monitors not only published advertisements but also advertisements prior to publication. To perform that task, advertising material for certain products may be required to be submitted for scrutiny prior to issue (vetting). Circumstances where vetting may be required include:

i. where a newly licensed product, subject to intensive monitoring, is placed on the market;
ii. where a product is reclassified, such as from POM to P; or
iii. where previous advertising for a product has breached the Regulations.

Within the first criterion above and as a matter of policy, the MHRA has committed to vet initial advertising for all new chemical entities.

The period of vetting of all advertising for a product will normally be no longer than six months. The marketing authorisation holder (MAH) will be advised of the requirement for vetting and of the reasons for, and duration of, the requirement in each case. This time period may be reduced or extended depending on the quality of the initial advertising material submitted and other relevant factors. Promotional material submitted for vetting to the MHRA should indicate the target audience (public or POPS) and include references in support of claims in the promotional material. All material should have already undergone a full set of internal quality control and compliance checks before submission to the MHRA. The MHRA will undertake to give its opinion on the advertising material within a given time-scale and will take account of any realistic deadlines indicated by the company involved. Normally five working days should be allowed for assessment but where substantial data are submitted this will not be possible and the MHRA will give an estimate of the time necessary to complete the assessment if a delay is unavoidable. The company may be asked to advise the MHRA of the form of the advertisement, the intended audience and the intended date and duration of issue for each piece of copy submitted.

7.3 Scrutiny of current advertising Material: In order to perform its supervisory functions under the Regulations, the MHRA is obliged to monitor published advertisements. The MHRA examines various health professional and consumer journals and other types of media for advertisements relating to any medicinal product, which are then checked against the Advertising Regulations for compliance. Should there be a cause for concern the Agency will contact the MAH for supporting evidence, comment or clarification on advertising and will initiate action as for a complaint if necessary (see below for further details).

7.4 Complaints about medicines Advertising: A complainant can choose to refer directly to any self-regulatory or regulatory body which deals with complaints, including the MHRA.

7.5 Corrective statements: The MHRA has statutory powers to compel the publication of a corrective statement where advertising has been found to be in breach of the Regulations, although most companies agree voluntarily to issue the correction. The following provides guidance on the recommended format of a corrective statement:

Opening statement: This should clearly indicate that this is a corrective statement issued at the request of the MHRA and the product concerned. Example wording: “The MHRA have asked ... to provide a corrective statement regarding the promotion of ...”

Description of the case: This should include when and where the original advertisement was used and what type of advertisement/promotional material it was and whether it has been withdrawn or not.
**Statement on the breach:** This should outline how the advertisement was in breach of the Advertising Regulations without repeating the original wording and give a description of the correct facts including a summary of the MHRA view. In the first instance companies should refer queries to their trade association or the relevant self-regulatory body (e.g. PAGB or PMCPA). For advertising to the public, the Committee of Advertising Practice (CAP) operates a free copy advice service for non-broadcast advertisements and pre-clearance centres also exist for radio and television advertising. Further details about these bodies can be found in chapter 8 and at Annex 8.

**7.6 Seeking advice on advertising:** Should a company, or an agency or trade association acting on behalf of that company, have a specific query regarding an advertisement they should submit the advertisement to the MHRA for review and advice on its suitability for issue. The MHRA will assess the advertising in the normal way and provide suggested amendments, if any, where appropriate. If the material is issued without amendment, and the MHRA considers that it is potentially in breach of the Advertising Regulations, consideration of enforcement will be initiated. This service is provided to assist in those cases where there is genuine uncertainty over the legal requirements and the point at issue needs to be clearly defined. The MHRA is not, however, able to provide a routine vetting service on request. The report is then published on the Agency’s website. Occasionally, the MHRA may also issue a statement about a particular case in order to highlight concerns and provide guidance on good practice. The MHRA endeavours to complete investigations of complaints within 30 days. This time may however, be extended where there is detailed discussion between the Agency and the company, or when statutory action is taken.

**Statutory Action:** The Independent Review Panel for Advertising (IRP) will usually consist of a legally-qualified chairman and two other members, one with medical or pharmacy expertise and the other representing the interest of the consumer.

**8.1 Introduction:** This chapter describes the formal statutory procedures that the MHRA may use to regulate the advertising of medicinal products and the provision for review by an Independent Review Panel (IRP). The MHRA can and will resort to formal procedures if it considers there to be a public health justification, either in the form of notices issued at any stage during the investigation of a case or through enforcement action and prosecution.

**8.2 Taking statutory action:** Although the Monitoring Regulations clearly set out the statutory powers available to the MHRA, it is expected that, in the majority of cases, companies will work with the MHRA to issue acceptable advertising without the need to resort to the formal procedures laid down under the Schedule to the Monitoring Regulations. The MHRA can serve a “minded to” notice upon any person responsible for the issue or publication of an advertisement, although such action is usually taken against the MAH. The Regulations provide for representations made by the person on whom a “minded to” notice has been served to be considered by the Health Ministers. The advertiser may be issued with a notice under the Schedule to the Monitoring Regulations advising him that:

i. the MHRA is “minded to” determine that the advertisement, if published, would be in breach of the Advertising Regulations and the reasons why they are “minded to” make such a determination;

ii. if such a determination is made, that person may be required to refrain from publishing that advertisement; and

iii. the person on whom the notice is served has twenty-one days from the date of the notice in which to make written representations that the proposed determination should not be made. The notice may require that person to refrain from publishing the advertisement until such time as the notice has been withdrawn by Health Ministers. The MHRA is entitled to seek an injunction to prevent the publication of an advertisement in the courts as part of its investigation of a complaint or of its own volition.
8.3 Independent Review Panel (IRP): The Monitoring Regulations make provision for the advertiser to make written representations as to why the proposed determination should not be made. These representations, if made, are referred to a nonstatutory body, the Independent Review Panel for Advertising (IRP) for consideration. The IRP’s view on whether the advertisement breaches the Advertising Regulations must be taken in to account by the MHRA when making a final determination on behalf of the Health Ministers.

8.4 Determinations: If, following consideration and having taken into account the views of the IRP, the MHRA decides that the advertisement would not be in breach of the Advertising Regulations, a notice will be issued informing the advertiser of that decision and withdrawing the previous notice. Alternatively, the MHRA may, in the light of advice received from the Independent Review Panel, make a determination that the advertisement, if published, would be in breach of the Advertising Regulations.

8.5 Sanctions: A breach of any of the provisions of the Advertising Regulations listed in Regulation 23 of those Regulations is a criminal offence. This covers the vast majority of requirements set down by the Advertising Regulations. The penalty is a fine and/or imprisonment for up to two years in most cases. A failure to comply with any requirement imposed by a notice served under the Monitoring Regulations is a criminal offence. The penalty is a fine and/or imprisonment for up to two years. Where the MHRA believe that a criminal offence has been committed, it will always consider enforcement action, i.e. prosecution. Civil sanctions are also available under the Monitoring Regulations, for example, requiring publication of a corrective statement where Health Ministers have prohibited publication of an advertisement for breaching the Advertising Regulations. Further guidance on the format of corrective statements is provided in Section 7.5.

Self-Regulation

Advertising Standards Authority (ASA) and Committees of Advertising Practice (CAP): The ASA is responsible for ensuring that all advertising, wherever it appears, is honest and decent. For more than forty years, the ASA has been responsible for administering the British Code of Advertising, Sales Promotion and Direct Marketing (the CAP Code) to uphold advertising standards in non-broadcast media.

9.1 Introduction: This chapter describes the various bodies involved in the process of self-regulation and the responsibilities each organisation has to regulate the advertising industry with specific reference to medicines advertising.

9.2 The regulatory regime: The control of medicines advertising in the UK is based on a long-established system of self-regulation. The statutory powers of the MHRA, acting on behalf of Health Ministers, underpin and support this system. There are a number of regulatory bodies the majority of which operate their own Codes of Practice.

Prescription Medicines Code of Practice Authority (PMCPA): The PMCPA, which operates independently of the Association of the British Pharmaceutical Industry (ABPI), administers the ABPI Code of Practice for the Pharmaceutical Industry. The Code applies to the promotion of medicines to members of the United Kingdom health professions and to appropriate administrative staff and to information made available to the public about those medicines.

Proprietary Association of Great Britain (PAGB): The PAGB is the largest trade association and self-regulatory body for the over-the-counter (OTC) medicines industry. Its Codes of Practice for Advertising Over-The-Counter Medicines include a Consumer Code that lays down standards for the advertising of OTC medicines to the general public.
Health Food Manufacturers' Association (HFMA): The HFMA is a trade association operating on behalf of the UK specialist health product industry. They operate a Code of Advertising Practice covering advertising to the public and to healthcare professionals.

British Dental Trade Association (BDTA): The BDTA is a group of manufacturers, wholesalers, distributors and suppliers of products and services to the dental profession. They provide a Code of Practice for their members to follow to ensure the highest quality of service.

Office of Communications (OFCOM): OFCOM is the independent regulatory and competition authority for the UK communications industries. It has a statutory role to ensure that the contents of programmes and broadcast advertising meet appropriate standards.

9.3 Vetting of advertising material: Several trade associations for the pharmaceutical industry provide, as a condition of membership, that advertising material should be submitted to them for vetting against their Codes of Practice before issue. (www.pagb.org.uk.)

Labelling: Clear labelling is crucial for the safe use of all medicines and its primary purpose is for the clear and unambiguous identification of the product and the conditions for safe use. Similarity in packaging is known to contribute to medication error and MHRA has published guidance for those involved in the design and layout of labelling to help improve the way in which labelling information is presented both to health care professionals and patients. This guidance applies to medicines available on prescription and also over the counter.

Best Practice Guidance on The Labeling And Packaging Of Medicines

1. Introduction: The safe use of all medicines depends on users reading the labelling and packaging carefully and accurately and being able to assimilate and act on the information presented. The primary purpose of medicines labelling and packaging should be the clear unambiguous identification of the medicine and the conditions for its safe use. Common factors affecting all users of medicines may be summarised under three headings:

Information: Certain items of information are vital for the safe use of the medicine.

Format: The information must be presented in a legible manner that is easily understood by all those involved in the supply and use of the medicine.

Style: There is potential for confusion between both similarity in drug names and similarity in medicines packaging.

Medication errors occur due to many factors. “Building a Safer NHS for Patients”

(1) published in April 2001, which implemented “Organisation With A Memory”
(2) identified such factors as training, communication, storage, and supervision. Problems with labelling have also been associated with a high percentage of errors
(3) Within the current regulatory framework there is the potential for improving the layout of medicines labelling to aid clarity. This would assist healthcare professionals and patients/carers to select the correct medicine and use it safely, thereby helping to minimise medication errors.

2. Purpose: The purpose of this guidance is to expand a set of principles which have been agreed by the Committee on Safety of Medicines. When the guidance is applied it will help to ensure that the critical information necessary for the safe use of the medicine is legible, easily accessible and that users of
medicines are assisted in assimilating this information so that confusion and error are minimised. In preparing this guidance, it is acknowledged that different users of medicines require and use information differently. Those involved in the design of labelling and packaging components should ensure that the following sections are taken into account prior to submission to the Medicines and Healthcare products Regulatory Agency as any deviations from this guidance may need to be justified.

3. Scope: This is best practice guidance to be read alongside the legislative requirements, which are set out in Council Directive 2001/83/EEC (4). The guidance has no legal standing but it will be taken into account when the Medicines and Healthcare products Regulatory Agency assesses the labelling provided with mutual recognition and national licence applications. The guidance applies primarily to prescription only medicines but the principles should be applied as appropriate to all medicines, including those available over the counter. In assessing applications, the Agency will consider patient safety, in the light of experience and any adverse incidents reported.

4. General Consideration: The following items will apply to all labelling components, where relevant, whether or not a lesser information set is applicable by virtue of Article 55 of Council Directive 2001/83/EEC.

4.1. Labelling must contain all elements required by article 54 of Council Directive 2001/83/EEC. Nevertheless, certain items of information are deemed critical for the safe use of the medicine. These items are:

- name of the medicine
- expression of strength (where relevant)
- route of administration
- posology
- warnings

Clarification on these items is provided below.

4.2. These critical items of information should be located together on the pack and appear in the same field of view where practicable. These items should not be broken up by additional information, logos or background texts or graphics.

4.2.1 Name of the medicine: The name that is registered in the summary of product characteristics (SPC) must be used on all packaging components. The name is defined as comprising the name, strength and pharmaceutical form of the medicine. For medicines that include either a company name or a trademark as part of the product name, this must be reflected on all packaging components where the name is required to appear.

The full name of the medicine should appear on at least three nonopposing faces of the pack to aid accurate identification of the drug. This is applicable only to carton presentations in which case the end-face of the pack should include the full name of the product. Where the medicine contains a single active ingredient, the common name of this active ingredient should immediately follow the name of the medicine on the pack, unless it is part of the name. The recommended International Non-proprietary Name should be used, or the usual common name where no rINN exists.

Where the common name appears after the brand name, it should be given due prominence. Generally this will be determined by the relative size of the text but other factors may be relevant such as colour of text and the font used. If a medicine contains more than one active ingredient consideration should be given to including all common names on the front of the pack where practicable.
If a "Co-" name is used for the medicine, this should be registered in the SPC and appear on the labelling as part of the name.

4.2.2 Strength: It may be necessary in some cases to express the strength as quantity per unit volume and also as the total quantity per total volume. Reference to the total quantity per total volume should be highlighted. This is particularly important for injectable products and other medicines available in solution or suspension. In addition, different strengths of the same drug should be expressed in the same manner: for example 250mg, 500mg, 750mg, 1000mg and NOT 1g. Trailing zeros should not appear (2.5mg and NOT 2.50mg). The decimal point need not be centred, provided that if a full stop is used it is clearly visible. For safety reasons it is important that micrograms is spelt out in full and not abbreviated.

4.2.3 Route of administration: This should be as registered in the SPC only. Positive messages should be used; for example “give by ...” and only standard abbreviations will be acceptable. Non-standard routes of administration should be spelt out in full to avoid confusion. Some routes of administration will be unfamiliar to patients and may need careful explanation. This is particularly important when medicines are made available for self-selection.

4.2.4 Posology: This will be necessary only when the product is intended for self-medication. In general, posology will not appear on medicines that are intended to be supplied on prescription. Posology remains a legal requirement for products marketed for retail sale. Medicines that are supplied on prescription would have the posology added at the time of dispensing.

4.2.5 Warnings: Only those warnings, specifically required by the terms of the marketing authorisation to be stated on the labelling, will form part of the critical labelling. Many medicines will not need the addition of any warnings on the front of the pack. This section is intended to convey only those critical warnings necessary immediately prior to administering the product. Examples of warnings that are considered appropriate for the critical field include:

- Fatal if given by other routes
- Vinca alkaloids
- Check dose and frequency
- Methotrexate is usually taken Oral methotrexate once a week
- Dilute before use
- Concentrated potassium chloride
- Contains paracetamol
- Paracetamol containing medicines

4.3. The critical information should appear in as large font as possible to maximise legibility, on at least one face of the presentation. It should not be broken up or separated by non-critical information.

4.4. Innovative pack design that may incorporate the judicious use of colour is to be encouraged to ensure accurate identification of the medicine. In considering the acceptability of a particular pack design it will be necessary to consider the relative distinguishing features compared to other packs in a range (a range may mean all packs bearing a corporate livery or a group of packs carrying the same design theme). The primary aim of innovative design of packaging is to aid in the identification and selection of the medicine.

4.5. Where practicable, packs should include space for the placement of the dispensing label. It is recommended that this should be a blank white space in which there is no text of any kind, to aid legibility of the dispensing label. Where it is not possible to employ a blank space, use of a colour that will not interfere with the readability of the dispensing label should be considered. This consideration need not apply to products intended for over-the-counter sale directly to the patient.

4.6. Only positive statements should appear on medicines labelling to avoid ambiguity of the message. For example, "For intravenous use only". Negative statements such as "Not for intravenous use" should not be used.
4.7. Undertaking a user test to ensure the maximum clarity of the critical information is desirable and recognised as best practice. Care should be taken to ensure that the test undertaken is applicable to the “user” because health care professionals have different needs compared to patients in relation to the same pack. Testing must therefore be tailored to the needs of the particular user groups. It will not be necessary to user test all labelling components but consideration should be given to carrying out a user test when significant changes are proposed to the layout and colour of the information presented, such as the introduction of innovative pack design. In addition to a formal user test, focus groups and panels may be useful means of evaluating the changes.

5. Small Containers

5.1. Where the labelling requirements of article 54 of Council Directive 2001/83/EEC cannot be legibly applied to a container, the requirements of article 55(3) should be applied. The criteria for small container status would normally be considered to apply to containers with a nominal volume of 10mls or less. However, other factors may need to be considered such as the amount of information which needs to appear on the label and the font size necessary to achieve legibility of the information.

5.2. The critical items outlined above (4.1) are not additional requirements here.

5.3. The use of innovative pack design will be applicable to small containers also and is regarded to be of particular importance where space is at a premium.

5.4. For traceability purposes it is recommended that the following additional information should appear on the labelling of small containers:

- PL number
- The MA holder’s name. This may be replaced by the company logo where the MAH name is an integral part of it, but the use of a logo should not be at the expense of other critical information and it should be of a small size relative to the rest of the text. Where space is at a premium, the inclusion of the MA holder’s name will not be mandatory.

6. Blister Packs

6.1. Where a blister or strip pack is enclosed in a container which meets the requirements of article 54 of Council Directive 2001/83/EEC, the requirements of article 55(2) apply to the blister or strip packs.

6.2. Where practicable, the name and strength of the product should appear over each blister pocket or be oriented centrally across the pack. It is important that the particulars remain available to the user up to the point at which the last dose is removed from the blister pack. Often it will not be possible to apply all the information over each blister pocket, consequently where a random display of the information is proposed it should frequently appear across the pack. In all cases it will be acceptable to apply the batch number and expiry date to the end of the blister strip. If technically possible this could be applied to both ends of each strip.

6.3. In addition, blister foils should be printed to ensure maximum legibility of the statutory information using a sufficiently large font.

6.4. Colour for the text and the font style, should be chosen carefully as the legibility of the text on the foil is already impaired due to the nature of the material. Where possible non-reflective material
or coloured foils should be considered to enhance the readability of the information presented and the correct identification of the medicine.

7. Conclusion: All applications submitted for assessment to the Medicines and Healthcare products Regulatory Agency that include a labelling component will be considered against the criteria in this document. This will apply in all areas of MHRA work (new MAs, PLPIs, renewals, variations and applications to the product information unit). Assessment may involve the comparison of the proposed packaging against others in a range already approved in order to consider whether safety in use will become an issue. Innovation in pack design will be a significant factor in the correct identification and selection of medicines. Where an applicant deviates from this guidance a full justification for this should be provided with the application. Once approved, amended components will be expected to be introduced ideally within three months and within six months at most.

(http://www.mhra.gov.uk/Howweregulate/Medicines/Labelspatientinformationleafletsandpackaging/index.htm)

Recent amendments to the requirements include:

* The introduction in Article 54(a) for up to three active substances to be included immediately after the registered name on the front of pack label.
* The introduction in Article 54(e) for space for the prescribed dose to be added to the label. In the UK this should be a blank space 35 mm by 70 mm to allow the pharmacist to apply a dispensing label.
* The introduction of Article 56a into the Directive makes provision for the name of the medicinal product to be expressed in Braille format on the packaging. Additionally, the Patient Information Leaflet (PIL) should be provided in formats suitable for the blind or partially-sighted. This was implemented in October 2005 and consultation on these new requirements and further guidance will be published in the near future.
* Amendments to Article 59 of the Directive include a new order for the required information to appear in the PIL. This is drawn up in accordance with the Summary of Product Characteristics (SPC).
* Further amendments to Article 59 require consultation with target patient groups to ensure that the PIL is legible, clear and easy to use (user testing).

Amendments to articles 54 and 56 have been implemented into UK legislation via the Statutory Instrument SI 2005/2759 and affect all new applications submitted to the Agency from 30 October 2005. Existing marketing authorisations have until 30 October 2010 to comply. Guidance has been developed in this area and is available in the Braille section.

Amendments to article 59 have been implemented into UK legislation via the Statutory Instrument SI 2004/3224 and affect all new applications submitted to the Agency from 1 July 2005. Existing marketing authorisations have until 1 July 2008 to comply. We have published the following guidance and questions and answers to assist companies comply with the new requirements on patient consultation which are available in the user testing section.

Article 65 of the Directive makes provision for the publication of guidelines to be used in conjunction with the Directive.

Excipients in the label and package leaflet of medicinal products for human use. The revised version (July 2003) is in The rules governing medicinal products in the European Union.

Naming of medicines: The MHRA considers each application for a product name to ensure that the proposed name will allow the medicine to be taken safely and correctly. The name must also comply with legislative requirements and the MHRA has issued naming policy guidance with respect to umbrella segments of product names. This section also helps explain the change of names of some medicines.
which previously could exist with two different names which was done in order to reduce the risk of errors. (www.mhra.gov.uk)

4.3 CANADA

Before drug products are authorized for sale in Canada, Health Canada reviews them to assess their safety, efficacy and quality. Drug products include prescription and non-prescription pharmaceuticals, disinfectants and sanitizers with disinfectant claims. Prior to being given market authorization, a manufacturer must present substantive scientific evidence of a product's safety, efficacy and quality as required by the Food and Drugs Act and Regulations. When a product is offered for sale in Canada to treat or prevent diseases or symptoms, it is regulated as a drug under the Food and Drugs Act.

FOODS, DRUGS, COSMETICS AND DEVICES

GENERAL

Prohibited advertising: No person shall advertise any food, drug, cosmetic or device to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A of the 'Act'.

Prohibited label or advertisement where sale made: No person shall sell any food, drug, cosmetic or device

(a) that is represented by label, or

(b) that the person advertises to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A of the 'Act'.

Labelling: Once a therapeutic product is approved for the Canadian market, it must be packaged and distributed with information that will help consumers make an informed choice about its use. Labels serve this purpose, as does any literature that accompanies or belongs to the therapeutic product. This includes the product monograph, the label on the product package and the label on the product container.

Since October 2004, the specifications for drug product monographs have changed. These monographs must now include a new consumer information section clearly explaining what the medication is for, how to use it and what the potential side effects are. There is also a new section intended to give health care professionals the information they need to counsel patients.

Regulatory Requirements for Advertising: Only health products that Health Canada authorizes for sale in Canada may be advertised. Specific requirements exist for advertisements of prescription drugs to consumers.

Health Canada's Role: Health Canada is the National Regulatory Authority for health product advertisements. It provides policies to effectively regulate marketed health products, put in place guidelines for the interpretation of the Regulations, and oversee regulated advertising activities.

The department is committed to ensuring that information in a health product advertisement is not false, misleading or deceptive. It may intervene when an advertisement poses a significant safety concern, in the event that resolution is not achieved through the independent agencies' complaints mechanism, when
a prescription drug is illegally advertised to the general public or when an unauthorized health product is promoted.

**Who reviews advertisements?**: Health product advertisements are reviewed and precleared by independent agencies. The List of Canadian Advertising Preclearance Agencies may be consulted for their contact information and roles. Advertising material for nonprescription drugs and natural health products directed to consumers is reviewed and precleared by independent agencies that have publicly self-attested to meeting Health Canada’s recommended attestation criteria. Advertising material for all health products directed to health professionals is reviewed and precleared by the Pharmaceutical Advertising Advisory Board (PAAB), an independent agency recognized by Health Canada.

Advisory opinions on messages directed to consumers for prescription drugs and on educational material discussing a medical condition/disease: The PAAB, as well as Advertising Standards Canada (ASC), provide advisory opinions on messages directed to consumers for prescription drugs and on educational material discussing a medical condition/disease to ensure that they meet the regulatory requirements.

**What information can be found here?**: This section, one will find regularly updated information on regulatory advertising requirements, sources of assistance in meeting those requirements, as well as information about some of the projects that Health Canada involved in, are available.

**Advertising Preclearance**: Health Canada is committed to protecting the health and safety of Canadians by establishing regulatory standards for the advertising of health products. The preclearance of advertising material by arms-length agencies continues to be voluntary for industry.

**Overview of Health Product Advertising**

**What is health product advertising?**: Health product advertising is considered to be any representation, by any means (e.g. television, radio, Internet, print, etc.), for the purpose of promoting directly or indirectly the sale or distribution of any health product (drugs, natural health products, medical devices, vaccines and biological products, etc.).

**What health products can be advertised?**: Only health products that have been authorized for sale in Canada by the Health Products and Food Branch (HPFB) of Health Canada may be advertised. The advertising must not exceed the terms of market authorization. In addition, specific regulatory provisions exist to limit the type/extent of advertisements of prescription drugs to consumers. Advertising of narcotic and controlled drugs to consumers is prohibited.

**How to Ascertain whether a specific health product has been authorized for sale in Canada?**: Health products which are authorized for sale in Canada bear an eight-digit identification number preceded by a specific acronym. Authorized drugs bear the acronym “DIN” (Drug Identification Number), while authorized natural health products and homeopathic medicines respectively bear the acronyms “NPN” (Natural Product Number) and “DIN-HM” (Drug Identification Number - Homeopathic Medicine).

**Are all messages which refer to health products considered to be advertising?**: No. Some messages, depending upon the content and the context in which they are disseminated may be considered non-promotional. These could include press releases, consumer brochures, help-seeking...
announcements, scientific exhibits and journal articles. If they meet the criteria that are outlined in the Health Canada policy "The Distinction Between Advertising and Other Activities".

**What factors determine whether or not a message is health product advertising?** No one factor alone determines whether or not a message is advertising. Each message must be assessed individually. The purpose, content and context of the message is examined to determine if the intent is to promote the sale of a health product or to provide information. Other factors which must be considered include how and when the message is being delivered, to whom and by whom and how often the message is being conveyed.

**Why do advertising preclearance agencies review health product advertisements?** Advertising preclearance agencies review and preclear advertising material in order to help industry ensure compliance with the regulatory provisions of the Food & Drugs Act and Regulations, the Natural Health Products Regulations and the various Health Canada guidance documents and codes of advertising. The regulatory framework is intended to protect the health of Canadians. The agencies also offer independent mechanisms to resolve complaints on advertising for authorized health products.

**What is Health Canada’s role?** Health Canada is the regulatory authority for health product advertisements and bears the ultimate responsibility for enforcing the Food & Drugs Act and related Regulations. Health Canada:

- Provides policies to effectively regulate marketed health products;
- Develops guidance documents for the interpretation of the regulatory framework; and
- Oversees regulated advertising activities.

**Health Canada may intervene:**
- When an advertisement poses a significant safety concern;
- When an unauthorized product is oromoted.

Health Canada sets the standards for health product advertising material that is not false, misleading or deceptive. Health Canada reserves the right to enforce the provisions contained in the federal legislation through a national compliance and enforcement program which applies on a risk-based approach.

**Is it mandatory to have health product advertisements reviewed prior to their release?** Although it is not mandatory, various manufacturer associations such as NDMAC and Canada’s Research-Based Pharmaceutical Companies (Rx&D) support pre-clearance by independent advertising preclearance agencies. Health Canada strongly encourages all sponsors to comply with the voluntary preclearance review prior to exposure to health care professionals and consumers.

**Where a complaint about an advertisement for an authorized health product can be filed?** The first route for adjudication of complaints for authorized health products is through advertising preclearance agencies. More specifically, complaints related to: Consumer advertising of nonprescription drugs and natural health products should be submitted to advertising preclearance agencies that have publicly self-attested to meeting Health Canada’s recommended criteria.
Health professional advertising of prescription drugs and other health products should be submitted to: Pharmaceutical Advertising Advisory Board (www.paab.ca)

Direct-to-consumer advertising of prescription drugs should be submitted to: Regulatory Advertising and Risk Communications Section Email: MHPD_DPSC@hc-sc.gc.ca

What enforcement actions will be taken on non-compliant advertising?: Advertising preclearance agencies have complaint adjudication mechanisms in place which outline appropriate corrective actions.

If an advertisement continues to be non-compliant with the Food and Drugs Act and its Regulations, enforcement actions will be undertaken by Health Canada in accordance with the Health Products and Food Branch Compliance and Enforcement Policy.

Where one can find additional information about health product advertising requirements and guidance documents? Additional information about health product advertising (reports, consultations, meetings, etc.) are available on the Regulatory Requirements for Advertising section of the Health Canada website www.hc-sc.ca

REGULATIONS RESPECTING FOOD AND DRUGS PART A : ADMINISTRATION

General

A.01.001. These Regulations may be cited as the Food and Drug Regulations.

A 01.023 Analysts Inspectors: The authority of an inspector extends to and includes the whole of Canada.

A 01.044 No person shall sell a food or drug that has been imported into Canada under subsection (1) unless the food or drug has been relabelled or modified within three months after the importation or within such longer period as may be specified by authority.

C.01.003. No person shall sell a drug that is not labeled as required by these Regulations.

C.01.004. (1) The inner and outer labels of a drug shall show:

(a) on the principal display panel:

(i) the proper name, if any, of the drug which, if there is a brand name for the drug, shall immediately precede or follow the brand name in type not less than one-half the size of that of the brand name,

(ii) if there is no proper name, the common name of the drug,

(iii) where a standard for the drug is prescribed a statement that the drug is a Canadian Standard Drug, for which the abbreviation C.S.D. may be used,

(iv) where a standard for the drug is not prescribed but is contained in a publication mentioned in the Act, the name of the publication containing the standard used or its abbreviation as provided therein or, if a manufacturer's standard is used, a statement setting forth the fact that such a standard is used, and

(v) in both official languages, the notation "sterile" if the drug is required to be sterile by these Regulations;
(b) on the upper left quarter of the principal display Panel:

(i) the symbol \( \text{Pr} \) in the case of a drug required by this Part or Part D to be sold on prescription, but in no other case shall the symbol \( \text{Pr} \) appear on the label of a drug,

(ii) the symbol "\( \text{C} \)" in a clear manner and a conspicuous colour and size, in the case of a controlled drug, other than a controlled drug contained in an agricultural implant.

(iii) the symbol "\( \text{N} \)" in a colour contrasting with the rest of the label or in type not less than half the size of any letters used thereon, in the case of a narcotic as defined in the Narcotic Control Regulations, and

(iv) in the case of a targeted substance as defined the prescribed symbol in a colour contrasting with the rest of the label and in type not less than half the size of any other letter used on the main panel, namely,

(c) on any panel:

(i) the name and address of the manufacturer of the drug,
(ii) the lot number of the drug,
(iii) adequate directions for use of the drug,
(iv) a quantitative list of the medicinal ingredients of the drug by their proper names or, if they have no proper names, by their common names, and
(v) the expiration date of the drug.

(2) In addition to the requirements of subsection (1), the outer label of a drug shall show

(a) the net amount of the drug in the container in terms of weight, measure or number;
(b) in the case of a drug intended for parenteral use, a quantitative list of any preservatives present therein by their proper names or, if they have no proper names, by their common names.

C.01.005. (1) The principal display panel of both the inner and outer label of a drug sold in dosage form shall show in a clear and legible manner the drug identification number assigned by the Director for that drug pursuant to subsection C.01.014.2(1), preceded by the words "Drug Identification Number" or both, or the letters "DIN".

(2) Subsection (1) does not apply to a drug

(a) compounded by a pharmacist pursuant to a prescription or by a practitioner; or

(b) sold pursuant to a prescription, where the label of that drug indicates:

(i) the proper name, the common name or the brand name of the drug,
(ii) the potency of the drug, and
(iii) the name of the manufacturer of the drug

C.01.009. Where by any statute of the Parliament of Canada or any regulation made thereunder a standard or grade is prescribed for a drug and that standard is given a name or designation by such statute or regulation, no person shall on a label of or in any advertisement for that drug use that name or designation unless the drug conforms with the standard or grade.
C.01.011. (1) A drug referred to in subsection 10(2) of the Act shall be exempt from the standard for any drug contained in any publication mentioned in Schedule B to the Act to the extent that such drug differs from that standard with respect to colour, flavour, shape and size, if such difference does not interfere with any method of assay prescribed in any such publication.

(2) Where a manufacturer's standard is used for a drug, the manufacturer shall make available to the Director, on request, details of that standard and of a method of analysis for the drug acceptable to the Director.

(3) No person shall use a manufacturer's standard for a drug that provides:

(a) a lesser degree of purity than the highest degree of purity, or
(b) a greater variation in potency than the least variation in potency provided for that drug in any publication.

C.01.012. A manufacturer who makes representations on a label of a drug in oral dosage form, or in any advertisement, with respect to the site, rate or extent of release to the body of a medicinal ingredient of the drug, or the availability to the body of a medicinal ingredient of the drug, shall:

(a) before making the representations, conduct such investigations, using an acceptable method, as may be necessary to demonstrate that the site, rate or extent of release to the body of the medicinal ingredient of the drug and the availability to the body of the medicinal ingredient of the drug, correspond to the representations; and

(b) on request submit the record of such investigations to the Director.

C.01.013. (1) Where the manufacturer of a drug is requested in writing by the Director to submit on or before a specified day evidence with respect to a drug, the manufacturer shall make no further sales of that drug after that day unless he has submitted the evidence requested.

(2) Where the Director is of the opinion that the evidence submitted by a manufacturer, pursuant to subsection (1), is not sufficient, he shall notify the manufacturer in writing that the evidence is not sufficient.

(3) Where, pursuant to subsection (2), a manufacturer is notified that the evidence with respect to a drug is not sufficient, he shall make no further sales of that drug unless he submits further evidence and is notified in writing by the Director that further evidence is sufficient.

(4) A reference in this section to evidence with respect to a drug means evidence to establish the safety of the drug under the conditions of use recommended and the effectiveness of the drug for the purposes recommended.

Assignment and Cancellation of Drug Identification Numbers

C.01.014: No manufacturer shall sell a drug in dosage form unless a drug identification number has been assigned for that drug and the assignment of the number has not been cancelled.

C.01.014.1. (1) A manufacturer of a drug, a person authorized by a manufacturer or, in the case of a drug to be imported into Canada, the importer of the drug may make an application for a drug identification number for that drug.
(2) An application under subsection (1) shall be made to the Director in writing and shall set out the specified required informations.

(3) In the case of a new drug, a new drug submission or an abbreviated new drug submission filed shall be regarded as an application for a drug identification number, application and the date of signature.

C.01.014.2. (1) Subject to subsection (2), if a manufacturer or importer has provided all the information described in subsection C.01.014.1(2) or section C.08.002 or C.08.002.1, as the case may be, in respect of a drug, the Director shall issue to the manufacturer or importer DIN.

(2) Where the Director believes on reasonable grounds that a product in respect of which an application referred to in section C.01.014.1 has been made

(a) is not a drug, or
(b) a drug but that its sale would cause injury to the health of the consumer or purchaser or would be a violation of the Act or these Regulations, he may refuse to issue the DIN.

(3) Where the Director, pursuant to subsection (2), refuses to issue the document, the applicant may submit additional information and request the Director to reconsider his decision.

(4) On the basis of the additional information submitted pursuant to subsection (3), the Director shall reconsider the grounds on which the refusal to issue the document was made. 

(http://laws.justice.gc.ca/PDF/CRCJ_70.pdf)

Only health products that Health Canada authorizes for sale in Canada may be advertised. Specific requirements exist for advertisements of prescription drugs to consumers.

Our department is committed to ensuring that information in a health product advertisement is not false, misleading or deceptive. We may intervene when an advertisement poses a significant safety concern, in the event that resolution is not achieved through the independent agencies' complaints mechanism, when a prescription drug is illegally advertised to the general public or when an unauthorized health product is promoted. (http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/index-eng.php)

Prohibited advertising

3. (1) No person shall advertise any food, drug, cosmetic or device to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A.

Prohibited label or advertisement where sale made

(2) No person shall sell any food, drug, cosmetic or device

(a) that is represented by label, or

(b) that the person advertises to the general public.
as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A.

Unauthorized advertising of contraceptive device prohibited

(3) Except as authorized by regulation, no person shall advertise to the general public any contraceptive device or any drug manufactured, sold or represented for use in the prevention of conception. (www.hc-sc.gc.ca)

4.4 AUSTRALIA

Therapeutic Goods Act 1989 Therapeutic Goods Order No. 69

General requirements for labels for medicines

1 Application and exemptions

1(1) This Order applies to those therapeutic goods that are medicines except goods:

(a) intended solely for use in animals;
(b) intended for use in the treatment of another person.
(c) intended for use solely for experimental purposes in humans;
(d) that fall within the description of Item 9(a) of Schedule 5 of the Regulations;
(e) that have not reached their final stage of manufacture;
(f) that are personal imports as described under Item 1 of Schedule 5 of the Regulations;
(g) that are medicinal gases;
(h) that are solely for export;

(i) made up or compounded in accordance with the individual prescription of a medical practitioner, dentist or veterinary surgeon by a pharmacist or by a person in the course of his or her employment by a pharmacist and under the actual personal supervision of that pharmacist;
(j) made up or compounded extemporaneously for a specific or individual case by a pharmacist in the lawful practice of his or her profession;
(k) supplied in the course of treating a patient or animal by a medical practitioner, dentist or veterinary surgeon in the lawful practice of his or her profession, other than professional starter packs;
(l) made up or compounded extemporaneously for a specific and individual case, in that person's presence, by a complementary healthcare practitioner in the lawful practice of his or her profession.

1(2) Where transparent covering encloses or wraps a container or primary pack containing goods and the particulars which are required to be set out on the label of the container or on the primary pack are clearly visible through that transparent covering, the requirements of this Order do not apply to that transparent covering.

2 Interpretation

2(1) In this Order —

’Act’ means the Therapeutic Goods Act 1989, as amended from time to time;

‘active ingredient’ means a therapeutically active substance included in a medicine;
Drugs Legislation - Globalization, Vis-à-Vis, Indian Drug Laws

'batch number' means a number, or a combination of numerals, symbols or letters, which is given by a manufacturer to a batch of goods, to uniquely identify that batch and from which it is possible to trace that batch through all stages of manufacture and distribution;

complementary healthcare practitioner means a person described in paragraph 4(1)(c) of the Regulations

"persons who are registered under a law of a State or Territory as herbalists, homoeopathic practitioners, chiropractors, naturopaths, nutritionists, practitioners of traditional Chinese medicine, podiatrists or osteopaths";

concentrated solution for injection means a liquid which must be diluted with another liquid in order to prepare an injection;

container means an article that immediately covers the goods, and includes an ampoule, blister pack, bottle, sachet, dial dispenser pack, strip pack, syringe, tube, vessel, vial, wrapper or other similar article, but does not include an article intended for ingestion;

date of manufacture means: (a) for a biological product, the date (month and year) of the latest quality control analysis performed on the product and which may be preceded by a period during which the product is stored under conditions which have been shown to preserve the potency of the product; or

(b) for a product other than a biological product, the date (month and year) during which the processing of the bulk product, from which the goods are to be packaged, is completed;

expiry date means the date (month and year) after which the goods should not be used, being a date not more than five years after the date of manufacture;

'goods' means a medicine;

herbal substance means all or part of a plant or substance (other than a pure chemical or a substance of bacterial origin):

(a) that is obtained only by drying, crushing, distilling, extracting, expressing, comminuting, mixing with an inert diluent substance or another herbal substance or mixing with water, ethanol, glycerol or aqueous ethanol; and

(b) that is not subjected to any other treatment or process other than a treatment or process that is necessary for its presentation in a pharmaceutical form;

homoeopathic preparation means a preparation:

(a) formulated for use on the principle that it is capable of producing in a healthy person symptoms similar to those which it is administered to alleviate; and

(b) prepared according to the practices of homoeopathic pharmacy using the appropriate methods.

label means a display of printed information upon, or securely affixed to, the container and any primary pack containing the goods;

large volume injection means an injection having a volume of greater than 100 millilitres;
main label means: (a) where there are two or more labels or two or more portions of a single label — that label or portion of the label where the product name is more or most conspicuously shown; or

(b) where the product name is equally conspicuous on two or more labels or portions of a label — each such label or portion;

name and address in respect of a sponsor or supplier, means the name of the sponsor or supplier and sufficient information to allow the Australian sponsor or supplier to be uniquely identified so as to facilitate public contact on matters of complaint, use or general enquiry. The address must include information such as the city or suburb of the sponsor's/supplier's principal place of business in Australia. The Australian telephone number may also be included;

name of an active ingredient means: (a) the name of the active ingredient that is approved for inclusion in the Australian Approved Names List; or

(b) where the ingredient is a homoeopathic preparation:

(i) either the name of the active ingredient, or the substance from which the dilution was prepared, that is approved for inclusion in the Australian Approved Names List, together with a statement of the homoeopathic potency; or

(ii) until such time as a name appears in the Australian Approved Names List, a traditional homoeopathic name in full or as traditionally abbreviated with a statement of the homoeopathic potency;

non-proprietary name means the name used to describe the goods in a specific standard. It includes the name of the dosage form. If no specific standard exists, a name comprising the name(s) of the active ingredient(s) and the name of the dosage form;

product name means the proprietary name of the goods, or if there is no proprietary name, the non-proprietary name of the goods;

proprietary name means the registered trademark of the therapeutic goods or the unique name assigned to the goods by the sponsor and appearing on a label;

Regulations means the Therapeutic Goods Regulations 1990, as amended from time to time;

small volume injection means an injection having a volume of less than or equal to 100 millilitres;

Sponsor sponsor in relation to therapeutic goods, means:

(a) a person who exports, or arranges the exportation of, the goods from Australia; or

(b) a person who imports, or arranges the importation of, the goods into Australia; or

(c) a person who, in Australia, manufactures the goods, or arranges for another person to manufacture the goods, for supply (whether in Australia or elsewhere); but does not include a person who:

(d) exports, imports or manufactures the goods; or
(e) arranges the exportation, importation or manufacture of the goods; on behalf of another person who, at the time of the exportation, importation, manufacture or arrangements, is a resident of, or is carrying on business in, Australia;

**standard** standard, in relation to therapeutic goods, means a standard that:

(a) is specified in an order under section 10 that is applicable to the goods; or

(b) if no such order is applicable to the goods but the goods are the subject of a monograph:

(i) in the case of goods for use in humans — the British Pharmacopoeia; or

(ii) in the case of goods for use in animals — the British Pharmacopoeia (Veterinary) is constituted by the statements in that monograph;

**Note:** New editions of, or additions or amendments to, the British Pharmacopoeia or British Pharmacopoeia (Veterinary) apply from the day specified by the Minister administering the Act by Order published in the Commonwealth of Australia Gazette;

3 **Label requirements** The Regulations, the requirements set out under this clause apply to therapeutic goods to which this Order applies. Containers, and the primary packs (if any) in which therapeutic goods are packed, must each bear a label or labels which comply with the following requirements:

3(1) **General** The particulars required by this Order to be included on a label or labels must be clearly visible and must be written:

(a) in the English language;

(b) in durable and legible characters; and

(c) in a metric unit of measurement. For active ingredient(s), where a particular is a statement of quantity for which there is a metric unit of measurement.

3(2) **Particulars to be included on a label** Subject to the qualifications contained in regulations the label or labels must include:

(a) the product name;

(b) the name(s) of all active ingredients in the goods;

(c) the quantity or proportion of all active ingredients in the goods in accordance with clause 4;

(d) where the medicine contains any ingredient referred to in the First Schedule as an excipient, and:

(e) the name of the dosage form;

(f) the quantity of the goods (except for medicines for injection);

(g) warning statements, where these apply to the medicines;

(h) the batch number of the goods preceded by the batch number prefix;

(i) the expiry date of the goods preceded by the expiry date prefix;
(j) the storage conditions applicable to the goods in accordance with clause 7;

(k) directions for use of the goods;

(l) the name and address of the sponsor or supplier of the goods; 17 General requirements for labels for medicines

(m) a statement of the purpose or purposes for which it is intended that the goods be used,

(n) where the goods are included in the Australian Register of Therapeutic Goods, the registration or listing number is to be:

(i) on the label; or
(ii) on a securely affixed label adjacent to the main label; or
(iii) if the container is enclosed in a primary pack, on the primary pack label.

3(3) Particulars to be included on a main label Subject to other regulations the particulars required under subclauses 3(2)(a), (b), (c), (e), (f) and (n) must appear on the main label of the goods further subject to specified exceptions.

3(4) Preparations for ophthalmic use The label on the container and on the primary pack or, where subclause 3(11) applies, on the primary pack, must include, in addition to the requirements of subclauses 3(2) and 3(3):

(a) the name of any antimicrobial preservative in the goods; or

(b) where the goods, other than an ophthalmic ointment, do not contain an antimicrobial preservative, the words ‘Contains no antimicrobial preservative. Use once only and discard residue.’ or a statement to that effect; and

(c) where the goods consist of eye drops for multidose use — a statement to the effect that the eye drops should not be used later than four weeks after the container of the goods is first opened; and

(d) where the goods consist of a solid ophthalmic medicine for preparing eye drops for multidose use — a statement to the effect that the goods when prepared should not be used later than four weeks after the container is first opened, or where the shelf life of the prepared goods is less than four weeks, this lesser period shall be stated; and

(e) where the goods consist of a solid ophthalmic medicine — the label must include the words ‘for eye drops’ or ‘for eye lotion’ (as the case may be) in or adjacent to the product name; and

(f) where the goods consist of a solution or a suspension in an oil — the word ‘oily’ in or adjacent to the product name.

3(5) Injections other than large volume injections In addition to the requirements referred to in subclauses 3(2) and 3(3), where the goods are an injection or a medicament for injection other than a large volume injection: (a) the main label on the container and on the primary pack of the goods must include:

‘the approved route(s) of administration, such as ‘intravenous’, ‘intramuscular’, or ‘subcutaneous’ or other phrase, word or abbreviation denoting the approved route(s) of administration’.
3(6) Large volume injections

Are required to comply with subclauses 3(2) and 3(3) subject to the following qualifications:

(a) in cases where there is no proprietary name of the goods, the product name must include the name of the active ingredient(s) and the name of the dosage form, or where there are more than three active ingredients belonging to the same class of substances, such as amino acids, carbohydrates or electrolytes, the name of the class of substances and the name of the dosage form;

(b) in cases where the goods are intended for electrolyte replacement or nutritional therapy or are intended for use as a radio-contrast agent or as a plasma volume expander or replacement, the product name must include a statement of the proportions of dissolved, emulsified or suspended active ingredient in the goods in terms of percentages;

(c) in cases where the goods contain an active ingredient which is not intended for electrolyte replacement or nutritional therapy and is not intended for use as a radio-contrast agent or as a plasma volume expander or replacement, the product name must include a statement of the proportion of that active ingredient expressed in terms of weight (or potency, if appropriate) in the stated volume of injection in the container;

And in addition to these requirements, the label on the container and on the primary pack of goods which are large volume injections must include:

(d) the names and quantities of all excipients in the stated volume of injection in the container;

(e) where one or more active ingredients are amino acids and/or protein, a statement in grams of the total amount of nitrogen in the stated volume of injection in the container;

(f) where the goods are intended for use as an energy source, a statement in kilojoules of the energy equivalent of the stated volume of injection in the container;

(g) where the goods are intended for use as a radio-contrast agent, a statement of the equivalent amount of iodine in terms of milligrams of iodine per millilitre;

(h) the osmolality;

(i) a statement specifying whether the injection is 'hypotonic' or 'hypertonic' or 'isotonic';

(j) the pH range of the injection;

(k) the words 'single use' or 'single dose'.

3(7) Dialysis concentrates

In addition to the requirements referred to in subclauses 3(2) and 3(3), the label on the container and on the primary pack of goods which are a concentrated solution for use in dialysis must include specified informations.

3(8) Peritoneal dialysis solutions

In addition to the requirements referred to in subclause 3(2) and 3(3), the label on the container and on the primary pack of goods that are a solution for use in peritoneal dialysis must include specified informations.

3(9) Preparations for use on skin or mucous membranes

In addition to the requirements referred to in subclauses 3(2) and 3(3), the label of goods which are preparations for use on skin and mucous
membranes, but not intended for ophthalmic use, must include the name of any antimicrobial preservative in the goods.

3(10) **Biological products** In addition to the requirements referred to in subclauses 3(2), 3(3) and 3(5), the label of goods which are biological products must include specified informations.

3(11) **Small containers** Where:

(a) the goods are enclosed in a container which has a capacity of 20 millitres or less; and

(b) the container is enclosed in a primary pack; and

(c) they are included, in a label on the primary pack, the particulars referred to in subclauses 3(2), 3(3) and where applicable, subclause 3(4) and 3(5): then, in relation to the label on the container, it shall be sufficient compliance with clauses 3(2), 3(3), 3(4) and subclauses 3(5)(b) and 3(5)(c), if there are set out, on the label on the container, the particulars referred to in subclauses 3(2)(a), (b), (c), (e), (f) and (h) and the name or registered trade mark of the sponsor or supplier or the proprietary name; except that:

(d) for viral vaccines only, the particulars referred to in subclause 3(2)(i) must also be set out on the label of the container; and

(e) where it is not practicable to set out these particulars in full on a label on the container, the particulars referred to in subclauses 3(2)(a), (b) and (c) may be abbreviated, provided the abbreviation is unambiguous.

3(12) **Individually wrapped goods** (a) Where:

(i) the goods consist of individual dosage units such as tablets, capsules, pastilles, cachets, lozenges, pessaries, suppositories or single doses of powder;

(ii) each such dosage unit is individually wrapped in an unsealed protective cover;

(iii) each such dosage unit is, after being so wrapped, enclosed in a primary pack; and

(iv) the primary pack is labelled with the particulars referred to in subclauses 3(2) and 3(3) - then, in relation to the label for each individual wrapper, it shall be sufficient compliance with this Order if there are set out, on the individual wrapper, the particulars referred to in subclauses 3(2)(a), (b) and (c) and the name or registered trade mark of the sponsor or supplier; or

(b) where:

(i) the goods consist of individual dosage units such as tablets, capsules, pastilles, cachets, lozenges, pessaries, single doses of a powder or single doses of a liquid or a patch; and

(ii) each such single dose or packet is sealed into an individual sachet or individual blister; and

(iii) one or more than one sealed dosage unit is enclosed in a primary pack; and

(iv) the outside of the primary pack is labelled with the particulars specified in subclauses 3(2) and 3(3) — then, in relation to the label on each individual sachet or blister, it shall be sufficient compliance with this Order if there are set out, on the individual sachet or blister, the particulars specified in subclauses 3(2)(a), (b), (c), (h) and (i) and the name or registered trademark of the sponsor or supplier of the goods; or (c)
(i) the goods consist of dry loose herbs contained in individual bags for infusion where the bag is retained around the herbs during infusion; and
(ii) the bags are contained in a primary pack; and
(iii) the primary pack is labelled with the particulars referred to in subclauses 3(2) and 3(3) — then the individual bag need not include the particulars referred to in subclauses 3(2) and 3(3).

24 General requirements for labels for medicines

3(13) Strip, blister and dial dispenser packs

(a) Where:
(i) the goods consist of individual dosage units such as tablets, capsules, pastilles, cachets, lozenges, pessaries, suppositories or single doses of powder; and
(ii) two or more of the dosage units are individually enclosed in a strip, blister or dial dispenser pack such that the dosage units can only be extracted individually; and
(iii) the container is enclosed in a primary pack; and
(iv) the primary pack is labelled with the particulars referred to in subclauses 3(2) and 3(3) — then, in relation to the label on the container, it shall be sufficient compliance with this Order if there are set out on that container, the particulars referred to in subclauses 3(2)(a), (b), (c), (h) and (i) together with the name or registered trade mark of the sponsor or supplier; or

(b) in the case of a container described in subclause 3(13)(a)(ii) in which each dosage unit is enclosed in such a manner that an individual segment containing the dosage unit can be readily detached, the particulars referred to in subclauses 3(2)(a), (b) and (c) must appear at least once in relation to every two dosage units enclosed in the container.

3(14) Directions for use Where there is insufficient space on the label of the container or on the primary pack to include directions for use, it shall be sufficient compliance with subclause 3(2)(k) if there is included in a label on that container or primary pack, as the case may be, a statement to the effect that those directions for use are set out on a leaflet inserted in the primary pack of the goods provided that such a leaflet is in fact so inserted.

3(15) Homoeopathic preparations Where all the active ingredients in the goods are homoeopathic preparations then:

(a) the label on the container and the label on the outside of the primary pack if any, must include, in addition to the relevant requirements in subclauses 3(2) and 3(3), a statement indicating that the active ingredients in the goods are homoeopathic preparations, such as, ‘homoeopathic product’ or ‘homoeopathic preparation’; and

(b) where the indications for use are of a kind permitted to be advertised only to persons described in the Regulations, the label on the container and the label on the outside of the primary pack if any, must include a statement that the therapeutic indications have not been approved, such as ‘Homoeopathic product without approved therapeutic indications’.

3(16) Formulations containing both homoeopathic and nonhomoeopathic ingredients Where goods contain active ingredients that are homoeopathic preparations and other active ingredients that are not homoeopathic preparations —
(a) the label on the container and the label on the outside of the primary pack, if any, must include, in addition to the relevant requirements in subclauses 3(2) and 3(3), a statement that the goods include ingredients that are homoeopathic preparations, such as "Contains homoeopathic ingredients"; and

(b) where the indications for use are of a kind permitted to be advertised only to persons described in the Regulations, the label on the container and the label on the outside of the primary pack, if any, must include a statement that the therapeutic indications of the homoeopathic ingredients have not been approved, such as, "Contains homoeopathic ingredients without approved therapeutic indications."

3(17) Plastic ampoules Where:

(a) the medicine is presented in a plastic ampoule, the label on the container may be formed by way of embossing;

(b) the nominal volume of the medicine in the plastic ampoule is between 5 millilitres and 20 millilitres inclusive, the label on the container must be in accordance with subclause 3(11), relating to small containers and must include a statement of the approved route(s) of administration such as 'intravenous', 'intramuscular', 'subcutaneous', 'inhalation' or other phrase, word or abbreviation denoting the approved route(s) of administration and a warning statement where the incorrect route of administration may be hazardous;

(c) the nominal volume of the medicine in the plastic ampoule is greater than 20 millilitres, the label on the container must meet the requirements of subclauses 3(2), 3(3) and any other subclause relevant to the route of administration of the medicine, including a warning statement where the incorrect route of administration may be hazardous;

(d) the nominal volume of the medicine in the plastic ampoule is less than 5 millilitres and two or more ampoules are attached to a connecting strip in such a way that the seal is broken when an ampoule is detached, it will be sufficient for compliance with subclauses 3(2) and 3(3) if there are set out on the label on each ampoule the product name, the strength expressed as the amount of active in the nominal volume of the ampoule and the approved route of administration. The label on the connecting strip must include the name of the active ingredient, and the name or registered trade mark of the sponsor or supplier and a warning statement where the incorrect route of administration could be hazardous.

3(18) Composite packs Where a primary pack contains more than one kind of item, such as a vial containing a powder for reconstitution and an ampoule containing a diluent, which have different expiry dates, the expiry date included in the label on the primary pack shall be the expiry date indicating the shorter shelf life.

4 Expression of quantity or proportion of active ingredient in medicines Except as provided in clause 6 (Expression of activity of radionuclides in radiopharmaceutical preparations) and subclause 3(7) (Dialysis concentrates), the quantity or proportion of an active ingredient to be included on a label as required by subclause 3(2)(c) must be expressed:

4(1) for a discrete dosage unit — as the quantity of the active ingredient in the dosage unit;
4(2) for a liquid for ingestion — as the quantity of the active ingredient contained in the stated volume of a suitable dose of the liquid;

4(3) for a solid for ingestion, where there is no discrete dosage unit — as the quantity of the active ingredient contained in the stated weight of a suitable dose of the solid;

4(4) for a transdermal patch — as the quantity of the active ingredient released in a stated time;

4(5) for a homoeopathic preparation, where all the active ingredients are homoeopathic preparations:

(a) notwithstanding subclauses 4(1), 4(2) and 4(3), as the quantity of the ingredient in one millilitre or in one gram of the preparation; or

(b) where each active ingredient is included in the preparation in the same proportion as every other active ingredient — expressed as 'Contains equal parts of' followed by the name of each homoeopathic ingredient;

4(6) for goods which are required to be prepared before use and which after preparation are a liquid for ingestion — as the quantity of the active ingredient contained in the stated volume of a suitable dose of the liquid, after preparation in accordance with the instructions set out on the label of the goods;

4(7) for a preparation for injection: (a) where the preparation is a medicament for injection — as the nominal quantity of the active ingredient in the container;

(b) where the injection is intended for multidose use and

(i) the volume in the container is 1 millilitre or greater — as the quantity of the active ingredient in one millilitre of the injection; or (ii) the volume in the container is less than 1 millilitre — as the quantity of the active ingredient in a suitable dose volume of the injection;

(c) where the injection is a small volume injection and is usually intended for administration as a single dose — as the quantity of active ingredient in the stated volume of the injection in the container.

Note: In justified cases the strength may also be incorporated in the product name as a percentage (w/v or v/v) or another concentration term, but not including the quantity of active ingredient per millilitre; (d) where the preparation is a large volume injection intended for electrolyte replacement or nutritional therapy or is intended as a plasma volume expander or is intended as an additive to any of these types of large volume injection —

(i) as the number of millimoles in the stated volume of the injection in the container for each active ingredient or ion of precisely known molecular weight; or

(ii) as the weight contained in the stated volume of the injection in the container for each active ingredient for which the molecular weight is not precisely known; (e) where the preparation is a large volume injection containing an active ingredient which is not intended for electrolyte replacement or nutritional therapy or as a plasma volume expander — as the weight of the active ingredient in the stated volume of injection in the container;

4(8) for antibiotic preparations, where potency units are used as a measure of activity — as the number of such units expressed as International Units (IU) established by the World Health Organization;
4(9) for any other goods which are required to be prepared before use — as the weight or volume of active ingredient in a stated weight or volume of the goods, after preparation in accordance with the instructions included in the label of the goods;

4(10) for preparations applied to the skin and mucous membranes (other than those covered by subclause 4(8) above) as a percentage expressed in terms of w/w, w/v, v/v or v/w, as appropriate, or as the weight or volume in a stated weight or volume of the goods, as appropriate;

4(11) for preparations including a herbal substance: (a) where a herbal substance is a dry herb, fresh herb, powder, oil, fresh juice or dry juice preparation — as the quantity of the herbal substance in the preparation;

(b) where a herbal substance is an extract, tincture, decoction, infusion or spagyric — as the quantity of the raw material herb used to make the ingredient expressed as the equivalent dry or fresh weight, or

(c) where a herbal substance is a concentrated or diluted juice — as the quantity of the raw material juice used to make the concentrate or dilution expressed as the equivalent dry weight, fresh volume or fresh weight;

4(12) for preparations containing trace elements as salts intended as mineral supplements — as the quantity of the element with the name of the salt being indicated;

4(13) for preparations containing Vitamin A — as the quantity or proportion of Vitamin A expressed in terms of International Units (IU);

4(14) for pressurised metered dose inhalers and dry powder inhalers — as the delivered dose, except where the medicine is the subject of a monograph of the British Pharmacopoeia (BP) and the dose has been established as a metered dose. Where the powder for inhalation is supplied as a single dose in a capsule, or as a well in a blister tray or other suitable pharmaceutical form — as the quantity of active ingredient in each dosage unit;

4(15) for a preparation containing biological organisms — as the number of organisms present per metric unit for liquids and powders and as the number per dosage unit for other dosage forms;

4(16) for any other goods: (a) where the goods are a liquid and include an active ingredient which is a liquid — as the appropriate amount of the active ingredient, either by weight or volume, in a stated volume of the goods;

(b) where the goods are a liquid and include an active ingredient which is a solid — as the weight of active ingredient in a stated volume of the goods;

(c) where the goods are a liquid and include an active ingredient which is a gas — as the weight of the active ingredient in a stated volume of the goods;

(d) where the goods are a solid and include an active ingredient which is a liquid — as the appropriate amount of the active ingredient, either by weight or volume, in a stated weight of the goods;

(e) where the goods are a solid and include an active ingredient which is a solid — as the weight of the active ingredient in a stated weight of the goods;
(f) where the goods are a solid and include an active ingredient which is a gas — as the weight of the active ingredient in a stated weight of the goods.

5 Expression of potency in biological products

5(1) (a) The potency of liquid biological products or biological products which are required to be prepared before use must be included on labels and must be expressed as potency units or weight of active ingredient per dose or per unit volume or as the volume which contains the recommended dose.

(b) The potency unit to be used must be the International Unit (IU) established by the World Health Organisation.

5(2) The potency of probiotic biological products must be included on labels and must be expressed as the number of each probiotic organism per dose unit.

6 Expression of activity of radionuclides in radiopharmaceutical preparations The quantity or proportion of an active ingredient, which is a radionuclide, included in a radiopharmaceutical preparation must be included on labels and must be expressed in terms of the total activity of the radionuclide in the container, in becquerels, at a specified date and hour.35

7 Permitted statements of storage conditions

7(1) For the purposes of subclause 3(2):

(a) the following statements of storage conditions are permitted —

(i) 'Store below -18°C (Deep freeze)';
(ii) 'Store below -5°C (Freeze)';
(iii) 'Store below 8°C (Refrigerate)';
(iv) 'Store at 2°C to 8°C (Refrigerate. Do not freeze)';
(v) 'Store below 25°C'; and
(vi) 'Store below 30°C';

(b) if none of the statements of storage conditions included in subclauses 7(a)(i) to (vi) inclusive are applicable, the sponsor must apply to the Secretary for permission to use an alternative statement; and

(c) a statement of storage conditions specifying a maximum temperature in excess of 30°C may be permitted on application to the Secretary, subject to the review of data to establish the stability of the goods at the higher temperature.

First schedule: Excipients required to be declared on the label of medicines Reference to an excipient in this Schedule includes all salts and derivatives of the excipient. Ingredient names are indicative and do not constitute a complete or formal list.

Regulation of advertising of therapeutic goods in Australia

Introduction: Advertisements for therapeutic goods are subject to the requirements of the Therapeutic Goods Act 1989 ("the Act") and Regulations, the Trade Practices Act 1974 and other relevant laws. Additionally, advertisements for therapeutic goods directed to consumers must comply with the Therapeutic Goods Advertising Code (TGAC) (http://www.tga.gov.au/advert/tgac.htm)
Advertisement, in relation to therapeutic goods, includes any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use of supply of the goods (Therapeutic Goods Act 1989).

Section 22(5) of the Act specifies that advertising of a therapeutic good can only refer to the indications which are included in the Australian Register of Therapeutic Goods for that specific good.

Prescription only medicines

- Advertising direct to consumers is not permitted (prohibited by the Act).
- Advertising to healthcare professionals is permitted and is regulated by a self-regulatory scheme operated by Medicines Australia.
- Prior approval of advertisements is not applicable.
- Complaints about advertisements for prescription medicines directed to healthcare professionals are handled by Medicines Australia.
- TGA's letter of marketing approval requires the promotion of all prescription products (whether member or non-member) to comply with the requirements of the Medicines Australia Code of Conduct (available from the Medicines Australia website (http://www.medicinesaustralia.com.au).
- If a complaint is made about the advertising activities of a non-member, the complaint is forwarded to the non-member with an invitation to have the complaint adjudicated by the Medicines Australia Code of Conduct Committee. If the non-member declines the invitation for adjudication, the Medicines Australia may forward the complaint to the Therapeutic Goods Administration (TGA) or the Australian Competition and Consumer Commission.
- Where it has been determined that a breach of the Code has occurred, the Committee may impose a range of fines, depending on the nature of the breach. The Committee may also recommend to the Medicines Australia Board that a member be suspended or expelled.

Non-prescription medicines

- Non-prescription medicines are over-the-counter (OTC) medicines and non-prescription complementary medicines.
- Generally, advertisements for non-prescription medicines may be directed both to consumers and to healthcare professionals. However, the Regulations also prohibit the advertising to consumers of certain goods included in Schedule 3 of the Standard for the Uniform Scheduling of Drugs and Poisons (http://www.tga.gov.au/ndpsc/susdp.htm) (pharmacist only medicines).
- Advertisements for non-prescription medicines are regulated by both co-regulatory and self-regulatory arrangements operated by the TGA, the Therapeutic Goods Advertising Code Council, the Australian Self-Medication Industry (ASMI) and the Complementary Healthcare Council (CHC).
- Certain types of advertisements directed to consumers require prior approval by a Delegate of the Secretary of the Department of Health and Ageing.

Approval processes for direct to consumer advertising of non-prescription medicines

- Prior approval is required for certain types of advertisements and generic information advertised directly to consumers, specifically:

  Broadcast media - TV and radio. Print media - newspapers & magazines (including inserts). Outdoors - including billboards, bus shelters, sices & interiors of buses, taxi

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Devi Ahilya Vishwavidyalaya Indore - 337 -
* The Secretary of the Department of Health and Ageing or his/her delegate is responsible for approving advertisements. Under co-regulatory arrangements, this responsibility has been delegated to industry associations:

### Complaints handling processes for advertising of non-prescription medicines

- Complaints about direct to consumer advertising requiring approval are considered by the Complaints Resolution Panel, a body established in the Therapeutic Goods Regulations.
- The TGA reserves the right to intervene in matters where the breaches in advertising are of a serious nature, especially where consumer safety is a concern.
- Complaints about direct to consumer advertising that does not require approval or advertising to healthcare professionals are handled by the relevant industry association under their codes of practice.

These complaints follow a similar process to that for complaints about advertising of prescription medicines to healthcare professionals.

### Summary of regulation of advertising of therapeutic goods in Australia

<table>
<thead>
<tr>
<th></th>
<th>Prescription Medicines</th>
<th>Non-prescription medicines</th>
<th>Medical devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advertising direct to consumers</td>
<td>No</td>
<td>Yes, except for certain pharmacist only goods</td>
<td>Yes</td>
</tr>
<tr>
<td>Advertising healthcare professionals</td>
<td>Yes</td>
<td>Yes, Broadcast media (TV, radio); cinema; mainstream print media (newspapers &amp; magazines; displayed outdoors (eg billboards); No, Other advertisements (eg indoor posters, letterbox drops, brochures, catalogues, internet, etc.)</td>
<td>Yes</td>
</tr>
<tr>
<td>Approval required?</td>
<td>n/a</td>
<td>Yes</td>
<td>No, Other advertisements (eg indoor posters, letterbox drops, brochures, catalogues, internet, etc.)</td>
</tr>
<tr>
<td>Complaint handling process</td>
<td>TGA</td>
<td>TGA, Medicines Australia Code of Conduct</td>
<td>TGA, Trade Practices Act</td>
</tr>
</tbody>
</table>

Devi Ahilya Vishwavidyalaya Indore

- 338 -
4.5 INDIA

**THE DRUGS AND COSMETICS RULES, 1945**

Packing and labelling of imported drugs: No drug shall be imported unless it is packed and labelled in conformity with the Rules in Parts IX and X and further conform to the standards laid down in Part XII provided that in the case of drugs intended for veterinary use, the packing and labelling shall conform to the rules in Parts IX and X and Schedule F(1). (Subs. by Ministry of Health, F. P. & W. H. & U. D. Notfn. No. F. 1-6/62-D, dt. 2-7-1969.)

32A Packing and Labelling of Homoeopathic medicine.—No Homoeopathic medicine shall be imported unless it is packed and labelled in conformity with the rules in Part IX-A. (Ins. by S. O. No. 2139, dt. 12-8-1972.)

37. Packing of patent or proprietary medicine. — Patent or proprietary medicines shall be imported in containers intended for retail sale: (Amended by Notfn. No. F-1-3/51-D, dt. 15-10-1954.) Provided that such medicines may be imported in bulk containers by any person who holds a licence to manufacture, if such person has obtained permission in writing to import such medicines from the licensing authority at least three months prior to the date of import and the imports are made within a period of twelve months from the date of issue of such permission. (Amended by Notfn. No. F-1-45/58-D, dt. 4-1-1961)

87. Labelling.—Any drug manufactured `for the purpose of examination, test or analysis shall be kept in containers bearing labels indicating the purpose for which it has been manufactured.

88. Labelling of drugs supplied to other persons.—If any drug manufactured for the purpose of examination, test or analysis is supplied by the manufacturer to any other person, the container shall bear a label on which shall be stated the name and address of the manufacturer, the accepted scientific name of the substance if known, or if not known a reference which will enable the substance to be identified and the purpose for which it has been manufactured.

PART IX:

94. Exemption of certain drugs from certain provisions of this Part: (1) Labels on packages or containers of drugs for export shall be adapted to meet the specific requirements of the law of the country to which the drug is to be exported but the following particulars shall appear in a conspicuous position on the innermost container in which the drug is packed and every other covering in which that container is packed—

(a) name of the drug
(b) the name, address of the manufacturer and the number of the licence under which the drug has been manufactured;

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Devi Ahilya Vishwavidyalaya Indore - 339 -
(c) batch or lot number;
(d) date of expiry; if any;

Provided that where a drug not classified under Schedule F, Schedule F(1) and Schedule X, blood products, Narcotic and Psychotropic Substances is required by the consignee to be not labelled with the name and address of the manufacturer, the labels on packages or containers shall bear a code number as a approved by the Licensing Authority mentioned in Rule 21]

(2) The provisions of Rules 96 to 101 inclusive, shall not apply to a medicine made up ready for treatment, whether after or without dilution, which is supplied on the prescription of a registered medical practitioner provided that –

(i) the medicine is labelled with the following particulars –

(a) the name and address of the supplier;
(b) the name of the patient and the quantity of the medicine;
(c) the number of representing serial number of the entry in the prescription register;
(d) the dose, if the medicine is for internal use;
(e) the words 'For External use only' shall be printed on the label if the medicine is for external application;]

(ii) Condition (3) of the conditions in Rule 65 is satisfied.

95. Prohibition of sale or distribution unless labelled: Subject to the other provisions of these Rules, no person shall sell or distribute any drug (including a patent or proprietary medicine) unless it is labelled in accordance with these Rules.

96. Manner of Labelling: (1) Subject to the other provisions of these Rules, the following particulars shall be either printed or written in indelible ink and shall appear in a conspicuous manner on the label of the innermost container of any drug and on every other covering in which the container is packed, namely -

(i) The name of the drug;

1[(A) For this purpose], 1 [the proper name of the drug shall be printed or written in a more conspicuous manner than the trade name, if any which shall be shown immediately after or under the proper name and shall be ] –

(a) for drugs included in Schedule F or Schedule F91), the name given therein;
(b) for drugs included in the Indian Pharmacopoeia or the official pharmacopoeias and official compendia of drug standards prescribed in Rule 124, the name or synonym specified in the respective official pharmacopoeias and official compendia of drug standards followed by the letters 'I.P.', or, as the case may be, by the recognized abbreviations of the respective official pharmacopoeias and official compendia of drug standards;

(c) for drugs included in the National Formulary of India, the name or synonym specified therein followed by the letters 'N.F.I.';

(d) for other drugs, the international non-proprietary name, if any, published by the World Health Organisation or where an international non-proprietary name is not published, the name descriptive of the true nature or origin of the substance;
(ii) A correct statement of the net content in terms of weight, measure, volume, number of units of contents, number of units of activity, as the case may be, and the weight, measure and volume shall be expressed in Metric system.

(iii) The content of active ingredients—

This shall be expressed—

(a) for oral liquid preparations in terms of the content per single dose, being indicated in 5 millilitres

Provided that where the dose is below 5 millilitres the contents of active ingredients may be expressed in terms of 1 millilitre; [or fraction thereof:]

Provided further that where the single dose is more than 5 millilitres, the content of active ingredients shall be expressed in terms of minimum single dose as approved by the licensing authority;

(b) for liquid parenteral preparations ready for administration in terms of 1 millilitre or percentage by volume or per dose in the case of single dose container:

Provided that if the preparation is contained in an ampoule it will be enough if the composition is shown on the label or wrapper affixed to any package in which such ampoule is issued for sale;

(c) for drugs in solid form intended for parenteral administration, in terms of units or weight per milligram or gram;

(d) for tablets, capsules, pills and the like, in terms of the content in each tablet, capsule, pill or other unit, as the case may be;

(e) for other preparations, in terms of percentage by weight or volume or in terms of unitage per gram or millilitre, as the case may be:

Provided that clause (iii) shall not apply to the pharmacopoeial preparations where the composition of such preparation is specified in the respective pharmacopoeia and to a preparation included in the National Formulary of India.

(iv) The name of the manufacturer and the address of the premises of the manufacturer where the drug has been manufactured:

Provided that if the drug is contained in an ampoule or a similar small container, it shall be enough if only the name of the manufacturer and his principal place of manufacture is shown.

(v) A distinctive batch number, that is to say, the number by reference to which details of manufacture of the particular batch from which the substance in the container is taken are recorded and are available for inspection, the figure representing the batch number being preceded by the words ‘Batch No.’ or ‘B. No.’ or ‘Batch’ or ‘Lot No.’ or ‘Lot’.

NOTES

(1) In the case of drugs manufactured by a continuous process, like manufacture of magnesium sulphate, pharmaceutical chemicals etc., the production resulting in one homogenous mix of the finished products shall be considered as one “Batch”.

Devi Ahilya Vishwavidyalaya Indore
(2) In the case of powders, liquid orals, ointments etc., one “Batch Number” shall be assigned to all the containers filled from one homogenous bulk.

(3) In the case of tablets, capsules, lozenges, troches, etc., one “Batch Number” shall be assigned to the products manufactured from one homogenous mix ready for compression or filling.

(4) In the case of parenteral preparations sterilized by steam under pressure, one “Batch Number” shall be assigned to all containers filled from one homogenous bulk solution and sterilized in one sterilizer load.

(5) In the case of containers of parenteral preparations filled from one homogenous bulk solution and sterilized in more than one sterilizer load, the “Batch Number” assigned to the containers in the different sterilizer loads shall be the same “Batch Number” as is assigned to the homogenous bulk solution, provided the samples taken from all the sterilizer loads pass the sterility test, and are kept separate from one another until the report of the sterility test is available.

**Explanation.**—For the purpose of chemical and other tests, representative samples from all containers filled from the homogenous bulk solution should be taken.

(6) In the case of parenteral and other sterile products filled aseptically, a “Batch Number” shall be assigned to all containers filled from one homogenous mix during one filling operation, the filling operation being completed in a period of not more than a day and during which no schedule change in the filling assembly is made.

When containers are filled from one homogenous mix, in a number of filling operations, the “Batch Number” assigned to the containers filled in individual filling operations shall be the same “Batch Number” as is assigned to the homogenous mix, provided the samples taken from all the different filling operations pass the sterility tests, and are kept separate from one another until the report of the sterility test is available.

**Explanation.**—For the purpose of chemical and other tests, representative samples from all containers filled from the homogenous mix should be taken.

(7) In the case of medicinal gases produced by a continuous process of operation a week’s production from one tank load shall be considered as a Batch.

(vi) Every drug manufactured in India shall bear on its label the number of the licence under which the drug is manufactured, the figure representing the manufacturing licence number being preceded by the words “Manufacturing Licence Number” or “Mfg. Licence No.” or “M.L.”.

(vii) Drugs specified in Schedule P and their preparations including combinations with other drugs shall bear on their labels the date of manufacture, and the date of expiry of potency, and the period between the date of manufacture and the date of expiry shall not exceed that laid down in the said Schedule [under the conditions of storage specified therein. Drugs and their preparations not included in Schedule P], shall bear on their labels the date of their manufacture and also the date of their expiry which shall not exceed sixty months from the date of manufacture:

**Provided** that this period may be extended by the Licensing Authority specified in clause (b) of Rule 21 in respect of any specified drug if satisfactory evidence is produced by the manufacturer to justify such an extension.

(viii) Drugs specified in Schedule C(1) and their preparations including combinations with other drugs shall bear on the labels (a) the date of manufacture, (b) date of expiry of potency fixed by the
manufacturer, and (c) where such drugs are imported, also the number of licence under which the drug is imported, preceded by the words "Import Licence":

Provided that drugs in bulk form included in Schedule C(l) which are not ready for use and not included in Schedule P need not bear on the label the date of expiry of potency fixed by the manufacturer:

Provided further that no reference shall be made to any other licence number granted by any authority outside India on any label or container or in any covering in which the container is packed or in any other matter or advertisement enclosed therewith.

(ix) Every drug intended for distribution to the medical profession as a free sample shall, while complying with the labelling provisions under clauses (i) to (viii), further bear on the label of the container the words 'Physician's Sample—Not to be sold' which shall be overprinted.

(x) If any preparation contains not less than 3 per cent by volume of alcohol the quantity of alcohol shall be stated in terms of the average percentage by volume of absolute alcohol in the finished products.

(xi) In addition to the other particulars which are required to be printed or written under these Rules, the label of innermost container of the following categories of drugs and every other covering in which the container is packed shall bear a conspicuous red vertical line on the left side running throughout the body of the label which should not be less than 1mm in width and without disturbing the other conditions printed on the label under these rules, namely: —

Narcotic analgesics, hypnotics, sedatives, tranquilisers, corticosteroids, hormones, hypoglycemics, antimicrobials, antiepileptics, antidepressants, anticoagulants, anti-cancer drugs and all other drugs falling under Schedules 'G', 'H', and 'X' whether covered or not in the above list:

Provided that the provisions of this clause shall not apply to: -

(a) preparations intended for animal treatment;
(b) preparations intended for external use;
(c) ophthalmic preparations and ear drops; and
(d) sterile preparations such as sutures, surgical dressings and preparations intended for parenteral use.

(2)(i) The particulars to be printed or written on the label of a mechanical contraceptive shall be as specified in Schedule R.

(ii) The following particulars, in addition to those specified under sub-rule (1) shall be either printed or written in indelible ink and shall appear in a conspicuous manner on the label of the innermost container and on every other covering in which the container of a contraceptive, other than a mechanical contraceptive, is packed, namely: -

(a) the date of manufacture;
(b) the date upto which the contraceptive is expected to retain its properties;
(c) the storage conditions necessary for preserving the properties of the contraceptive upto the date indicated in sub-clause (b):

Provided that for oral contraceptives it shall be sufficient to display on the label of the container the date of manufacture only.

(3)(i) The particulars prescribed in sub-rule (1) shall be printed or written in indelible ink either on the label borne by a container of vaccine lymph or on a label or wrapper affixed to any package in which the
container is issued for sale. The said particulars shall be indelibly marked on the sealed container of
surgical ligature or suture or printed or written in indelible ink on a label enclosed therein.

(ii) Nothing in these rules shall be deemed to require the labelling of any transparent cover or of any
wrapper, case or other covering used solely for the purpose of packing, transport or delivery.

(4) Where by any provision of these rules any particulars are required to be displayed on a label on the
container, such particulars may, instead of being displayed on a label, be etched, painted or otherwise
indelibly marked on the container:

Provided that, except where otherwise provided in these rules, the name of the drug or any distinctive
letters intended to refer to the drug shall not be etched, painted or otherwise indelibly marked on any
glass container other than ampoules.

Explanation.— For the purpose of this rule, the date of expiry shall be in terms of month and year and it
shall mean that the drug is recommended till the last day of the month. The date of expiry shall be
preceded by the words ‘Expiry date’.

97. Labelling of medicines.—(1) The container of a medicine for internal use shall—
(a) if it contains a substance specified in Schedule G, be labelled with the words “Caution: it is
dangerous to take this preparation except under medical supervision” — conspicuously printed and
surrounded by a line within which there shall be no other words;
(b) if it contains a substance specified in Schedule H, be labelled with the symbol Rx and conspicuously
displayed on the left top corner of the label and be also labelled with the following words:

‘Schedule H drug - Warning: To be sold by retail on the prescription of a Registered Medical
Practitioner only’;

(c) if it contains a substance specified in Schedule H, and comes within the purview of the Narcotic
Drugs and Psychotropic Substances Act, 1985 (61 of ‘985) be labelled with the symbol NRx which
shall be in red and conspicuously displayed on the left top corner of the label, and be also labelled with the following words:

‘Schedule H drug - Warning: To be sold by retail on the prescription of a Registered Medical
Practitioner only’;

(d) If it contains a substance specified in Schedule X, be labelled with the symbol XRx which shall be in
red conspicuously displayed on the left top corner of the label and be also labelled with the following words :

‘Schedule X drug - Warning: To be sold by retail on the prescription of a Registered Medical
Practitioner only’;

(2) The container of an embrocation, liniment, lotion, [ointment, antiseptic cream,] liquid antiseptic or other
liquid medicine for external application shall be labelled with the words : “FOR EXTERNAL USE
ONLY”.

(3) The container of a medicine made up ready only for treatment of an animal shall be labelled
conspicuously with the words ‘Not for human use; for animal treatment only’ and shall bear a symbol
depicting the head of a domestic animal.
(4) The container of a medicine prepared for treatment of human ailments shall if the medicine contains industrial methylated spirit, indicate this fact on the label and be labelled with the words: “For External Use only”.

(5) Substances specified in Schedule X in bulk form shall bear a label wherein the symbol as specified in sub-Rule (1) shall be given conspicuously in red letters.

102. Non-Sterile Surgical Ligature and Suture.- Every container of, and wrapper enclosing surgical ligature or suture other than a ligature or suture offered or intended to be offered for sale as sterile, shall bear a label on which are printed or written in a conspicuous manner in indelible red ink the words “Non-sterile surgical ligature (suture) – not to be used for operations upon the human body unless efficiently sterilized”.

103. * * * * *

(2) The name and address of the manufacturer shall be printed on the label of the container of a patent or proprietary medicine.

(3) The true formula or list of the ingredients shall be printed or written in indelible ink on the outer label of every package containing patent or proprietary medicine.

104. Use of letter I.P. etc.-The letters ‘I.P.’ and recognized abbreviations of pharmacopoeias and official compendia of drug standards prescribed under these Rules shall be entered on the label of the drug only for the purpose of indicating that the drug is in accordance with standards set out in the Indian Pharmacopoeia or in any such pharmacopoeia or official compendium of drug standards recognized under the Rules.

104A. Prohibition against altering inscriptions on containers, labels or wrappers of drug.- No person shall alter, obliterate or deface any inscription or mark made or recorded by the manufacturer on the container, label or wrapper of any drug:

Provided that nothing in this rule shall apply to any alteration, any inscription or mark made on the container, label or wrapper of any drug at the instance or direction or with the permission of the Licensing Authority.

105. Packing of drugs.- (1) The pack sizes of drugs meant for retail sale shall be as prescribed in Schedule P1 to these rules.

(2) The pack sizes of drugs not covered by Schedule P-1 shall be as given below:

(i) The pack sizes for Tablets/Capsules shall be: Where the number of Tablets (coated or uncoated)/Capsules (hard or soft gelatin) is less than 10, such packing shall be made by the integral number. For numbers above 10, the pack size of Tablets/Capsules shall contain multiples of 5.

(ii) The pack sizes for liquid Oral preparations shall be 30 ml (paediatric only)/60 ml/100 ml/200 ml/450 ml.

(iii) The pack sizes for Paediatric Oral Drops shall be 5 ml/10 ml/15 ml.

(iv) The pack sizes for Eye/Ear/Nasal Drops shall be 3 ml/5 ml/10 ml.
(v) The pack size for Eye Ointment shall be 3 gm/5 gm/ 10 gm:

Provided that the provisions of the pack sizes covered under this rule shall not apply to: –

1. Pack sizes or dosage forms not covered by the foregoing provisions of this rule.
2. The imported formulations in finished form.
3. Preparations intended for Veterinary use.
4 Preparations intended for Export.
5. Vitamins/Tonics/Cough Preparations/Antacids/Laxatives in Liquid Oral forms, Unit dose (including applicaps).
6. Pack sizes of dosage forms meant for retail sale to Hospitals, Registered Medical Practitioners, Nursing Homes.
7. Physician’s Samples.
8. Pack sizes of large volume Intravenous Fluids:

Provided also that pack sizes of any of the new drug as and when approved by the Licensing Authority appointed under Rule 21 and if not covered under this rule, shall be examined for the purpose of approval with the specific justification by the said Licensing Authority:

Provided further that Oxytocin injection meant for sale shall be in single unit blister pack only:

105A. Packings of drugs specified in Schedule X.- The drugs specified in Schedule X shall be marketed in packings not exceeding-

(i) 100 unit doses in the case of tablets/capsules;
(ii) 300 ml in the case of oral liquid preparations; and
(iii) 5 ml in the case of injections:

Provided that nothing in this rule shall apply to packing meant for use of a hospital or a dispensary subject to the conditions that–

(i) such supplies are made by the manufacturers or distributors direct to the hospital/dispensaries; and

(ii) hospital packs shall not be supplied to a retail dealer or to a Registered Medical Practitioner.

106. Diseases which a drug may not purport to prevent or cure.—(1) No drug may purport or claim to prevent or cure or may convey to the intending user thereof any idea that it may prevent or cure one or more of the diseases or ailments specified in Schedule J.

(2) No drug may purport or claim to procure or assist to procure, or may convey to the intending user thereof any idea that it may procure or assist to procure, miscarriage in women

PART IXA:

Labelling And Packing Of Homoeopathic Medicines

106-A. Manner of labelling of Homoeopathic medicines.—(A) The following particulars shall be either printed or written in indelible ink and shall appear in a conspicuous manner on the label of the innermost container of any Homoeopathic medicine and on every other covering in which the container is packed—

(i) The words 'Homoeopathic medicine',
(ii) The name of the medicine—
(a) For drugs specified in the Homoeopathic Pharmacopoeias of India or the United States of America or the United Kingdom, or the German Homoeopathic Pharmacopoeia, the name specified in that Pharmacopoeia.

(b) For other drugs, the name descriptive of the true nature of the drugs.

(iii) The potency of the Homoeopathic medicine—For this purpose the potency shall be expressed either in decimal, centesimal or millisimal systems.

(iiiA) In case of Homoeopathic medicine containing two or more ingredients the name of each ingredient together with its potency and proportion expressed in metric system shall be stated on the label.

(iv) Name and address of the manufacturer when sold in original containers of the manufacturer. In case a Homoeopathic medicine is sold in a container other than that of the manufacturer—the name and address of the seller.

(v) In case the Homoeopathic medicine contains alcohol, the alcohol content in percentage by volume in terms of ethyl alcohol shall be stated on the label:

Provided that in case the total quantity of the pharmacopoeial homoeopathic medicine in the container is 30 millilitres or less, it will not be necessary to state the content of alcohol on the label.

(B) In addition to the above particulars the label of a Homoeopathic mother tincture shall display the following particulars:

(i) A distinctive batch number, that is to say, the number by reference to which details of manufacture of the particular batch from which the substance in the container is taken are recorded and are available for inspection, the figures representing the batch number being preceded by the words “Batch No.” or “Batch” or “Lot Number” or “Lot No.” or “Lot” or any distinguishing prefix.

(ii) Manufacturing licence number, the number being preceded by the words “Manufacturing Licence Number” or “Mfg. Lic. No.” or “M.L.”.

Explanation.—This clause shall not apply to a Homoeopathic mother tincture manufactured outside India.

(C) No Homoeopathic medicine containing a single ingredient shall bear a proprietary name on its label.

106-B. Prohibition of quantity and percentage.—No Homoeopathic medicine containing more than 12% alcohol v/v (Ethyl alcohol) shall be packed and sold in packing or bottles of more than 30 millilitres, except that it may be sold to hospitals/dispensaries in packings or bottles of not more than 100 millilitres.

PART X:
Special Provisions Relating To Biological And Other Other Special Products

107. Name of substance.—If any substance specified in Schedule C is advertised or sold as a proprietary medicine or is contained in a medicine so advertised or sold, the proper name of the substance shall appear on the label in the manner prescribed in this Part.

Explanation.—For the purpose of this rule the expression “proper name” means the proper name stated in Schedule F or if no such name is stated, the name descriptive of the true nature and origin of the substance. Provided that in the case of veterinary biological product the expression “proper name” means...
the proper name stated in Schedule F (1) or if no such name is stated, the name or synonym given in the current edition for the time being of the British Pharmacopoeia (Veterinary), or, if no such name is stated either in Schedule F (1) or the British Pharmacopoeia (Veterinary), the name descriptive of the true nature and origin of the substance approved by the Licensing Authority.

108. Container.—(1) No substance specified in Schedule C shall be sold or offered for sale unless it has been sealed in a previously sterilized container made of glass or any other suitable material approved for the purpose by the Licensing Authority appointed under rule 21, in such manner as may, in the opinion of the Licensing Authority, suffice to preclude the access of bacteria:

Provided that it shall not be necessary to use a previously sterilized container if the filled and sealed container is to be sterilized after the sealing and such sterilizing procedure would render the product sterile. However, the Licensing Authority may, for any special reasons, direct the licensee to pre-sterile such containers.

(2) When any such substance is issued in liquid form in containers which are sealed in such a manner that portions of the contents can be withdrawn for use on different occasions, the liquid shall contain a sufficient proportion of some antiseptic to prevent the growth of any organism which may be accidentally introduced in the process of removing a portion of the contents of the container:

Provided that nothing in this sub-rule shall apply to a penicillin suspension in oil and wax.

(3) The container shall comply with such further requirements, if any, as are specified in Schedule F or Schedule F (1) as the case may be, in that behalf.

(4) The Licensing Authority may in the case of any particular preparation of any such substance dispense with any of the requirements of this Rule or Schedule F or Schedule F (1) as the case may be, and may make such additional requirements, as having regard to the nature of the preparation, they may deem necessary.

109. Labelling.—(1) The following particulars and such further particulars, if any, as are specified in Schedule F or Schedule F (1) as the case may be, shall be printed or written in indelible ink on the label of every phial, ampoule or other container of a substance specified in Schedule C and on every other covering in which such phial, ampoule or container is packed—

(a) where a drug is imported, the number of licence under which it is imported, preceded by the words 'Import Licence';

Provided that no reference shall be made to any other import licence number granted by any authority outside India on any label or container or in any covering in which the container is packed or in any other matter of advertisement enclosed therein;

(b) where a test for potency in units is required by these rules, a statement of the potency in units defined in terms of relation to the standard preparation specified in Schedule F or F (1) as the case may be:

Provided that this clause shall not apply in the case of vaccine lymph;

(c) where a test for potency or maximum toxicity is required the date up to which the substance if kept under suitable conditions may be expected to retain a potency not less than stated on the label of the container or not to acquire a toxicity greater than that permitted by the test, as the case may be. The date
of expiry shall be in terms of month and year and it shall mean that the drug is recommended for use till the last day of the month. The date of expiry shall be preceded by the words 'Expiry date':

Provided that nothing in these rules shall be deemed to require the labelling of any transparent cover or any wrapper, case or other covering used solely for the purpose of packing, transport or delivery.

(2) The particulars prescribed in clause (a) of the preceding sub-rule shall be printed or written in indelible ink either on the label borne by a container of vaccine lymph or on a label or wrapper affixed to any package in which the container is issued for sale. The said particulars shall be indelibly marked on the sealed container of surgical ligature or suture or printed or written in indelible ink on a label enclosed therein.

(3) The following particulars, and such further particulars, if any, as are specified in Schedule F or Schedule F (1), as the case may be, shall be printed or written in indelible ink either on the label borne by the container of any substance specified in Schedule C or on a label or wrapper affixed to any package in which any such container is issued for sale, namely:—

(a) the date on which the manufacture of the particular batch from which the substance in the container is taken was completed as defined in Schedule F or Schedule F (1), or if there is no definition in Schedule F or Schedule F (1) as hereafter defined in this rule and in the case of vaccine prepared from concentrates, the date of completion of the final products and the bottling for issue;

(b) where an antiseptic substance has been added, the nature and the percentage proportion introduced;

(c) the precaution necessary for preserving the properties of the contents up to the date indicated in clause (c) of sub-rule (1).

(4) For the purpose of clause (a) of sub-rule (3), the date on which the manufacture of a batch is completed shall be—

(a) in cases where a test for potency or toxicity is required by these rules or not being so required, is accepted by the Licensing Authority as sufficient for the purpose of fixing the date of completion of manufacture, the date on which the substance was removed from cold storage after having been kept at a temperature not exceeding 5° C continuously for a period not exceeding two years from the time when the last test was completed,

(b) in cases where no such test is required or accepted—

(i) if the substance is a serum obtained from a living animal, the earliest date on which any material contributing to the batch was removed from the animal;

(ii) if the substance was obtained by the growth of organisms or artificial media, the earliest date on which growth was terminated in any of the material contributing to the batch;

Provided that if a batch of the substance (including all material contributing to this batch) has for a period of not more than three years been kept in cold storage at a temperature not exceeding 5° C continuously from the earliest practicable date after that on which growth was terminated in the material as the case may be, the date of removal from cold storage shall be treated as the date on which the manufacture of the batch is completed;

(c) in all other cases, the date on which the substance is filled in the container.
109-A. Labelling of Medical Devices.—The labelling of Medical Devices shall conform to the Indian Standards Specifications laid down from time to time by the Bureau of Indian Standards in addition to any other requirement prescribed under the said rules.

110. Prohibition of sale of substance after prescribed date.—No person shall sell, or exhibit for sale any substance specified in Schedule C after the date recorded on the container, label or wrapper as the date upto which the substance may be expected to retain a potency not less than, or not to acquire a toxicity greater than that required or permitted by the prescribed test as the case may be.

Labelling, Packing And Limit of Alcohol In Ayurvedic (Including Siddha) Or Unani Drugs

161. Labelling, packing and limit of alcohol.—(1) There shall be conspicuously displayed on the label of the container or package of an Ayurvedic (including Siddha) or Unani drug, the true list of all the ingredients used in the manufacture of the preparation together with quantity of each of the ingredients incorporated therein and a reference to the method of preparation thereof as detailed in the standard test and Adikaranas, as are prescribed in the authoritative books specified in the First Schedule to the Act:

Provided that if the list of ingredients contained in the medicine is large and cannot be accommodated on the label, the same may be printed separately and enclosed with packing and reference be made to this effect on the label.

(2) The container of a medicine for internal use made up ready for the treatment of human ailments shall, if it is made up from a substance specified in Schedule E (1), be labelled conspicuously with the words 'Caution: To be taken under medical supervision' both in English and Hindi language.

(3) (i) Subject to the other provisions of these rules, the following particulars shall be either printed or in indelible ink and shall appear in a conspicuous manner on the label of the innermost container of any Ayurvedic (including Siddha) or Unani drug and on any other covering in which the container is packed, namely:

- A correct statement of the net content in terms of weight, measure or number as the case may be. The weight and volume shall be expressed in metric system.
- The name and address of the manufacturer.
- The number of the licence under which the drug is manufactured, the figure representing the manufacturing licence number being preceded by the words 'Manufacturing Licence Number' or 'Mfg. Lic. No.' or 'M.L.'
- A distinctive batch number, that is to say, the number by reference to which details of manufacture of the particular batch from which the substance in the container is taken are recorded and are available for inspection, the figure representing the batch number being preceded by the words 'Batch No.' or 'Batch' or 'Lot Number' or 'Lot No.' or 'Lot' or any distinguishing prefix.
- Preparation (Asavas) with high content of alcohol as base

(4) Nothing in these rules shall be deemed to require the labelling of any transparent cover or of any wrapper case or other covering used solely for the purpose of packing, transport or delivery.
[161A. Exemption in labeling and packing, provisions for export of Ayurvedic (including Siddha) and Unani drugs.- (1) Labels and packages or containers of Ayurvedic, Siddha and Unani drugs for export may be adopted to meet the specific requirements of the law of the country to which the said drug is to be exported, but the following particulars shall appear in conspicuous position on the container in which drug is packed and on every other covering in which that container is packed, namely:

(a) Name of the Ayurvedic, Siddha and Unani drug (Single or compound formulations);
(b) the name, address of the manufacturer and the number of licence under which the drug has been manufactured;
(c) batch or lot number;
(d) date of manufacture, along with the date for "Best for use before";
(e) main ingredients, if required by the importing country;
(f) for export:

Provided that where Ayurvedic, Siddha and Unani Single or compound drug not classified under the First Schedule or Schedule E, is required by the consignee to be not labeled with the name and address of the manufacturer, the labels on packages or containers shall bear a code number as approved by the Licensing Authority mentioned in rule 152.

(2) the provisions of Rule 161 shall not apply to a medicine made up "ready for treatment", whether after, or without, alteration, which is supplied on the prescription of a registered medical practitioner if the medicine is labeled with the following particulars, namely –

(a) the name and address of the suppliers;
(b) the words "For External Use Only", if the medicine is for external application.]

The prevailing Indian Law does not stipulate any provision on requirement of pre approval of advertisement of drugs except as provided under Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954.

THE DRUGS AND MAGIC REMEDIES (OBJECTIONABLE ADVERTISEMENTS) ACT, 1954
[30th April, 1954.]
An Act to control the advertisement of drugs in certain cases, to prohibit the advertisement for certain purposes of remedies alleged to possess magic qualities and to provide for matters connected therewith.

1. (2)It extends to the whole of India except the State of Jammu and Kashmir, and applies also to persons domiciled in the territories to which this Act extends who are outside the said territories

(a) * advertisement * includes any notice, circular, label, wrapper, or other document, and any announcement made orally or by any means of producing or transmitting light, sound or smoke;

(b) drug * includes: (i) a medicine for the internal or external use of human beings or animals ; (ii) any substance intended to be used for or in the diagnosis, cure, mitigation, treatment or prevention of disease in human beings or animals; (iii)any article, other than food, intended to affect or influence in any way the structure or any organic function of the body of human beings or animals;

(iv)any article intended for use as a component of any medicine, substance or article, referred to in subclauses (i), (ii) and (iii);
(c) "magic remedy" includes a talisman, mantra, kavacha, and any other charm of any kind which is alleged to possess miraculous powers for or in the diagnosis, cure, mitigation, treatment or prevention of any disease in human beings or animals or for affecting or influencing in any way the structure or any organic function of the body of human beings or animals;

(cc) "registered medical practitioner" means any person,- (i) who holds a qualification granted by an authority specified in, or notified under, section 3 of the Indian Medical Degrees Act, 1916 (7 of 1916) or specified in the Schedules to the Indian Medical Council Act, 1956 (102 of 1956); or (ii) who is entitled to be registered as a medical practitioner under any law for the time being in force in any State to which this Act extends relating to the registration of medical practitioners;

(d) 'taking any part in the publication of any advertisement' includes- (i) the printing of the advertisement, (ii) the publication of any advertisement outside the territories to which this Act extends by or at the instance of a person residing within the said territories;

3. Prohibition of advertisement of certain drugs for treatment of certain diseases and disorders. Subject to the provisions of this Act, no person shall take any part in the publication of any advertisement referring to any drug in terms which suggest or are calculated to lead to the use of that drug for-

(a) the procurement of miscarriage in women or prevention of conception in women; or
(b) the maintenance or improvement of the capacity of human beings for sexual pleasure; or
(c) the correction of menstrual disorder in women; or
(d) the diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition specified in the Schedule, or any other disease, disorder or condition (by whatsoever name called) which may be specified in the rules made under this Act:

Provided that no such rule shall be made except: (i) in respect of any disease, disorder or condition which requires timely treatment in consultation with a registered medical practitioner or for which there are normally no accepted remedies, and (ii) after consultation with the Drugs Technical Advisory Board constituted under the Drugs and Cosmetics Act, 1940 (23 of 1940) and, if the Central Government considers necessary, with such other persons having special knowledge or practical experience in respect of Ayurvedic or Unani systems of medicines as that Government deems

4. Prohibition of misleading advertisements relating to drugs. Subject to the provisions of this Act, no person shall take any part in the publication of any advertisement relating to a drug if the advertisement contains any matter which-

(a) directly or indirectly gives a false impression regarding the true character of the drug; or
(b) makes a false claim for the drug; or (c) is otherwise false or misleading in any material particular.

5. Prohibition of advertisement of magic remedies for treatment of certain diseases and disorders. No person carrying on or purporting to carry on the profession of administering magic remedies shall take any part in the publication of any advertisement referring to any magic remedy which directly or indirectly claims to be efficacious for any of the purposes specified in section 3.

6. Prohibition of import into, and export from India of certain advertisements. No person shall import into, or export from, the territories to which this Act extends any document containing an advertisement of the nature referred to in section 3, or section 4, or section 5, and any documents containing any such advertisements shall be deemed to be goods of which the import or export has been prohibited under section 19 of the Sea Customs Act, 1878 (8 of 1878) and all the provisions of that Act shall have effect accordingly, except that section 183 thereof shall have effect as if for the word "shall" therein the word "may" were substituted.

Devi Ahilya Vishwavidyalaya Indore
7. Penalty. Whoever contravenes any of the provisions of this Act or the rules made thereunder shall, on conviction, be punishable-

(a) in the case of a first conviction, with imprisonment which may extend to six months, or with fine, or with both;

(b) in the case of a subsequent conviction, with imprisonment which may extend to one year, or with fine, or with both.

8. Powers of entry, search, etc. (1) Subject to the provisions of any rules made in this behalf, any Gazetted Officer authorised by the State Government may, within the local limits of the area for which he is so authorised,-

(a) enter and search at all reasonable times, with such assistants, if any, as he considers necessary, any place in which he has reason to believe that an offence under this Act has been or is being committed;

(b) seize any advertisement which he has reason to believe contravenes any of the provisions of this Act:

Provided that the power of seizure under this clause may be exercised in respect of any document, article or thing which contains any such advertisement, including the contents, if any, of such document, article or thing, if the advertisement cannot be separated by reason of its being embossed or otherwise, from such document, article or thing without affecting the integrity, utility or saleable value thereof;

(c) examine any record, register, document or any other material object found in any place mentioned in clause (a) and seize the same if he has reason to believe that it may furnish evidence of the commission of an offence punishable under this Act.

(2) The provisions of the Code of Criminal Procedure, 1898 (5 of 1898), shall, so far as may be, apply to any search or seizure under this Act as they apply to any search or seizure made under the authority of a warrant issued under section 98 of the said Code.

(3) Where any person seizes anything under clause (b) or clause (c) of sub-section (1), he shall, as soon as may be, inform a Magistrate and take his orders as to the custody thereof.

9. Offences by companies. (1) If the person contravening any of the provisions of this Act is a company, every person who at the time the offence was committed, was in charge of, and was responsible to, the company for the conduct of the business of the company as well as the company shall be deemed to be guilty of the contravention and shall be liable to be proceeded against and punished accordingly:

Provided that nothing contained in this sub-section shall render any such person liable to any punishment provided in this Act if he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence.

(2) Notwithstanding anything contained in sub-section (1) where an offence under this Act has been committed by a company and it is proved that the offence was committed with the consent or connivance of, or is attributable to any neglect on the part of, any director or manager, secretary or other officer of the company, such director manager, secretary or other officer of the company shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

Explanation.-For the purposes of this section,-

(a) "company" means any body corporate and includes a firm or other association of individuals, and
(b) "director" in relation to a firm means a partner in the firm.

9A. Offences to be cognizable. Notwithstanding anything contained in the Code of Criminal Procedure, 1898, (5 of 1898) an offence punishable under this Act shall be cognizable.

10. Jurisdiction to try offences. No court inferior to that of a presidency magistrate or a magistrate of the first class shall try any offence punishable under this Act.

10A. Forfeiture. Where a person has been convicted by any court for contravening any provision of this Act or any rule made thereunder, the court may direct that any document (including all copies thereof), article or thing, in respect of which the contravention is made, including the contents thereof where such contents are seized under clause (b) of sub-section (1) of section 8, shall be forfeited to the Government.

11. Officers to be deemed to be public servants. Every person authorised under section 8 shall be deemed to be a public servant within the meaning of section 21 of the Indian Penal Code. (45 of 1860).

12. Indemnity. No suit, prosecution or other legal proceeding shall lie against anyone for anything which is in good faith done or intended to be done under this Act.

13. Other laws not affected. The provisions of this Act are in addition to, and not in derogation of the provisions of any other law for the time being in force.

14. Savings. Nothing in this Act shall apply to-
(a) any sign board or notice displayed by a registered medical practitioner on his premises indicating that treatment for any disease, disorder or condition specified in section 3, the Schedule or the rules made under this Act, is undertaken in those premises; or
(b) any treatise or book dealing with any of the matters specified in section 3 from a bona fide scientific or social standpoint; or
(c) any advertisement relating to any drug sent confidentially in the manner prescribed under section 16 only to a registered medical practitioner; or
(d) any advertisement relating to a drug printed or published by the Government; or
(e) any advertisement relating to a drug printed or published by any person with the previous sanction of the Government granted prior to the commencement of the Drugs and Magic Remedies (Objectionable Advertisements) Amendment Act, 1963 (42 of 1963);

Provided that the Government may, for reasons to be recorded in writing, withdraw the sanction after giving the person in opportunity of showing cause against such withdrawal.

15. Power to exempt from application of Act. If in the opinion of the Central Government public interest requires that the advertisement of any specified drug or class of drugs or any specified class of advertisements relating to drugs should be permitted, it may, by notification in the Official Gazette, direct that the provisions of sections 3, 4, 5 and 6 or any one of such provisions shall not apply or shall apply subject to such conditions as may be specified in the notification to or in relation to the advertisement of any such drug or class of drugs or any such class of advertisements relating to drugs. 16. Power to make rules.
16. **Power to make rules.** (1) The Central Government may, by notification in the Official Gazette, make rules for carrying out the purposes of this Act.

(2) In particular and without prejudice to the generality of the foregoing power, such rules may-

(a) specify any "disease, disorder or condition" to which the provisions of section 3 shall apply

(b) prescribe the manner in which advertisements of articles or things referred to in clause (c) of sections 14 may be sent confidentially.

(3) Every rule made under this Act shall be laid as soon as may be after it is made, before each House of Parliament while it is in session for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if before the expiry of the session in which it is so laid or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule. (www.cdsco.nic.in)

A report of FDA Maharashtra State:

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(Kerala drug regulator challenges herbal Musli Power Xtra\'s claims as impotency medicine in court)

Drug regulatory authorities in south Indian state of Kerala has moved court challenging the efficacy of Musli Power Xtra - one of the widely popular herbal medicine with claims to boost sexual prowess in both men and women.

The cases that were filed include, one under Spurious Drugs Act, and another one under Drugs and Magic Remedies (objectionable advertisement) Act, 1955
Despite warnings, Kunnath Pharma continued giving wide publicity through promotional advertisements claiming that Musli Power Xtra has the potential to increase the sexual prowess of both men and women and can be even a reliable remedy for infertility related problems.

The State Drug Regulator has booked Kunnath under Section 33 EE A (d) of D&C Act says any drug which has been substituted wholly or in part by any other drug or substance could come under the provisions of Spurious Drugs Act.

A second lawsuit has also been initiated against Kunnath Pharma with the Chief Judicial Magistrate Court at Moovattupuzha for promoting Musli Power Xtra with the proclaimed label as "aphrodisiac" for increasing sexual potency in both men and women stating that such claim is a clear violation of the Drugs and Magic Remedies (objectionable advertisement) Act. (http://www.dancewithshadows.com/pillscribe/kerala-dmg-regulator-challenges-herbal-musli-power-xtras-claims-as-impotency-medicine-in-court/)

4.6 CHINA

Chinese law requires that all advertisements for pharmaceuticals be approved by the provincial FDA where the manufacturing enterprise or importing agency is located. Approved advertisements will receive an approval number, without which the advertisements may not be published. Advertisements may be published outside the area where the enterprise is located pending approval from the provincial FDA of that area.

Chinese law further imposes restrictions on the contents of pharmaceutical advertisements. Advertisement may not contain any unscientific assertions or guarantees of efficacy, claims of a successful healing rate of efficacy; the representation of authorities, scholars or patients as proof; or a comparison with the functions and safety of other pharmaceuticals or medical devices. Specific types of drugs may have further restrictions (e.g. the phrase " purchase and use under a physician’s prescription" must appear on prescription drugs)

Illegal advertising, however remains a major issue. A survey by the SFDA of 466 newspapers and 55 local TV stations from January to November in 2006 apparently discovered 48990 illegal advertisements for drug products. The SFDA has announced a series of measures over the past years designed at improving advertising standards, including prohibiting advertisement of certain classes of prescription drugs and issuing standards for labelling and instructions to be included in the packaging for non-prescription drugs. Further measures aimed at improving regulation of pharmaceutical advertising are expected in few years to come. (www.hg.org/articles/article_1901.html)

Control over Drug Packaging

Article 52 Immediate packaging materials and containers shall meet the requirements for medicinal use and the standards for ensuring human health and safety. They shall, along with the drugs, be subject to examination and approval by the drug regulatory department. No drug manufacturers may use immediate packaging materials and containers for which no approval is obtained. If the immediate packaging materials and containers are not up to standard, the drug regulatory department shall give orders stopping the use of such materials and containers.

Article 53 Drug packaging shall conform to drug quality requirements and be convenient for storage, transportation and medical use.
Chinese crude drugs shall be packed for transportation. On each package shall be indicated the name of the drug, the origin of production, the date and the name of the consignor, with a quality certification mark attached.

**Article 54** A label shall be printed or stuck on the drug package together with an insert sheet, as required by regulations. In the label or insert sheet shall be indicated the adopted name of the drug in China, its ingredients, strength, manufacturer, approval number, product batch number, production date, date of expiry, indications or functions, usage, dosage, contraindications, adverse drug reactions, and precautions. Specified marks shall be printed in the label of narcotic drugs, psychotropic substances, toxic drugs for medical use, radioactive pharmaceuticals, drugs for topical use, and non-prescription drugs.

**Article 60** Drug advertisements shall be subject to approval by the drug regulatory department of the people’s government of the province, autonomous region or municipality directly under the Central Government where the enterprise is located, an approval number of drug advertisement shall be issued. No one may launch advertisements without the approval number. Prescription drugs may be introduced in the medical or pharmaceutical professional publications jointly designated by the administrative department for health and the drug regulatory department under the State Council, but their advertisements may not be released by mass media or disseminated to the general public by other means.

**Article 61** The content of drug advertisements shall be truthful and lawful, and the insert sheet approved by the drug regulatory department under the State Council shall be taken as the basis, and no false content may be contained in them. No unscientific, categorical assertion or warranty of described function may be contained in drug advertisements; no names or images of government departments, medical or pharmaceutical research institutions, academic institutions, or experts, scholars, physicians and patients may be used as evidence for drug advertising. No-drug advertisements may not deal with drug promotion.

**Article 62** Drug regulatory departments of the people’s governments of provinces, autonomous regions or municipalities directly under the Central Government shall inspect the drug advertisements approved by them, and inform the advertisement regulatory authority of those advertisements that violate this Law or the Advertisement Law of the People’s Republic of China, and put forward suggestions for their handling, and the said authority shall deal with such cases according to law.

**Article 63** Where drug pricing and advertising are not governed by the provisions of this Law, the provisions of the Pricing Law of the People’s Republic of China and the Advertisement Law of the People’s Republic of China shall be applicable.

*Provisions for Drug Advertisement Examination*

**Effective 1st May 2007**

**Article 1** The Provisions are formulated for the purposes of strengthening regulation on drug advertisements and ensuring the authenticity and legality of drug advertisements in accordance with the Advertisement Law of the People’s Republic of China (hereinafter referred to as Advertisement Law), the Drug Administration Law of the Peoples Republic of China (hereinafter referred to as Drug Administration Law), the Regulations for the Implementation of Drug Administration Law of the Peoples Republic of China (hereinafter referred to as Regulations for the Implementation of Drug Administration Law) and other regulations related to supervision on advertisements and drugs.

**Article 2** A drug advertisement refers to any advertisement published through various media or forms containing drug name, indications (functions) or other relevant contents, and shall be examined and approved in accordance with the Provisions.
Where only the names of non-prescription drugs (including adopted names and trade names) are publicized or only the names of prescription drugs (including adopted names and trade names) are publicized in professional medical or pharmaceutical journals, the examination is not required.

**Article 3** The drug advertisement applied for examination shall be approved provided that it conforms to the following laws, regulations and related provisions:

1. Advertisement Law;
2. Drug Administration Law;
3. Regulations for Implementation of Drug Administration Law;
5. Other provisions of the State on advertisement regulation.

**Article 4** The drug regulatory departments of the provinces, autonomous regions or municipalities directly under the Central Government are the drug advertisement examination authorities responsible for examining drug advertisements within their administrative regions. The administrative departments for industry and commerce at or above the county level are supervision and control authorities for drug advertisements.

**Article 5** The State Food and Drug Administration shall guide and supervise the examination conducted by drug advertisement examination authorities and punish, in accordance with law, the examination authorities that have violated the Provisions.

**Article 6** An applicant for a drug advertisement approval number must be an eligible drug manufacturer or distributor. Where the applicant is a drug distributor, the consent of the drug manufacturer is required.

An applicant may entrust an agent with the application for a drug advertisement approval number.

**Article 7** An application for a drug advertisement approval number shall be submitted to the drug advertisement examination authority in the place where the drug manufacturer is located. An application for an import drug advertisement approval number shall be submitted to the drug advertisement examination authority in the place where the agent of the import drug is located.

**Article 8** Where a drug manufacturer or distributor applies for a drug advertisement approval number, it shall submit an Application Form for Drug Advertisement (Appendix 1) with sample manuscript (sample film or sample record) of which the content is consistent with that to be published attached, and an electronic document of drug advertisement application. It shall also submit the following proof documents that are authentic, legal and valid:

1. Copy of the Business License of the applicant;
2. Copy of the Drug Manufacturing Certificate or the Drug Supply Certificate of the applicant;
3. Where the applicant is a drug distributor, the original document proving that the drug manufacturer authorizes the drug distributor to be the applicant shall be submitted;
4. Where an agent submits an application for a drug advertisement approval number on behalf of the applicant, an original authorization letter given by the applicant to the agent, a copy of business license of the agent and other documents proving the subject’s qualifications shall be submitted;
5. Copies of the drug approval document (including Import Drug License or Pharmaceutical Product License), copy of approved insert sheet, and label and insert sheet used in practice;
(6) For non-prescription drug advertisement, a copy of registration certificate of non-prescription drug examination or copies of relevant certificates is required;

(7) Where an applicant applies for an import drug advertisement approval number, copies of qualification certificates of the agent of the import drug shall be submitted;

(8) Where the trade name, registered trademark and patent of the drug are involved in an advertisement, copies of the valid certificates and other relevant documents proving the authenticity of the advertisement shall be submitted. The copy of any approval document prescribed in this Article shall be sealed by the document holder.

Article 9  An advertisement application by an enterprise for a drug shall not be accepted by the drug advertisement examination authorities under any of the following circumstances:

(1) Any of the circumstances under which the application shall be rejected as prescribed in Article 20, Article 22 and Article 23 of the Provisions;

(2) An administrative procedure to withdraw a drug advertisement approval number is in process.

Article 10  After receiving an application for drug advertisement approval number, where the dossier is complete and in conformity with statutory requirements, the drug advertisement examination authority shall issue an Acceptance Notice of Drug Advertisement; where the dossier is incomplete or not conforming to the statutory requirements, one notification on all the content to be supplemented or corrected shall be given to the applicant on the spot or within five working days; if the notification to the applicant is not issued within the timeline, the application is deemed as being accepted upon the date when the dossier is received.

Article 11  Within ten working days upon accepting an application, the drug advertisement examination authority shall check the authenticity, legality and validity of the documents submitted by the applicant, and shall examine the advertisement content in accordance with law. For the drug advertisement in conformity with statutory requirements, a drug advertisement approval number shall be issued; for those not in conformity with statutory requirements, the authority shall make a decision of not issuing a drug advertisement approval number and notify the applicant of the decision with reasons in written form and the applicant's right to apply for administrative reconsideration or to bring an administrative suit by law.

For approved drug advertisement, the drug advertisement examination authority shall report to the State Food and Drug Administration for records and send the approved Application Form for Drug Advertisement to the authority responsible for advertisement supervision and control at the same level for records. Where there is any problem in the drug advertisement reported to the State Food and Drug Administration for records, the State Food and Drug Administration shall instruct the drug advertisement examination authority to correct it. The drug regulatory departments shall announce the approved drug advertisement timely.

Article 12  Where a drug advertisement is to be published in the province, autonomous region or municipality directly under the Central Government other than the place where the drug manufacturer and the agent of the import drug are located (hereinafter referred to as "non-local drug advertisement"), it shall, before being published, be submitted for records to the drug advertisement examination authority in the place where the advertisement is to be published.

Article 13  The following materials for non-local drug advertisement shall be submitted for record:

Devi Ahilya Vishwavidyalaya Indore
(1) Copy of the Application Form for Drug Advertisement;
(2) Copy of the approved drug insert sheet;
(3) For television or audio broadcast advertisement, it is required to submit the audio tape, compact disc
or other medium carrier on which the content is consistent with the approved content.
The copy of any document prescribed in this Article shall be sealed by the document holder.

Article 14 For application for putting non-local drug advertisement on record in accordance with Articles
12 and Article 13 of the Provisions, the drug advertisement examination authority shall, within five working
days after accepting the application, put such drug advertisement on record, endorse the word “recorded”
on the Application Form for Drug Advertisement, affix the seal specific for drug advertisement
examination and send the form to the supervision and control authorities for advertisements at the same
level for future reference.

Where the drug advertisement examination authority of a place where a drug advertisement is to be put
on record finds that the drug advertisement is not conformed with the relevant provisions, it shall fill in the
Opinion on the Record of Drug Advertisement Examination (Appendix 2), submit it to the original drug
advertisement examination authority for check, and copy it to the State Food and Drug Administration.

Within five working days upon receiving the Opinion on the Record of Drug Advertisement Examination,
the original drug advertisement examination authority shall give its opinions to the drug advertisement
examination authority of the place where the drug advertisement is to be put on record. Where no
consensus is achieved between the original drug advertisement examination authority and the drug
advertisement examination authority of the place where a drug advertisement is to be put on record, the
case may be submitted to the State Food and Drug Administration that shall make a final judgment.

Article 15 The valid term of a drug advertisement approval number is one year. It shall become invalid
upon expiration.

Article 16 The content of an approved drug advertisement is not allowed to be changed when being
published. Where any change to the drug advertisement is needed, a new drug advertisement approval
number shall be obtained.

Article 17 Where an advertisement applicant publishes a drug advertisement by itself, it shall keep the
original Application Form for Drug Advertisement for two years for future check.
Where an advertisement publisher or advertising operator is authorized by the applicant to publish a drug
advertisement, it shall check the original Application Form for Drug Advertisement, publish the
advertisement in accordance with the approved content and keep a copy of the Application Form for Drug
Advertisement for two years for future check.

Article 18 Where there is any of the following circumstances for an approved drug advertisement, the
original drug advertisement examination authority shall issue a Notice of Drug Advertisement Re-
examination (Appendix 3) and conduct the re-examination. The drug advertisement may continue to be
published during the re-examination.

(1) The State Food and Drug Administration finds that the content of the drug advertisement approved by
the drug advertisement examination authority is not in conformity with the provisions;
(2) A supervision and control authority for advertisement at or above provincial level makes a re-
examination proposal;
(3) Other circumstances where a re-examination is required by a drug advertisement examination authority.

After re-examination, where the drug advertisement is not in conformity to the statutory requirements, the Application Form for Drug Advertisement shall be taken back and the original drug advertisement approval number shall become invalid.

**Article 19** Drug advertisement examination authorities shall cancel the drug advertisement approval number in any of the following circumstances:

1. Where a Drug Manufacturing Certificate or the Drug Supply Certificate is revoked;
2. Where a drug approval document is withdrawn or cancelled;
3. Where the State Food and Drug Administration or the drug regulatory department of the province, autonomous region or municipality directly under the Central Government instructs to stop the production, sales and use of the drug.

**Article 20** For any alteration to the approved content of a drug advertisement for false propaganda, the drug regulatory departments shall instruct to stop the publication of the advertisement immediately, revoke the drug advertisement approval number, and shall not accept any application for advertisement of the drug within one year.

**Article 21** Where any illegal advertisement in which the scope of indications (functions) of the drug is expanded without authorization, the therapeutic effectiveness is exaggerated extremely, or which seriously cheats or misleads the customers, is found, the drug regulatory department at or above the provincial level shall take mandatory administrative measures to suspend the sales of the drug within their administrative area and order the enterprise that illegally publishes the drug advertisement to issue a correction notice in relevant local media.

After the enterprise that illegally publishes the drug advertisement issues a correction notice as required, the drug regulatory department at or above the provincial level shall make a decision on lifting the mandatory administrative measures within 15 working days; where it is necessary to test the drug, the drug regulatory departments shall determine whether to lift the mandatory administrative measures within 15 days as from the day when the test report is issued.

**Article 22** Where a drug advertisement application providing false materials is found by the drug advertisement examination authority during the examination, no further application of the enterprise in respect of the advertisement of the drug shall be accepted within one year.

**Article 23** Where a drug advertisement with an approval number is found by the drug advertisement examination authority to have provided false materials, such drug advertisement approval number shall be revoked and no further application from the enterprise in respect of the advertisement of the drug shall be accepted within three years.

**Article 24** Any drug advertisement, of which the approval number is taken back, cancelled or revoked in accordance with Article 18, Article 19, Article 20 and Article 23 of the Provisions, shall be discontinued for publication immediately; non-local drug advertisement examination authorities shall stop filing the record of the advertisement of the enterprise with the drug advertisement approval number.

Where a drug advertisement examination authority takes back, cancels or withdraws a drug advertisement approval number in accordance with Article 18, Article 19, Article 20 and Article 23 of the Provisions, it shall notify the supervision and control authority for advertisements at the same level within five working days from the day when the administrative decision on the matter is made; the supervision and control authority for advertisements shall handle it in accordance with law.
Article 25  Where a non-local drug advertisement is found not put on record in the drug advertisement examination authority of the place where it is published, the authority shall instruct to file its record within a time limit. If the record is not filed within the time limit, the drug advertisement in the above-mentioned place shall be suspended.

Article 26  The drug regulatory department at or above the county level shall monitor and check the publishing of drug advertisement that has been examined and approved. For any illegal drug advertisements, drug regulatory departments at all levels shall fill in the Notice on the Transfer of Illegal Drug Advertisement (Appendix 4) and transfer it to an supervision and control authority for advertisements at the same level together with such materials as samples of illegal drug advertisement; where the content of approved non-local drug advertisement is altered without permission, the drug advertisement examination authority of the place where the advertisement is published shall advise the original drug advertisement examination authority to revoke its approval number in accordance with Article 92 of the Drug Administration Law and Article 20 of the Provisions.

Article 27  Where an illegal drug advertisement is published and the circumstances are serious, the drug regulatory department of province, autonomous region or municipality directly under the Central Government shall announce the matter to the public and timely report it to the State Food and Drug Administration. The State Food and Drug Administration shall summarize and release the collected information periodically.

Where any false or illegal drug advertisement is published and the circumstances are serious, it shall be announced to the public jointly by the State Administration for Industry and Commerce and the State Food and Drug Administration if necessary.

Article 28  For any drug advertisement published without approval, or the contents published inconsistent with the approved ones, the supervision and control authority for advertisements shall impose a punishment in accordance with Article 43 of the Advertisement Law; where it constitutes false advertisement or misleading propaganda, the supervision and control authorities for advertisements shall impose a punishment in accordance with Article 37 of the Advertisement Law and Article 24 of Anti-Unfair Competitions Law.

In the process of investigation of an illegal drug advertisement, where there is a need to affirm any drug technical information, the supervision and control authority for advertisements shall notify the drug regulatory department at or above the provincial level. The drug regulatory department at or above the provincial level shall give the affirmation result to the supervision and control authorities for advertisements within ten working days after receiving the notification.

Article 29  The staff members that examine and supervise drug advertisements shall be trained in such laws and regulations as the Advertisement Law and the Drug Administration Law. Where the staff members in drug advertisement examination department or in supervision and control authority for drug advertisements neglect their duty, abuse their power, or practice favoritism and commit irregularities, they shall be given an administrative sanction in accordance with law. If a crime is constituted, they shall be investigated for their criminal liabilities in accordance with law.

Article 30  A drug advertisement approval number shall be “X Yao Guang Shen (Shi) No. 0000000000”, “X Yao Guang Shen (Sheng) No. 0000000000”, “X Yao Guang Shen (Wen) No. 0000000000”. “X” is the abbreviation for a province, autonomous region or municipality directly under the Central Government. “0000000000” is a number with ten digits, in which the first six represent year and month of the
examination, and the last four represent advertisement approval sequence number. "Shi", "Sheng" or "Wen" represents certain classification code used in advertising media.


Chapter VI Supplementary Provisions
Article 31 These Provisions shall come into force as of June 1, 2006. the Provisions for Drug Packaging, Labels and Insert Sheets (Provisional) issued by State Food and Drug Administration on October 15, 2000 shall be annulled therefrom.

Standards for Drug Names: The most critical issue in drug name selection is that one name should not be easily confused with another. This applies to both generic and brand names. A name must neither sound like that of another drug (which leads to errors when oral orders are given) nor look like another drug name when it is written out by hand. From the industry's standpoint, the challenge is to find a name that is intriguing and appropriate for the connotation desired, safe, and not already trademarked.

Increasingly sophisticated and effective methods are available for determining the likelihood of confusion by sound or sight. Bruce Lambert, a pharmacist at the University of Illinois, has developed a failuremode and effects analysis computer program that identifies lexical similarity and confusion between pairs of drug names. ISMP provides a namechecking service. It uses Lambert's program and supplements it by analyzing the legibility of proposed names as handwritten by eight physicians.

Labeling Standards: To minimize the possibility of error, labels should be easy to read and devoid of nonessential material. The name of the drug (and not the name of the manufacturer) should be the most prominent feature and should be in at least 12-point type. The use of color is very controversial; some believe that all colors should be prohibited to force personnel to read the labels.

Packaging Standards: While there is no evidence that trademark colors and logos on boxes pose a problem, the use of color on bottle tops and labels creates many difficulties. There are dozens of drugs whose names are quite different but whose packages look alike. This creates the potential for error when people "see" what they expect to see on the label.

Obstacles to Implementing Safe Practices: While the transformations needed to implement safety standards for the drug approval process are the same as those needed to modify the name, label, or package for a drug currently in use, a name change for a successful drug represents a much greater challenge for a pharmaceutical company. But either type of change is difficult, expensive, and generates enormous resistance. The obstacles to change arise from the nature of this problem, the regulatory structure governing pharmaceuticals, and pharmaceutical companies and how they perceive their mission.

Standards for names, labels, and packages that fully incorporate human factors principles have not been developed. Much of the information on labeling and packaging problems is anecdotal, or at least not comprehensive and systematic. Those who resist change can argue successfully that no one has proved that a particular change will make a difference. When the difference has been proved, they can argue that the difference is not significant enough to justify the cost.

Most of the present labeling and packaging rules were created when safety was not recognized as
Drug Enforcement Laws - Globalization, Vis-a-Vis, Indian Drug Laws

a significant issue. USP and FDA have approved existing standards and therefore "own" the problem. It is difficult to change what one has helped to create. In addition, there may be overlapping jurisdictions between USP and FDA, so their ownership of many aspects of the problem is shared; this creates an additional layer of complexity. Even experienced observers of the system have difficulty attributing responsibility.

USP and FDA are large, complex organizations that change very slowly. The entire regulatory system appears to be designed to make change an arduous process. The path to a new regulation is long and difficult, and a determined opponent often can stop, or at least slow, the process. When the political climate favors less regulation, change comes even more slowly.

Regulatory agencies are consensus driven and conservative. They respond to pressure, but when the pressure declines, so does the likelihood of change. It is difficult for FDA to exert pressure on pharmaceutical companies. FDA is often subjected to intense pressure by Congress when it attempts to make changes. Congress, in turn, is very sensitive to the desires of the pharmaceutical industry.

In general, many pharmaceutical companies do not accept the premise of those seeking change. They do not consider design for safety to be a primary responsibility of theirs. Those in the industry who are willing to speak frankly tend to argue along the following lines: "The information is on the label, the label meets all the requirements of FDA, and all practitioners have to do is read the label -- so read it and leave us alone. We already are regulated nearly to death."

It is competitively advantageous for drug companies to have cultures that are geared toward successful product development in as short a period as possible. Any issue or regulation that interferes with that process generally is regarded as a problem.

The pressure to avoid changing a brand name increases significantly as a drug moves closer to approval. The estimated pretax research and development cost per NCE at the time of market approval averaged $359 million in 1997. Anything that slows the process increases both the cost and the risk of failure, as well as the possibility of a loss of competitive advantage. These are not small issues.

Liability concerns are also significant. Looking for name confusion, finding what appears to be a minor problem, and approving the name anyway is interpreted by some industry attorneys as leaving their companies wide open to aggressive personal-injury litigation. After a product is marketed, companies may be reluctant to follow up on all complaints for fear of creating an incriminating paper trail. If it is difficult to raise safety concerns before a product is released, it is more challenging afterward. All the other factors are in play -- coupled with the added expenses and risks of making a change.

(www.sfda.gov.cn)

4.7 NEWZEALAND

Medicines Act 1981 No 118 (as at 16 October 2008), Public Act

Containers and packages of medicines: (1) Except as may be permitted by regulations made under this Act, no person shall, in the course of any business, pack, store, sell, supply, or cause to be transported any medicine, unless—

(a) The medicine is in a container that—

(i) Is impervious to the medicine; and
(ii) Is so constructed that it can be readily and effectively resealed after any portion of the contents has been used; and
(iii) Is of the prescribed character or type; and
(iv) Is labelled in the prescribed manner; and
(b) If the container is enclosed in a package that is required to be of a prescribed character or type, or to be labelled in a prescribed manner, the package is of that character or type, or is labelled in that manner.

(2) Notwithstanding subsection (1)(a)(ii) of this section, where—

(a) The container bears a label with directions to the effect that the whole of the contents must be used immediately on opening; and

(b) The quantity and nature of the contents are such that it is unlikely that less than the whole of the contents will be used on any one occasion—

the container need not be of a type that can be readily and effectively resealed.

(3) Every person commits an offence against this Act who contravenes subsection (1) of this section.

Restrictions on advertisements:

(1) No person shall publish or cause to be published, either on that person's own account or as the agent or employee of the person seeking to promote the sale, any medical advertisement that—

(a) Directly or by implication qualifies or is contrary to any statement or other particulars required by regulations made under this Act to be marked on or attached to medicines or medical devices of the description, kind, or class, to which the medicines or medical devices advertised, or appearing to be advertised, belong or appear to belong or on or to packages or containers enclosing medicines or medical devices of that description, kind, or class; or

(b) Is prohibited by any such regulations from being marked on or attached to, or on or to packages or containers enclosing, medicines or medical devices of that description, kind, or class; or

(c) Omits from the name or description of the medicines or medical devices advertised any word or words required by any such regulations to be included in the name or description marked on or attached to, or on or to packages or containers enclosing, medicines or medical devices of that description, kind, or class; or

(d) Fails to make any statement required by any such regulations to be made in an advertisement relating to medicines or medical devices of that description, kind, or class; or

(e) Makes any statement prohibited by any such regulations from being made in an advertisement relating to medicines or medical devices of that description, kind, or class; or

(f) Is false, or is likely to mislead any other person, with regard to the nature, quality, strength, purity, composition, origin, age, uses, or effects of medicines or medical devices of that description, kind, or class or of any ingredient or component thereof; or

(g) Directly or by implication states or suggests that medicines or medical devices of that description, kind, or class, cannot harm any person, or any person belonging to a particular class of persons, or is not habit-forming.

(2) For the purposes of subsection (1) of this section, any words that must be included in an advertisement in order to avoid a contravention of that subsection shall, where they appear in an advertisement published by television or otherwise in a transitory manner on a screen, be disregarded unless they are exposed in clearly legible lettering for a length of time sufficient to enable them to be read by the ordinary viewer.
(3) For the purposes of subsection (1)(f) of this section, a medical advertisement shall be deemed to be likely to mislead any person with regard to the uses or effects of medicines or medical devices of a particular description, kind, or class, or of any ingredient or component thereof, if it is likely to mislead with regard to—

(a) Any purposes for which medicines or medical devices of that description, kind, or class, or any ingredient or component thereof, can be used with reasonable safety; or

(b) Any purposes for which such medicines or medical devices, or any such ingredient or component, cannot be so used; or

(c) Any effects that such medicines or medical devices, or any such ingredient or component, when used, or when used in any particular way referred to in the advertisement, produce or are intended to produce.

(4) Without prejudice to any liability in respect of any offence against any regulations made under this Act, every person commits an offence against this Act who contravenes any of the provisions of subsection (1) of this section.

Further restrictions on advertisements: (1) Subject to section 60 of this Act, no person shall publish, or cause or permit to be published, any medical advertisement that—

(a) Directly or by implication claims, indicates, or suggests that medicines of the description, or medical devices of the kind, or the method of treatment, advertised will prevent, alleviate, or cure any disease, or prevent, reduce, or terminate any physiological condition specified, or belonging to a class of disease or physiological condition specified; or

(b) Directly or by implication claims, indicates, or suggests that medicines of the description, or medical devices of the kind, or the method of treatment, advertised will prevent or cure any disease, or prevent or terminate any physiological condition specified, or belonging to a class of disease or physiological condition specified, in Part 2 of Schedule 1 to this Act; or

(c) Directly or by implication claims, indicates, or suggests that a medicine of the description, or a medical device of the kind, or the method of treatment, advertised—

(i) Is a panacea or infallible; or

(ii) Is or has been used or recommended by a practitioner, nurse, or pharmacist, or by any other person qualified to provide therapeutic treatment in the course of a profession or occupation and registered under any enactment as a person so qualified, or by a person who is engaged in study or research in relation to any of those professions or occupations or the work performed by persons employed therein; or

(iii) Has beneficially affected the health of a particular person or class of persons, whether named or unnamed, and whether real or fictitious, referred to in the advertisement; or

(d) Invites correspondence or the sending of hair, blood, urine, or other bodily specimens or photographs for the purposes of diagnosis or treatment concerning any disease or physiological condition.

(2) Every person commits an offence against this Act who contravenes any of the provisions of subsection (1) of this section.

(3) It shall be a good defence in a prosecution for an offence against paragraph (a) or paragraph (b) of subsection (1) of this section if the defendant proves that the matter claimed, indicated, or suggested in the advertisement is true.
Advertisements to contain true name of advertiser: (1) Subject to subsection (2) of this section, no person shall publish, or cause or permit to be published, any medical advertisement that does not contain a statement of the true name of the person for whom or on whose behalf the advertisement is published, and the address of that person’s place of residence or business.

(2) In the case of a body corporate, it shall be sufficient compliance with subsection (1) of this section if, instead of the address of the body corporate’s place of business, the advertisement states the name of the place where the body corporate has its registered office, or, if it is not a registered company, other headquarters.

(3) Any statement that is contained in any medical advertisement and purports to set forth the name of the person for whom or on whose behalf the advertisement is published, shall, until the contrary is proved, be sufficient evidence of the name of the person for whom or on whose behalf the advertisement has been published.

(4) Nothing in this section applies to—

(a) Any medical advertisement that complies with any regulations made under this Act relating to the disclosure or otherwise of the name and address of the place of residence or business of the manufacturer or seller of the medicines of the description or medical devices of the kind advertised, or the agent of either of them; or

(b) Any medical advertisement relating to any description of medicines or any kind of medical devices in respect of which an exemption granted under or by virtue of this Act from the material provisions of any such regulations is for the time being in force.

(5) Every person commits an offence and is liable to a fine not exceeding $1,000 who contravenes subsection (1) of this section.

Exemption for certain advertisements: Without limiting any power to make regulations under this Act, nothing in this Act shall apply to any medical advertisement that—

(a) Is distributed only to persons referred from Medical Profession/ Pharmacist; or

(b) Is contained in a publication that in the ordinary course circulates solely or principally, or is distributed solely or principally, to those persons; or

(c) Not being an advertisement relating to a prescription medicine, or a restricted medicine, or a pharmacy-only medicine, is distributed solely to persons claiming to be available for consultation by other persons for therapeutic purposes and to persons privately consulting them.

Misleading branding: (1) No person shall sell any medicine or medical device—

(a) That bears or has attached to it, or is enclosed in a package or container that bears or has attached to it, any false or misleading statement, word, brand, picture, label, or mark purporting to indicate the nature, suitability, quantity, quality, strength, purity, composition, weight, origin, age, effects, or proportion, of the medicine or medical device, or of the medicine or medical device enclosed in the package or container, or of any ingredient thereof; or

(b) That has been packed, processed, or treated in a manner that is false or misleading in relation to any of the matters mentioned in paragraph (a) of this subsection.

(2) Every person commits an offence against this Act who contravenes subsection (1) of this section.
Regulations relating to advertisements: (1) Without limiting of this Act but subject to subsection (2) of this section, the Governor-General may from time to time, by Order in Council, make regulations for all or any of the following purposes:

(a) Requiring and regulating the insertion in any medical advertisement, or any particular class of medical advertisement, of such information or warning, or kind of information or warning, concerning any unwanted, incidental, or untoward effects of medicines of the description, or of medical devices of the kind, or of the method of treatment, advertised, and such statement or kind of statement of the precautions to be taken by any user of medicines of that description, or of medical devices of that kind, or of that method of treatment, as may be prescribed:

(b) Prohibiting the advertising of any specified description of medicine, or kind of medical device, or method of treatment, or of any specified class of medicine, medical device, or method of treatment, in any medical advertisement, or a particular class of medical advertisement, and prohibiting, or requiring and regulating, the mention in any medical advertisement of such matters relating to the composition, properties, nomenclature, origin, and use of medicines of the description or medical devices of the kind or the method of treatment advertised, as may be prescribed:

(c) Enabling the Minister to require, after consultation with such organisations as appear to him to represent any class or classes of persons whose interests might be affected by the requirement, the insertion of particular words specified by the Minister in, or the omission of particular words or other matter so specified from, any particular medical advertisement or class of medical advertisement, and to give directions with respect to the location, size, and appearance of any such insertion and with respect to other matters incidental thereto, and providing a right of appeal in respect of any such requirement or direction:

(d) Generally regulating medical advertisements or any particular class of medical advertisements, or medical advertisements relating to medicines of a particular description, or to medical devices of a particular kind, or to a particular method of treatment, or relating to particular classes of medicines, medical devices, or methods of treatment.

(2) Any regulations made under subsection (1)(a) of this section—

(a) Shall be made only on the recommendation of the Minister after consultation with such organisations or bodies as the Minister considers likely to be substantially affected by the regulations; and

(b) Shall be designed to achieve a fair and balanced indication of the potential effects of the medicine or medical device or method of treatment advertised; and

(c) Shall not require the disclosure of information that may reasonably be regarded as confidential, or that cannot reasonably be expected to be in the possession of the person on whose behalf the advertisement is published, or the inclusion of which in the advertisement is otherwise impracticable.

4.8 SOUTH AFRICA

LABELLING OF MEDICINES INTENDED FOR ADMINISTRATION TO HUMANS

8. (1) Save as provided in sub-regulations (2), (3) and (4), the immediate container of every medicine in which medicine intended for administration to humans is sold shall have a label attached to it on which
only the following particulars shall appear in clearly legible indelible letters in English and in at least one other official language:

(a) a distinct boxed signal word indicating the Schedule number;

(b) the proprietary name of the medicine;

(c) the registration number of the medicine allocated;

(d) the dosage form of the medicine;

(e) the approved name of each active ingredient of the medicine and the quantity thereof contained in a dosage unit, or per suitable mass or volume or unit, starting with an active ingredient of a high Schedule, in lettering which has minimum legibility;

(f) the name and percentage of any bacteriostatic or bactericidal agent which has been added to the medicine as a preservative;

(g) the approved name of any anti-oxidant contained in the medicine;

(h) in the case of a medicine for oral or parental administration, the quantity of sugar or ethyl alcohol contained in the medicine, expressed as a percentage of the total volume of the medicine, if such quantity exceeds two per cent by volume;

(i) the content of the medicine package expressed in the appropriate unit or volume of the medicine;

(j) the indications for use of the medicine;

(k) the recommended dosage of the medicine;

(l) where applicable, the instruction 'Shake the bottle before use';

(m) in the case of a medicine intended for injection by a particular route of administration only, that route of administration by means of suitable words or abbreviations;

(n) in the case of a medicine listed in any Schedule made in terms of the Act, the letter 'S' followed by the number of the relevant Schedule, in a prominent type size and face and surrounded by a square border, immediately preceding the proprietary name of such medicine;

(o) the lot number of the medicine;

(p) the expiry date of the medicine;

(q) the name of the applicant for registration of the said medicine;

(r) the requirements regarding the manner in which the medicine shall be stored with specific reference to the applicable storage temperature and other precautions required for the preservation of the medicine;
(s) where applicable, the statement: 'For external use only';

(t) the warning: 'Keep out of reach of children';

(u) in the case of a medicine intended for oral or parental administration which contains aspirin or paracetamol the warning: 'Do not use continuously for more than 10 days without consulting your doctor';

(v) in the case of a medicine for oral administration which contains fluorides, the warning: 'Contains fluoride';

(w) in the case of a medicine for oral administration which contains an antihistamine, the warning: 'This medicine may lead to drowsiness and impaired concentration, which may be aggravated by simultaneous intake of alcohol or other central nervous system depressant agents';

(x) in the case of eye drops or artificial tear solutions in respect of which evidence concerning the self-sterilising ability of the medicine has not been approved by the Council, the warning 'Do not use more than 30 days after opening';

(y) any specified warning required to be given on the label of the medicine as a condition of registration thereof.

(z) in the case of a medicine that contains TARTRAZINE, the warning: 'Contains TARTRAZINE.'

(2) If the medicine package bears both an immediate container label and an outer label, the requirements of sub-regulation (1) shall apply to the outer label as well; Provided that it shall be sufficient to give on the immediate container label –

(i) in the case of medicines intended for administration by injection and having a total volume not exceeding 5 ml, the details prescribed in paragraphs (b), (e), (m), (o), (p) and (q) of sub-regulation (1);

(ii) in the case of an ointment, cream, gel or powder having a net mass not exceeding 10 grams, the details prescribed in paragraphs (b), (c), (e), (f), (o), (p) and (u) of sub-regulation (1);

(iii) in the case of liquid, solution or suspension having a total volume of more than 1 ml, but not exceeding 15 ml, the details prescribed in paragraphs (b), (c), (d), (e), (n), (o), (p), (q) and (y) of sub-regulation (1);

(iv) in the case of a liquid, solution or suspension having a total volume not exceeding 1 ml, the details prescribed in paragraphs (a) and (o) of subregulation (1);

(v) in the case of a medicine packed in blister or similar packaging, the details prescribed in paragraphs (b), (o), (p) and (q) of sub-regulation (1), repeated as frequently as its practicable.

(3) The Council may authorise the inclusion on the label of a medicine of any special information that is not required by this regulation to be so included.

(4) The requirements of sub-regulation (1) shall not apply to –

Devi Ahilya Vishwavidyalaya Indore
- 370 -
(a) any medicine sold in accordance with section 14(4) of the Act;

(b) any medicine sold by a person authorised to prescribe or a pharmacist in the course of his or her professional activities for the treatment of a particular patient; or

(c) any medicine sold by a pharmacist, a person authorised to compound and dispense, or in a hospital pharmacy in accordance with a prescription issued by a medical practitioner or dentist for the treatment of a particular patient. Provided that such medicine shall be sold in a package to which is attached a label containing the following information:

(i) the name of the medicine or the name of each active ingredient or constituent medicine;
(ii) the name of the person for whose treatment such medicine is sold;
(iii) the directions (if any) in regard to the manner in which such medicine should be used;
(iv) the name and business address of the medical practitioner, dentist, pharmacist, pharmacy or hospital selling such medicine;
(v) date of dispensing;
(vi) reference number.

Package Inserts For Medicines For Humans: 9. (1) Save as provided in subregulations (2) and (3), each package of a medicine shall be accompanied by a package insert, either as a separate entity or as an integral part of the package, on which are printed in English and at least one other official language and in type having a minimum legibility as defined in regulation 1, under the headings and in the format specified in this regulation, and which shall contain the following particulars

(a) Scheduling status, that is the scheduling status of the medicine as determined from time to time by the Minister;

(b) Proprietary name (and dosage form)

(c) Composition, that is the approved name of each active ingredient and the quantity thereof contained in a dosage unit or per suitable mass or volume or unit of the medicine, as well as the approved name and quantity of any bactericidal or bacteriostatic agent included in the medicine as a preservative (expressed as a percentage) and the quantity of ethyl alcohol included in a preparation for oral or parenteral administration (if such quantity exceeds two per cent by volume) and the words "contains TARTRAZINE" should the medicine contain such ingredient;

(d) Pharmacological classification, i.e. the category, the number and the description of the classification as stated in regulation 25;

(e) Pharmacological action, that is a description of the pharmacological action of the medicine; The pharmacokinetic properties of the medicine shall be described, where applicable under a sub heading written in bold type:

Pharmacokinetics.

(f) Indications;

(g) Contra-indications;

(h) Warnings;

(i) Interactions;

(j) Pregnancy and lactation
(k) Dosage and directions for use;
(l) Side effects and special precautions;
(m) Known symptoms of overdosage and particulars of its treatments;
(n) Conditions of registrations
(o) Identification;
(p) Presentation;
(q) Storage instructions that are practically formulated and which indicate storage temperatures;
(r) Registration number, that is –

(i) the number allocated in terms of the Act; or
(ii) in the case of a medicine the registration of which has been applied for, the reference number allocated to such application, followed by the expression “Act 101/1965”

(s) name and business address of the applicant for registration of the medicine and the holder of the certificate of registration, or in case of a parallel imported medicine, the name and business address of the holder of the parallel importer license;
(t) date of publication of this package insert: Provided that –

(i) if the Council determines that there is no applicable information to be furnished under a particular heading, such heading may be omitted with the approval of Council;
(ii) The Council may, on application to it by an applicant, authorise the deviation from the format and content of a package insert prescribed as a condition of registration of a medicine; and
(iii) The Council may, on application by an applicant, Authorise the inclusion on a package insert of any specified information not required by this regulation to be so included.

(2) The requirements of subregulation (1) shall not apply in the case of medicines in respect of which exclusion from the operation the Act has been granted by the Minister in terms of the Act.

(3) The requirements of subregulation (1) shall not apply to –

(a) any medicine sold in accordance with the provisions of section 14 (4);
(b) any medicine compoundec and/or sold by a medical practitioner, dentist or pharmacist in the course of his professional activities for the treatment of a particular patient; or
(c) any medicine sold by a pharmacist or by a hospital in accordance with a prescription issued by a medical practitioner or dentist for the treatment of a particular patient.

(4) Nothing contained in subregulation (2) and (3) shall be construed as prohibiting the inclusion of a package insert in the medicine.

Patient Information Leaflet: 10.(1) Each package of a medicine shall have a patient information leaflet that must contain the following information with regard to the medicine in English and at least in one other official language:

(a) Scheduling status;
(b) proprietary name and dosage form;
(c) what the medicine contains, which includes-

(i) the approved name of each active ingredient and the quantity thereof contained in each dosage unit or per suitable mass or volume or unit of the medicine; and
(ii) all inactive ingredients that must be listed qualitatively;
(d) the approved indications and use;
(e) instructions before taking the medicine, which include –

(i) contra-indications;
(ii) precautions;
(iii) warnings e.g. concerning sedative properties of the medicine or risks involved with sudden withdrawal of the medicine;
(iv) interactions;
(v) the following general statements: "If you are taking medicines on a regular basis, using the medicine at the same time with another medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice."

"If you are pregnant or breast feeding your baby while taking this medicine please consult your doctor, pharmacist or other health care professional for advice."

(f) how to take the medicine, including the following statements:

"Do not share medicines prescribed for you with other persons. "In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre;"

(g) side effects, including the following general statement:

"Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice."

(h) storage and disposal information, including the following general statement:

"store all medicines out of reach of children."

(i) presentation, which includes the number, volume or mass per package unit and a description of the packaging material, e.g. bottle, blisterpack, etc;

(j) identification of the medicine, i.e. the description of its physical appearance as tablet capsule, etc;

(k) registration number of the medicine;

(l) the name, business and telephone number of the holder of the certificate of registration; and

(m) the date of publication of the patient information leaflet;

(2) The Council may authorise a deviation from sub-regulation (1)

Advertising Of Medicines Intended For Administration To Humans: 47 (1) The undermentioned requirements shall apply to any advertisement of a medicine intended for administration to humans.

(2) (a) Medicines which do not contain a scheduled substance and medicines which contain a substance appearing in Schedule 1 or Schedule 2 may be advertised to the public; and

(b) Medicines which contain a substance appearing in Schedule 3, Schedule 4, Schedule 5, Schedule 6 or Schedule 7 may be advertised only for the information of medical practitioners, dentists, veterinarians
and pharmacists or in a publication which is normally or only made available to members of the said professions.

(c) Paragraph (b) shall not be so construed as to prohibit the announcement to the public of the prices of medicines which contain a substance appearing in Schedule 3, Schedule 4, Schedule 5, Schedule 6 or Schedule 7.

(3) No advertisement for a medicine may contain a statement which deviates from, is in conflict with or goes beyond the evidence submitted in the application for registration of such medicine with regard to the safety of the use of the ingredients in human beings or the efficacy of such ingredients in relation to the purpose for which it is intended that they should be used, where such evidence has been accepted by the Council in respect of such medicine and incorporated into the approved package insert of such medicine.

(4) A written advertisement for a medicine shall contain

(a) the proprietary name of such medicine;

(b) the approved name and quantity of each active ingredient of such medicine in lettering having a minimum legibility as defined in regulation (vi) of the regulations: Provided that, in the case of a medicine containing only one active ingredient, such lettering shall be not less than one half the size of the largest lettering used for the said proprietary name;

(c) in the case of-

(i) a registered medicine, the registration number allocated to it in terms of section 15 (6); or

(ii) a medicine in respect of which an application for registration has been submitted in accordance with the provisions of section 14, the reference number allocated to such application by the Registrar, followed by the words 'Wet/Act 101/1965'.

(d) in any case where a name other than the proprietary name is also used, such other name in lettering one half the size of the largest type size in which the proprietary name appears in such advertisement.

(5) In the case of an advertisement for a medicine which contains more than one active ingredient, no specific reference shall be made to the specific properties of any individual active ingredient unless a reference of this nature has been approved by the Council for inclusion in the package insert of such medicine.

(6) When a medicine is advertised orally for the first time by or on behalf of the applicant to any member of the medical or dental profession or the pharmaceutical profession, written information, which shall include at least the information called for in terms of regulation 10, shall simultaneously be given to the person to whom the oral advertisement is directed, and when the medicine is advertised orally on subsequent occasions such information shall be available on request (http://www.doh.gov.za/docs/pharmis-f.html).

4.8 NIGERIA

DRUGS AND RELATED PRODUCTS (REGISTRATION, ETC) ACT 1999 (AS AMENDED)
Drug Labelling Regulations 2005

In the exercise of the power conferred on the Governing Council of the National Agency for Food and Drug Administration and Control (NAFDAC) by section 8 of the Drug and Related Products (Registration, etc) Act 1999 (as amended) and all the powers enabling it in that behalf, THE GOVERNING COUNCIL OF THE NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL with the approval of the Honorable Minister of Health hereby makes the following Regulations:-

1. **Scope:** These Regulations shall apply to all labelling of Drugs and Related Products.

2. **Prohibition:** Except as provided in these Regulations, no person shall manufacture, import, export, distribute, advertise, display for sale or sell any drug that is not adequately labelled.

3. **No reference to International bodies, etc.:** No reference, direct or indirect to international bodies shall be made upon any label of a drug, except as is prescribed by the Agency.

4. **Adequate and clear Labeling information:**
   (1) All information required to be indicated on the label shall be prominent, legible and distinct.
   (2) All information shall be in English Language, and may include other languages.
   (3) Labelling shall be informative and accurate.
   (4) Labelling shall not be false or misleading.

5. **Name and Address of manufacturer, packer or distributor on label:**
   (1) The label of a drug shall specify conspicuously the name and location address of the manufacturer, and where applicable the name and address of the packer or distributor.
   (2) Where a drug is not manufactured by the person whose name appears on the label, the name and location address of the manufacturer shall be indicated by a phrase that reveals the connection with the person e.g. “Manufactured by...........for................”, “Manufactured for..............by....................”, or any other wording that expresses the facts.

6. **Display of proper name, brand name etc.:**
   (1) The packaging components of a drug shall bear the name, active ingredients, strength and dosage form of the drug.
   (2) The outer and inner labels of a drug shall show the generic name and strength thereof.
   (3) Where a drug is branded, the generic and brand names shall be reflected on the outer and inner labels.
   (4) The name shall prominently appear on the principal display panel of the package to aid accurate identification.
   (5) Where a drug contains a single active ingredient, the common or generic name shall appear in conjunction and in close proximity to the brand name (if any) of the drug.
   (6) Where a drug contains more than one active ingredient, all the common names shall appear on the principal display panel of the drug. However, if the drug is packaged in a container too small to bear this information, it may appear elsewhere on the label.

Devi Ahilya Vishwavidyalaya Indore
(7) The location address of the manufacturer of a drug shall be complete on the outer label, unless the immediate container of the drug contains 5 ml (or equivalents) or less of the drug product, in which case the address need not be shown on the inner label.

7. Declaration of net content of drug: (1) The outer label of a drug shall indicate:

(a) the net content of the drug in the container in terms of unit weight, measure or number; and

(b) for sterile drugs, a quantitative list of preservatives present therein shall be indicated where applicable by their generic or common names.

8. Trade mark: (a) where a drug product have a trade mark displayed on the label, the trade mark shall not give a wrong impression of the nature, quality or substance of the drug product;

(b) where the trademark registration is in conflict with any regulations or requirements of the Agency, the latter shall supersede.

9. Registration number assigned by the Agency: (1) The outer and inner labels of a drug shall show clearly the Agency registration number (NAFDAC REG. NO.) assigned to it as indicated on the certificate of registration in a manner prescribed by the Agency.

(2) Where a drug product has tertiary, secondary and primary packaging materials, the NAFDAC REG. NO. shall be shown on the tertiary and secondary packaging materials.

10. Identification mark tablets, capsules, etc.: (1) All tablets, capsules, caplets and similar dosage forms shall bear identification marks traceable to the manufacturer or holder of a certificate of registration of the drug product unless otherwise exempted by the Agency.

(2) The following classes of drug products are exempt from the requirements in regulation 10(1):

(a) drug products intended for use in a clinical trial investigation or bioequivalence studies;

(b) radiopharmaceutical drug products;

(c) drug products with product size, shape, physical characteristics which make imprinting technologically infeasible or impossible; and

(d) drugs administered solely in controlled healthcare settings.

(3) Exemptions request shall be made in writing to the Agency giving reasons why a waiver is justified.

11. Dispensing measure: All packages for oral paediatric liquid drug or drug products shall have included in them an appropriate measuring device graduated in 0.5ml to 10ml as applicable.

12. Package insert: All prescription only drugs shall be accompanied by a package insert with relevant information as required in these Regulations and any other information as may be required by the Agency.

13. Exemptions, etc: (a) Drugs in 5 cm container: Notwithstanding the provisions of these Regulations a drug packed in a container that is 5 cm (or equivalents) or less shall indicate the following:

(i) the brand name (where applicable),
(ii) the generic or common name,
(iii) lot or batch number,
(iv) net content,
(v) manufacture and expiry dates,
(vi) manufacturer's name,
(vii) registration number assigned to it in a manner prescribed by the Agency.

(b) **Blister packs.** Where a drug is packed in a container which meets the requirements specified in these Regulations, each blister strip shall indicate the following:

(i) the brand name (where applicable),
(ii) the generic or common name,
(iii) the strength of the drug,
(iv) lot or Batch number, and
(v) expiry date.

(c) **Bulk drugs.** A drug in a bulk package, except tablets, capsules or other dosage unit forms, intended for processing, repackaging or use in the manufacture or another drug shall be exempt from the labeling provisions of these Regulations, provided that, the label of the bulk drug contains the following information:

(i) the brand name (where applicable),
(ii) the generic or common name,
(iii) net content,
(iv) lot or batch number,
(v) manufacture and expiry dates,
(vi) name and location address of manufacturer, distributor or vendor,
(vii) storage conditions, and
(viii) the statement "Caution: For Bulk Drug Manufacturing Purposes Only".

14. **Labelling of Parenteral preparations.** (1) The labelling of injectable drug products shall provide the health care practitioner and other users adequate information to ensure safe and proper use of the therapeutic agent and where all the information required may not be contained on the immediate container, they shall be accompanied by a leaflet insert.

(2) The labelling shall state the following:

(a) the name of the product;
(b) percentage content of the drug in liquid preparations;
(c) amount of active ingredients (for drug powder form);
(d) volume of liquid to be added for reconstitution of the drug powder;
(e) the route of administration (IM, IV, etc.);
(f) storage conditions;
(g) batch or lot number;
(h) manufacture and expiry dates;
(i) the full name and location address of the manufacturer;
(j) preparations intended for use in dialysis, haemofiltration and irrigation shall bear the statement "Not intended for intravenous injection"; and
(k) injection for veterinary use shall be so labelled, including the withdrawal period.

15. **Declaration of non-nutritive sweeteners.** (1) The outer and inner labels of all over-the-counter human drug products containing an approved non-nutritive sweetener as an inactive ingredient, shall
bear a conspicuous declaration as to the identity and quantity of the non-nutritive sweetener in milligram per dosage unit and shall also bear boldly and conspicuously, any precautionary warnings for the non-nutritive sweetener as may be prescribed by the Agency.

(2) The packaged insert providing information concerning prescription drugs for human use containing an approved non-nutritive sweetener as an inactive ingredient shall bear a conspicuous declaration as to the identity and quantity of the non-nutritive sweetener in milligram per dosage unit and shall also bear boldly and conspicuously any precautionary warnings for the non-nutritive sweetener as may be prescribed by the Agency.

16. Warning for children.: The labels of all drugs shall state prominently a warning statement to the following effect: "Keep this medicine out of reach of children"

17. Prescription drugs labeling, etc.: In addition to compliance with the provisions in paragraphs 1 to 15 of these Regulations, the following shall apply:-

(a) all prescription drugs shall be properly labelled with the information on the package label as follows –

(i) the brand name (where applicable),
(ii) the generic or common name,
(iii) dosage form and strength,
(iv) listing of active ingredients,
(v) net content,
(vi) name and location address of manufacturer,
(vii) batch or lot number,
(viii) manufacture and expiry dates,
(ix) storage conditions,
(x) warning for children,
(xi) the statement in bold: "For external use only" for topical drug products not intended for ingestion, or "For rectal or vaginal use only" etc. as appropriate, and
(xii) the statement “For veterinary use only” if for veterinary only use and the withdrawal Period shall also be distinctly stated;
(b) the leaflet insert in all prescription drugs shall provide the following information on the drug:-

(i) the description of the drug as required in regulation 16 of these Regulations,
(ii) clinical pharmacology,
(iii) indications and usage,
(iv) contraindications,
(V) Interactions,
(vi) warnings e.g. use in pregnancy, lactation etc.,
(vii) precautions,
(viii) adverse reactions,
(ix) drug abuse and dependence (where applicable),
(x) symptoms of overdose and antidote,
(xi) dosage and administration,
(xii) the preparation for use (shaking, dilution, etc.),
(xiii) presentation,
(xiv) storage condition, and
(xv) any other information;

(c) no prescription drugs shall bear on its package label any statement, pictorial or representations of the indications of the drug.
18. Over-the-counter Drugs Labeling, etc.: (1) In addition to compliance with the provisions of regulations 1 to 15 of these Regulations, the following shall apply:

(a) the outer and inner labels of over-the-counter drugs shall be properly labeled and shall bear the following information:-

(i) the brand name (where applicable),  
(ii) the generic or common name,  
(iii) quantitative list of all active ingredients,  
(iv) indications for the drug,  
(v) the net content of the drug in terms of weight, measure or numerical count,  
(vi) the name and address of the manufacturer,  
(vii) lot or batch number,  
(viii) adequate directions for safe use of the drug,  
(ix) dosage including amounts for use in specific age groups,  
(x) route and frequency of administration,  
(xi) warnings e.g. use in pregnancy, lactation etc.,  
(xii) contra-indications,  
(xiii) side effects,  
(xiv) instruction for use (shaking, dilution, refrigeration etc.),  
(xv) a statement to the effect that a physician should be consulted if symptoms persists for over the counter drugs that are self-limiting e.g. analgesics, cough remedies etc.,  
(xvi) the statement in bold: “For external use only” for topical drug products not intended for ingestion, or  
“For rectal or vaginal use only” etc. as appropriate,  
(xvii) a statement “For Veterinary use only” if for veterinary use and the withdrawal period shall also be distinctly stated;

(b) where all the information required in this Regulation may not be contained on the labels of the over-the-counter drugs, they shall be accompanied by a leaflet insert; and

(c) no person shall label over-the-counter drugs as treatment, preventive or cure for any of the diseases, disorders or abnormal states as identified in Schedule I of Food and Drugs Act Cap 150 of the Laws of the Federation of Nigeria1990.

19. Penalty: (1) A person who contravenes a provision of these Regulations is guilty of an offence and liable on conviction:-

(a) in case of an individual, to imprisonment for a term not exceeding two years or to a fine not exceeding N50,000 or to both fine and imprisonment; and

(b) in case of a body corporate, to a fine not exceeding N100,000.

(2) Where an offence under these Regulations is committed by a body corporate or firm or other association of individuals:-

(a) every director, manager, secretary or other similar officer of the body corporate; or

(b) every partner or officer of the firm; or

(c) every trustee of the body concerned; or
(d) every person concerned in the management of the affairs of the association; or

(e) every person who was purporting to act in a capacity referred to in this regulation, are severally guilty of that offence and liable to be proceeded against and punished for that offence in the same manner as if they had themselves committed the offence unless they prove that the act or omission constituting the offence took place without their knowledge, consent or connivance.

20. Forfeiture: In addition to the penalty specified in regulation 19 of these Regulations, a person convicted of an offence under these Regulations shall forfeit to the Agency the Drug Product and whatsoever is used in connection with the commission of the offence.

21. Interpretation: In these Regulations, unless the context otherwise requires –

active ingredient means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure or any function of the body of humans and the term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect;

Agency means The National Agency for Food and Drug Administration and Control;

batch means a defined quantity of material manufactured in one process, a series of processes or in a given part of a continuous process so that it may be expected to be homogeneous;

common name means with reference to a drug, the name in English Language by which the drug is commonly known;

Council means the Governing council of the Agency;

drug or drug product include any substances of vegetable, animal or mineral origin or any preparation or admixture thereof manufactured, sold or advertised for use in:

(a) the diagnosis, treatment, mitigation, in man or animal;
(b) restoring, correcting or modifying organic function in man and animal;
(c) disinfections or the control of vermin, insects or pest; or
(d) contraception;

expiry date means any date after which a drug is not recommended for use;

identification mark means any single letter or combination of letters and numbers including e.g. words, company, mark, symbol, logo or monogram or a combination of letters, numbers and marks or symbols assigned by a drug firm to a specific drug product;

inactive ingredient means any component other than an active ingredient;

inner label means primary packaging material label;

label includes any legend, word or mark attached to, included in, belonging to or accompanying any drug or package;
lot or batch number means the number or a combination of numbers and letters specifically given to a drug which is linked to the manufacturing history of the drug;

outer label means secondary packaging material label;

over-the-counter drug means any drug other than a prescription drug;

prescription drug means a drug which can only be made available to a patient through a written prescription signed by a duly qualified and registered medical or dental practitioner or veterinary surgeon and dispensed by a registered and licenced pharmacist and such drug shall not be made available or sold to the general public without the said prescription

primary packaging material means packaging material that come in direct contact with the product e.g. bottle, blister, alufoils, etc;

principal display panel means the part of a package or label that is most likely to be displayed, presented, shown or examined under customary conditions of display for retail sale;

proper name means, with reference to a drug, the name, strength and pharmaceutical form;

(i) Registration of a product does not automatically confer Advertising permit. A separate approval by the Agency shall be required if the product is to be advertised.

(ii) NAFDAC may withdraw the certificate of Registration in the event that the product is advertised without express approval from the Agency.

(iii) NAFDAC reserves the right to revoke, suspend or vary the certificate during its validity period.

(iv) FILLING AN APPLICATION FORM OR PAYING FOR AN APPLICATION FORM DOES NOT CONFER REGISTRATION STATUS.

(v) FAILURE TO RESPOND PROMPTLY TO QUERIES ON ENQUIRIES RAISED BY NNAFDAC ON THE APPLICATION, WILL AUTOMATICALLY LEAD TO SUSPENSION OF FURTHER PROCESSING OF THE APPLICATION.

End of chapter 04