CHAPTER 02

IMPORTS AND EXPORTS

2.1 UNITED STATES OF AMERICA

At FDA, the statutory responsibility is to assure the American public that the drug supply is safe, secure, and reliable. For more than 60 years, the Federal Food, Drug, and Cosmetic (FD&C) Act has ensured that Americans can be confident that, when they use an FDA-approved drug, the medicine will be safe and effective and will work as intended in treating their illness and preventing complications.

Sixty five years ago the Congress responded to widespread instances of unsafe drugs by directing FDA to create a system for assuring that Americans have a drug supply they can trust will not harm them. Over forty years ago, Congress required that legal drugs be proven to be effective as well, because modern medicines—when they are produced, distributed, prescribed and used properly—should not only be safe but also should prevent the many complications and side effects of diseases.

Unfortunately, the drug supply is under unprecedented attack from a variety of increasingly sophisticated threats. This is evident in the recent significant increase in efforts to introduce counterfeit drugs into the U.S. market. FDA has seen its number of counterfeit drug investigations increase four fold since the late 1990s.

FDA is doing its best to use its limited international authorities to stop the increasing flow of violative drugs into U.S., but the task is daunting. Each day, thousands of individual packages containing prescription drugs are imported illegally into the U.S., simply because the sheer volume has grown to exceed the capability of FDA field personnel to properly process. FDA’s Office of Regulatory Affairs has inspectors who work in the field who perform investigational work pertaining to imported prescription drugs, a job that is not limited to inspections at ports-of-entry.

FDA remains concerned about the public health implications of unapproved prescription drugs from entities seeking to profit by getting around U.S. legal standards for drug safety and effectiveness. Many drugs obtained from foreign sources that either purport to be or appear to be the same as U.S. approved prescription drugs are, in fact, of unknown quality. Consumers are exposed to a number of potential risks when they purchase drugs from foreign sources or from sources that are not operated by pharmacies properly licensed under state pharmacy laws. These outlets may dispense expired, subpotent, contaminated or counterfeit product, the wrong or a contraindicated product, an incorrect dose, or medication accompanied by inadequate directions for use. The labeling of the drug may not be in English and, therefore, important information regarding dosage and side effects may not be available to the consumer. The drugs may not have been packaged and stored under appropriate conditions to prevent against degradation, and there is no assurance that these products were manufactured under current good manufacturing practice standards. When consumers take such medications, they face risks of dangerous drug interactions and/or of suffering adverse events, some of which can be life threatening. More commonly, if the drugs are subpotent or ineffective, they may suffer complications from illnesses that their prescriptions were intended to treat, without ever knowing the true cause.
With a fledgling domestic industry, the drug supply in 19th century America depended largely on imports. But as the health sciences, professions, institutions, and legal framework in the U.S. lagged noticeably behind European nations, America became a dumping ground for adulterated drugs. British statesman and prominent pharmacist Jacob Bell noted that manufacturers understood that drugs reduced by decay or ingenuity were still "good enough for America." A concern for drug quality led to the establishment of the first pharmacy schools in this country and the publication of the United States Pharmacopoeia, all in the 1820s.

The Drug Importation Act, signed by President James K. Polk on June 26, 1848, prohibited the importation of unsafe or adulterated drugs, enforced by a cadre of inspectors stationed at key ports of entry. While the law worked well at first, inspector appointments soon were made on the basis of political spoils rather than qualifications. In addition, the law did not address the proliferating problem of domestic patent medicines. According to eminent physician and pharmacist Edward R. Squibb, the Drug Importation Act was a dead letter by the beginning of the Civil War.

Recent spot examinations of mail shipments of foreign drugs to U.S. consumers revealed that these shipments often contain dangerous or unapproved drugs that pose potentially serious safety problems. In 2003, inspectors found that the majority of the packages examined in these "blitzes" contained illegal, unapproved drugs.

Today, FDA drug approvals are manufacturer-specific, product-specific, and include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. Under sections 801 of the FD&C Act, only manufacturers may import drugs into U.S. The drugs must be produced in FDA inspected facilities. These facilities and the drugs produced in them are currently covered by the U.S. regulatory system and it is legal to import these drugs. It is important that in considering legislation to allow expanded importation of drugs by persons other than the manufacturer, Congress should not bypass the protections provided by FDA's drug approval process and by state regulation of firms that dispense drugs within their jurisdictions.

In the year 2003, when Congress enacted the Medicare Modernization Act, it recognized these safety issues and included language that required that the Secretary certify the safety of prescription drugs prior to authorizing their importation. At the same time, Congress directed the Department to conduct a comprehensive study and prepare a report to Congress on whether and how importation could be accomplished in a manner that assures safety.

The standards for drug review and approval in the U.S. are the best in the world, and the safety of drug supply mirrors these high standards. The employees of FDA constantly strive to maintain these high standards. Often the imported drugs arriving through the mail, through private express couriers, or by passengers arriving at ports-of entry are unapproved drugs that may not be subject to any reliable regulatory oversight. FDA can not assure the safety of drugs purchased from such sources. (www.fda.gov/ola/2004/importeddmgs0520.html)

The Food and Drug Administration (FDA) mission is to enforce the Federal Food, Drug, and Cosmetic (FD&C) Act and other laws which are designed to protect consumers’ health, safety, and pocketbook. These laws apply equally to domestic and imported products.

With the exception of most meat and poultry, all food, drugs, biologics, cosmetics, medical devices, and electronic products that emit radiation, as defined in the FD&C and related Acts, are subject to examination by FDA when they are being imported or offered for import into the United States.
All imported products are required to meet the same standards as domestic goods. Imported; drugs and devices must be safe and effective; cosmetics must be safe and made from approved ingredients; radiation-emitting devices must meet established standards; and all products must contain informative and truthful labeling in English.

As defined in the FD&C Act the term adulteration has to do with the content of a product (such as the addition of a substance which makes a product inferior, impure, not genuine, etc.) while misbranding includes statements on labels or labeling that are false or misleading.

FOREIGN TRADE ZONES: ADDITIONAL FORMS: In addition to required entry forms, certain products require specific information to be presented to FDA at time of importation:

Although it is not a requirement for foreign drug firms to register their establishments, their products must be listed with the FDA. Forms required obtaining a labeler code (FD 2656) and drugging list their product (FD 2657) should be requested from the Center for Drug Evaluation and Research, Product Information Management Branch (HFD-058), 5600 Fishers Lane, Rockville, MD 20857.

Drugs are restricted from importation unless they are covered under an Investigational New Drug Exemption (IND) or by an approved New Drug Application (NDA). Information on regulations covering INDs or NDAs and application forms should be requested from CDER Executive Secretariat (HFD-8), Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857.

INTRODUCTION TO FDA'S IMPORT REFUSAL REPORT (IRR): This report replaces the FDA Import Detention Report (IDR).

The Food, Drug, and Cosmetic Act (the Act) authorizes FDA to detain a regulated product that appears to be out of compliance with the Act. The FDA district office will then issue a "Notice of FDA Action" specifying the nature of the violation to the owner or consignee.

The owner or consignee is entitled to an informal hearing in order to provide testimony regarding the admissibility of the product. If the owner fails to submit evidence that the product is in compliance or fails to submit a plan to bring the product into compliance, FDA will issue another "Notice of FDA Action" Refusing admission to the product. The product then has to be exported or destroyed within 90 days.

The IDR gave an incomplete picture in that it only reflected the initial action by the Agency and not the ultimate determination of the compliance status of the product. The IRR reports on those products for which that determination was to refuse admission to the product.

The IRR is generated from data collected by FDA's Operational and Administrative System for Import Support (OASIS) and is updated monthly. Each month, the IRR is available sorted by country and by product based on the industry code which is the first two characters of FDA's product code (e.g., all fishery/seafood products will be coded 15...).

FDA has prepared this information in an effort to provide the importing community with information on products that have been found to appear in violation of the Act.

THE IRR PROVIDES THE FOLLOWING INFORMATION:

Devi Ahilya Vishwavidyalaya Indore
<table>
<thead>
<tr>
<th>COUNTRY</th>
<th>The country of origin of the FDA manufacturer. This may be different than the country of origin for U.S. Customs purposes. Note: This field is only provided for the IDR sorted by product.</th>
</tr>
</thead>
<tbody>
<tr>
<td>MANUFACTURER</td>
<td>Identifies the name and city of the foreign establishment responsible for the product refused.</td>
</tr>
<tr>
<td>NAME/CITY</td>
<td>Identifies FDA District Offices that have jurisdiction over the refused product.</td>
</tr>
<tr>
<td>ENTRY NO.</td>
<td>A unique identifier assigned to each entry.</td>
</tr>
<tr>
<td>DOCUMENT/LINE</td>
<td>A unique identifier for the product within an entry. An entry may have one or more of these number/letter identifiers.</td>
</tr>
<tr>
<td>SUFFIX</td>
<td>A unique identifier assigned to products regulated by FDA.</td>
</tr>
<tr>
<td>PRODUCT CODE</td>
<td>Identifies or describes the product offered for entry.</td>
</tr>
<tr>
<td>DATE</td>
<td>Identifies the date when the action was taken.</td>
</tr>
<tr>
<td>REASON</td>
<td>Identifies the reason for the agency actions. The specific reason for the detention can be accessed by double clicking the reason given in the IRR or by searching under the file titled &quot;Violation Code Translations.&quot;</td>
</tr>
</tbody>
</table>

**Partial Refusal**: If this is present on a listing, it means that there was a reconditioning action which resulted in a portion of the shipment being refused.

<table>
<thead>
<tr>
<th>COUNTRY</th>
<th>MANUFACTURER</th>
<th>ENTRY NO.</th>
<th>DOCUMENT/LINE</th>
<th>SUFFIX</th>
<th>PRODUCT CODE</th>
<th>PRODUCT DESCRIPTION</th>
<th>DATE</th>
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<td>Ranbaxy New Delhi</td>
<td>Place, IN</td>
<td>112-6912290-61/1</td>
<td>SERLIF05-JUL-2007</td>
<td>UNAPPROVED</td>
<td></td>
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<td>Johnson &amp; Johnson Limited Aurangabad, IN</td>
<td>431136</td>
<td>6912290-1/1/266MCY03</td>
<td>RESPIRERTIDAL</td>
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<tr>
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<td>ALPRAX</td>
<td>05-JUL-2007</td>
<td>UNAPPROVED</td>
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<tr>
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<td>NYK-DO DO7-8707943-6/1/166JDY99</td>
<td>THYROXINE SODIUM</td>
<td>05-JUL-2007</td>
<td>ELTROXIN</td>
<td>UNAPPROVED</td>
<td></td>
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<tr>
<td>Ted Cure Ambala, IN</td>
<td>NYK-DO AEK-7188295-1/1/166VAL99</td>
<td>MORUS ALBA</td>
<td>05-JUL-2007</td>
<td>HOMEOPATHIC MEDICINE FOR THYROID EYE DISEASE</td>
<td>NOT LISTED</td>
<td></td>
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Ted Cure Ambala, IN NYK-DO AEK-7188295-1/1/2 66VAL99  5PHOS-HOMEOPATHIC MEDICINE FOR THYROID EYE DISEASE
05-JUL-2007  NOT LISTED

Ted Cure Ambala, IN NYK-DO AEK-7188295-1/1/3 66VAL99  RETIFIED SPIRIT-HOMEOPATHIC MEDICINE FOR THYROID EYE DISEASE
05-JUL-2007  NOT LISTED

Pravinchandra Jethalal & Co. Mumbai, IN 400009 0399793-6/6/2 60LBJ99  AMRUNTANJAN BALM
10-JUL-2007  NO ENGLISH

Pravinchandra Jethalal & Co.Mumbai, IN 400009 0399793-6/6/3 60LBJ99  VICKS BALM
10-JUL-2007  NO ENGLISH

Pravinchandra Jethalal & Co.Mumbai, IN 400009 0399793-6/6/4 60LBJ99  IODEX
10-JUL-2007  NO ENGLISH

Pravinchandra Jethalal & Co.Mumbai, IN 400009 0399793-6/6/5 60LBJ99  MOOVE
10-JUL-2007  NO ENGLISH

Franco-Indian Pharmaceuticals Pvt., Ltd. Maharashtra MS, IN 400093  ATL-DO XXX-0150730-1/1/11 61WD099 Surfaz-SN Triple Action Cream in metal tubes
10-JUL-2007  NOT LISTED

Renuga Chennai, IN NYK-DO AEK-7190090-2/1/1 61BAA02  CYPROTERONE ACETATE & ETHINYLLOSTRADIOL TABLETS
11-JUL-2007  NOT LISTED

Strides Arcolab Ltd Navi Mumbai Vashi, IN NOL-DO 112-7081932-1/1/1 66VDB99  86085541503  MULTIVITAMIN
11-JUL-2007  DIRECTIONS UNAPPROVED

Scitech Health Care Pvt Ltd Mumbai, IN 6/1/1 56KCS11  CHLORAMPHENICOL PALMITATE (CERTIFIABLE); HUMAN - RX/SINGLE IN
11-JUL-2007  DIRECTIONS

Rahul Products Limited Indore IN-MP, IN 452001 6/1/1 62GAL99  DERMOSOL FOR PSORIASIS
NYK-DO AEK-7187726-
11-JUL-2007

Rahul Products Limited Indore IN-MP, IN 452001
6/1/2 62GAH99 SCABILEX FOR PSORIASIS
11-JUL-2007

NOT LISTED UNAPPROVED

Rahul Products Limited Indore IN-MP, IN 452001
6/1/3 62GAJ99 PURODERM OINTMENT FOR PSORIASIS
11-JUL-2007

NOT LISTED UNAPPROVED

Rahul Products Limited Indore IN-MP, IN 452001
6/1/4 62GAL99 HEPORYL FOR PSORIASIS
11-JUL-2007

NOT LISTED UNAPPROVED

Rahul Products Limited Indore IN-MP, IN 452001
6/1/5 62GAL99 OMNI FOR PSORIASIS
11-JUL-2007

NOT LISTED UNAPPROVED

Rahul Products Limited Indore IN-MP, IN 452001
6/1/6 62GAL99 GOAMRUT FOR PSORIASIS
11-JUL-2007

NOT LISTED UNAPPROVED

Anuh Pharma Limited Mumbai, IN 400004 FLA-DO T94-0045276-7/1/1 61FAY33
ERYTHROMYCIN STEARATE
25-JUL-2007

UNAPPROVED

Viral Rana Ankleshwar, IN NYK-DO XXX-0151449-7/1/1 66VCY99 cardiovascular
medicaments
27-JUL-2007

UNAPPROVED

Food, Drug and Cosmetics Act: CHAPTER II—RELEVANT, DEFINITIONS

SEC. 201. [21 U.S.C. 321] For the purposes of this Act—
The term "interstate commerce" means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.
The term "Department" means the Department of Health and Human Services.
The term "Secretary" means the Secretary of Health and Human Services.
The term "person" includes individual, partnership, corporation, and association.
The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.
The term "drug" means (A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any
supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) or sections 403(r)(1)(B) and 403(r)(5)(D), is made in accordance with the requirements of section 403(r) is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) is not a drug under clause (C) solely because the label or the labeling contains such a statement.

The term "counterfeit drug" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

The term "device" (except when used in paragraph (m) of this section and in sections 301(i), 403(f), 502(c), and 602(c)) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

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 "immediate container" does not include package liners.

The term "labeling" means all labels and other written, printed, or graphic matter (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.

The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.
The term "new drug" means—

Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a “new drug” if at any time prior to the enactment of this Act it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

For purposes of section 306, the term “high managerial agent”— means—

1) an officer or director of a corporation or an association,
2) a partner of a partnership, or
3) any employee or other agent of a corporation, association, or partnership, having duties such that the conduct of such officer, director, partner, employee, or agent may fairly be assumed to represent the policy of the corporation, association, or partnership, and includes persons having management responsibility for—

1. submissions to the Food and Drug Administration regarding the development or approval of any drug product, any drug product, or
2. production, quality assurance, or quality control of any drug product, or
3. research and development of any drug product.

For purposes of sections 306 and 307, the term “drug product” means a drug subject to regulation under section 505, 512, or 802 of this Act or under section 351 of the Public Health Service Act.

The term “Commissioner” means the Commissioner of Food and Drugs.

The term "antibiotic drug" means any drug (except drugs for use in animals other than humans) composed wholly or partly of any kind of penicillin, streptomycin, chlorotetracycline, chloramphenicol, bacitracin, or any other drug intended for human use containing any quantity of any chemical substance which is produced by a micro-organism and which has the capacity to inhibit or destroy micro-organisms in dilute solution (including a chemically synthesized equivalent of any such substance) or any derivative thereof.

Information on importation of drugs prepared by the division of import operations and policy,

FDA

The United States Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. section 331) prohibits the interstate shipment (which includes importation) of unapproved new drugs. Thus, the importation of drugs that lack FDA approval, whether for personal use or otherwise, violates the Act. Unapproved new drugs are any drugs, including foreign-made versions of U.S. approved drugs that have not been manufactured in accordance with and pursuant to an FDA approval. Under the Act, FDA may refuse admission to any drug that “appears” to be unapproved, placing the burden on the importer to prove that the drug sought to be imported is in fact approved by FDA. Absent evidence that the specific drugs sought to be imported from a foreign country have been
manufactured pursuant to an approved new drug application, in the manufacturing facility permitted under the application, such drugs would appear to be unapproved new drugs subject to FDA enforcement action.

The use of FDA resources to provide comprehensive coverage of unapproved new drugs imported for personal use is generally not justified, however, the agency developed guidance in its Regulation Procedures Manual (RPM) entitled "Coverage of Personal Importations". This guidance sets forth the agency's enforcement priorities related to the personal importation of unapproved new drugs, with enforcement being focused on products apparently intended for the commercial market and on fraudulent products and those that pose an unreasonable health risk. The guidance recognizes that circumstances may exist where, for example, a person has begun treatment with an unapproved drug in a foreign country or suffers from a condition for which there exists no FDA approved treatment. If such circumstances can be substantiated, as the text of the guidance quoted below notes, the guidance suggests that refraining from taking action against the illegal importation, in the exercise of enforcement discretion, may be appropriate. The guidance document is not, however, a license for individuals to import unapproved (and therefore illegal) drugs for personal use into the U.S., and even if all the factors noted in the guidance are present, the drugs remain illegal and FDA may decide that such drugs should be refused entry or seized. Similarly, the factors noted in the guidance, and documentation that should be obtained from individuals importing the drugs, are not mandatory requirements. They are intended to guide FDA enforcement discretion and should not be represented as binding requirements. The statements in the RPM are intended only to provide operating guidance for FDA personnel and are not intended to create or confer any rights, privileges, or benefits on or for any private person.

That said, FDA's guidance for coverage of personal importations of unapproved drugs identifies several factors that should be considered by FDA personnel when determining whether to exercise enforcement discretion and refrain from taking action against the importation of unapproved drugs. The General Guidance Section states that FDA should consider not taking enforcement actions against such importation:

"when 1) the intended use [of the drug] is unapproved and for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means; 2) there is no known commercialization or promotion to persons residing in the U.S. by those involved in the distribution of the product at issue; 3) the product is considered not to represent an unreasonable risk; and 4) the individual seeking to import the product affirms in writing that it is for the patient's own use (generally not more than 3 month supply) and provides the name and address of the doctor licensed in the U.S. responsible for his or her treatment with the product or provides evidence that the product is for the continuation of a treatment begun in a foreign country." (Emphasis added)

The above guidance does not specify that a U.S. citizen may import an unapproved drug only with a prescription from a U.S. licensed physician, or that a foreign citizen may import an unapproved new drug only with a foreign prescription. Rather, to ensure that the importation is for personal use only (and not for resale), and to ensure that the use of the unapproved new drug sought to be imported into the U.S. is supervised and does not represent an unreasonable rsk, the guidance provides that the individual affirm in writing that the drug is for his or her personal use, and provide either the name and address of the U.S. licensed physician who will supervise its use or some evidence that the treatment was begun in a foreign country and that the drugs are being imported to continue/conclude the already begun treatment. Thus, while not the only documentation, either a U.S. or foreign prescription, along with an affirmation of personal use, could be supplied as evidence that this factor exists.
The guidance also provides that the importation should generally not represent more than a 3 month supply of the unapproved products. The purpose for this provision is in keeping with the intent that the guidance relate to only drugs for personal use, not commercial distribution. As the document sets forth only guidance, the 3 month limitation is not a "requirement" or a "restriction."

A person may decide that his or her FDA approved heart medication is cheaper in Mexico, and attempt to import the unapproved version of the drug from Mexico. FDA cannot assure that such products have been properly manufactured and are effective; therefore, given that such products are available in the U.S., their use would present an unreasonable risk and the guidance would not apply (unless the person seeking their importation could establish that the drugs were needed to refill a prescription while traveling or were otherwise needed while traveling).

Likewise, a drug such as Valium is available in the U.S. and, as such, a foreign-made version of the U.S. approved drug would not generally be considered a candidate to be permitted entry under the guidance. However, because the United States Drug Enforcement Administration (DEA) may have specific requirements that apply to the importation of controlled substances such as Valium, FDA's guidance on personal importations specifically provides that controlled substances should be returned to Customs for handling.

The Act properly regulates personal articles imported into the United States for personal consumption. The Act also prohibits the importation into the United States of any unapproved new drug.

It is appreciated that there is a significant cost differential between drugs available in U.S. and those in other countries. However, many drugs sold in foreign countries as "foreign versions" of approved prescription drugs sold in the United States are often of unknown quality with inadequate directions for use and may pose a risk to the patient's health. FDA approves a drug on the basis of scientific data proving it to be safe and effective. FDA approved labeling provides information on how and when the drug can be used to maximize effectiveness and minimize any harmful side effects. The manufacturing facilities and procedures for approved products are also carefully regulated by FDA to ensure product integrity. Since FDA cannot assure the consumer that the drug purchased in the foreign country would be the same product his or her physician's prescription is written for, it is recommended that the product covered by the prescription be acquired in the United States.

PERSONAL BAGGAGE: FDA personnel are not to examine personal baggage. This responsibility rests with the U.S. Customs Service.

It is expected that a Customs officer will notify their local FDA district office when he or she has detected a shipment of an FDA-regulated article intended for commercial distribution (see GENERAL GUIDANCE below) an article that FDA has specifically requested be detained, or an FDA-regulated article that appears to represent a health fraud or an unknown risk to health.

MAIL SHIPMENTS: FDA personnel are responsible for monitoring mail importations. It is expected that a Customs officer from the Customs Mail Division will examine a parcel and will set it aside if it appears to contain a drug, biologic, or device, an article that FDA has specifically requested be held, or an FDA-regulated article that appears to represent a health fraud or unknown risk to health. FDA should audit those parcels set aside by Customs in accordance with the guidance provided under GENERAL GUIDANCE.
GENERAL GUIDANCE: The statements in this chapter are intended only to provide operating guidance for FDA personnel and are not intended to create or confer any rights, privileges, or benefits on or for any private person.

FDA personnel may use their discretion to allow entry of shipments of violative FDA regulated products when the quantity and purpose are clearly for personal use, and the product does not present an unreasonable risk to the user. Even though all products that appear to be in violation of statutes administered by FDA are subject to refusal, FDA personnel may use their discretion to examine the background, risk, and purpose of the product before making a final decision. Although FDA may use discretion to allow admission of certain violative items, this should not be interpreted as a license to individuals to bring in such shipments.

Commercial or Promotional Shipments: Commercial and promotional shipments are not subject to this guidance. Whether or not a shipment is commercial or promotional may be determined by a number of factors including, for example, the type of product, accompanying literature, size, value, and/or destination of the shipment. FDA personnel may also consider whether an importation of drugs or medical devices is a commercial shipment by evaluating whether the article appears to have been purchased for personal use or whether the quantity suggests commercial distribution (i.e., the supply exceeds what one person might take in approximately three months). Commercial shipments generally include shipments other than those products that are personally carried, shipped by a personal non-commercial representative of a consignee, or shipped from a foreign medical facility where a person has undergone treatment.

Drugs, Biologies, and Devices: When personal shipments of drugs and devices that appear violative are brought to FDA’s attention by Customs, FDA personnel will use their discretion to decide on a case by case basis whether to detain, refuse, or allow entry of the product. Generally, drugs and devices subject to Import Alerts are not amenable to this guidance. Devices to be used by practitioners for treating patients should not be viewed as personal importations subject to this chapter. Drugs subject to Drug Enforcement Agency (DEA) jurisdiction should be returned to Customs for handling.

When a shipment is not refused entry, FDA personnel may consider issuing a "Release with Comment" and, as appropriate, advise the recipient that 1) the drug (or device) that has been obtained for personal use appears to be unapproved in the United States; 2) the drug (or device) should be used under medical supervision; 3) FDA may detain future shipments of this product; and 4) the patient’s physician should consider for example, enrolling the patient in an Investigational study or applying for Investigation New Drug (IND), Compassionate IND, or Treatment IND exemption.

The United States Federal Food, Drug, and Cosmetic Act (The Act) prohibits the interstate shipment (which includes importation) of unapproved new drugs. Thus, the importation of drugs that lack FDA approval, whether for personal use or otherwise, violates the Act and is illegal. Unapproved new drugs are any drugs -- including foreign-made versions of U.S. approved drugs -- that have not been manufactured in accordance with and pursuant to an FDA approval.

FDA guidance is not, however, a license for individuals to import unapproved (and therefore illegal) drugs for personal use into the U.S. Even if all of the factors noted in the guidance are present, the drug remains illegal and FDA may determine that such drugs should be refused entry or seized. The guidance does not create any legally enforceable rights for the public; nor does it operate to bind FDA or the public. Most importantly, this policy is not intended to allow importation of foreign versions of drugs that are approved in the U.S. (http://www.fda.gov/ora/import/ora_import_program.html)

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SEC. 801. [21 U.S.C. 381] (a) The Secretary of the Treasury shall deliver to the Secretary of Health and Human Services, upon his request, samples of food, drugs, devices, and cosmetics which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Secretary of Health and Human Services and have the right to introduce testimony.

The Secretary of Health and Human Services shall furnish to the Secretary of the Treasury a list of establishments registered pursuant to subsection (i) of section 510 and shall request that if any drugs or devices manufactured, prepared, propagated, compounded, or processed in an establishment not so registered are imported or offered for import into the United States, samples of such drugs or devices be delivered to the Secretary of Health and Human Services, with notice of such delivery to the owner or consignee, who may appear before the Secretary of Health and Human Services and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions or, in the case of a device, the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation of the device do not conform to the requirements of section 520(f), or (2) such article is forbidden or restricted in sale in the country n which it was produced or from which it was exported, or (3) such article is adulterated, misbranded or in violation of section 505, then such article shall be refused admission, except as provided in subsection (b) of this section. The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within ninety days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations. Clause (2) of the third sentence of this paragraph shall not be construed to prohibit the admission of narcotic drugs the importation of which is permitted under the Controlled Substances Import and Export Act.

(b) Pending decision as to the admission of an article being imported or offered for import, the Secretary of the Treasury may authorize delivery of such article to the owner or consignee upon the execution by him of a good and sufficient bond providing for the payment of such liquidated damages in the event of default as may be required pursuant to regulations of the Secretary of the Treasury. If it appears to the Secretary of Health and Human Services that an article included within the provisions of clause (3) of subsection (a) of this section can, by relabeling or other action, be brought into compliance with the Act or rendered other than a food, drug, device, or cosmetic, final determination as to admission of such article may be deferred and, upon filing of timely written application by the owner or consignee and the execution by him of a bond as provided in the preceding provisions of this subsection, the Secretary may, in accordance with regulations, authorize the applicant to perform such relabeling or other action specified in such authorization (including destruction or export of rejected articles or portions thereof, as may be specified in the Secretary's authorization). All such relabeling or other action pursuant to such authorization shall in accordance with regulations be under the supervision of an officer or employee of the Department of Health and Human Services designated by the Secretary, or an officer or employee of the Department of the Treasury designated by the Secretary of the Treasury.

(c) All expenses (including travel, per diem or subsistence, and salaries of officers or employees of the United States) in connection with the destruction provided for in subsection (a) of this section and the supervision of the relabeling or other action authorized under the provisions of subsection (b) of this section, the amount of such expenses to be determined in accordance with regulations, and all expenses in connection with the storage, cartage, or labor with respect to any article refused admission under subsection (a) of this section, shall be paid by the owner or consignee and, in default of such payment, shall constitute a lien against any future importations made by such owner or consignee.
(d) (1) Except as provided in paragraph (2) and section 804, no drug subject to section 503(b) or composed wholly or partly of insulin which is manufactured in a State and exported may be imported into the United States unless the drug is imported by the manufacturer of the drug.

(2) The Secretary may authorize the importation of a drug the importation of which is prohibited by paragraph (1) if the drug is required for emergency medical care.

(3) (A) Subject to subparagraph (B), no component of a drug, no component part or accessory of a device, or other article of device requiring further processing, which is ready or suitable for use for health-related purposes, and no article of a food additive, color additive, or dietary supplement, including a product in bulk form, shall be excluded from importation into the United States under subsection (a) if each of the following conditions is met:

(i) The importer of such article of a drug or device or importer of such article of a food additive, color additive, or dietary supplement submits to the Secretary, at the time of initial importation, a statement in accordance with the following:

(I) Such statement provides that such article is intended to be further processed by the initial owner or consignee, incorporated by the initial owner or consignee, into a drug, biological product, device, food, food additive, color additive, or dietary supplement that will be exported by the initial owner or consignee from the United States in accordance with subsection (e) of section 802, or with section 351(h) of the Public Health Service Act.

(II) The statement identifies the manufacturer of such article and each processor, packer, distributor, or other entity that had possession of the article in the chain of possession of the article from the manufacturer to such importer of the article.

(III) The statement is accompanied by such certificates of analysis as are necessary to identify such article, unless the article is a device or is an article described in paragraph (4).

(ii) At the time of initial importation and before the delivery of such article to the importer or the initial owner or consignee, such owner or consignee executes a good and sufficient bond providing for the payment of such liquidated damages in the event of default as may be required pursuant to regulations of the Secretary of the Treasury.

(iii) Such article is used and exported by the initial owner or consignee in accordance with the intent described under clause (i)(I), except for any portions of the article that are destroyed.

(iv) The initial owner or consignee maintains records on the use or destruction of such article or portions thereof, as the case may be, and submits to the Secretary any such records requested by the Secretary.

(v) Upon request of the Secretary, the initial owner or consignee submits a report that provides an accounting of the exportation or destruction of such article or portions thereof, and the manner in which such owner or consignee complied with the requirements of this subparagraph.

(B) Notwithstanding subparagraph (A), the Secretary may refuse admission to an article that otherwise would be imported into the United States under such subparagraph if the Secretary determines that there is credible evidence or information indicating that such article is not intended to be further processed by the initial owner or consignee, or incorporated by the initial owner or consignee, into a drug, biological product, device, food, food additive, color additive, or dietary supplement that will be exported by the initial owner or consignee from the United States in accordance with subsection (e) or section 802, or with section 351(h) of the Public Health Service Act.
(C) This section may not be construed as affecting the responsibility of the Secretary to ensure that articles imported into the United States under authority of subparagraph (A) meet each of the conditions established in such subparagraph for importation.”

(4) The importation into the United States of blood, blood components, source plasma, or source leukocytes or of a component, accessory, or part thereof is not permitted pursuant to paragraph (3) unless the importation complies with section 351(a) of the Public Health Service Act or the Secretary permits the importation under appropriate circumstances and conditions, as determined by the Secretary. The importation of tissue or a component or part of tissue is not permitted pursuant to paragraph (3) unless the importation complies with section 361 of the Public Health Service Act.

(e)(1) A food, drug, device, or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this Act if it—

(A) accords to the specifications of the foreign purchaser,
(B) is not in conflict with the laws of the country to which it is intended for export,
(C) is labeled on the outside of the shipping package that it is intended for export, and
(D) is not sold or offered for sale in domestic commerce.

(2) Paragraph (1) does not apply to any device—
(A) which does not comply with an applicable requirement of section 514 or 515,
(B) which under section 520(g) is exempt from either such section, or
(C) which is a banned device under section 516, unless, in addition to the requirements of paragraph (1), either (i) the Secretary has determined that the exportation of the device is not contrary to public health and safety and has the approval of the country to which it is intended for export or (ii) the device is eligible for export under section 802.

(3) A new animal drug that requires approval under section 512 shall not be exported pursuant to paragraph (1) if such drug has been banned in the United States.

(4)(A) Any person who exports a drug, animal drug, or device may request that the Secretary—
(i) certify in writing that the exported drug, animal drug, or device meets the requirements of paragraph (1) or section 802; or
(ii) certify in writing that the drug, animal drug or device being exported meets the applicable requirements of this Act upon a showing that the drug or device meets the applicable requirements of this Act.

The Secretary shall issue such a certification within 20 days of the receipt of a request for such certification.

(B) If the Secretary issues a written export certification within the 20 days prescribed by subparagraph (A), a fee for such certification may be charged but shall not exceed $175 for each certification. Fees collected for a fiscal year pursuant to this subparagraph shall be credited to the appropriation account for salaries and expenses of the Food and Drug Administration and shall be available in accordance with appropriations Acts until expended without fiscal year limitation. Such fees shall be collected in each fiscal year in an amount equal to the amount specified in appropriations Acts for such fiscal year and shall only be collected and available for the costs of the Food and Drug Administration.

(f)(1) If a drug (other than insulin, an antibiotic drug, an animal drug, or a drug exported under section 802) being exported in accordance with subsection (e) is being exported to a country that has different or additional labeling requirements or conditions for use and such country requires the drug to be labeled in accordance with those requirements or uses, such drug may be labeled in accordance with such requirements and conditions for use in the country to which such drug is being exported if it also is labeled in accordance with the requirements of this Act.
(2) If, pursuant to paragraph (1), the labeling of an exported drug includes conditions for use that have not been approved under this Act, the labeling must state that such conditions for use have not been approved under this Act. A drug exported under section 802 is exempt from this section.

(g) (1) With respect to a prescription drug being imported or offered for import into the United States, the Secretary, in the case of an individual who is not in the business of such importations, may not send a warning notice to the individual unless the following conditions are met:

(A) The notice specifies, as applicable to the importation of the drug, that the Secretary has made a determination that—

(i) importation is in violation of section 801(a) because the drug is or appears to be adulterated, misbranded, or in violation of section 505;

(ii) importation is in violation of section 801(a) because the drug is or appears to be forbidden or restricted in sale in the country in which it was produced or from which it was exported;

(iii) importation is or appears to be in violation of section 801(d)(1); or

(iv) importation otherwise is or appears to be in violation of Federal law.

(B) The notice does not specify any provision described in subparagraph (A) that is not applicable to the importation of the drug.

(C) The notice states the reasons underlying such determination by the Secretary, including a brief application to the principal facts involved of the provision of law described in subparagraph (A) that is the basis of the determination by the Secretary.

(2) For purposes of this section, the term "warning notice", with respect to the importation of a drug, means a communication from the Secretary (written or otherwise) notifying a person, or clearly suggesting to the person, that importing the drug for personal use is, or appears to be, a violation of this Act.

(h) (1) 2 The Secretary shall give high priority to increasing the number of inspections under this section for the purpose of enabling the Secretary to inspect food offered for import at ports of entry into the United States, with the greatest priority given to inspections to detect the intentional adulteration of food.

(2) The Secretary shall give high priority to making necessary improvements to the information management systems of the Food and Drug Administration that contain information related to foods imported or offered for import into the United States for purposes of improving the ability of the Secretary to allocate resources, detect the intentional adulteration of food, and facilitate the importation of food that is in compliance with this Act.

(3) The Secretary shall improve linkages with other regulatory agencies of the Federal Government that share responsibility for food safety, and shall with respect to such safety improve linkages with the States and Indian tribes (as defined in section 4(e) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b(e))).

(i) (1) 2 For use in inspections of food under this section, the Secretary shall provide for research on the development of tests and sampling methodologies—
(A) whose purpose is to test food in order to rapidly detect the adulteration of the food, with the greatest priority given to detect the intentional adulteration of food; and

(B) whose results offer significant improvements over the available technology in terms of accuracy, timing, or costs.

(2) In providing for research under paragraph (1), the Secretary shall give priority to conducting research on the development of tests that are suitable for inspections of food at ports of entry into the United States.

(3) In providing for research under paragraph (1), the Secretary shall as appropriate coordinate with the Director of the Centers for Disease Control and Prevention, the Director of the National Institutes of Health, the Administrator of the Environmental Protection Agency, and the Secretary of Agriculture.

(4) The Secretary shall annually submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate, a report describing the progress made in research under paragraph (1), including progress regarding paragraph (2).

(i) (1) If an officer or qualified employee of the Food and Drug Administration has credible evidence or information indicating that an article of food presents a threat of serious adverse health consequences or death to humans or animals, and such officer or qualified employee is unable to inspect, examine, or investigate such article upon the article being offered for import at a port of entry into the United States, the officer or qualified employee shall request the Secretary of Treasury to hold the food at the port of entry for a reasonable period of time, not to exceed 24 hours, for the purpose of enabling the Secretary to inspect, examine, or investigate the article as appropriate.

(2) The Secretary shall request the Secretary of Treasury to remove an article held pursuant to paragraph (1) to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be. Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held.

(3) An officer or qualified employee of the Food and Drug Administration may make a request under paragraph (1) only if the Secretary or an official designated by the Secretary approves the request. An official may not be so designated unless the official is the director of the district under this Act in which the article involved is located, or is an official senior to such director.

(4) With respect to an article of food for which a request under paragraph (1) is made, the Secretary, promptly after the request is made, shall notify the State in which the port of entry involved is located, and as applicable, that such article is being held under this subsection.

(k)(1) If an article of food is being imported or offered for import into the United States, and the importer, owner, or consignee of the article is a person who has been debarred under section 306(b)(3), such article shall be held at the port of entry for the article, and may not be delivered to such person. Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held. The article shall be removed to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be.
(2) An article of food held under paragraph (1) may be delivered to a person who is not a debarred person under section 306(b)(3) if such person affirmatively establishes, at the expense of the person, that the article complies with the requirements of this Act, as determined by the Secretary.

(i)(1) If an article of food is being imported or offered for import into the United States, and such article is from a foreign facility for which a registration has not been submitted to the Secretary under section 415, such article shall be held at the port of entry for the article, and may not be delivered to the importer, owner, or consignee of the article, until the foreign facility is so registered. Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held. The article shall be removed to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be.

(m)(1) In the case of an article of food that is being imported or offered for import into the United States, the Secretary, after consultation with the Secretary of the Treasury, shall by regulation require, for the purpose of enabling such article to be inspected at ports of entry into the United States, the submission to the Secretary of a notice providing the identity of each of the following: The article; the manufacturer and shipper of the article; if known within the specified period of time that notice is required to be provided, the grower of the article; the country from which the article originates; the country from which the article is shipped; and the anticipated port of entry for the article. An article of food imported or offered for import without submission of such notice in accordance with the requirements under this paragraph shall be refused admission into the United States. Nothing in this section may be construed as a limitation on the port of entry for an article of food.

(2)(A) Regulations under paragraph (1) shall require that a notice under such paragraph be provided by a specified period of time in advance of the time of the importation of the article of food involved or the offering of the food for import, which period shall be no less than the minimum amount of time necessary for the Secretary to receive, review, and appropriately respond to such notification, but may not exceed five days. In determining the specified period of time required under this subparagraph, the Secretary may consider, but is not limited to consideration of, the effect on commerce of such period of time, the locations of the various ports of entry into the United States, the various modes of transportation, the types of food imported into the United States, and any other such consideration. Nothing in the preceding sentence may be construed as a limitation on the obligation of the Secretary to receive, review, and appropriately respond to any notice under paragraph (1).

(B)(i) If an article of food is being imported or offered for import into the United States and a notice under paragraph (1) is not provided in advance in accordance with the requirements under paragraph (1), such article shall be held at the port of entry for the article, and may not be delivered to the importer, owner, or consignee of the article, until such notice is submitted to the Secretary, and the Secretary examines the notice and determines that the notice is in accordance with the requirements under paragraph (1). Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held. The article shall be removed to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be.

(ii) In carrying out clause (i) with respect to an article of food, the Secretary shall determine whether there is in the possession of the Secretary any credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals.

(3)(A) This subsection may not be construed as limiting the authority of the Secretary to obtain information under any other provision of this Act.
(B) This subsection may not be construed as authorizing the Secretary to impose any requirements with respect to a food to the extent that it is within the exclusive jurisdiction of the Secretary of Agriculture pursuant to the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.).

(n) (1) If a food has been refused admission under subsection (a), other than such a food that is required to be destroyed, the Secretary may require the owner or consignee of the food to affix to the container of the food a label that clearly and conspicuously bears the statement: "UNITED STATES: REFUSED ENTRY".

(2) All expenses in connection with affixing a label under paragraph (1) shall be paid by the owner or consignee of the food involved, and in default of such payment, shall constitute a lien against future importations made by such owner or consignee.

(3) A requirement under paragraph (1) remains in effect until the Secretary determines that the food involved has been brought into compliance with this Act.

(o) If an article that is a drug or device is being imported or offered for import into the United States, and the importer, owner, or consignee of such article does not, at the time of offering the article for import, submit to the Secretary a statement that identifies the registration under section 510(i) of each establishment that with respect to such article is required under such section to register with the Secretary, the article may be refused admission. If the article is refused admission for failure to submit such a statement, the article shall be held at the port of entry for the article, and may not be delivered to the importer, owner, or consignee of the article, until such a statement is submitted to the Secretary. Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held. The article shall be removed to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be.

EXCEPDS OF CERTAIN UNAPPROVED PRODUCTS

SEC. 802. [21 U.S.C. 382] (a) A drug or device—

(1) which, in the case of a drug—

(A)(i) requires approval by the Secretary under section 505 before such drug may be introduced or delivered for introduction into interstate commerce; or

(ii) requires licensing by the Secretary under section 351 of the Public Health Service Act or by the Secretary of Agriculture under the Act of March 4, 1913 (known as the Virus-Serum Toxin Act) before it may be introduced or delivered for introduction into interstate commerce:

(B) does not have such approval or license; and

(C) is not exempt from such sections or Act;

(2) which, in the case of a device—

(A) does not comply with an applicable requirement under section 514 or 515;

(B) under section 520(g) is exempt from either such section; or

(C) is a banned device under section 516, is adulterated, misbranded, and in violation of such sections or Act unless the export of the drug or device is, except as provided in subsection (f), authorized under subsection (b), (c), (d), or (e) or section 801(e)(2); and

(2) may be exported under subsection (b) and if an application for such drug or device under section 505 or 515 or section 351 of the Public Health Service Act was disapproved, the Secretary shall notify the appropriate public health official of the country to which such drug will be exported of such disapproval.
(b)(1)(A) A drug or device described in subsection (a) may be exported to any country, if the drug or device complies with the laws of that country and has valid marketing authorization by the appropriate authority—

(i) in Australia, Canada, Israel, Japan, New Zealand, Switzerland, or South Africa; or

(ii) in the European Union or a country in the European Economic Area (the countries in the European Union and the European Free Trade Association) if the drug or device is marketed in that country or the drug or device is authorized for general marketing in the European Economic Area.

(B) The Secretary may designate an additional country to be included in the list of countries described in clauses (i) and (ii) of subparagraph (A) if all of the following requirements are met in such country:

(i) Statutory or regulatory requirements which require the review of drugs and devices for safety and effectiveness by an entity of the government of such country and which authorize the approval of only those drugs and devices which have been determined to be safe and effective by experts employed by or acting on behalf of such entity and qualified by scientific training and experience to evaluate the safety and effectiveness of drugs and devices on the basis of adequate and well-controlled investigations, including clinical investigations, conducted by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs and devices.

(ii) Statutory or regulatory requirements that the methods used in the manufacture, processing, and packing of drugs in the country are adequate to preserve their identity, quality, purity, and strength; and

(iii) Statutory or regulatory requirements for the reporting of adverse reactions to drugs and devices and procedures to withdraw approval and remove drugs and devices found not to be safe or effective.

(iv) Statutory or regulatory requirements that the labeling and promotion of drugs and devices must be in accordance with the approval of the drug or device.

(v) The valid marketing authorization system in such country or countries is equivalent to the systems in the countries described in clauses (i) and (ii) of subparagraph (A).

The Secretary shall not delegate the authority granted under this subparagraph.

(C) An appropriate country official, manufacturer, or exporter may request the Secretary to take action under subparagraph (B) to designate an additional country or countries to be added to the list of countries described in clauses (i) and (ii) of subparagraph (A) by submitting documentation to the Secretary in support of such designation. Any person other than a country requesting such designation shall include, along with the request, a letter from the country indicating the desire of such country to be designated.

(2) A drug described in subsection (a) may be directly exported to a country which is not listed in clause (i) or (ii) of paragraph (1)(A) if—

(A) the drug complies with the laws of that country and has valid marketing authorization by the responsible authority in that country; and

(B) the Secretary determines that all of the following requirements are met in that country:

(i) Statutory or regulatory requirements which require the review of drugs for safety and effectiveness by an entity of the government of such country and which authorize the approval of only those drugs which have been determined to be safe and effective by experts employed by or acting on behalf of such entity and qualified by scientific training and experience to evaluate the safety and effectiveness
of drugs on the basis of adequate and well-controlled investigations, including clinical investigations, conducted by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs.

(ii) Statutory or regulatory requirements that the methods used in, and the facilities and controls used for the manufacture, processing, and packing of drugs in the country are adequate to preserve their identity, quality, purity, and strength.

(iii) Statutory or regulatory requirements for the reporting of adverse reactions to drugs and procedures to withdraw approval and remove drugs found not to be safe or effective.

(iv) Statutory or regulatory requirements that the labeling and promotion of drugs must be in accordance with the approval of the drug.

(3) The exporter of a drug described in subsection (a) which would not meet the conditions for approval under this Act or conditions for approval of a country described in clause (i) or (ii) of paragraph (1)(A) may petition the Secretary for authorization to export such drug to a country which is not described in clause (i) or (ii) of paragraph (1)(A) or which is not described in paragraph (2). The Secretary shall permit such export if—

(A) the person exporting the drug—

(i) certifies that the drug would not meet the conditions for approval under this Act or the conditions for approval of a country described in clause (i) or (ii) of paragraph (1)(A); and

(ii) provides the Secretary with credible scientific evidence, acceptable to the Secretary, that the drug would be safe and effective under the conditions of use in the country to which it is being exported; and

(B) the appropriate health authority in the country to which the drug is being exported—

(i) requests approval of the export of the drug to such country;

(ii) certifies that the health authority understands that the drug is not approved under this Act or in a country described in clause (i) or (ii) of paragraph (1)(A); and

(iii) concurs that the scientific evidence provided pursuant to subparagraph (A) is credible scientific evidence that the drug would be reasonably safe and effective in such country.

The Secretary shall take action on a request for export of a drug under this paragraph within 60 days of receiving such request. (c) A drug or device intended for investigational use in any country described in clause (i) or (ii) of subsection (b)(1)(A) may be exported in accordance with the laws of that country and shall be exempt from regulation under section 505(i) or 520(g).

(d) A drug or device intended for formulation, filling, packaging, labeling, or further processing in anticipation of market authorization in any country described in clause (i) or (ii) of subsection (b)(1)(A) may be exported for use in accordance with the laws of that country.

(e) (1) A drug or device which is used in the diagnosis, prevention, or treatment of a tropical disease or another disease not of significant prevalence in the United States and which does not otherwise qualify for export under this section shall, upon approval of an application, be permitted to be exported if the Secretary finds that the drug or device will not expose patients in such country to an unreasonable risk of illness or injury and the probable benefit to health from the use of the drug or device (under conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling of the
Drug or device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available drug or device treatment.

(2) The holder of an approved application for the export of a drug or device under this subsection shall report to the Secretary—

(A) the receipt of any credible information indicating that the drug or device is being or may have been exported from a country for which the Secretary made a finding under paragraph (1)(A) to a country for which the Secretary cannot make such a finding; and

(B) the receipt of any information indicating adverse reactions to such drug.

(3)(A) If the Secretary determines that—

(i) a drug or device for which an application is approved under paragraph (1) does not continue to meet the requirements of such paragraph; or

(ii) the holder of an approved application under paragraph (1) has not made the report required by paragraph (2), the Secretary may, after providing the holder of the application an opportunity for an informal hearing, withdraw the approved application.

(B) If the Secretary determines that the holder of an approved application under paragraph (1) or an importer is exporting a drug or device from the United States to an importer and such importer is exporting the drug or device to a country for which the Secretary cannot make a finding under paragraph (1) and such export presents an imminent hazard, the Secretary shall immediately prohibit the export of the drug or device to such importer, provide the person exporting the drug or device from the United States prompt notice of the prohibition, and afford such person an opportunity for an expedited hearing.

(f) A drug or device may not be exported under this section—

(1) if the drug or device is not manufactured, processed, packaged, and held in substantial conformity with current good manufacturing practice requirements or does not meet international standards as certified by an international standards organization recognized by the Secretary;

(2) if the drug or device is adulterated under clause (1)(2)(A), or (3) of section 501(a) or subsection (c) or (d) of section 501;

(3) if the requirements of subparagraphs (A) through (D) of section 801(e)(1) have not been met;

(4)(A) if the drug or device is the subject of a notice by the Secretary or the Secretary of Agriculture of a determination that the probability of reimportation of the exported drug or device would present an imminent hazard to the public health and safety of the United States and the only means of limiting the hazard is to prohibit the export of the drug or device; or

(B) if the drug or device presents an imminent hazard to the public health of the country to which the drug or device would be exported;

(5) if the labeling of the drug or device is not—

(A) in accordance with the requirements and conditions for use in—

(i) the country in which the drug or device received valid marketing authorization under subsection (b); and
(ii) the country to which the drug or device would be exported; and

(B) in the language and units of measurement of the country to which the drug or device would be exported or in the language designated by such country; or

(6) if the drug or device is not promoted in accordance with the labeling requirements set forth in paragraph (5).

In making a finding under paragraph (4)(B), (5), or (6) the Secretary shall consult with the appropriate public health official in the affected country.

(g) The exporter of a drug or device exported under subsection (b)(1) shall provide a simple notification to the Secretary identifying the drug or device when the exporter first begins to export such drug or device to any country listed in clause (i) or (ii) of subsection (b)(1)(A). When an exporter of a drug or device first begins to export a drug or device to a country which is not listed in clause (i) or (ii) of subsection (b)(1)(A), the exporter shall provide a simple notification to the Secretary identifying the drug or device and the country to which such drug or device is being exported. Any exporter of a drug or device shall maintain records of all drugs or devices exported and the countries to which they were exported.

(h) For purposes of this section—

(1) a reference to the Secretary shall in the case of a biological product which is required to be licensed under the Act of March 4, 1913 (37 Stat. 832-833) (commonly known as the Virus-Serum Toxin Act) be considered to be a reference to the Secretary of Agriculture, and

(2) the term "drug" includes drugs for human use as well as biologicals under section 351 of the Public Health Service Act or the Act of March 4, 1913 (37 Stat. 832-833) (commonly known as the Virus-Serum Toxin Act).

(i) Insulin and antibiotic drugs may be exported without regard to the requirements in this section if the insulin and antibiotic drugs meet the requirements of section 801(e)(1).

OFFICE OF INTERNATIONAL RELATIONS

SEC. 803. [21 U.S.C. 383] (a) There is established in the Department of Health and Human Services an Office of International Relations.

(b) In carrying out the functions of the office under subsection (a), the Secretary may enter into agreements with foreign countries to facilitate commerce in devices between the United States and such countries consistent with the requirements of this Act. In such agreements, the Secretary shall encourage the mutual recognition of—

(1) good manufacturing practice regulations promulgated under section 520(f), and

(2) other regulations and testing protocols as the Secretary determines to be appropriate.

(c)(1) The Secretary shall support the Office of the United States Trade Representative, in consultation with the Secretary of Commerce, in meetings with representatives of other countries to discuss methods and approaches to reduce the burden of regulation and harmonize regulatory requirements if the Secretary determines that such harmonization continues consumer protections consistent with the purposes of this Act.
(2) The Secretary shall support the Office of the United States Trade Representative, in consultation with the Secretary of Commerce, in efforts to move toward the acceptance of mutual recognition agreements relating to the regulation of drugs, biological products, devices, foods, food additives, and color additives, and the regulation of good manufacturing practices, between the European Union and the United States.

(3) The Secretary shall regularly participate in meetings with representatives of other foreign governments to discuss and reach agreement on methods and approaches to harmonize regulatory requirements.

(4) The Secretary shall, not later than 180 days after the date of enactment of the Food and Drug Administration Modernization Act of 1997, make public a plan that establishes a framework for achieving mutual recognition of good manufacturing practices inspections.

(5) Paragraphs (1) through (4) shall not apply with respect to products defined in section 201(ff).


(a) DEFINITIONS—In this section:

(1) IMPORTER—The term "importer" means a pharmacist or wholesaler.

(2) PHARMACIST.—The term "pharmacist" means a person licensed by a State to practice pharmacy, including the dispensing and selling of prescription drugs.

(3) PRESCRIPTION DRUG.—The term "prescription drug" means a drug subject to section 503(b), other than—

(A) a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));

(B) a biological product (as defined in section 351 of the Public Health Service Act (42 U.S.C. 262));

(C) an infused drug (including a peritoneal dialysis solution);

(D) an intravenously injected drug;

(E) a drug that is inhaled during surgery; or

(F) a drug which is a parenteral drug, the importation of which pursuant to subsection (b) is determined by the Secretary to pose a threat to the public health, in which case section 801(d)(1) shall continue to apply.

(4) QUALIFYING LABORATORY.—The term "qualifying laboratory" means a laboratory in the United States that has been approved by the Secretary for the purposes of this section.

(5) WHOLESALE.—

(A) IN GENERAL.—The term "wholesaler" means a person licensed as a wholesaler or distributor of prescription drugs in the United States under section 503(e)(2)(A).
(B) EXCLUSION.--The term "wholesaler" does not include a person authorized to import drugs under section 801(d)(1).

(b) REGULATIONS.--The Secretary, after consultation with the United States Trade Representative and the Commissioner of Customs, shall promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States.

(c) LIMITATION.--The regulations under subsection (b) shall—

(1) require that safeguards be in place to ensure that each prescription drug imported under the regulations complies with section 505 (including with respect to being safe and effective for the intended use of the prescription drug), with sections 501 and 502, and with other applicable requirements of this Act;

(2) require that an importer of a prescription drug under the regulations comply with subsections (d)(1) and (e); and

(3) contain any additional provisions determined by the Secretary to be appropriate as a safeguard to protect the public health or as a means to facilitate the importation of prescription drugs.

(d) INFORMATION AND RECORDS.—

(1) IN GENERAL.--The regulations under subsection (b) shall require an importer of a prescription drug under subsection (b) to submit to the Secretary the following information and documentation:

(A) The name and quantity of the active ingredient of the prescription drug.
(B) A description of the dosage form of the prescription drug.
(C) The date on which the prescription drug is shipped.
(D) The quantity of the prescription drug that is shipped.
(E) The point of origin and destination of the prescription drug.
(F) The price paid by the importer for the prescription drug.
(G) Documentation from the foreign seller specifying—

(i) the original source of the prescription drug; and

(ii) the quantity of each lot of the prescription drug originally received by the seller from that source.

(H) The lot or control number assigned to the prescription drug by the manufacturer of the prescription drug.

(I) The name, address, telephone number, and professional license number (if any) of the importer.

(J) In the case of a prescription drug that is shipped directly from the first foreign recipient of the prescription drug from the manufacturer:

(I) Documentation demonstrating that the prescription drug was received by the recipient from the manufacturer and subsequently shipped by the first foreign recipient to the importer.

(II) Documentation of the quantity of each lot of the prescription drug received by the first foreign recipient demonstrating that the quantity being imported into the United States is not more than the quantity that was received by the first foreign recipient.

(III) In the case of an initial imported shipment, documentation demonstrating that each batch of the prescription drug in the shipment was statistically sampled and tested for authenticity and degradation.
(bb) In the case of any subsequent shipment, documentation demonstrating that a statistically valid sample of the shipment was tested for authenticity and degradation.

(ii) In the case of a prescription drug that is not shipped directly from the first foreign recipient of the prescription drug from the manufacturer, documentation demonstrating that each batch in each shipment offered for importation into the United States was statistically sampled and tested for authenticity and degradation.

(K) Certification from the importer or manufacturer of the prescription drug that the prescription drug--

(i) is approved for marketing in the United States and is not adulterated or misbranded; and

(ii) meets all labeling requirements under this Act.

(L) Laboratory records, including complete data derived from all tests necessary to ensure that the prescription drug is in compliance with established specifications and standards.

(M) Documentation demonstrating that the testing required by subparagraphs (J) and (L) was conducted at a qualifying laboratory.

(N) Any other information that the Secretary determines is necessary to ensure the protection of the public health.

(2) MAINTENANCE BY THE SECRETARY.—The Secretary shall maintain information and documentation submitted under paragraph (1) for such period of time as the Secretary determines to be necessary.

(e) TESTING.—The regulations under sub section (b) shall require—

(1) that testing described in sub paragraphs (J) and (L) of subsection (d)(1) be conducted by the importer or by the manufacturer of the prescription drug at a qualified laboratory;

(2) if the tests are conducted by the importer—

(A) that information needed to—

(i) authenticate the prescription drug being tested; and

(ii) confirm that the labeling of the prescription drug complies with labeling requirements under this Act; be supplied by the manufacturer of the prescription drug to the pharmacist or wholesaler; and

(B) that the information supplied under subparagraph (A) be kept in strict confidence and used only for purposes of testing or otherwise complying with this Act; and

(3) may include such additional provisions as the Secretary determines to be appropriate to provide for the protection of trade secrets and commercial or financial information that is privileged or confidential.

(f) REGISTRATION OF FOREIGN SELLERS.—Any establishment within Canada engaged in the distribution of a prescription drug that is imported or offered for importation into the United States shall register with the Secretary the name and place of business of the establishment and the name of the United States agent for the establishment.
(g) SUSPENSION OF IMPORTATION.--The Secretary shall require that importations of a specific prescription drug or importations by a specific importer under subsection (b) be immediately suspended on discovery of a pattern of importation of that specific prescription drug or by that specific importer of drugs that are counterfeit or in violation of any requirement under this section, until an investigation is completed and the Secretary determines that the public is adequately protected from counterfeit and violative prescription drugs being imported under subsection (b).

(h) APPROVED LABELING.--The manufacturer of a prescription drug shall provide an importer written authorization for the importer to use, at no cost, the approved labeling for the prescription drug.

(i) CHARITABLE CONTRIBUTIONS.--Notwithstanding any other provision of this section, section 801(d)(1) continues to apply to a prescription drug that is donated or otherwise supplied at no charge by the manufacturer of the drug to a charitable or humanitarian organization (including the United Nations and affiliates) or to a government of a foreign country.

(j) WAIVER AUTHORITY FOR IMPORTATION BY INDIVIDUALS.---

(1) DECLARATIONS.--Congress declares that in the enforcement against individuals of the prohibition of importation of prescription drugs and devices, the Secretary should—

(A) focus enforcement on cases in which the importation by an individual poses a significant threat to public health; and

(B) exercise discretion to permit individuals to make such importations in circumstances in which—

(i) the importation is clearly for personal use; and

(ii) the prescription drug or device imported does not appear to present an unreasonable risk to the individual.

(2) WAIVER AUTHORITY.—

(A) IN GENERAL.--The Secretary may grant to individuals, by regulation or on a case-by-case basis, a waiver of the prohibition of importation of a prescription drug or device or class of prescription drugs or devices, under such conditions as the Secretary determines to be appropriate.

(B) GUIDANCE ON CASE-BY-CASE WAIVERS.—The Secretary shall publish, and update as necessary, guidance that accurately describes circumstances in which the Secretary will consistently grant waivers on a case-by-case basis under subparagraph (A), so that individuals may know with the greatest practicable degree of certainty whether a particular importation for personal use will be permitted.

(3) DRUGS IMPORTED FROM CANADA.--In particular, the Secretary shall by regulation grant individuals a waiver to permit individuals to import into the United States a prescription drug that—

A. is imported from a licensed pharmacy for personal use by an individual, not for resale, in quantities that do not exceed a 90-day supply;

B. is accompanied by a copy of a valid prescription;

C. is imported from Canada, from a seller registered with the Secretary;

D. is a prescription drug approved by the Secretary under chapter V;

E. is in the form of a final finished dosage that was manufactured in an establishment registered under section 510; and
F. is imported under such other conditions as the Secretary determines to be necessary to ensure public safety.

(k) CONSTRUCTION—Nothing in this section limits the authority of the Secretary relating to the importation of prescription drugs, other than with respect to section 801(d)(1) as provided in this section.

(l) EFFECTIVENESS OF SECTION.—

(1) COMMENCEMENT OF PROGRAM.—This section shall become effective only if the Secretary certifies to the Congress that the implementation of this section will—

(A) pose no additional risk to the public’s health and safety; and

(B) result in a significant reduction in the cost of covered products to the American consumer.

(2) TERMINATION OF PROGRAM.—

(A) IN GENERAL.—If, after the date that is 1 year after the effective date of the regulations under subsection (b) and before the date that is 18 months after the effective date, the Secretary submits to Congress a certification that, in the opinion of the Secretary, based on substantial evidence obtained after the effective date, the benefits of implementation of this section do not outweigh any detriment of implementation of this section, this section shall cease to be effective as of the date that is 30 days after the date on which the Secretary submits the certification.

(B) PROCEDURE.—The Secretary shall not submit a certification under subparagraph (A) unless, after a hearing on the record under sections 556 and 557 of title 5, United States Code, the Secretary—

(i) (i) determines that it is more likely than not that implementation of this section would result in an increase in the risk to the public health and safety;

(ii) identifies specifically, in qualitative and quantitative terms, the nature of the increased risk;

(iii) identifies specifically the causes of the increased risk; and

(iv) (aa) considers whether any measures can be taken to avoid, reduce, or mitigate the increased risk; and

(bb) if the Secretary determines that any measures described in item (aa) would require additional statutory authority, submits to Congress a report describing the legislation that would be required;

(ii) identifies specifically, in qualitative and quantitative terms, the benefits that would result from implementation of this section (including the benefit of reductions in the cost of covered products to consumers in the United States, allowing consumers to procure needed medication that consumers might not otherwise be able to procure without foregoing other necessities of life); and

(iii) (i) compares in specific terms the detriment identified under clause (i) with the benefits identified under clause (ii); and

(ii) determines that the benefits do not outweigh the detriment.
(m) **AUTHORIZATION OF APPROPRIATIONS.**--There are authorized to be appropriated such sums as are necessary to carry out this section. ([www.fda.gov](http://www.fda.gov))

### 2.2 EUROPE: European Regulatory Structure

**Treaties:** Signed by all Member States.

**Directives:** Defines objectives to be achieved. Member States have to define compliance in their own law.

**Regulations:** Directly applicable to all Member States.

**Decisions:** Applicable to a specific case, person, organisation...

**Opinions:** Does not need to be enforced, but MSs can use them to support national law.

**Manufacturing authorization:** Granted by the Competent Authorities of each member state for all manufacturing activities (including import) occurring in their territory.

- Regardless as to which marketing authorization procedure the products concerned are subject to.

- **A Manufacturing authorisation is also required for products produced solely for export.**

- Manufacturing authorisations follow a Community format and are mutually recognised by all Member States.

**Supervisory authority:** The competent authority that grants the manufacturing authorisation. For third country imports, the competent authority that grants the manufacturing authorisation to the importer.


### 2.2.1 UNITED KINGDOM

The Medicines Act contains certain important exemptions from licensing. One of these exemptions is for the importation and supply of unlicensed relevant medicinal products for individual patients; and herbal remedies exemptions.

**Before a medicine can be placed on the UK market it must have a licence (marketing authorisation) already granted, setting out its agreed terms and conditions of use such as indications and dosage. Obviously there are products where it is not easy to distinguish a medicine from, for example, cosmetics or food supplements. This section helps describe how a medicine is defined and how the Agency deals with such products that appear to fall within this borderline.**

This section describes how a medicinal product is defined and how the MHRA determines whether a product falls within that definition explains what borderline products are and gives an overview of the borderline legislation which came into force on 1 March 2000.

**What is a medicine?**
Article 1 of Directive 2001/83/EC as amended defines a "medicinal product" as:

"Any substance or combination of substances presented as having properties for treating or preventing disease in human beings;"

Medicine Act 1908

7.- (1) the following provisions of this section shall have general effect subject to provisions as

(a) Any exemption conferred by or under this Part of this relating to Medicinal Act

(b) the provisions of this Part of this Act relating to clinical trials and medicinal tests on animals; and

(c) the provisions of section 48 of this Act.

(2) Except in accordance with a licence granted for the purposes of this section (in this Act referred to as a 'product licence') no person shall, in the course of a business carried on by him, and in circumstances to which this subsection applies,-

(a) sell, supply or export any medicinal product, or

(b) procure the sale, supply or exportation of any medicinal product, or

(c) procure the manufacture or assembly of any medicinal product for sale, supply or exportation.

(3) No person shall import any medicinal product except in accordance with a product licence.

(4) In relation to an imported medicinal product, subsection (2) of this section applies to circumstances in which the person selling, supplying or exporting the medicinal product in question, or procuring the sale, supply or exportation or the manufacture or assembly for sale, supply or exportation of that product, has himself imported the product or procured its importation.

(5) In relation to any medicinal product which has not been imported, subsection (2) of this section applies to any circumstances in which the person selling, supplying or exporting the medicinal product in question, or procuring the sale, supply or exportation or the manufacture or assembly for sale, supply or exportation of that product, is responsible for the composition of the product.

(6) For the purposes of subsection (5) of this section a person shall be taken to be responsible for the composition of a medicinal product if (but only if) in the course of a business carried on by him-

(a) he procures the manufacture of the product to his order by another person, where the order specifies, or incorporates by reference to some other document, particulars of the composition of the product ordered, whether those particulars amount to a complete specification or not, or

(b) he manufactures the product otherwise than in pursuance of an order which fulfills the conditions specified in the preceding paragraph.

Importing medicinal products holding marketing authorisations within the EU. Importation from another EU Member State is considered to be ‘wholesale distribution’, for which a Wholesale dealer’s licence is required. (Medicines Act Section 8 [external link] and The Medicines for Human Use [Manufacturing, Wholesale Dealing and Miscellaneous Amendments] Regulations 2005 No. 2789

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A medicinal product may be imported into the UK in accordance with the rules of the European Commission relating to parallel imports. In such cases, a marketing authorisation must be held in the UK before such a product can be placed on the market – a parallel import licence.

**Imports from non EU/European Economic Area (EEA) countries:** Medicinal products from outside the EU must conform to Good Manufacturing Practices at least equivalent to EU standards. The importer must hold a manufacturer’s licence covering importation (Medicines Act Section 8 and The Medicines for Human Use [Manufacturing, Wholesale Dealing and Miscellaneous Amendments] Regulations 2005 No. 2789).

**Parallel Importing:** Parallel Importing (also known as parallel distribution) occurs when a product placed on the market in one country is bought by an intermediary who exports it to another country, without permission of the marketing authorisation holder. Parallel Importing is permitted between EU Member States and occurs where products are priced differently in each country.

Parallel imports must be manufactured to GMP standards, the importer must hold a wholesale dealer’s licence covering importation, storage and release and a manufacturer’s licence covering assembly to enable the re-packaging and re-labelling of products.

The requirements relating to parallel imports are described in the Commission Communication on Parallel Imports: COM(2003) 839 Final.

To ensure that the imported product complies with UK national regulations, companies wishing to import medicinal products on this basis must apply for a licence for each individual product and the importer must hold the relevant Wholesale Dealers' licence. The MHRA operates a simplified procedure to approve authorisations for parallel importation.

**Parallel import licences**

**Unlicensed Medicinal Products:** Import of unlicensed medicines may be necessary if there is no UK licensed equivalent suitable for an individual patient. Unlicensed medicines.

The importer must hold a Wholesale Dealer's Licence which specifies that it covers unlicensed relevant medicinal products.

The relevant legislation is The Medicines for Human Use [Manufacturing, Wholesale Dealing and Miscellaneous Amendments] Regulations 2005 No. 2789. The European legal basis for this is Article 5 of Directive 2001/83/EC.

**Exports:** Exporting to another EU Member State is considered to be wholesale distribution as described in the importing section above. If any assembly activity is required, then a Manufacturer’s Licence would be required as well. Guidance is available to exporters.

**Trading medicines for human use: Shortages and supply chain obligations**

To export to countries outside the EU, the destination country will usually require evidence of the marketing authorisation and/or manufacturing status in the country of origin. The MHRA can provide the following types of export certificate:

- Certificate of a Pharmaceutical Product - which conforms to the WHO Export Certificate
• Certificate of Manufacturing Status
• Certificate of Licensing Status
• Certificate of Pharmaceutical Constituent.

Further details and forms are available in the Exporting Medicines section of the website.

Exporting Medicines Related Information: The MHRA, on behalf of the Department of Health, issues export certificates on request to assist exporters of medicinal products to satisfy the import requirements of other countries. The certificates issued by MHRA indicate whether the product or manufacturer to which the certificate applies has met statutory requirements. Where necessary, the format of certificates complies with that specified by international authorities, for example, the World Health Organisation (WHO) and the MHRA will not deviate from the agreed format. Details about charges for issuing certificates, further details about the certificates available and forms to make applications are available in this section.

While issuing of certificates is managed by MHRA, the requirement for having a certificate is not - it is determined by the importing country. As such, the MHRA has no legislative authority over the requirements of the importing country and cannot specify whether or not certificates are needed.

Guidance published on UK exporting of medicines - 13 November 2009: Guidance helping pharmaceutical manufacturers and distributors to meet their obligations regarding the supply of medicines has been jointly published by nine organisations including the MHRA. The new guidance aims to reduce future problems with the export of medicines for profit by setting out the key legal and ethical obligations for manufacturers, wholesalers, NHS Trusts, registered pharmacies and dispensing doctors in relation to the supply and trading of medicines.

Trading Medicines for human use shortages and supply chain obligations

Information on types of export certificates: The MHRA issues four different types of export certificates, two of which comply with the format established by the WHO and reflect UK participation in the WHO scheme. Each type of certificate is country specific, naming one individual country - the EU is not acceptable as a one-country unit. The fee charged is the same for each type of certificate but varies dependant on the service level (24-hour or five-day turnaround) requested and the number of original copies required. Details about charges for issuing certificates can be found in our licensing fees section. The certificates that can be supplied are:

Certificate of a pharmaceutical product (CPP): This certificate complies with the format specified by WHO. The certificate will provide details about a single named medicinal product which may be licensed or unlicensed in the UK. It provides details about the product and its manufacture including (but not limited to) the marketing authorisation (MA) holder, the active ingredients and excipients, the manufacturing and packaging sites and whether or not the product is placed on the market in the UK. CPPs for licensed products are generally but not exclusively, applied for by the marketing authorisation holder. For the MHRA to issue a certificate to an applicant other than the marketing authorisation holder written permission from the marketing authorisation holder will be required before the application can be accepted.

Certificate of licensing status (CLS): This certificate complies with the format specified by the WHO. It is intended for use by importing agents who are required to screen bids made in response to an international tender and can apply to licensed or unlicensed products. It provides less information than the CPP and can include a maximum of ten products per certificate.
Certificate of manufacturing status (CMS): Does not provide any product specific information, but it confirms whether named sites meet Good Manufacturing Practice (GMP) requirements on a specified manufacturing licence number. All or any of the sites named on the manufacturing licence may be listed on the certificate.

Certificate for the importation of a pharmaceutical constituent (CPC): Is available for a named constituent of a medicinal product. The MHRA will only issue certificates for unlicensed medicinal products that are manufactured in the UK on a site holding a manufacturer's licence appropriate to the dosage form of the product for which the certificate applies. If an application is made for a certificate for a medicinal product that is not manufactured in the UK it will only be issued if the product has a UK (not EMEA) product licence. It is not possible to issue a certificate for unlicensed products manufactured outside the UK.

The European Medicines Agency (EMEA)
7 Westferry Circus, Canary Wharf, London E14 4HB
Tel: 020 7418 8400
Website: http://www.emea.europa.eu/ (external link)

Export certificate application forms

Export certificate forms

Certificate of pharmaceutical product (Licenced products): Guidance notes for completion of application form
Certificate of pharmaceutical products (unlicenced products): Guidance notes for completion of application form
Certificate of manufacturing status, guidance notes for completion of application form
Statement of licencing status of pharmaceutical products: Guidance notes for completion of application form
Certificate for the importation of a pharmaceutical constituent, guidance notes for the completion of application form

Information for completion of export certificate application forms: The certificate of a pharmaceutical product (CPP) requires the most detailed information. All forms ask for date of application, your reference, your name and business name and address, invoice details if different from the applicant's, name of importing country, standard or urgent service, language and number of copies required.

The CPP is usually applied for by the marketing authorisation holder. This is not mandatory but if you are not the MA holder you must submit authorisation from the MA holder permitting you to export on their behalf. It must be on headed paper, should stipulate the product or give open authorisation for all products. It can specify a date range within which applications are acceptable or can be open ended.

The MA/PL number must be quoted along with the name and dosage form of the product. A certificate can only state one strength. A product may be registered under several names but only one name can be quoted on the certificate. However, a different name may be quoted in the importing country. If the name in the importing country is the same as the registered name it is not necessary to complete this box on the application form (1.8).
The list of actives and excipients and their full quantitative formulation must be as detailed against the MA/PL number. Any variations to the MHRA database will be queried and it may be necessary to submit a copy of the licence or MHRA variation letter to support any differences. It is optional whether the amounts of the excipients appear on the certificate but they must be quoted on the application form.

The status of the MA holder can only be a, b or c. The fourth option, d, is only available to applicants of unlicensed products. The MA holder is considered to be ultimately responsible even if they are not involved in the manufacture or packaging processes. If option a applies the applicant should complete section 3.4 but the name and address will not be stated again on the certificate. If option b applies and there is more than one manufacturer the applicant can opt whether to have one or more manufacturers listed. If there are more packagers the applicant can choose which to include. If option c applies and there are multiple manufacturers or packagers the applicant can opt which ones to include on the certificate. The applicant can also opt whether to name the manufacturing licence holder provided it is a UK licence holder. Overseas licence holders cannot be quoted.

The unlicensed CPP is very similar but without the requirements of a MA/PL number and MA holder details. Also the manufacturing site must be located in the UK and hold a current manufacturer’s licence. The certificate of manufacturing status requires the manufacturing licence holder number - this must be a UK licence holder, an overseas licence number is not acceptable. If more than one site is included on the licence the applicant can select which or all of the sites to include on the certificate.

The certificate of licensing status is limited to ten products per certificate and is country specific. Details of the product name, dosage form, active ingredients and amounts should all be quoted in accordance with their product licence (if applicable) and these details will be checked against the MHRA database. Any differences will be queried and will need to be verified.

The certificate for the importation of a pharmaceutical constituent is country and ingredient specific. The specific active or excipient must be included as an ingredient in a current licensed medicinal product or the material must be included in a national or international pharmacopoeia, the specification being equivalent to that monograph. A schedule and certificate of analysis will be attached to each certificate.

**Quick guide to licence / certificate requirements:**

- If you are a manufacturer sending licensed pharmaceutical goods abroad
  - an export certificate may be required by the importing country. You should check with the appropriate embassy.
  - If you buy and distribute licensed or unlicensed* pharmaceutical products within the UK
    - wholesale dealer’s licence is required
  - If you buy licensed or unlicensed* pharmaceutical products outside the UK or EEA and distribute within the UK
    - wholesale dealer’s import licence is required.

*Unlicensed pharmaceutical products are subject to the provisions of the 1999 Statutory Instrument No. 4. Further details can be found in the interim Guidelines on the Import and Supply of Unlicenced Medicinal Products.

Individuals looking to export over-the-counter medicinal products. Distributing to countries in the EEA will require a wholesale dealer’s licence, exporting to third countries may not but if products need to be distributed.
stored a licence may be required. Please see 'Manufacturer's and wholesale dealer's licences' section for details of wholesale dealer's and wholesale dealer's import licences.

Contacts for further information: email info@mhra.qsi.gov.uk.

Investigational medicinal products: The manufacture and/or importation of investigational medicinal products requires a manufacturing licence (MIA[IMP]). The licence is also required if products manufactured in the UK are to be exported to third countries for use in clinical trials.

Manufacturers and Wholesale Dealers licences

Herbal medicines: There are three possible routes for herbal medicines to be placed on the UK market:

1. as an unlicensed herbal remedy (no longer applicable after 2011)
2. registered under the Traditional Herbal Medicines Registration Scheme
3. licensed with a marketing authorisation as a herbal medicine. Full details of these alternative routes and the relevant legislation are available on the website.

Placing a herbal medicine on the UK market

Homeopathic medicines: A homeopathic medicinal product is defined in European legislation (Article 1(5) of Directive 2001/83/EC (external link) as amended by 2004/27/EC as:

'Any medicinal product prepared from substances called homoeopathic stocks in accordance with a homoeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in the Member States. A homoeopathic medicinal product may contain a number of principles'.

Currently, there are two ways in which new homeopathic products may be registered in the UK.

1. the Simplified Scheme.
2. the National Rules Scheme (in operation since September 2006).

The Simplified Scheme: In 1992, Directive 92/73/EC (external link) introduced a Simplified Scheme for homeopathic products. It is regarded as simplified because although the safety and quality of products has to be demonstrated, products are not permitted to make medical claims.

The scheme is restricted to products for oral and external use and does not allow indications (the descriptions of diseases or conditions for which the medicine is intended to be used).

In order to qualify for registration, the products must:

- be for oral or external use - this includes all methods of administration with the exception of injections
- be sufficiently dilute to guarantee their safety
- make no therapeutic claims.
The National Rules Scheme: The purpose of the scheme is to enable homeopathic medicinal products to be registered with indications for the relief or treatment of minor symptoms and conditions (those that can ordinarily be relieved or treated without the supervision or intervention of a doctor).

Applications under the National Rules Scheme must be supported by a dossier of data on quality, safety and efficacy, together with appropriate product labelling and product literature. Guidance documents on both schemes are available on the website, (www.mhra.gov.uk)

2.2.2 GERMANY

Authorisation, Registration, and Risk Monitoring of Medicinal Products: Since 1978, finished medicinal products have been required to undergo an authorisation procedure before they can be placed on the market. The pharmaceutical companies must provide proof of the pharmaceutical quality, efficacy, and safety of the product. If they fail to do so the BfArM refuses authorisation.

After a period of 5 years, marketing authorisation must be renewed by the BfArM. Renewal of authorisation will be granted provided the pharmaceutical company files an application for renewal in due time and a new review shows that there are no objections.

Variations to already authorised medicinal products have to be notified to the BfArM. Significant variations to medicinal products may be implemented after authorisation by the BfArM only.

Homoeopathic medicinal products only need to be registered, provided that no indication claims are made for them and that adequate quality is demonstrated. If indication claims are made the homoeopathic medicinal product has to be authorised. The BfArM is also involved in authorisation procedures for medicinal products in the European Union.

According to Section 55 German Medicines Act (Arzneimittelgesetz) reference can be made to the pharmacopoeia in the course of authorisation of finished drugs and registration of homoeopathic medicinal products. This serves as a relief to both industry and authorities. The pharmacopoeia is a collection of quality specifications which is continuously updated and consists of the German, the European, and the Homoeopathic Pharmacopoeia. The European Pharmacopoeia contributes considerably to the international harmonisation of quality specifications.

If a medicinal product is marketed after authorisation and is used by many patients, rare adverse effects may be detected which had not attracted attention before. The BfArM collects and verifies such reports forwarded by German physicians and pharmaceutical companies. The BfArM decides whether the SPC and the Package Leaflet need to be changed in order to allow for such risks. Should identified adverse effects of a medicinal product prove to be severe or occur frequently so that they exceed the benefit the BfArM withdraws the license. In the course of determination, evaluation, and prevention of drug-related risks the BfArM communicates constantly with other European authorities and the World Health Organisation (WHO).

Authorisation Procedures: Apart from the national authorisation procedures in Germany, new authorisation procedures have been created on the basis of regulations and directives of the European Commission. A Centralised Procedure (CP) affects a license throughout the EU. In order to obtain a license within more than one EU country at the same time the applicant has to initiate a so-called "Decentralised Procedure" (DCP) or apply for a "Mutual Recognition Procedure" (MRP).

National Authorisation Procedures: In Germany, finished medicinal products are only to be put into
circulation after having been authorised (Section 21 sub-section 1 German Medicines Act, AMG) or registered (Section 38 sub-section 1 AMG respectively Section 39a AMG) by the competent higher federal authority.

The competent authority for human medicinal products is the BfArM, while sera, vaccines, test allergens, test sera and test antigens as well as blood preparations are the responsibility of the ‘Paul-Ehrlich-Institut’ in Langen. Veterinary medicinal products are authorised by the Federal Agency of Consumer Protection and Food Safety in Bonn. In order to apply for a marketing authorisation for a finished medicinal product the appropriate application form is to be used:

The necessary forms and annotations to the application as well as the text of the German Medicines Act can be obtained from the Bundesanzeiger-Verlagsgesellschaft mbH, Postfach 10 05 34, 50445 Köln, the latter is also available at bookshops.

**Centralised Authorisation Procedures:** In this type of procedure, authorisation of medicinal products is not granted by a national agency but by the European Commission in Brussels. The organisational process is handled by the EMEA in London. The submitted documentation is reviewed by the scientists from the licensing agencies of the EU Member States, among them those of the BfArM.

**Decentralised Authorisation Procedures:** If a medicinal product has not yet been marketed in any EU Member State it may be recognised by the licensing authorities of other Member States within 210 days. Thereafter, the authorisation will be granted unless one of the CMS determines “serious risks to public health” for the medicinal product.

**Mutual Recognition Procedures:** The marketing authorisation already granted by one EU Member State is to be recognised by the licensing agencies of other Member States within 90 days, unless there are major objections against doing so. The short review periods place a great demand on all those involved in the procedure. (http://www.bfarm.de/cln_012/nn_424928/EN/drugs/drugs-node-en.htm)

**IMPORT AND EXPORT:** Section 72 Import authorization (1) A party wishing to bring medicinal products within the meaning of Section 2 subsection 1 or sub-section 2 no. 1, test sera, test antigens or active substances which are of human, animal or microbial origin and not intended for the manufacture of a medicinal product according to a procedure described in the homeopathic section of the Pharmacopoeia, or active substances manufactured using genetic engineering, as well as other substances of human origin intended for the manufacture of medicinal products, on a commercial or professional basis into the purview of the present Act from countries which are not Member States of the European Communities or other States Parties to the Agreement on the European Economic Area for the purpose of supplying others or for further processing, shall require an authorisation by the competent authority. Section 13 sub-section 1 sentence 2 and sub-section 4 and Sections 14 to 20a shall apply mutatis mutandis.

(2) A party wishing to bring medicinal products of human origin for direct use in humans into the purview of the present Act from the countries specified in sub-section 1, on a commercial or professional basis, shall also require an authorisation by the competent authority. The authorisation shall be refused if the applicant is unable to show evidence that qualified and experienced personnel are available to assess the quality and safety of the medicinal products according to the state of scientific and technical knowledge.

3) Sub-section 1 shall not apply to tissue within the meaning of Section 1a no. 4 of the Transplantation Act and to tissue preparations within the meaning of Section 20c.
Section 72a Certificates (1) The importer may only introduce medicinal products within the meaning of Section 2 sub-sections 1 and 2 nos. 1, 1a, 2 and 4 which are not intended for clinical trials on human beings, or active substances, from countries which are not Member States of the European Union or other States Parties to the Agreement on the European Economic Area into the purview of the present Act, if:

1. the competent authority of the manufacturing country has confirmed by certificate that the medicinal products or active substances are being manufactured in compliance with the requirements of the recognized Good Practices in the Manufacture and Quality Control of Drugs especially those adopted by the European Communities, the World Health Organization or the Pharmaceutical Inspection Convention, and on condition that such certificates as refer to medicinal products within the meaning of Section 2 sub-sections 1 and 2 no. 1, which are intended for administration to human beings, and active substances which are of human, animal or microbial origin, and are not intended for the manufacture of a medicinal product according to a procedure described in the homeopathic section of the Pharmacopoeia or are active substances manufactured using genetic engineering are mutually recognised,

2. the competent authority has certified that the afore-mentioned requirements have been adhered to in manufacturing the medicinal products and the active substances used in their manufacture in so far as they are of human or animal origin or are manufactured using genetic engineering, or in the manufacture of the active substances, or

1. the competent authority has certified that the import is in the interests of the general public.

The competent authority may only issue a document of certification

a) as specified in number 2, if no certificate pursuant to number 1 exists and it or a competent authority of a Member State of the European Union or of another State Party to the Agreement on the European Economic Area has satisfied itself regularly in the country of manufacture that the above-mentioned requirements are being observed in manufacturing the medicinal products or the active substances,

b) as specified in number 3, if no certificate pursuant to number 1 exists and the granting of a certification as specified in number 2 is not envisaged or not possible.

(1a) Sub-section 1 sentence 1 does not apply to:

1) medicinal products intended for a clinical trial on human subjects,
2) medicinal products of human origin for immediate use, active substances which are of human, animal or microbial origin and are intended for the manufacture of a medicinal product according to a procedure described in the homeopathic section of the Pharmacopoeia,
3) active substances which are or contain substances pursuant to Section 3 no. 2 in unprocessed or processed form, in so far as the processing does not go beyond drying, chopping and initial extraction.

(1b) The provisions laid down in subsection 1 sentence 1 nos. 1 and 2 for active substances of human, animal or microbial origin or for active substances manufactured using genetic engineering shall apply mutatis mutandis to other substances of human origin intended for the manufacture of medicinal products.
(1c) Medicinal products and active substances of human, animal or microbial origin or active substances manufactured using genetic engineering as well as other substances of human origin intended for the manufacture of medicinal products with the exception of those medicinal products specified in sub-section 1a nos. 1 and 2, may not be imported on the basis of a certificate pursuant to sub-section 1 sentence 1 no. 3.

(1d) Sub-section 1 sentence 1 shall be applicable to the import of active substances as well as other substances of human origin intended for the manufacture of medicinal products, in so far their supervision is regulated by an ordinance pursuant to Section 54.

(2) The Federal Ministry is hereby empowered to mandate, by ordinance subject to the approval of the Bundesrat, that substances and preparations from substances which can be used as medicinal products or in the manufacture of medicinal products may not be imported from certain countries which are not Member States of the European Union or other States Parties to the Agreement on the European Economic Area, in so far as this is necessary to prevent hazards to human health or for the purpose of taking precautions against risks.

(3) The Federal Ministry is hereby also empowered to specify, by means of ordinance with the approval of the Bundesrat, the additional requirements for the import of the medicinal products specified under sub-section 1a nos. 1 and 2 from countries which are not Member States of the European Union or other States Parties to the Agreement on the European Economic Area, in so far as necessary to ensure that the medicinal products are of proper quality. In this context, the Ministry can lay down regulations, in particular, which govern the tests to be carried out by the competent person pursuant to Section 14 and the possibility of supervision by the competent authority of the manufacturing country.

(4) Sub-section 1 shall not apply to tissues within the meaning of Section 1a no. 4 of the Transplantation Act and to tissue preparations within the meaning of Section 20c.

Section 72b Import authorisations and certificates for tissues and specific tissue preparations:

(1) Any person who intends to import, from a country which is not a Member State of the European Union or a State Party to the Agreement on the European Economic Area, tissues within the meaning of Section 1a no. 4 of the Transplantation Act or tissue preparations within the meaning of Section 20c, on a commercial or professional basis, for the purpose of distribution to others or for processing into the territory governed by the present Act, shall require an authorisation to do so from the competent authority. Section 20c sub-section 1 sentence 3 and sub-sections 2 to 7 shall apply mutatis mutandis.

(2) The importer pursuant to sub-section 1 may only import tissues or tissue preparations into the territory governed by the present Act if:

1. the authorities of the country of origin have confirmed in a certificate that the removal or processing and the laboratory tests were conducted according to standards which are at least equivalent to the Standards of Good Practice laid down by the Community, and such certificates are mutually recognised, or

2. the authority responsible for the importer certifies that the basic rules specified for the removal and processing of tissues as well as for laboratory tests are being observed after that authority or a competent authority of another Member State of the European Union, or a State Party to the Agreement on the European Economic Area has satisfied itself, in the country of origin, that the Standards of Good Practice are being observed in the removal or processing of tissues, or
3. the authority responsible for the importer has certified that importing is in the public interest, if a certificate pursuant to number 1 is not available and an attestation pursuant to number 2 is not possible.

By way of derogation from sentence 1 no. 2, the competent authority can dispense with an inspection of the removal facility in the country of origin if the documents submitted by the importer give no reason for complaint or if his/her facilities or factory sites, as well as the quality assurance system of the party procuring the tissue in the country of origin, is already known to them.

(3) The Federal Ministry is hereby empowered to stipulate the additional requirements for the import of tissues or tissue preparations pursuant to sub-section 2, by ordinance subject to the approval of the Bundesrat, so as to guarantee that tissues and tissue preparations are of proper quality. It can lay down, in particular, regulations concerning the tests to be conducted by the responsible person pursuant to Section 20c and the conduct of surveillance in the country of origin by the competent authority.

(4) Sub-section 2 sentence 1 shall apply to the import of tissues and tissue preparations within the meaning of sub-section 1, in so far as its surveillance is regulated by an ordinance pursuant to Section 54, Section 12 of the Transfusion Act or pursuant to Section 16a of the Transplantation Act.

Section 73

Prohibition of introduction: (1) Medicinal products which are subject to compulsory marketing authorisation or registration may only be introduced into the purview of the present Act, with the exception of a free zone of control type I or a bondec warehouse, if they are authorised for marketing or registered within the purview of the present Act or if they have been exempted from the obligation to obtain the marketing authorisation or registration and if:

1. in the case of introduction from a Member State of the European Union or another State Party to the Agreement on the European Economic Area, the recipient is a pharmaceutical entrepreneur, a wholesaler or veterinarian or runs a pharmacy, 1a. in the case of dispatch to the final consumer, the medicinal product is intended for use on or in the human body and is shipped, according to the German regulations governing distance selling or electronic commerce, by a pharmacy of a Member State of the European Union or another State Party to the Agreement on the European Economic Area, which is authorised to conduct distance selling under its national laws, in so far as they correspond to German pharmacy law as regards the provisions governing distance selling, or according to the German Act on Pharmaceutical Services, or

2. in the case of introduction from a country which is not a Member State of the European Union or another State Party to the Agreement on the European Economic Area, the recipient is the holder of an authorisation as specified in Section 72.

The medicinal products specified in Section 47a sub-section 1 sentence 1 shall only be introduced into the purview of the present Act if the recipient is one of the facilities mentioned there. The Federal Ministry shall publish at regular intervals an updated overview of the Member States of the European Union and the other States Party to the Agreement on the European Economic Area, in which safety standards exist with respect to distance selling and electronic commerce in medicinal products which are comparable with those laid down in German law.

(1a) Medicated feedingstuffs may only be introduced into the purview of the present Act if:
1. They comply with the medicinal product-related provisions in force within the purview of the present Act, and

1. The recipient belongs to the group of persons mentioned in sub-section 1, or is an animal keeper in the case of Section 56 sub-section 1 sentence 1.

(2) Sub-section 1 sentence 1 shall not apply to medicinal products which:

1) Are intended, in individual cases and in small amounts, for supplying particular animals with medicinal products at animal shows, tournaments or similar events,

2) Are intended for scientific and research establishments' own requirements and needed for scientific purposes with the exception of medicinal products intended for use in clinical trials on human beings, 2a. are needed in small quantities by a pharmaceutical entrepreneur as samples for inspection or for analysis purposes,

3) Are conveyed under customs supervision through the territory governed by the present Act or are transferred to a bonded warehouse procedure or a free zone of control type II, 3a. are authorised in a Member State of the European Union or another State Party to the Agreement on the European Economic Area and after transit storage with a pharmaceutical entrepreneur or wholesaler, are to be re-exported, shipped onwards or shipped back,

4) Are introduced for the head of state of a foreign country or for his escort and are intended for use during his stay within the purview of the present Act,

5) Are intended for the personal use or consumption of members of diplomatic missions or consular representations within the purview of the present Act or of officials of international organizations located there or of their family members, in so far as these persons are neither German nor have their permanent residence within the purview of the present Act,

6) Are introduced when entering into the purview of the present Act in an amount corresponding to the normal personal requirement, 6a. may be marketed in the country of origin and are purchased, without a commercial or professional intermediary, in a quantity which corresponds to the amount needed for normal personal use in a Member State of the European Union or another State Party to the Agreement on the European Economic Area,

1. Are carried on board any means of transport and are intended exclusively for the use of or consumption by persons conveyed by these means of transport,

2. Are intended for use or consumption on sea-going vessels and are consumed on board ships,

3. Are sent as samples to the competent higher federal authority for the purpose of obtaining a marketing authorisation or for official batch testing,

4. Are procured by federal or Land authorities in interstate commerce.

(3) By way of derogation from sub-section 1 sentence 1, finished medicinal products which are not authorised for marketing or registered for trade within the purview of the present Act or which are not exempted from the obligation to obtain a marketing authorisation or registration, may be introduced into the purview of the present Act if they are authorised for marketing in the State from which they are being introduced into the purview of the present Act and have been ordered by pharmacies or as part of the operation of a veterinary practice dispensary by the veterinarian for the animals treated by him. Pharmacies may obtain such medicinal products, except in cases in which they are ordered on behalf of a veterinarian and dispensed to same,

1) Only in small quantities and upon the specific order of individual persons and dispense them only within the framework of the existing pharmacy operating license and,
a) if they are not medicinal products from Member States of the European Union or other States Parties Agreement on the European Economic Area, may obtain them only on prescription from a doctor or dentist if, with respect to the active substance, no identical medicinal product, and with respect to the strength, no comparable medicinal product are available, within the purview of the present Act, for the field of application in question,

b) if they are medicinal products from Member States of the European Union or other States Parties to the Agreement on the European Economic Area and intended for use on food-producing animals, may obtain them only on prescription by a veterinarian,

2) in so far as they are being held in stock for emergencies according to the provisions of the law on pharmacies or the requirements of occupational accident insurance, or must be procurable at short notice, may only obtain and distribute them within the framework of the normal operation of the pharmacy, if medicinal products for the specific field of application are not available within the purview of the present Act, more detailed particulars shall be settled by the Pharmacies Operation Regulations. Veterinarians and, where medicinal products within the meaning of sentence 1 are ordered on behalf of a veterinarian and dispensed to same, pharmacies may only purchase such medicinal products,

3) if these are medicinal products intended for administration to animals from Member States of the European Union or other States Parties to the Agreement on the European Economic Area, and

4) if within the purview of this Act no suitable authorised medicinal product intended for administration to animals is available to achieve the treatment objective.

Immediately after his order, his instruction and any prescription of a medicinal product according to sentence 3, the veterinary surgeon must notify same to the competent authority pursuant to sentence 5. The notification must state the species and field of application for which the medicinal product is intended, the State from which the medicinal product is brought into the purview of the present Act, the name and quantity of the medicinal product ordered as well as its active substances by type and quantity.

(4) The provisions of the present Act shall not be applicable to medicinal products pursuant to sub-section 2 nos. 4 and 5. The provisions of the present Act shall not be applicable to medicinal products pursuant to sub-section 2 nos. 1 to 3 and 6 to 10 and sub-section 3 sentences 1 and 2 with the exception of Sections 5, 6a, 8, 64 to 59a and 78, and furthermore in the cases referred to in sub-section 2 no. 2 and sub-section 3 sentences 1 and 2 and also with the exception of Sections 48, 95 sub-section 1 nos. 1 and 3a, sub-sections 2 to 4, Section 96 nos. 3, 10 and 11 and Section 97 sub-sections 1, 2 nos. 1 and 9 and sub-section 3 and furthermore in the cases referred to in sub-section 3 sentence 1, also in conjunction with sentence 3, and sentence 2, also with the exception of Sections 56a, 57, 58 sub-section 1 sentence 1, Sections 59, 95 sub-section 1 nos. 6, 8, 9 and 10, Section 96 nos. 15 to 17 and Section 97 sub-section 2 nos. 21 to 24 and 31 and of the ordinance on veterinarian practice dispensers issued on the basis of Section 12 sub-section 1 nos. 1 and 2 and sub-section 2, of Section 48 sub-section 2 no. 4 and sub-section 4 of Section 54 sub-sections 1, 2 and 3 as well of Section 56a subsection 3 and of the ordinance on the obligation to produce supporting documents for medicinal products intended for use on animals issued on the basis of Sections 12, 54 and 57.

(5) When exercising their profession in local border traffic, physicians and veterinarians may only carry medicinal products with them which have been authorised for marketing or registered within the purview of the present Act or which are exempted from the obligation to obtain a marketing authorisation or registration. By way of derogation from sentence 1, veterinarians who render services as nationals of a Member State of the European Union or of another State Party to the Agreement on the European Economic Area, may carry with them small amounts of medicinal products which are authorised for marketing in the place where they are established, in a quantity which is necessary for the performance of the services, and in their original packaging, if and in so far as medicinal products
with the same composition and intended for the same fields of application are also authorised for marketing within the purview of the present Act; the veterinarian may only administer these medicinal products himself and shall inform the animal keeper of the withdrawal period specified for the corresponding medicinal product authorised for marketing within the purview of the present Act.

(6) In the case of sub-section 1 no. 2, as well as sub-section 1a no. 2, in conjunction with sub-section 1 no. 2, the presentation of a certificate issued by the authorities competent in the recipient's case, containing information on the type and quantity of the medicinal product and confirming that the requirements specified in sub-section 1 or sub-section 1a have been met, shall be necessary for customs clearance for free circulation. The customs office shall forward the certificate to the authorities which issued it, at the expense of the party paying the customs duties.

(7) In the case of sub-section 1 no. 1, a recipient who is a wholesaler or who runs a pharmacy shall prove the existence of the provision for coverage pursuant to Section 94.

Section 73a Export: (1) By way of derogation from Sections 5 and 8 sub-sections 1, the medicinal products referred to there may be exported if the competent authority of the country of destination has authorised the import of such medicinal products. The import authorisation must state that the competent authority of the country of destination is cognisant of the grounds for refusal which prevent the marketing of said medicinal products within the purview of the present Act.

(2) The competent authority shall issue a certificate corresponding to the World Health Organization's Certification Scheme. At the request of the pharmaceutical entrepreneur, the manufacturer, the importer or the competent authority of the country of destination. If the request is submitted by the competent authority of the country of destination, the consent of the manufacturer is to be obtained prior to issuing the certificate.

Section 74 Participation of customs offices: (1) The Federal Ministry of Finance and the customs offices specified by it shall participate in the supervision of the introduction of medicinal products and active substances into the purview of the present Act and of the export of the same. The authorities named may

1. retain for inspection consignments of the type named in sentence 1, as well as their means of conveyance, containers, loading and packing material,

2. inform the competent administrative authorities of suspected violations of prohibitions and restrictions of the present Act or of the ordinances issued in accordance with the present Act, if this suspicion becomes evident during customs clearance,

3. issue instructions to the effect that, in instances defined in no. 2, consignments of the type named in sentence 1 shall be presented to a competent medicinal product supervision authority at the cost and at the risk of the person holding the right of disposal of the consignment.

(2) The Federal Ministry for Finance shall settle the details of the procedure indicated in sub-section 1, in agreement with the Federal Ministry, by ordinance not subject to the approval of the Bundesrat. In particular, it may thereby envisage obligations to notify, register, submit information and provide assistance, as well as to tolerate the inspection of business papers and other documents and of premises and the taking of samples free of charge. The ordinance shall be issued in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, as far as radiopharmaceuticals and active substances or medicinal products and active substances in the manufacture of which ionizing radiation is used are concerned and in agreement with the Federal
2.3 CANADA

Commercial Importation and Exportation of Drugs in Dosage Form under the Food and Drugs Act

1. Purpose: The purpose of this guidance is to explain the current responsibilities of establishments which import into or export drug products out of Canada under the Food and Drugs Act (FDA) or the Act, including establishments which fabricate and package drugs for export and choose to avail themselves of the provisions of section 37 of the said Act.

2. Background: Pursuant to the Act and its Regulations (FDR), drugs imported into or fabricated in Canada for commercial use must comply with the Act and the FDR which includes Good Manufacturing Practices (GMP) and Establishment Licence (EL) requirements. Section A.01.040 of the FDR specifies that: "...no person shall import into Canada for sale a food or drug the sale of which in Canada would constitute a violation of the Act or these Regulations".

Section 37 exempts certain drugs from the application of the FDA:

37. (1) "This Act does not apply to any packaged food, drug, cosmetic or device, not manufactured for consumption in Canada and not sold for consumption in Canada, if the package is marked in distinct overprinting with the word "Export" or "Exportation" and a certificate that the package and its contents do not contravene any known requirement of the law of the country to which it is or is about to be consigned has been issued in respect of the package and its contents in prescribed form and manner."

Thus, pursuant to section 37, an establishment in Canada that fabricates a drug in Canada for export is not subject to the requirements of the Act in relation to that product, provided the product:

i. has been manufactured in Canada solely for export;
ii. complies with the labelling requirements of section 37; and
iii. is the subject of an Export Certificate, in the form prescribed in Appendix III of the FDR, that has been attested to under oath by the exporter of the drug.

This exemption applies only to drugs fabricated in Canada. If a Canadian fabricator chooses to invoke section 37 for a drug, the Inspectorate will not verify GMP compliance for the process related to that specific drug, and therefore the Inspectorate cannot attest to the quality of the fabricator's products.

On an annual basis, when renewing establishment licences, the Inspectorate asks Canadian establishments to supply a list of drugs for which the establishments intend to invoke the exemption in section 37. This list is provided to foreign regulatory authorities requesting a GMP compliance certificate from the Inspectorate.

3. Scope: This guidance document applies to:

- drugs imported into Canada for commercial purposes;
- drugs fabricated in Canada and sold for consumption outside of Canada when the package is clearly marked "Export" or "Exportation" and a certificate has been issued in the prescribed
form and manner, stating that the package and its contents do not contravene any known requirements of the law of the country to which it is or is about to be consigned; and

- drugs for clinical trials.

This guidance document does not apply to:

- Active Pharmaceutical Ingredients (API) and
- importation of drugs for personal use

4. Definitions:

Certificate of a Pharmaceutical Product (CPP): A certificate issued by the Inspectorate establishing the status of the pharmaceutical, biological or radiopharmaceutical product listed and the GMP status of the applicant. This certificate is in the format recommended by the World Health Organization (WHO).

Drug: Any substance or mixture of substances manufactured, sold or represented for use in:

- the diagnosis, treatment, mitigation or prevention of disease, disorder, abnormal physical state, or its symptoms, in human beings or animals;
- restoring, correcting or modifying organic functions in human beings or animals, or
- disinfection in premises in which food is manufactured, prepared or kept.

Export Certificate (under Section 37 of the Food and Drugs Act): A certificate signed by the fabricator and a Commissioner for Taking Oaths to attest that the drug for which the certificate is prepared is not manufactured or sold for consumption in Canada and that its package and the contents do not contravene any known requirement of the law of the country to which it is or is about to be consigned.

Certificate of Compliance (CoC): A certificate issued by a Regulatory Authority attesting the GMP compliance of a site in that country. In Canada, this certificate is issued by the Inspectorate.

Inspectorate: The Health Products and Food Branch Inspectorate.


Package: In this guidance document, package refers to the packaging boxes used for shipping.

Regulatory Authority: A government agency or other entity in an MRA country that has a legal right to control the use or sale of drugs within that country and that may take enforcement action to ensure that drugs marketed within its jurisdiction comply with legal requirements.

5. Statement: Considering that section 37 of the FDA applies only to drugs fabricated in Canada, the Inspectorate’s position is as follows:

1. All drugs fabricated in Canada or commercially imported into Canada must meet all applicable requirements of the Act and the FDR, including labelling and Drug Identification Number (DIN) requirements, EL requirements and GMP requirements.
2. Drugs with respect to which the fabricator in Canada has not notified the Inspectorate of its intention to invoke section 37 are subject to compliance and enforcement activities against the requirements of the Act and Regulations, even those destined for export.

3. Drugs with respect to which the fabricator in Canada has notified the Inspectorate of its intention to invoke section 37 but which are not properly packaged in accordance with section 37 (i.e., marked "export" or "exportation" on the package), are subject to inspection under Division 2 of the FDR. In-process drugs, that are for export only and for which the packaging is not yet complete should be clearly identified as such during the fabrication process, either by written indication on the manufacturing order, packaging order or on the bulk containers.

4. Drugs with respect to which the fabricator in Canada has notified the Inspectorate of its intention to invoke section 37 but in respect of which the export certificate prescribed in section 37 is not available are subject to inspection under Division 2 of the FDR.

5. The Inspectorate will not issue a Certificate of a Pharmaceutical Product (CPP) for a drug exempted under section 37, or with respect to which the firm notified the Inspectorate of its intention to invoke section 37.

6. Responsibilities: The Inspectorate is responsible for applying this guidance. It is the responsibility of the importer to declare all the foreign sites from which it imports drugs. It is the establishment's responsibility to notify the Inspectorate of its intention to invoke section 37 of the Act with respect to drugs fabricated for export.

If an establishment invokes section 37, it is its responsibility to ensure that the package be marked in distinct overprinting with the word "Export" or "Exportation" and to have in its possession a completed export certificate stating that the package and its contents do not contravene any known requirement of the law of the country to which it is or is about to be consigned.

7. Procedures: The Inspectorate will verify that:

- the foreign supplier is listed on the importer's Establishment Licence;
- the drugs for which section 37 has been invoked are packaged in accordance with the requirements of section 37, and that the export certificate prescribed in Appendix III of the FDR is available.

Where non-conformity with the Act and with the FDR is identified, the firm will have the opportunity to correct deficiencies. The Inspectorate will consider actions where necessary in accordance with its Compliance and Enforcement Policy.

Policy on Importations of Drugs for Human Use Including Natural Health Products into Canada

1. PURPOSE: This policy outlines the conditions under which drugs for human use, including Natural Health Products (NHPs), may be imported into Canada. It differentiates commercial activities from personal use importation, and describes the approach that will be taken by the Health Products and Food Branch Inspectorate (HPFBI) in order to assess the compliance of imported drugs for human use and to take appropriate compliance and enforcement action.

BACKGROUND: The Inspectorate works in partnership with the Canada Border Services Agency (CBSA) to enforce the Acts and the Regulations administered by Health Canada to prevent the importation of violative drugs into Canada. Commercial and personal importations of drug products for
human use are subject to referral to Health Canada by the CBSA in order to assess compliance with the applicable legislative and regulatory requirements. HPFBI Inspectors assess the compliance of the shipments, and recommend release or refusal of entry to the CBSA. This policy provides criteria for the release or refusal of importations of drug products for human use, including NHPs.

The Controlled Drugs and Substances Act (CDSA) prohibits the importation of all controlled substances and Class A precursors unless authorized by the regulations. Authorization to import or export these drugs is generally limited to licensed dealers, and is provided by the Office of Controlled Substances, Healthy Environments and Consumer Safety Branch (HECSB) of Health Canada. The Benzodiazepines and Other Targeted Substances Regulations and the Precursor Control Regulations (PCR) do have provisions for the import of targeted substances and Class A precursors for personal use, however, presently, these provisions do not exist under the Narcotic Control Regulations or Part G of the Food and Drug Regulations.

In order to permit Canadians and visitors to Canada to export or import prescription drug products containing a narcotic or controlled drug for their own continued medical treatment or the medical treatment of a person for whom they are responsible and who is travelling with them, an exemption under section 56 of the CDSA has been provided as an interim measure to allow for the development of Regulations that will authorize the import/export of narcotic or controlled drugs by travellers. This exemption was effective August 31, 2005 and details of it are available on the Health Canada web site at the address found under section 8.0 Associated Documents.

The Food and Drugs Act and the Regulations regulate the importation of drugs for sale. Drugs for human use imported for sale in Canada must meet all applicable requirements of the Food and Drugs Act (the Act or FDA), the Food and Drug Regulations (FDR), the Natural Health Products Regulations (NHPR), and the Processing and Distribution of Semen for Assisted Conception Regulations (Semen Regulations) including labelling and market authorization requirements, establishment licensing (EL) or site licensing (SL) requirements (including the listing of the exporting foreign site on the Canadian establishment or site licence), and good manufacturing practices (GMP) requirements, and where applicable, the Controlled Drugs and Substances Act and its Regulations. The Food and Drugs Act and Regulations regulate the importation for personal use of drugs listed in Schedule F to the Regulations (prescription drugs).

Health Canada is concerned that importations of drugs for personal use may be diverted for commercial or illicit purposes. This policy states the intention and direction of Health Canada in applying the Acts and Regulations under its mandate in order to prevent illegal import of drugs for sale under the guise of personal importation.

This policy is an interpretive tool. To the extent there is an inconsistency between the policy and the law, the law governs over this administrative policy.

3. SCOPE: This policy applies to all drugs for human use in final dosage form being imported into Canada, including combination products regulated as drugs, NHPs, controlled substances and Class A precursors. The importation of bulk raw materials for further manufacturing or modification before use is not included in this policy.

4. DEFINITIONS: For the purpose of this Policy:

| CBSA: Canada Border Services Agency | CDSA: Controlled Drugs and Substances Act | CTA: Clinical Trial Application |

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Combination Product: A therapeutic product that combines a drug component and a device component (which by themselves would be classified as a drug or a device), or a biological pharmaceutical combination, such that the distinctive nature of the two components are integrated in a singular product. Does not apply to combinations of drugs and medical devices where the two drug components and/or drug and device components can be used separately (i.e. products sold together in procedure packages and trays).

Controlled Drug: As defined in Part G of the Food and Drug Regulations, a drug set out in the schedule to that Part, and includes a preparation.

Controlled Substance: As defined in the CDSA, means a substance included in Schedule I, II, III, IV or V.

Dosage Form: The final physical form of the drug product which may be used by the consumer without requiring any further manufacturing.

Drug: Refers to the definition of “drug” in the Food and Drugs Act. "Drug" includes any substance or mixture of substances manufactured, sold or represented for use in:

- the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or its symptoms, in human beings or animals,
- restoring, correcting or modifying organic functions in human beings or animals, or
- disinfection in premises in which food is manufactured, prepared or kept.

Drug for Human Use: A "drug" as defined in the Food and Drugs Act which is intended for use in humans.

Enforcement discretion: Enforcement discretion is the ability of those with enforcement responsibilities to determine when and in what manner to undertake enforcement actions.

Import: "Import" as defined in the Food and Drug Regulations means to import into Canada a drug for the purposes of sale. (See C.01A.001.) In the case of a drug which is also a controlled substance or precursor, import means any movement across the border into Canada, regardless of purpose.
Narcotic: As defined in the Narcotic Control Regulations, any substance set out in the schedule or anything containing any substance set out in the schedule to those Regulations.

Natural Health Product: Means a substance set out in Schedule 1 in the Natural Health Products Regulations or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine, that is manufactured, sold or represented for use in

a. the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;

1) restoring or correcting organic functions in humans; or

a. modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

However, a natural health product does not include a substance set out in Schedule 2 in the Natural Health Products Regulations, any combination of substances that includes a substance set out in Schedule 2 or a homeopathic medicine or a traditional medicine that is or includes a substance set out in Schedule 2.

Personal Use Importation: Refers to importation by an individual for his or her own use, or for a person under that individual's care or guardianship, and not for further sale. It does not apply to a practitioner importing drugs for a patient under his or her care. Under this definition, drugs and NHPs imported into Canada for personal use are not considered to be imported for sale.

Precursor: As defined in the CDSA, is a substance included in Schedule VI. This includes Class A Precursors which are listed in Schedule VI, Part I, Class B Precursors which are listed in Schedule VI, Part II and mixtures containing precursors as per Schedule VI, Part III.

Sell: "Sell" includes offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration.

Targeted Substance: As defined in the Benzodiazepines and Other Targeted Substances Regulations, means a controlled substance that is included in Schedule 1; or a product or compound that contains a controlled substance that is included in Schedule 1 to those Regulations.

5.0 Policy Statement 5.1 Commercial Importation 5.1.1 Requirements in the CDSA

Regulatory requirements under the CDSA for the commercial importation of controlled substances and Class A precursors include the following:

- the importer must be licensed for importing the controlled substance or Class A precursor,
- an import permit is required for each individual shipment,
- a copy of the import permit for a Class A precursor must be presented to the CBSA officer at the port of entry,
- the imported quantity can not exceed the quantity authorized in the permit, and
- the licensed dealer must inform the Office of Controlled Substances (OCS), HECSB, of the actual quantity and entry date of the shipment.
5.0 Policy Statement; 5.1 Commercial Importation; 5.1.1 Requirements in the CDSA

5.1.2 Requirements in the FDA: All drugs commercially imported into Canada must meet all applicable requirements of the Food and Drugs Act and its associated Regulations, including, but not limited to, labelling and marketing authorization requirements, EL or SL requirements (including foreign sites as regulated), and GMP requirements.

5.1.3 Interpretation of "drugs for sale": Health Canada considers that commercial importation activities include, but are not limited to importations:

1. where the shipment is destined for a retailer, distributor, or other commercial establishment. This would include shipments being sent to independent sales contractors/distributors, or to a practitioner for use in his or her practice.
2. where the shipment was "caused to be imported" by a contractor/distributor in Canada (who placed the order on behalf of the customer). In order for the sale to be considered a personal use importation it must occur directly between a person in Canada and a company located outside Canada: there can be no intervention of a Canadian company offering the product for sale and importing it for sale.
3. where the shipment from a single foreign supplier consists of individually addressed parcels, and the importer of record as indicated on a separate invoice for each parcel is not unique for each parcel.
4. where the shipment is part of a pattern of repeat personal importations of the same drug to the same individual at the same address within a 90-day period totalling more than a 90 day supply.
5. where more than a 90-day supply of a drug for use by one person, based on its directions for use or reasonable intake, is being imported.
6. where the shipment is accompanied by or associated with materials to be used for advertising or promotion. In this case the importer is considered to be a distributor.
7. where the shipments are destined for export (s. 37 of the Food and Drugs Act does not apply).

5.1.4 Specific Import Requirements for Drugs for Sale: Commercial shipments of drugs in final dosage form must comply with the additional requirements.

6.0 Responsibilities: The implementation of this Policy is the responsibility of staff of the HPFBI. Compliance and enforcement action will be taken by the Inspectorate with respect to the above requirements based on POL-0001 Compliance and Enforcement Policy. These actions may include but are not limited to recommending to the CBSA the refusal of entry for violative products, requesting that the CBSA use targets and lookouts for products posing a risk to health in order to prevent their importation, and requesting voluntary detention, re-export or voluntary disposal when importers seek to import or have imported violative products. In addition, when a conditional entry is provided for violative products, the Inspectorate will follow up so that any corrective measures are completed before the importer sells the product in Canada.

7.0 Effective Date: This policy replaces the Importation of Human-Use Drugs for Personal Use Enforcement Directive issued 1998/06/01, and becomes effective on May 1, 2006.

Appendix 2: Relevant Statutes and Regulations for the Import of Drugs and NHPs into Canada
Food and Drugs Act

2. In this Act,

"Sell" includes offer for sale, expose for sale, have in possession for sale and distribute, whether or not
the distribution is made for consideration;

Food and Drug Regulations

A.01.040. Subject to section A.01.044, no person shall import into Canada for sale a food or drug the
sale of which in Canada would constitute a violation of the Act or these Regulations. SOR/82-626, s.
2(F).

C.01.004.1 (1) No person shall import a drug in dosage form into Canada for the purpose of sale
unless they have in Canada a person who is responsible for the sale of the drug.

(2) No person who imports a drug in dosage form into Canada shall sell any lot or batch of the drug
unless the name of the person who imports it, and the address of the principal place of business in
Canada of the person responsible for its sale, appears on the inner and outer labels of the drug.
SOR/82-524, s. 1; SOR/93-475, s. 1; SOR/97-12, s. 2.

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 "Drogue: identification numérique" 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.

(3) For the purposes of this section and section C.01.014, "a drug in dosage form" means a drug in a
form in which it is ready for use by the consumer without requiring any further manufacturing. SOR/81-
248, s. 1; SOR/93-202, s. 3; SOR/98-423, s. 2; SOR/2001-181, s. 4.

C.01.045. (1) Subject to subsection (2), no person other than

(a) a practitioner,

(b) a drug manufacturer,

(c) a wholesale druggist,
(d) a registered pharmacist, or
(e) a resident of a foreign country while a visitor in Canada, shall import a Schedule F Drug.

(2) Any person may import a Schedule F Drug listed in Part II of Schedule F if the drug is imported in such form or so labelled that it could be sold by that person pursuant to section C.01.046. SOR/93-407, s. 4.

C.01A.001. (1) The definitions in this subsection apply in this Division and in Divisions 2 to 4. *import* means to import into Canada a drug for the purpose of sale. (*importer*)

C.01A.004. (1) Subject to subsection (2), no person shall, except in accordance with an establishment licence,

(a) fabricate, package/label, distribute as set out in section C.01A.003, import or wholesale a drug; or

(b) perform the tests, including examinations, required under Division 2.

(2) A person does not require an establishment licence to perform tests under Division 2 if the person holds an establishment licence as a fabricator, a packager/labeller, a distributor referred to in paragraph C.01A.003(b) or an importer.

(3) No person shall carry on an activity referred to in subsection (1) in respect of a narcotic as defined in the Narcotic Control Regulations or a controlled drug as defined in subsection G.01.001 (1) unless the person holds a licence for that narcotic or drug under the Narcotic Control Regulations or Part G of these Regulations, as the case may be. SOR/97-12, s. 5; SOR/2002-368, s. 3.

C.02.003. No distributor referred to in paragraph C.01A.003 (b) and no importer shall sell a drug unless it has been fabricated, packaged/labelled, tested and stored in accordance with the requirements of this Division. SOR/82-524, s. 3; SOR/97-12, s. 7; SOR/2000-120, s. 8.

C.05.001. The definitions in this section apply in this Division. *import* means to import a drug into Canada for the purpose of sale in a clinical trial. (*importer*)

C.05.003. Despite sections C.01.014, C.08.002 and C.08.003, no person shall sell or import a drug for the purposes of a clinical trial unless

(a) the person is authorized under this Division

(b) the person complies with this Division and sections C.01.015, C.01.036, C.01.037 to C.01.040, C.01.040.2, C.01.064 to C.01.067, C.01.070, C.01.131, C.01.133 to C.01.136, and C.01.435, and

(c) if the drug is to be imported, the person has a representative in Canada who is responsible for the sale of the drug. SOR/2001-203, s. 4.

C.08.010. (1) The Director may issue a letter of authorization authorizing the sale of a quantity of a new drug for human or veterinary use to a practitioner named in the letter of authorization for use in the emergency treatment of a patient under the care of that practitioner, if
(a) the practitioner has supplied to the Director information concerning

i. the medical emergency for which the drug is required,

ii. the data in the possession of the practitioner with respect to the use, safety and efficacy of
that drug,

iii. the names of all institutions in which the drug is to be used, and

iv. such other data as the Director may require; and

(b) the practitioner has agreed to

i. report to the manufacturer of the new drug and to the Director on the results of the use of the
drug in the medical emergency, including information respecting any adverse reactions
encountered, and

ii. account to the Director on request for all quantities of the drug received by him.

(2) The Director shall, in any letter of authorization issued pursuant to subsection (1), state

(a) the name of the practitioner to whom the new drug may be sold;

(b) the medical emergency in respect of which the new drug may be sold; and

(c) the quantity of the new drug that may be sold to that practitioner for that emergency.

C.08.011. (1) Notwithstanding section C.08.002, a manufacturer may sell to a practitioner named in a
letter of authorization issued pursuant to section C.08.010, a quantity of the new drug named in that
letter that does not exceed the quantity specified in the letter.

(2) A sale of a new drug made in accordance with subsection (1) is exempt from the provisions of the
Act and these Regulations.

Natural Health Products Regulations: 1. (1) The following definitions apply in these
Regulations: "importer" means a person who imports a natural health product into Canada for the
purpose of sale. (importateur)

4. (1) Subject to subsections (2) and (3), no person shall sell a natural health product unless a product
licence is issued in respect of the natural health product.

27. (1) Subject to subsection (2), no person shall manufacture, package, label or import a natural
health product for sale unless

(a) the person holds a site licence issued in respect of the activity; and

(b) the person conducts the activity in accordance with the requirements set out in Part 3.

43. (1) Subject to subsection (2), no person shall sell a natural health product unless it is
manufactured, packaged, labelled, imported, distributed or stored, as the case may be, in accordance
with this Part.
(2) A person may sell a natural health product that is manufactured, packaged, labelled, imported, distributed or stored, as the case may be, in accordance with requirements that are equivalent to those set out in this Part if the natural health product is imported.

Controlled Drugs and Substances Act: 6. (1) Except as authorized under the regulations, no person shall import into Canada or export from Canada a substance included in Schedule I, II, III, IV, V or VI.

2.4 AUSTRALIA

Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

The sponsor of a medicine is the person or company responsible for applying to the TGA to have their medicine included in the ARTG. The ARTG is established under part 3 of the Act. It includes a computer database of information about therapeutic goods for human use which are approved for supply in, or export from, Australia. All medicines manufactured for supply in Australia must be listed or registered in the ARTG, unless they are specifically exempt or excluded.

ASSESSMENT CRITERIA: Whether a product is listed or registered in the ARTG depends largely on three things:

* The ingredients;
  
The dosage form of the product; and

* The promotional or therapeutic claims made for the product.

In assessing the level of 'risk' factors such as the strength of a product, side effects, potential harm through prolonged use, toxicity, and the seriousness of the medical condition for which the product is intended to be used are taken into account.

WHAT ARE 'THERAPEUTIC GOODS'? A 'therapeutic goods' is broadly defined as a goods which is represented in any way to be, or is likely to be taken to be, for therapeutic use, unless specifically excluded or included under section 7 of the Act.

RISK MANAGEMENT APPROACH: The TGA uses a 'risk management' approach in regulating medicines supplied in Australia. This refers to the level of scrutiny applied to individual applications for inclusion in the ARTG. Medicines used to treat serious conditions, or which need to be used under a doctor’s supervision, are subjected to a high level of scrutiny and evaluation to determine their quality, safety and efficacy.

Other products, for example many complimentary medicines (such as herbal, vitamin and mineral products) are not generally subject to the same level of evaluation and are assessed only for quality and safety.
SPECIAL ACCESS TO UNAPPROVED MEDICINES: In certain circumstances, individuals may be granted access to medicines that have not yet been approved for entry into ARTG, details thereof are available with TGA.

LISTED MEDICINES: Listed medicines are considered to be of lower risk than registered medicines, so the regulations allow sponsors to 'self assess' their products in some situations. The majority of listed medicines are self-selected by consumers and used for self-treatment.

Listed medicines may only contain well known established ingredients, usually with a long history of use, such as vitamin and mineral products or sunscreens. They DO NOT contain substances that are scheduled in the SUSDP. Listed medicines are assessed by the TGA for quality and safety but not efficacy. This means that the TGA has not evaluated them individually to see if they work.

It is the requirement under the Act that sponsors hold information to substantiate all of their products’ claims. Guidelines for levels and kinds of evidence to support indications and claims are available. Most complimentary medicines (Eg. Herbal, vitamin and mineral products) and sunscreens are examples of listed products. ([http://www.tga.gov.au/docs/gaccevi.htm](http://www.tga.gov.au/docs/gaccevi.htm))

Medicines which are for EXPORT ONLY are listed (not registered) on the ARTG. All listed medicines must display an “AUST L” number on the label as proof of listing.

REGISTERED MEDICINES: Medicines assessed as having a higher level of risk must be registered (not listed). The degree of assessment and regulation they undergo is rigorous and detailed, with sponsors being required to provide comprehensive safety, quality and efficacy data. All registered medicines:

- must display an AUST R number on the label as proof of registration;
- are evaluated as either 'high risk' or 'low risk' registered.

**NON-PRESCRIPTION (LOW RISK) REGISTERED**

- follow the route of evaluation described in Part 2 (Non-Complimentary), or Part 3 (Complimentary) of Schedule 10 of the Therapeutic Goods Regulations.
- Do not include ingredients which are described in Schedule 2, Schedule 8, or Schedule 9 of SUSDP;
- Usually contain ingredients which are described in Schedule 2, Schedule 3, or sometimes Schedules 5 or 6 of the SUSDP
- Are available without prescription.

Examples: Mild analgesics, cough/cold preparations, anti fungal creams.

**PRESCRIPTION (HIGH RISK) REGISTERED**

- follow the route of evaluation described in Part 1 (mainly prescription) of Schedule 10 of the Therapeutic Goods Regulations;
- may include ingredients described in Schedule 4, Schedule 8, or Schedule 9 of the SUSDP;
- are usually only available on prescription.
Examples: all prescription medicines; all injectables.

COMPLIMENTARY MEDICINES: Complimentary medicines (also known as ‘traditional’ or ‘alternative’ medicines) include vitamin, mineral, herbal, aromatherapy, and homeopathic products. A list of such products covered by the term ‘complimentary’ is available at Schedule 14 of the Regulations. Complimentary medicines may be either listed or registered, depending on their ingredients and the claims made. Most complimentary medicines are listed in the ARTG and some are registered.

EXEMPT OR EXCLUDED MEDICINES: All medicines manufactured for supply in Australia must be listed or registered in the Australian Register of Therapeutic Goods (ARTG) unless they are exempt or excluded.

EXCLUDED: Some products (mostly therapeutic devices, rather than medicines) may be unintentionally covered by the definition of a Therapeutic Good. They are, therefore, specifically excluded under section 7 of the Act. NONE OF THE REQUIREMENTS OF THE ACT APPLY TO EXCLUDED PRODUCTS.

Example: Unmedicated Soap.

EXEMPT: Some medicines do not need to be registered or listed in the ARTG as a result of a specific exemption or determination. However, it is important to note that all other applicable requirements under the Act and Regulations (eg. Standards and advertising or labelling) must be complied with.

EXEMPTION FROM ARTG LISTING

- some goods are exempt from the need to be included in the ARTG;
- see section 18 of the Act and Schedules 5 and 5A of the regulations.


IMPORT AND EXPORT-THERAPEUTIC GOODS ACT

1. Substances controlled under Custom’s Import/Export Legislation;

Australia is signatory to three International Drug Conventions namely:

i. The single convention on Narcotics Drugs 1961- This convention sets out measures designed to ensure that narcotics drugs continue to be available for pain relief and it ensures that effective measures are in place to contain the abuse of narcotics. Australia’s obligation as a signatory to the ‘convention’ requires the implementation of controls and procedures to prevent diversion and to prevent excess stock accumulation.

ii. The Convention on Psychotropic Substances 1971- Australia is obliged to exercise certain controls and procedures, particularly in relation to international trade in Psychotropic Drugs.

iii. The United Nations Convention against illicit traffic in Narcotics Drugs and Psychotropic Substances 1988- This convention expresses concern over the diversion of chemicals for use in the illicit manufacture of drugs. Articles 12 and 13 of the convention requires parties to control and monitor certain substances and equipment used in illicit drug manufacture. The TGA is responsible for implementing the measures required by Articles 12 and 13.
The basic concepts that determine inclusion of drugs and chemicals in these conventions are:

- the substances have, in general, legitimate scientific or medicinal use that must be protected,
- the abuse of certain substances gives rise to public health, social and economic consequences,
- vigorous measures are necessary to restrict their use to legitimate purposes; and
- to be effective such measures require coordinated and universal action at the international level.

**SUBSTANCES REQUIRING SPECIAL PERMISSION, WHICH SUBSTANCES ARE CONTROLLED**

Substances controlled under import and export legislation are those which are of sufficient public health concern internationally to warrant restrictions to ensure legitimate use only; these include:

- Hallucinogens
- Narcotics
- Barbiturates
- Benzodiazepines
- Tranquilisers
- Amphetamines

Some substances (Appendix A) are only controlled when importing but not exporting. These substances are of sufficient health concern in Australia to warrant controls but not controlled on an international basis; these include:

- injections containing substances of human or animal origin
- Androgenic or anabolic steroids
- Peptide and glucoprotein hormones (for example human growth hormone, human chorionic gonadotrophin)
- Erythropoietin (EPO)

**Appendix A - Substances subject to import controls**

Permit only required

Check this list before you bring a medicine into Australia: One must obtain permission from the Therapeutic Goods Administration before bringing into Australia a medicine containing any substance listed.


The following class of products (Appendix B) may contain substances that are prohibited unless an import licence and permit are held:

- Complimentary (Alternative) medicines including herbal preparations,
- Traditional medicines such as traditional Chinese medicines,
- Antibiotics
Drug Enforcement Laws - Globalization, Vis-a-Vis, Indian Drug Laws

• Dietary supplements

Appendix B - Substances subject to import and export controls

Annual licence + permit required [http://www.tga.gov.au/impexp/index.htm#contact]

PROHIBITED IMPORTS - PENALTIES IMPORTING CONTROLLED SUBSTANCES: Controlled substances which are imported into Australia without the appropriate licences and/or permit are prohibited imports. The Australian Customs Services may seize prohibited substances. Penalties may apply if the importer is found guilty of an offence and the goods may be destroyed.

IMPORTING INTO AUSTRALIA

* Most products for which therapeutic claims are made must be listed or registered in the ARTG before they can be supplied in Australia. (some exceptions do exist)

Prescription medicines, OTC medicines or Complimentary medicines depending upon the type of medicine one is intending to import.

* Just as Europe, the USA and other countries maintain the authority to decide which goods should be available in their country, so too does the Australian Government maintain its sovereignty in therapeutic goods regulation. However, agreements have been reached with some other countries to exchange information in order to facilitate the registration process.

EXPORT OF MEDICINES FROM AUSTRALIA- POLICY FOR: INTRODUCTION:

The export of medicines including prescription, OTC and Complimentary (Vitamins, mineral supplements and herbal products) medicines from Australia is regulated by Therapeutic Goods Act (TGA)

Exports are important to the future of the Australian Medicines Manufacturing Sector. The TGA is committed to the development of streamlined and responsive regulatory and administrative processes that protect public health and safety and support the export of quality therapeutic goods from Australia.

It comprises of the policy framework (Part A) or strategic commitments given by TGA in relation to export regulation. These support and direct the TGA's export related actions outlined in Part B.

BACKGROUND: The TGA policy for the export of medicines from Australia May 2002 supersedes the (Draft) August 1991 Policy for export only products and other TGA policy position and statements on export regulation. The integrity of Australia's export regulatory system including export certification relies on the quality of information provided to overseas authorities. (www.tga.gov.au/docs/pdf/exppol.pdf)

TGA issues three types of Export Certificates for medicinal products:

• A World Health Organisation (WHO) Certificates of Pharmaceutical Products (CPP) for products permitted to be supplied in Australia or for products authorised solely for export;
• A TGA export certificate of a listed product (For lower risk products permitted to be supplied in Australia)
• A TGA export certificate for an exempt product- (For products not required to be entered in the ARTG but still subject to therapeutic goods legislation). This certificate is generally

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designed for exempt medicines which are manufactured in a GMP licenced Manufacturing Facility. In this situation, the standard of manufacture may be certified in accordance with the WHO model.

INFORMATION ABLE TO BE CERTIFIED: The WHO export certification scheme was put into place to provide assurance regarding the quality and safety of pharmaceuticals being traded internationally for countries that do not have regulatory arrangements to undertake assessments themselves. The basis of the scheme is formed by WHO endorsed requirements for Good Practices in the Manufacture and Quality Control of Drugs. The scheme is an administrative instrument that requires a participating country on application from a product sponsor, to verify to another country that –

- a specific product is authorised to be placed on the market within its jurisdiction, or if it is not, the reason why; and
- the plant in which it is produced is periodically subject to GMP inspections; and
- that all aspects of the manufacture of the product are satisfactory.

If the GMP status of any manufacturers nominated in the export certificate is ‘unacceptable’ a CPP or CLP can not be issued until these matters have been resolved.

Therapeutic Goods Order No. 70B

Federal Register of Legislative Instruments (FRL): Legislative Instrument - F2007L00555 (5 March 2007)

Therapeutic Goods Act 1989- STANDARDS FOR EXPORT ONLY MEDICINE

I, DAVID GRAHAM, delegate of the Minister for Health and Ageing for the purposes of section 10 of the Therapeutic Goods Act 1989 and acting under that section, having consulted with the Therapeutic Goods Committee in accordance with subsection 10(4) of that Act, HEREBY:

1. REVOKE Therapeutic Goods Order No. 70 "Standards for Export Only Medicine" (TGO 70) made on 20 May 2002;
2. REVOKE Therapeutic Goods Order No. 7CA "Amendment to Therapeutic Goods Order No. 70 - Standards for Export Only Medicine" (TGO 70A) made on 5 December 2003; and
3. DETERMINE that the matters specified in a relevant monograph of each of the publications listed in column 1 below constitute alternative standards for medicine manufactured in Australia, or imported into Australia, for export only subject to the limitations (if any) set out in column 2:

<table>
<thead>
<tr>
<th>Column 1</th>
<th>Column 2</th>
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</thead>
<tbody>
<tr>
<td>British Pharmacopoeia</td>
<td>i) the medicine is not to be supplied for sale in Australia, including supply via duty free outlets; and</td>
</tr>
<tr>
<td>(2005 edition)</td>
<td>ii) if the medicine to be exported or any ingredient in the medicine to be exported is subject to the Customs (Prohibited Exports) Regulations 1958, an export permit has been obtained by the relevant authority (in Australia) prior to its export.</td>
</tr>
<tr>
<td>United States</td>
<td>i) the medicine is not to be supplied for sale in Australia, including supply via duty free outlets; and</td>
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<table>
<thead>
<tr>
<th>Pharmacopoeia</th>
<th>(29th edition-NF 24)</th>
<th>duty free outlets; and</th>
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<tbody>
<tr>
<td></td>
<td>ii) the exporter is to hold evidence that a relevant authority of the country to which the medicine is to be exported has confirmed its willingness to accept medicine which complies with this order, or confirmed that it would have no objection to accepting such medicine, except where the country to which the medicine is to be exported is a country where the medicine is regulated other than as a medicine;</td>
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<td>iii) if the medicine is regulated other than as a medicine in the country to which it is to be exported, it meets the regulatory requirements set out by that country for such products; and</td>
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<td>iv) if the medicine to be exported or any ingredient in the medicine to be exported is subject to the Customs (Prohibited Exports) Regulations 1958, an export permit has been obtained by the relevant authority (in Australia) prior to its export.</td>
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<tr>
<td>Japanese Pharmacopoeia</td>
<td>(14th edition including Supplements I and II)</td>
<td>i) the medicine is not to be supplied for sale in Australia, including supply via duty free outlets; and</td>
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<td>ii) the exporter is to hold evidence that a relevant authority of the country to which the medicine is to be exported has confirmed its willingness to accept medicine which complies with this order, or confirmed that it would have no objection to accepting such medicine, except where the country to which the medicine is to be exported is a country where the medicine is regulated other than as a medicine;</td>
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<td>European Pharmacopoeia</td>
<td>(5th edition including Supplements 5.1-5.6)</td>
<td>i) the medicine is not to be supplied for sale in Australia, including supply via duty free outlets; and</td>
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iv) if the medicine to be exported or any ingredient in the medicine to be exported is subject to the Customs (Prohibited Exports) Regulations 1958, an export permit has been obtained by the relevant authority (in Australia) prior to its export.

This Order commences from the day after the day it is registered on the Federal Register of Legislative Instruments. Dated this 26th day of February 2007, David Graham, Delegate of the Minister for Health and Ageing

Export of medicines for commercial supply

Introduction: Generally speaking, therapeutic goods which are intended to be exported from Australia for commercial supply, must first be included in the Australian Register of Therapeutic Goods (ARTG) in the name of the sponsor of the goods. There may be some exemptions contained in Schedule 5 of the Therapeutic Goods Regulations 1990 but they relate mainly to non-commercial exports.

"Sponsor" in this case means a person who exports, or arranges the exportation of, the goods from Australia, but does not include a person who exports the goods or arranges the exportation of the goods on behalf of another person who, at the time of the exportation, is a resident of Australia or is carrying on business in Australia.

In plain English, this generally means that intending exporters of such goods have two options:

- act as the sponsor of the goods and submit an application to include the goods in the ARTG prior to export; or
- arrange the exportation of the goods on behalf of the sponsor who already has the medicine included in the ARTG.

Clearly, both options require the support of the original Australian product sponsor. Note that the product then authorised to be exported under these arrangements would need to be identical to that which is included in the ARTG in the name of the original product sponsor (e.g., product name, container type, indications, dosage, etc).

In the case of medicines intended for sale overseas, a key issue for commercial suppliers is whether the goods are:

- intended exclusively for export; or
- intended for supply in Australia as well as export: The medicines listed or registered on the ARTG or exempt for listing on the ARTG can also be exported.

This distinction is dealt with in more detail later in this information.

Medicines solely for the purpose of export: Medicines intended solely for the purpose of export are required to be listed (not registered) on the ARTG before export is commenced. Broadly, these medicines must:

- be safe for their intended purpose of use;
- be manufactured under GMP;
- meet any standards applicable under Section 10 of the Therapeutic Goods Act; and
Sponsors requiring to list export products on the ARTG can opt to list their products either under Section 26 or Section 26A of the Therapeutic Goods Act 1989. The products listed under Section 26 are referred to as Export-only products and the products listed under Section 26A are termed as Solely for Export products. The two types of products do not differ from each other in the quality and safety criterion required by the TGA and are so named only to distinguish between the assessment pathways of the two product types. Both type of products are exclusively for export purpose and can not be supplied within Australia including Duty Free outlets.

The export labels can be printed in languages other than English, providing information on the label does not disagree with the draft label approved for the product at the time of listing. An English translation of the foreign label is required to be submitted to the Export Unit for record purposes.

If an export product is manufactured overseas, it is expected that the overseas manufacturer/s will have an equivalent level of GMP compared to licensed manufacturers in Australia. A valid Overseas Pre-clearance Certificate is required to be produced by sponsors at the time of listing of the product. This certificate can be obtained by applying to the TGA’s Manufacturers Assessment Branch (MAB).

Obviously, the requirements of governments overseas will vary greatly with regard to registration of medicines. These requirements should be thoroughly checked by the sponsor of the goods before applying for approval as the TGA cannot give advice on the policies of other countries. However, if you do have difficulties in accessing overseas markets due to export certification concerns you should contact the TGA. This will assist in identifying foreign regulatory agencies, which we need to focus on in promoting the strength of the Australian regulatory system.

Exporters should also check that they meet any State or Federal laws regarding the procurement and storage of medicines (eg. State poisons legislation), and other relevant legislation such as Trademarks, Patents, Wildlife Protection, Customs and Quarantine.

Safety approval process: Many countries which are importing medicines from Australian exporters look to our system of certification and regulation as an indication that the products involved have been assessed for safety or quality. This may be particularly relevant in countries where resources do not permit a dedicated effort to fully assess every medicine that enters the country.

Where the TGA has serious concerns about the safety of a product, it may seek a statement from the regulatory authorities in the importing country to confirm that they do not object to the listing of the product in the Australian Register of Therapeutic Goods (ARTG).

TGA Policy for the export of medicines from Australia

The procedure involves the TGA sending a letter to the authority involved and requesting whether the importing country is willing to accept the product. When consent is granted, the product is listed in the ARTG. The limited situations where the Safety Approval Process would be used are outlined in the Where there are no serious safety concerns but some other specific concerns about the export product need be communicated to the country of import, the TGA may adopt the Export Advisory Procedure. In this procedure, the TGA communicates with the importing country via conditions of listing which may
be imposed on the supply of the product or as a statement in the export certificate. Further details about this procedure are available in the TGA Policy for the export of medicines from Australia <http://www.tga.gov.au/docs/html/export/exppol.htm>.

**Medicines solely for the purpose of export - administrative procedure:** The process of listing of products solely for the purpose of export takes approximately 30 working days for completion from the time TGA receives an export listing application, unless the Safety Approval Process is required. The Certificate of Medicine Listing should not be confused with an Export Certificate.

The purpose of the export certificate is to assist overseas health authorities in determining the quality and safety of the medicine that is intended to be exported to their country from Australia.

**Medicines for export which are also supplied in Australia:** If the goods for export are already available in Australia, they will be on the ARTG, and one can export them without further regulation, provided that you are either the sponsor or the agent of the sponsor.

If you are a sponsor and you want to export a product under a different name, you can do this in either of two ways:

- notifying TGA of any 'export only' names at the time of listing or registration; or
- through a 'grouping' application for products already on the ARTG. The grouping application is submitted electronically and it follows a review process similar to the review process required for a new application.

**WHO Certification Scheme (CPPs):** Australia is a participant in the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. This scheme is intended to ensure the quality and safety of medicines which are ultimately sold in countries other than those where they were manufactured. The TGA, as part of its responsibilities under the WHO Certification Scheme, issues Certificates of a Pharmaceutical Product (CPP) to commercial exporters.

**Certificate of Listed Product:** Complementary healthcare products such as herbals, vitamins and minerals are regulated as foods or dietary supplements in many countries. However, in Australia they are generally regulated as listed complementary medicines. This can cause difficulties where overseas regulators request Certificates of Free Sale to be provided. Products, which are regulated as medicines in Australia, cannot be issued Certificates of Free Sale as they need to meet certain legislative requirements before they can be legally supplied. Instead of a Certificate of Free Sale, a Certificate of Listed Product may be requested for listed medicines, which have been approved for supply in Australia. This certificate is not issued under the WHO Scheme but does contain most of the information included in a CPP.

**Certificate of Exempt Product:** Some products such as certain sunscreens, shampoos and deodorants are considered to be therapeutic goods but are exempt from the requirement to be included in the ARTG or to be manufactured under GMP.

2.5 INDIA

**CHAPTER III – Drugs and Cosmetics Act: IMPORT OF DRUGS AND COSMETICS**
SECTION 8: Standards of quality. – [(1) for the purposes of this Chapter, the expression "standard quality" means –

(a) in relation to a drug, that the drug complies with the standard set out in the Second Schedule, and

(b) in relation to a cosmetic, may be prescribed.]

(2) The Central Government, after consultation with the Drugs Technical Advisory Board (DTAB) and notification in the Official Gazette not less than three months' notice of its intention so to do, may by notification add to or otherwise amend shall be deemed to be amended accordingly.

9. Misbranded drugs. – For the purposes of this Chapter, a drug shall be deemed to be misbranded, -

a) If it is so coloured, coated, powdered or polished that damage is concealed or if it is made to appear of better or greater therapeutic value than it really is ; or

b) If it is not labeled in the prescribed manner; or

c) If its label or container or anything accompanying the drug bears any statement, design or device which is false or misleading in any particular.]

9A. Adulterated drugs. – For the purposes of this Chapter, a drug shall be deemed to be adulterated,

a) If it consists, in whole or in part, of any filthy, putrid or decomposed substance; or

b) If it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health ; or

 c) If its container is composed in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

 d) If it bears or contains, for purposes of colouring only, a colour other than one which is prescribed; or

 e) If it contains any harmful or toxic substance which may render it injurious to health ; or

 f) If any substance has been mixed therewith so as to reduce its quality or strength

9B. Spurious drugs. – For the purposes of this Chapter, a drug shall be deemed to be spurious, -

a) If it is imported under a name which belongs to another drug ; or

b) If it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug ; or

 c) If the label or container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist ; or

 d) If it has been substituted wholly or in part by another drug or substance; or

 e) If it purports to be the product of a manufacturer of whom it is only truly a product

10. Prohibition of import of certain drugs or cosmetics. – From such date as may be fixed by the Central Government by notification in the Official Gazette in this behalf, no person shall import –

(a) Any drug which is not of standard quality;
(b) Any misbranded drug

(bb) Any adulterated or spurious drug;

(c) Any drug for the import of which a licence is prescr bed, otherwise than under, and in accordance with, such licence;

(d) Any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the true formula or list of active ingredients contained in it together with the quantities thereof;

(e) Any drug which by means of any statement, design or device accompanying it or by any other means, purports or claims to cure or mitigate any such disease or ailment, or to have any such other effect, as may be prescribed;

(ee) (Note: Ins. by Act 21 of 1962, sec. 8, w.e.f. 27-7-1964)) Any cosmetic containing any ingredient, which may render it unsafe or harmful for use under the directions indicated or recommended;

(f) Any drug [(Note: Subs. by Act 21 of 1962, sec. 8, for clause (b) (w.e.f. 27-7-1964)) or cosmetic] the import of which is prohibited by rule made under this Chapter.

Provided that nothing in this section shall apply to the import, subject to prescribed conditions, of small quantities of any drug for the purpose of examination, test or analysis or for personal use:

Provided further that the Central Government may, after consultation with the Board by notification in the Official Gazette, permit, subject to any conditions specified in the notification, the import of any drug or class of drugs not being of standard quality.

10A. Power of Central Government to prohibit import of drugs and cosmetics in public interest. – Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied that the use of any drug or cosmetic is likely to involve any risk to human beings or animals or that any drug does not have the therapeutic value claimed for it or contains ingredients and in such quantity for which there is no therapeutic justification and that in the public interest it is necessary or expedient so to do then, that Government may, by notification in the Official Gazette, prohibit the import of such drug or cosmetic.

11. Application of law relating to sea customs and powers of Customs Officers. – (1) The Law for the time being in force relating to sea customs and to goods, the import of which is prohibited by section 18 of the Sea Customs Act, 1878 (Note: Now see the Customs Act, 1962.) shall, subject to the provisions of section 13 of this Act, apply in respect of drugs [(Note: Ins. by Act 21 of 1962, sec. 9 (w.e.f. 27-7-1964)) and cosmetics] the import of which is prohibited under this Chapter, and officers of Customs and officers empowered under that Act to perform the duties imposed thereby on a Customs Collector and other officers of Customs, shall have the same powers in respect of such drugs [(Note: Ins. by Act 21 of 1962, sec. 9 (w.e.f. 27-7-1964)) and cosmetics] as they have for the time being in respect of such goods as aforesaid.

(2) (Note: Subs. by Act 11 of 1955, sec. 6, for sub-section (2)) Without prejudice to the provisions of sub-section (1), the Customs Collector or any officer of the Government authorised by the Central Government in this behalf, may detain any imported package which he suspects to contain any drug.
Drug Enforcement Laws - Globalization, Vis-à-Vis, Indian Drug Laws

[(Note: Ins. by Act 21 of 1962, sec.9 (w.e.f. 27-7-1964)) or cosmetic] the import of which is prohibited under this Chapter and shall forthwith report such detention to the Drugs Controller, India, and if necessary, forward the package or sample of any suspected drug [(Note: Ins. by Act 21 of 1962, sec.9 (w.e.f. 27-7-1964)) or cosmetic] found therein to the Central Drugs Laboratory.

12. Power of Central Government to make rules. - (1) The Central Government may, "after consultation with the Board" after consultation with or on the recommendation of the Board and after previous publication by notification in the Official Gazette, make rules for the purpose of giving effect to the provisions of this Chapter:

Provided that consultation with the Board may be dispensed with if the Central Government is of opinion that circumstances have arisen which render it necessary to make rules without such consultation, but in such a case the Board shall be consulted within six months of the making of the rules and the Central Government shall take into consideration any suggestions which the Board may make in relation to the amendment of the said rules.]

(2) Without prejudice to the generality of the foregoing power, such rules may—

(a) Specify the drugs or classes of drugs for the import of which a licence is required, and prescribe the form and conditions of such licences, the authority empowered to issue the same, the fees payable therefor and provide for the cancellation, or suspension of such licence in any case where any provision of this Chapter or the rules made there under is contravened or any of the conditions subject to which the licence is issued is not complied with;

(b) Prescribe the methods of test or analysis to be employed in determining whether a drug is of standard quality

(c) Prescribe, in respect of biological and organ metallic compounds, the units or methods of standardization;

(cc) Prescribe under clause (d) of the colour or colours which a drug may bear or contain for purposes of colouring;

(d) Specify the diseases or ailments, which an imported drug may not purport or claim and such other effects which such drug may not purport or claim to have;

(e) Prescribe the conditions subject to which small quantities of drugs, the import of which is otherwise prohibited under this Chapter, may be imported for the purpose of examination, test or analysis or for personal use;

(f)Prescribe the places at which drugs may be imported, and prohibit their import at any other place;

(g) Require the date of manufacture and the date of expiry of potency to be clearly and truly stated on the label or container of any specified imported drug or class of such drug, and prohibit the import of the said drug or class of drug after the expiry of a specified period from the date of manufacture;

(h) Regulate the submission by importers, and the securing, of samples of drugs for examination, test or analysis by the Central Drugs Laboratory, and prescribe the fees, if any, payable for such examination, test or analysis;

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(i) Prescribe the evidence to be supplied, whether by accompanying documents or otherwise, of the quality of drugs sought to be imported, the procedure of officers of Customs in dealing with such evidence, and the manner of storage at places of import of drugs detained pending admission;

(j) Provide for the exemption, conditionally or otherwise, from all or any of the provisions of this Chapter and the rules made thereunder of drugs imported for the purpose only of transport through, and export from;

(k) Prescribe the conditions to be observed in the packing in bottles, packages or other containers, of imported drugs including the use of packing material which comes into direct contact with the drugs;

(l) Regulate the mode of labeling drugs imported for sale in packages, and prescribe the matters which shall or shall not be included in such labels;

(m) Prescribe the maximum proportion of any poisonous substance which may be added to or contained in any imported drug, prohibit the import of any drug in which that proportion is exceeded, and specify substances which shall be deemed to be poisonous for the purposes of this Chapter and the rules made thereunder;

(n) Require that the accepted scientific name of any specified drug shall be displayed in the prescribed manner on the label or wrapper of any imported, patent or proprietary medicine containing such drug;

(o) Provide for the exemption, conditionally or otherwise, from all or any of the provisions of this Chapter or the rules made thereunder of any specified drug or class of drugs.

13. Offences. - (1) whoever himself or by any other person on his behalf imports,

(a) Any drug deemed to be adulterated under section 9A or deemed to be a spurious drug under section 9B or any spurious cosmetic referred to in section 9D or any cosmetic of the nature referred to in clause (ee) of section 10 shall be punishable with imprisonment for a term which may extend to three years and a fine which may extend to five thousand rupees;

(b) Any drug or cosmetic other than a drug or cosmetic referred to in clause (a), the import of which is prohibited under section 10, or any rule made under this Chapter, shall be punishable with imprisonment for a term which may extend to six months, or with fine which may extend to five hundred rupees, or with both;

(c) Any drug or cosmetic in contravention of the provisions of any notification issued under section 10A, shall be punishable with imprisonment for a term which may extend to three years, or with fine which may extend to five thousand rupees, or with both.

(2) Whoever having been convicted of an offence -

(a) Under clause (a) or clause (c) of sub-section (1), is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which may extend to five years, or with fine which may extend to ten thousand rupees, or with both;
(b) Under clause (b) of sub-section (1), is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which may extend to one year, or with fine which may extend to one thousand rupees, or with both.

(3) The punishment provided by this section shall be in addition to any penalty to which the offender may be liable under the provisions of section 11.

Note: Highlighted sections have been made cognizable offences vide 'The Drugs And Cosmetics (Amendment) Act, 2008

14. Confiscation. — Where any offence punishable under section 13 has been committed, the consignment of the drugs in respect of which the offence has been committed shall be liable to confiscation.

15. Jurisdiction. — No Court inferior to that of a Metropolitan Magistrate or of a Judicial Magistrate of the First Class (Drugs and Cosmetics Act 1940) shall try an offence punishable under section 13

Drugs and Cosmetics Rules 1945: Part IV: Import and Registration

In this Part-

(a) 'Import licence' means either a licence in Form 10 to import drugs, excluding those specified in Schedule X, or a licence in Form 10-A to import drugs specified in Schedule X);

(b) "Licensing authority" means the authority appointed by the Central Government to perform the duties of the licensing authority under these Rules and included any person to whom the power of a licensing authority may be delegated under Rule 22;

(c) "Licence for examination, test or analysis" means a licence in Form 11 to import small quantities of drugs the import of which is otherwise prohibited, for the purpose of examination, test or analysis.

(d) "manufacturer", includes a manufacturer of drugs, who may be a Company or a unit or a body corporate or any other establishment in a country other than India, having its drugs manufacturing facilities duly approved by the National Regulatory Authority of that country, and who also has a free sale approval of the drugs approved by the said authority in the concerned country, and/or in other major countries;

(e) Registration Certificate" means a certificate issued under rule 27A by the licensing authority in Form 41 for registration of the premises and the drugs manufactured by the manufacturer meant for import into and use in India'.

22. The licensing authority may with the approval of the Central Government by an order in writing delegate the power to sign licences and Registration Certificates, and such other powers as may be specified in the order to any other person under his control.

23. Import licences - An import licence in Form 10 shall be required for import of drugs excluding those specified in Schedule X, and an import licence in Form 10-A shall be required for the import of drugs specified in Schedule X.) Substituted by GSR 604 (E) dated 24.08.01 w.e.f 01.01.2003

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24. Form and manner of application for import licence - (1) An application for an import licence shall be made to the licensing authority in Form 8 for drugs excluding those specified in Schedule X, and in Form 8-A for drugs specified in Schedule X, either by the manufacturer himself having a valid wholesale licence for sale or distribution of drugs under these rules, or by the manufacturer's agent in India either having a valid licence under the rules to manufacture for sale of a drug or having a valid wholesale licence for sale or distribution of drugs under these rules, and shall be accompanied by a licence fee of one thousand rupees for a single drug and an additional fee at the rate of one hundred rupees for each additional drug and by an undertaking in Form 9 duly signed by or on behalf of the manufacturer:

Provided that in the case of any subsequent application made by the same importer for import licence for drugs manufactured by the same manufacturer, the fee to accompany each such application shall be one hundred rupees for each drug.

(2) Any application for import licence in Form 8 or Form 8-A, as the case may be, shall be accompanied by a copy of Registration Certificate issued in Form 41 under rule 27-A; Provided that in case of emergencies the licensing authority may, with the approval of the Central Government, issue an import licence in Form 10 or 10-A, as the case may be, without the issuance of Registration Certificate under rule 27-A, for reasons to be recorded in writing.

(3) A fee of two hundred and fifty rupees shall be paid for a duplicate copy of the licence issued under this rule, if the original is defaced, damaged or lost. (Inserted by GSR 604 (E) dated 24.08.2001 w.e.f. 01.01.2003)

24-A. Form and manner of application for Registration Certificate - (1) An application for issue of a Registration Certificate shall be made to the licensing authority in Form 40, either by the manufacturer himself, having a valid wholesale licence for sale or distribution of drugs under these rules, or by his authorised agent in India, either having a valid licence to manufacture for sale of a drug or having a valid wholesale licence for sale or distribution of drugs under these rules and shall be accompanied by the fee specified in sub-rule (3) and the information and undertakings specified in Schedules D-1 and D-II duly signed by or on behalf of the manufacturer.

(2) The authorisation by a manufacturer to his agent in India shall be documented by a power of attorney executed and authenticated either in India before a First Class Magistrate, or in the country of origin before such an equivalent authority, the certificate of which is attested by the Indian Embassy of the said country, and the original of the same shall be furnished along with the application for Registration Certificate.

(3) (i) A fee of one thousand and five hundred US dollars (or its equivalent in Indian rupees) shall be paid along with the application in Form 40 as registration fee for his premises meant for manufacturing of drugs intended for import into and use in India.

(ii) A fee of one thousand US dollars (or its equivalent in Indian rupees) shall be paid along with the application in Form 40 for the registration of a single drug meant for import into and use in India and an additional fee at the rate of one thousand US dollars for each additional drug:

Provided that in the case of any subsequent application for registration of additional drugs by the same manufacturer, the fee to accompany shall be one thousand US dollars (or its equivalent to Indian rupees) for each drug.
(4) The fees shall be paid through a Challan in the Bank of Baroda, Kasturba Gandhi Marg, New Delhi-110 001 or any other branch or branches of Bank of Baroda, or any other bank, as notified, from time to time, by the Central Government, to be credited under the Head of Account "0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines".

Provided that in the case of any direct payment of fees by a manufacturer in the country of origin, the fees shall be paid through Electronic Clearance System (ECS) from any bank in the country of origin to the Bank of Baroda, Kasturba Gandhi Marg, New Delhi, through the Electronic Code of the bank in the Head of Account "0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines", and the original receipt of the said transfer shall be treated as an equivalent to the bank challan subject to the approval by the Bank of Baroda that they have received the payment.

(5) The applicant shall be liable for the payment of a fee of five thousand US dollars (or its equivalent in Indian rupees) for expenditure as may be required for inspection or visit of the manufacturing premises or drugs, by the licensing authority or by any other persons to whom powers have been delegated in this behalf by the licensing authority under rule 22:

(6) The applicant shall be liable for the payment of testing fees directly to a testing laboratory approved by the Central Government in India or abroad, as may be required for examination, tests and analysis of drug.

(7) A fee of three hundred US dollars (or its equivalent in Indian rupees) shall be paid for a duplicate copy of the Registration Certificate, if the original is defaced, damaged or lost.

(8) No Registration Certificate shall be required under these rules in respect of an inactive bulk substance to be used for a drug formulation, with or without Pharmacopeial conformity.

25. Licences for import of drugs manufactured by one manufacturer - (1) A single application may be made, and a single licence may be issued, in respect of the import of more than one drug or class of drugs manufactured by the same manufacturer:

Provided that the drugs or classes of drugs are manufactured at one factory or more than one factory functioning conjointly as a single manufacturing unit

Provided further that if a single manufacturer has two or more factories situated in different places manufacturing the same or different drugs a separate licence shall be required in respect of drugs manufactured by each such factory.) (Substituted GSR 462 (E) dated 22.06.1982)

25-A. Conditions to be specified before a licence in Form 10 or Form 10-A is granted - (1) A licence in Form 10 or in Form 10-A shall be granted by the licensing authority having regard to-

i) the premises, where the imported substances will be stocked are equipped with proper storage accommodation for preserving the properties of the drugs to which the licence applies; and

ii) the occupation, trade or business ordinarily carried out by the applicant.

Provided that the licensing authority may refuse to grant a licence in Form 10-A in respect of any applicant where he is satisfied.
(a) that the applicant has not complied with the provisions of the Act or these rules, or

(b) that by reasons of-

(i) his conviction under the Act or these rules or the Narcotic Drugs and Psychotropic Substances Act, (61 of 1985) or the rules made thereunder;

(ii) previous suspension or cancellation of the licence granted to him; he is not a fit person to whom licence shall be granted.

(2) Any person who is aggrieved by the order passed by the licensing authority under this rule may, within thirty days of the receipt of the order, appeal to the Central Government and the Central Government may after such enquiry into the matter as it considers necessary and after giving the appellant an opportunity for making a representation in the matter, make such orders in relation thereto as it thinks fit.

(Inserted GSR 604(E) dated 24.08.2001 w.e.f. 01.01.2003)

25-B. Registration Certificate for import of drugs manufactured by one manufacturer - (1) A single application may be made, and a single Registration Certificate in Form 41 may be issued in respect of the import of more than one drug or class of drugs, manufactured by the same manufacturer:

Provided that the drug or classes of drugs, are manufactured at one factory or more than one factory functioning conjointly as a single manufacturing unit:

Provided further that if a single manufacturer has two or more factories situated in different places manufacturing the same or different drugs, separate Registration Certificates shall be required in respect of the drugs manufactured by each such factory.

26. Conditions of import licence. - An import licence shall be subject to the following conditions –

(i) the manufacturer shall at all times observe the undertaking given by him or on his behalf in Form 9;

(ii) the licensee shall allow any Inspector authorized by the licensing authority in that behalf to enter with or without notice any premises where the imported substance is stocked in inspect the means, if any, employed for testing the substance and to take samples;

(iii) the licensee shall on request furnish to the licensing authority from every batch of each substance or form such batch or batches as the licensing authority may from time to time specify a sample of such amount as the licensing authority may consider adequate for any examination required to be made, and the licensee shall, if so required, furnish full protocols of the tests, if any, which have been applied;

(iv) if the licensing authority so directs the licensee shall not sale or offer for sale any batch in respect of which a sample is or protocols are furnished under the Iasi preceding sub-rule until a certificate authorizing the sale of the batch has been issued to him by or on behalf of the licensing authority;

(v) the licensee shall, on being informed by the licensing authority that any part of any batch of the substance has been found by the licensing authority not to conform with the standards of strength, quality and purity prescribed by Chapter III of the Act, or the Rules thereunder and on being directed so
to do, withdraw the remainder of that batch from sale and, so far as may in particular circumstances of the case be practicable, recall the issues already made from that batch; (Inserted GSR 462(E) dated 22.06.1982)

(vi) the licensee shall maintain a record of all sales by him of substances for the import of which a licence is required, showing particular of the substance and of the person to whom sold and such further particulars, if any, as the licensing authority may specify and such record shall be open to the inspection of any Inspector authorized in that behalf by the licensing authority:

Provided that in respect of the sale or distribution of drugs specified in Schedule X, the licensee shall maintain a separate record or register showing the following particulars, namely:

1. Name of the drug,
2. Batch Number,
3. Name and address of the manufacturer.
4. Date of transaction.
5. Opening stock on the business day,
6. Quantity of drug received, if any, and the source from which received,
7. Name of the purchaser, his address and licence number,
8. Balance quantity of drug at the end of the business day,
9. Signature of the person under whose supervision the drugs have been supplied;

(vii) the licensee shall comply with such further requirements, if any, applicable to the holders of import licences, as may be specified in any Rules, subsequently made under Chapter III of the Act and of which the licensing authority has given to him not less than four months’ notice. (Inserted 462 (E) dt. 22.06.1982)

27. Grant of import licence - On receipt of an application for an import licence in the form and manner prescribed in Rule 24, the licensing authority shall on being satisfied, that, if granted, the conditions of the licence will be observed, issue an import licence in Form 10 or Form 10-A, as the case may be. (Inserted 604(E) dt. 24.08.201 w.e.f. 01.01.2003)

27-A. Grant of Registration Certificate - (1) On receipt of an application for Registration Certificate in the Form and manner specified in rule 24-A, the licensing authority shall, on being satisfied, that, if granted, the conditions of the Registration Certificate will be observed, issue a Registration Certificate in Form 41:

Provided further that if the application is complete in all respects and information specified in Schedules D-I and D-II are in order, the licensing authority shall, within nine months from the date of receipt of an application, issue such Registration Certificate, and in exceptional circumstances and for reasons to be recorded in writing, the Registration Certificate may be issued within such extended period, not exceeding three months as the licensing authority, may deem fit.

(2) If the applicant does not receive the Registration Certificate within the period as specified in proviso to sub rule (1), he may appeal to the Central Government and the Central Government may after such enquire into the matter, as it considers necessary, may pass such orders in relation thereto as it thinks fit.

28. Duration of import licence - A licence, unless, it is sooner suspended or cancelled, shall be (Amended 19.04.1964) valid for a period of three years from date of its issue.
Provided that if an application for a fresh licence is made three months before the expiry of the existing licence the current licence shall be deemed to continue in force until orders are passed on the application. *(Inserted GSR 604(E) dt. 24.08.2001 w.e.f. 01.01.2003)*

28-A. Duration of Registration Certificate A Registration Certificate, unless, it is sooner suspended or cancelled, shall be valid for a period of three years from the date of its issue:

Provided that if the application for a fresh Registration Certificate is made nine months before the expiry of the existing certificate, the current Registration Certificate shall be deemed to continue in force until orders are passed on the application.

29. Suspension and cancellation of import licence If the manufacturer or licensee fails to comply with any of the conditions of an import licence, the licensing authority may after giving the manufacturer or licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, suspend or cancel it for such period as it thinks fit either wholly or in respect of some of the substances to which it relates. *(Substituted GSR 604 (E) dt. 24.08.2001 w.e.f. 01.01.2003)*

Provided that a person who is aggrieved by the order passed by the licensing authority under this rule may, within thirty days of the receipt of the order, appeal to the Central Government, and the Central Government may, after such enquiry into the matter, as it considers necessary and after giving the said appellant an opportunity for representing his views, pass such orders in relation thereto as it thinks fit. *(Inserted GSR 604 (E) dt. 24.08.2001 w.e.f. 01.01.2003)*

29-A. Suspension and cancellation of Registration Certificate If the manufacturer fails to comply with any of the conditions of the Registration Certificate, the licensing authority may after giving him an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, suspend or cancel the Registration Certificate for such period as it thinks fit either wholly or in respect of some of the substances to which it relates:

Provided that a person, who is aggrieved by the order passed by the licensing authority under this rule may, within thirty days of the receipt of the order, appeal to the Central Government, and the Central Government may, after such enquiry into the matter as it considers necessary and after giving the appellant an opportunity for representing his views in the matter, pass such orders in relation thereto as it thinks fit.

30. Prohibition of import after expiry of potency No biological or other special product specified in Schedule C or C(1) shall be imported after the date shown on the label, wrapper or container of the drug as the date up to which the drug may be expected to retain a potency not less than, or not to acquire a toxicity greater than, that required, or as the case may be, permitted by the prescribed test.

30-AA. Import of New Homeopathic medicines *(1)* No New Homoeopathic medicine shall be imported except under and in accordance with the permission in writing of the Licensing Authority.

*(2)* The importer of a New Homoeopathic medicine when applying for permission shall produce before the Licensing Authority such documentary and other evidence as may be required by the Licensing Authority for assessing the therapeutic efficacy of the medicine including the minimum provings carried out with it. *(Substituted GSR 680 (E) dt. 05.12.1980)*
Explanation.- For the purpose of this rule, 'New Homeopathic medicine' means,-

(i) a Homeopathic medicine which is not specified in the Homeopathic Pharmacopoeia of India or the United States of America or the United Kingdom or the General Homeopathic Pharmacopoeia; or

(ii) which is not recognised in authoritative Homeopathic literature as efficacious under the conditions recommended; or

(iii) a combination of Homeopathic medicines containing one or more medicines which are not specified in any of the Pharmacopoeias referred to in clause (i) as Homeopathic medicines and also not recognised in authoritative Homeopathic literature as efficacious, under the conditions recommended.) (Added 04.01.1951)

30-B. Prohibition of import of certain drugs No drug, the manufacture, sale or distribution of which is prohibited in the country of origin, shall be imported under the same name or under any other name except for the purpose of examination, test or analysis. (Substituted GSR 604 (E) dt. 24.08.2001 w.e.f. 01.01.2003)

31. Standard for certain imported drugs No drug shall be imported unless it complies with the standard of strength, quality and purity, if any, and the test prescribed in the rules shall be applicable for determining whether any such imported drug complies with the said standards:

Provided that the drugs intended for veterinary use, the standards of strength, quality and purity, if any, shall be those that are specified in Schedule F(1) and the test prescribed in that Schedule shall be applicable for determining whether any such imported drug complies with the said standards and where no standards are specified in Schedule F(1) for any veterinary drug, the standards for such drug shall be those specified in the current edition, for the time being in force, of the British Pharmacopoeia Veterinary:

Provided further that the licensing authority shall not allow the import of any drug having less than sixty per cent. residual shelf-life period as on the date of import:

Provided also that in exceptional cases the licensing authority may, for reasons to be recorded in writing, may allow, the import of any drug having lesser shelf-life period, but before the date of expiry as declared on the container of the drug. (Amended 02.07.1969)

32. 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 conforms 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. (Added 05.06.1972)

32-A. Packing and labelling of Homeopathic medicine No Homeopathic medicine shall be imported unless it is packed and labelled in conformity with the rules in Part IX-A.

33. Import of drugs for examination, test or analysis Small quantities of drugs the import of which is otherwise prohibited under Section 10 of the Act may be imported for the purpose of examination, test or analysis subject to the following conditions:
(a) No drug shall be imported for such purpose except under a licence in Form 11;

(b) The licensee shall use the substances imported under the licence exclusively for purposes of examination, test or analysis and shall carry on such examination, test or analysis in the place specified in the licence, or in such other places as the licensing authority may from time to time authorize;

(c) The licensee shall allow any Inspector authorized by the licensing authority in this behalf to enter, with or without prior notice, the premises where the substances are kept, and to inspect the premises, and investigate the manner in which the substances are being used and to take samples thereof;

(d) The licensee shall keep a record of, and shall report to the licensing authority, the substances imported under the licence, together with the quantities imported, the date of importation, and the name of the manufacturer;

(e) The licensee shall comply with such further requirements, if any, applicable to the holders of licences for examination, test or analysis as may be specified in any rule subsequently made under Chapter III of the Act and of which the licensing authority has given to him not less than one month's notice. (Inserted GSR 604 (E) dt. 24.08.2001 w.e.f. 1.1.2003)

33-A. Import of drugs by a Government Hospital or Autonomous Medical Institution for the treatment of patients

Small quantities of a new drug, as defined in rule 122-E, the import of which is otherwise prohibited under section 10 of the Act, may be imported for treatment of patients suffering from life threatening diseases, or diseases causing serious permanent disability, or such disease requiring therapies for unmet medical needs, by a Medical Officer of a Government Hospital or an Autonomous Medical Institution providing tertiary care, duly certified by the Medical Superintendent of the Government Hospital, or Head of the Autonomous Medical Institution, subject to the following conditions, namely:

(a) no new drug shall be imported for the said purpose except under a licence in Form 11-A, and the said drug has been approved for marketing in the country of origin;

(b) the licensee shall use the substances or drugs imported under the licence exclusively for the purpose of treatment of patients suffering from life threatening diseases, or diseases causing serious permanent disability, or such diseases requiring therapies for unmet medical needs, under the supervision of its own Medical Officers at the place, specified in the licence or at such other places, as the licensing authority, may from time to time authorize;

(c) the licensee shall allow an Inspector authorised by the licensing authority in this behalf to enter, with or without prior notice, the premises where the substances or drugs are stocked, and to inspect the premises and relevant records and investigate the manner in which the substances or drugs are being used and to take, if necessary, samples thereof;

(d) the licensee shall keep a record of, and shall submit the said report half yearly to the licensing authority, the substances or drugs imported under the licence, together with the quantities imported and issued to the patients, the date of importation, the name of the manufacturer, the name and address of the patient for whom the drug is prescribed and the name of disease;
(e) the licencee shall comply with such other requirements, if any, applicable to the holders of import licences for import of new drugs for treatment of patients by Government Hospitals, as may be specified from time to time in any rule subsequently made under Chapter III of the Act and of which the licensing authority has given to him not less than one month's notice;

(f) the drug shall be stocked under proper storage conditions and shall be dispensed under the supervision of a registered pharmacist;

(g) the quantity of any single drug so imported shall not exceed 100 average dosages per patient:

Provided that the licensing authority may, in exceptional circumstances, sanction the import of drug a larger quantity.

34. Application for licence for examination, test or analysis (1) An application for a licence for examination, test or analysis shall be made in Form 12 and shall be made or countersigned by the Head of the Institution in which, or by a proprietor or director of the company or firm by which the examination, test or analysis will be conducted.

(2) The licensing authority may require such further particulars to be supplied as he may consider necessary.

(3) Every application in Form 12 shall be accompanied by a fee of one hundred rupees for a single drug and an additional fee of fifty rupees for each additional drug.

(4) The fees shall be paid through a challan in the Bank of Baroda, Kasturba Gandhi Marg, New Delhi-110 001 or any other branch or branches of Bank of Baroda, or any other Bank, as Notified, from time to time, by the Central Government, to be credited under the Head of Account "0210-Medical and Public Health, 04-Public Health, 104-Fees and Fine”.

34-A. Application for licence to import small quantities of new drugs by a Government Hospital or Autonomous Medical Institution for the treatment of patients (1) An application for an import licence for small quantities of a new drug, as defined in rule 122-E for the purpose of treatment of patients suffering from life threatening diseases, or diseases causing serious permanent disability, or -21- such diseases requiring therapies for unmet med cal needs, shall be made in Form 12-AA, by a Medical Officer of the Government Hospital or Autonomous Medical Institution, which shall be certified by the Medical Superintendent of the Government Hospital or Head of the Autonomous Medical Institution, as the case may be.

(2) The licensing authority may require such further particulars to be supplied, as he may consider necessary.

(3) Every application in Form 12-AA shall be accompanied by a fee of one hundred rupees for a single drug and an additional fee of fifty rupees for each additional drug.

(4) fees shall be paid through a challan in the Bank of Baroda, Kasturba Gandhi Marg, New Delhi-110 001 or any other branch or branches of Bank of Baroda, or any other Bank, as Notified, from time to time, by the Central Government, to be credited under the Head of Account "0210-Medical and Public Health, 04-Public Health, 104-Fees and Fine".
35. Cancellation of licence for examination, test or analysis (1) A licence for examination, test or analysis may be cancelled by the licensing authority for breach of any of the conditions subject to which the licence was issued.

(2) A licensee whose licence has been cancelled may appeal to the Central Government within three months of the date of the order. (Inserted GSR 604(E) dt. 24.08.2001 w.e.f. 01.01.2003)

35-A. Cancellation of licence for import of small quantities of new drugs (1) A licence for import of small quantities of a new drug, defined in rule 122-E, for the purpose of the treatment of patients suffering from life threatening diseases, or diseases causing serious permanent disability, or such diseases requiring therapies for unmet medical needs, by a Government Hospital or an Autonomous Medical Institution may be cancelled by the licensing authority for breach of any of the conditions subject to which the licence was issued or for contravention of any of the provisions of the Act and rules made thereunder. (2) A licensee whose licence has been cancelled may appeal to the Central Government within three months from the date of the receipt of the order, and the Central Government may after such enquiry into the matter, as it considers necessary and after giving the appellant an opportunity for representing his views, may pass such orders in relation thereto, as it thinks fit.*

36. Import of drugs for personal use Small quantities of drugs, the imports of which are otherwise prohibited under Section 10 of the Act, may be imported for personal use subject to the following conditions:

(i) the drugs shall form part of a passenger's bona fide baggage and shall be the property of, and be intended for, the exclusive personal use of the passenger;

(ii) the drugs shall be declared to the Customs Authorities if they so direct;

(iii) the quantity of any single drug so imported shall not exceed one hundred average does:

Provided that the licensing authority may in an exceptional case in any individual case sanction the imports of a large quantity: (Inserted 03.03.1955) Provided further that any drug, imported for personal use but not forming part of bona fide personal baggage, may be allowed to be imported subject to the following conditions, namely:

i) the licensing authority, on an application made to it in Form 12-A is satisfied that the drug is for bona fide personal use;

ii) the quantity to be imported is reasonable in the opinion of the licensing authority and is covered by prescription from a registered medical practitioner; and

iii) the licensing authority grants a permit in respect of the said drug in Form 12-B. (Amended 15.10.1954)

37. Packing of patent or proprietary medicines Patent or proprietary medicine shall be imported in containers intended for retail sale: (Amended 15.10.1954)

Provided that such medicine 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.

38. Statement to accompany imported drugs All consignments of drugs sought to be imported shall be accompanied by an invoice or other statement showing the name and address of the manufacturer and the name and quantities of the drugs.

39. Documents to be supplied to the Customs Collector Before drugs for the import of which a licence is not required are imported a declaration signed by or on behalf of the manufacturer or by or on behalf of the importer that the drugs comply with the provisions of Chapter III of the Drugs and Cosmetics Act, 1940 and the Rules thereunder shall be supplied to the Customs Collector. (Amended 03.11.1953)

40. Procedure for the import of drugs

(1) If the Customs Collector has reason to doubt whether any drugs comply with the provisions of Chapter III of the Act and Rules thereunder he may, and if requested by an officer appointed for this purpose by the Central Government shall, take samples of any drugs in the consignment and forward them to the director of the laboratory appointed for this purpose by the Central Government and may detain the drugs in the consignment of which samples have been taken until the report of the director of the said laboratory or any other officer empowered by him on this behalf, subject to the approval of the Central Government on such samples is received.

Provided that if the importer gives an undertaking in writing not to dispose of the drugs without the consent of the Customs Collector and to return the consignment or such portion thereof as may be required, the Customs Collector shall make over the consignment to the importer.

(2) If an importer who has given an undertaking under the proviso to sub-rule (1) is required by the Customs Collector to return the consignment or any portion thereof he shall return the consignment or portion thereof within ten days of receipt of the notice. (Amended 03.11.1954)

41. (1) If the director of the laboratory appointed for the purpose by the Central Government or any other empowered by him on this behalf subject to the approval of the Central Government reports to the Customs Collector that the samples of any drug in a consignment are not of standard quality, or that the drug contravenes in any other respect the provisions of Chapter III of the Act or the Rules thereunder and that the contravention is such that it cannot be remedied by the importer, the Customs collector shall communicate the report forthwith to the importer who shall, within two months of his receiving the communication either export all the drugs of that description in the consignment, to the country in which they were manufactured or forfeit them to the Central Government which shall cause them to be destroyed.

Provided that the importer may within fifteen days of receipt of the report make a representation against the report to the Customs collector, and the Customs Collector shall forward the representation with a further sample to the licensing authority, who after obtaining, if necessary, the report of the Director of the Central Drugs Laboratory, shall pass orders thereon which shall be final. (Added 15.1.1951)

(2) If the director of the laboratory appointed for the purpose by the Central Government or any other officer empowered by him on this behalf, subject to the approval of the Central Government reports to the Customs Collector that the samples of any drug contravene in any respect the provisions of Chapter III of the Act or the Rules thereunder and that the contravention is such that it can be remedied by the importer, the Customs Collector shall
communicate the report forthwith to the importer and permit him to import the drug on his giving an undertaking in writing not to dispose of the drug without the permission of the officer authorised in this behalf by the Central Government.

43. The drug specified in Schedule D shall be exempt from the provisions of Chapter III of the Act and of the Rules made thereunder to the extent, and subject to the conditions specified in that Schedule.
(Substituted 06.08.1981)

43-A. No drug shall be imported into India except through one of the following places, namely:

Firozepur Cantonment and Amritsar Railway Stations:
In respect of drugs imported by rail across the frontier with Pakistan. Ranaghat, Bongaon and Mohiassan Railway Stations:
In respect of drugs imported by rail across the frontier with Bangladesh.
Raxual: in respect of drugs imported by road and railway lines connecting Raxual in India and Birganj in Nepal.
Chennai, Calcutta, Mumbai Cochin and Nhava Sheva. In respect of drugs imported by sea into India
Chennai, Calcutta, Mumbai, Delhi Ahmedabad and Hyderabad. In respect of drugs imported by air into India. (Added 19.03.1964)

43-B. Drugs, consignments of which are in transit through India to foreign countries and which shall not be sold or distributed in India shall be exempted from the requirements of Chapter III of the Drugs and Cosmetics Act, *940 (23 of 1940) and rules made thereunder:

Provided that if the Government of the countries to which the drugs are consigned regulate their import by the grant of import licences, the importer shall at the time of import into India, produce such import licences.

*(Drug and Cosmetics Act 1940)*

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Documents to be submitted for grant of permission to conduct Bioequivalence (BE) studies for export purpose.

A large number of applications are being filed to the office of DCG (I) at CDSCO (HQ) by Pharmaceutical companies, both manufacturers and importers as well as CRO's on behalf of them, requesting for the approval to carry out BE studies with various pharmaceutical dosage formulations on Indian subjects.

In light of the above, for easy processing of such applications and to bring uniformity in decision making all stake holders of the above mentioned activities are hereby advised to submit their applications with following documents. All applications should accompany the documents with proper index & page number.

Requirements for BE study of a new molecule not approved in India but approved in the other countries.
1. Application in Form-44 duly signed, by the competent authority with name and designation.
2. Treasury Challan of Rs. 25000/- as per Drugs & Cosmetic Rules.
3. Undertaking by the Principal Investigator (PI) as per appendix VII of schedule “Y” of Drugs and Cosmetic Rules.
4. A copy of the approval granted to the BE study centre by CDSCO.
5. Sponsor’s Authorization letter duly signed by the competent authority on their letterhead.
6. The study protocols.
7. The study synopsis
8. Pre-clinical single dose data and repeated dose toxicity data.
9. Clinical study data and published report of pharmacokinetic and pharmacodynamic study carried out in healthy volunteers/patients data published in reputed journals.
11. Names of the countries where the drug is currently being marketed (to be mentioned in the covering letter also).
12. Package literature on the international product
13. Complete Certificate of Analysis of same batches (both test & reference formulations) to be used in the BE study.
14. In the case of multiple dose BE study adequate supporting safety data should be submitted.
15. In the case of injectable preparation the sub-acute toxicity should be submitted on the product of the sponsor, generated in two species for adequate duration.
16. Depending on the nature of the drug like cytotoxic agent, hormonal preparations etc. Proper justification for conducting studies on healthy volunteers/patients or male/ female should be submitted.

New Drugs approved in India within period of 1 year:-

1. Application in Form-44 duly signed, by the competent authority with name and designation
2. Treasury Challan of Rs. 25000/- as per Drugs & Cosmetic Rules.
3. Undertaking by the Principal Investigator (PI) as per appendix VII of schedule “Y” of Drugs and Cosmetic Rules.
4. A copy of the approval of the BE study centre from CDSCO.
5. Sponsor’s Authorization letter duly signed by the competent authority on their letterhead.
6. The study protocols.
7. Clinical study data and published report of pharmacokinetic and pharmacodynamic study carried out in healthy volunteers/patients data published in reputed journals.
8. Package literature on the international product.
9. Complete Certificate of Analysis of same batches (both test & reference formulations) to be used in the BE study.
10. In the case of multiple dose BE study adequate supporting safety data should be submitted.
11. In the case of Injectable preparation the sub-acute toxicity should be submitted on the product of the sponsor, generated in two species for adequate duration.

12. Depending on the nature of the drug like cytotoxic agent, hormonal preparations etc. Proper justification for conducting studies on healthy volunteers/patients or male/ female should be submitted.

New Drugs approved within period of more than 1 year & less than 4 years:-

1. Application in Form-44 duly signed, by the competent authority with name and designation
2. Treasury Challan of Rs. 15000/- as per Drugs & Cosmetic Rules.
3. Undertaking by the Principal Investigator (PI) as per appendix VII of schedule “Y” of Drugs and Cosmetic Rules.
4. A copy of the approval of the BE study centre from CDSCO.
5. Sponsor's Authorization letter duly signed on their letterhead by the competent authority.
6. The study protocols.
7. Complete Certificate of Analysis of same batches (both test & reference formulations) to be used in the BE study.
8. In the case of multiple dose BE study adequate supporting safety data should be submitted.
9. In the case of Injectable preparation the sub-acute toxicity should be submitted on the product of the sponsor, generated in two species for adequate duration.
10. Depending on the nature of the drug like cytotoxic agent, hormonal preparations etc. Proper justification for conducting studies on healthy volunteers/patients or male/ female should be submitted.

BE NOC for all the drug products in modified release form irrespective of their approval status:-

1. Application in Form-44 duly signed, by the competent authority with name and designation
2. Treasury Challan of Rs. 15000/- as per Drugs & Cosmetic Rules.
3. Undertaking by the Principal Investigator (PI) as per appendix VII of schedule “Y” of Drugs and Cosmetic Rules.
4. A copy of the approval of the BE study centre from CDSCO.
5. Sponsor's Authorization letter duly signed on their letterhead by the competent authority.
6. The study protocols.
7. Complete Certificate of Analysis of same batches (both test & reference formulations) to be used in the BE study.
8. In the case of multiple dose BE study adequate supporting safety data should be submitted.
9. In the case of Injectable preparation the sub-acute toxicity should be submitted on the product of the sponsor, generated in two species for adequate duration.
10. Depending on the nature of the drug like cytotoxic agent, hormonal preparations etc. Proper justification for conducting studies on healthy volunteers/patients or male/ female should be submitted.
All above requirements are general in nature, however depending on the nature of the drug, disease and studies further specific information may also be required to be furnished by the firm. (www.cdsco.nic.in)

India to check exports of counterfeits; ensure quality of ‘made-in-india’ drugs: India has initiated strategies to check the export of counterfeit medicines from India even as several countries continue to allege the generic hub of the world as a prime source of substandard and fake medicines.

In an effort to protect the Indian pharma industry’s brand image, the government is planning to roll out a unique identification system for exports of pharmaceuticals to curb the menace of counterfeit drugs.

The new system, which is likely to be operational in 3-4 months, will ensure that a drug exported from India is actually made in India and is not counterfeit.

“We want to have a technology by which the regulator of a particular country and if possible the consumer has access to information whether it is really made in India or not and some other information as well,” stated Ashok Kumar, secretary, department of pharmaceuticals.

There have been instances in the recent past of counterfeit drugs labelled as made in India sold in African countries, tarnishing the image of the Indian drug exporters.

Recently, the government has proposed to offer financial assistance to drug firms for upgrading manufacturing facilities according to the current quality standards.

Pharma Multinational Companys’s (MNCs) has been threatening the entry of legitimate generics exported from India under the garb of fake and counterfeits.

Recently, several drug shipments meant for some developing countries from India have been confiscated in European ports saying that they violated the IP rights of the countries through which the cargo passes.

Indian government has taken up the matter to the European countries involved in confiscation as well as to World Trade Organization (WTO).

This has huge ramifications particularly for India as consignments of generics have been seized while in transit in Netherlands and other European countries, on allegations of IP infringement.

WHO has created a global coalition of stakeholders called IMPACT (International Medical Products Anti-Counterfeiting Taskforce) to tackle the challenge of fake and counterfeit drugs.

IMPACT taskforce, created in 2006, has been active in forging international collaboration to seek global solutions to this global challenge and in raising awareness of the dangers of counterfeit medical products.

IMPACT aims to coordinate across and between countries in order to halt the production, trading and selling of fake medicines around the globe. IMPACT is a partnership comprised of all the major anti-counterfeiting players, including: international organizations, non-governmental organizations, enforcement agencies, pharmaceutical manufacturers associations and drug and regulatory authorities.
South-east Asia countries like India and Thailand had opposed the IMPACT Agenda in the World Health Assembly last year, as well as in the WHO's executive board meeting earlier in January this year.

India and other developing countries have been concerned that IMPACT's focus on policy and legislation on counterfeit drugs will be counter productive and will create barriers to trade in and access to legitimate medicines.

On the issue of counterfeits, WHO has urged member states to strengthen their national regulatory framework to ensure access of safe, quality and affordable medicines to all, particularly vulnerable groups.

WHO also asked for incorporating of public health safeguards, as mandated by the Doha Declaration on the TRIPS agreement and public health, in the states domestic intellectual property legislation?

WHO's member states should implement trade and intellectual property policies without constraining policy space on health, including access to safe, efficacious and quality and affordable medical products.

The counterfeiting of medicines has been a problem for at least two decades in many countries around the world. As international markets expand and become globalized the problem has extended to all countries and regions; even though it remains more prevalent in developing countries. The increase in the commercial use of the Internet has also contributed to a growth of the problem as many fake products are sold illegally on unauthorized web sites, WHO says.


An Article "Import & Export of Drugs & Cosmetics Regulatory supervision-Few Aspects"

True deficiencies in the Indian Regulatory laws in respect of Import-Export of Drugs and Cosmetics.

Some of his relevant observations are being reproduced below:

Validity of Import licence and / or Registration certificate on landing of goods in India.

Difference in specification of either API's or Formulations, which must meet the standards as prescribed in second schedule, this includes mention of older editions of Pharmacopoeas.

Labelling irregularities particularly in respect of API's, like non mention of - name and address of the manufacturer, Import licence number, Date of manufacturing and Expiry,

In respect of Formulations the item does not conform to labelling conditions of Indian Drug Rules.

The Author further underlines as:

All the labelling deficiencies ideally the item is to be returned back to the country of origin, this does not happen and it is agreed between importer and regulatory body that label can be corrected and item can be cleared for import.

Though correction of label appears simple, it is not so for the imported items. Drugs Controller (India) is the authority to grant permission under Rule 104 A to correct such labels. Secondly it is also to be ensured that the correction is done on all the packs those are imported; only few labels are corrected to
satisfy the authority. Imported containers of API's with incomplete label details on the facturing site are common.

The formulation sites in Europe, USA and other similar countries may not be making special packs for India and imported formulations are received in global packs. For sale in India these packs are to be further labelled with details as required in our rules. Sticker if used can not be considered compliance of labelling provisions. This will also require some permission from the Licensing Authority for undertaking this operation which is not obtained in more than 98% cases. In case the import is done by company's business office in India this labelling operations are done in premises where they possess a selling licence.

Ensuring quality is generally done through sample testing. To expect the GMP procedures within the custom shed is next to impossible, neither trained personnel nor proper facilities are available and sampling at numerous occasions is being done in open-to-sky are and no body objects. DCGI's representatives posted at the ports most of the time were such who did not have any exposure to GMP's or did not respect these aspects, claims the author.

The provision for additional fee $ 5000.00 was made for inspection of overseas manufacturing sites intending to register their products in India but hardly any of the sites were inspected, registration, however is not being denied and sites are being registered with Govt. of India and the site inspection is not being carried out even at the time of renewal of registration. More than excess confidence is generated for the site's activities through DMF submitted and coming to conclusion that full compliance of regulations will be there, the inspection is not considered necessary, or officials in DCGI's office have no confidence in the capabilities of inspectors that inspectors can not inspect the units out side the country and so on. Reasons for not having the site inspected could be different and the main could be that there is no will with the officials for permitting inspections.

Another important Regulatory-supervision aspect is official import of counterfeit items (mainly API's). Product labels on API containers are simply typewritten and are computer print outs on white paper. These types of labels on the products manufactured outside and imported in India from China do not generate confidence that these are either not genuine products or labelling of API's has been harmonised completely and API manufacturers follow this type of labelling for products meant for export to India. If this is not correct, the imported AP can be termed as counterfeit. Items imported into India has not been produced at the registered site has or ginated from some unregistered site and found its way to India inspite of India's efforts of site registration. As per Author's own assessment more than 50% of API's imported into India are in this category of counterfeit. Author further mentions that such items are imported by trade community, mostly from China, invoice is not directly from the manufacturer and is issued by one of the traders. Link between registered manufacturer and trader is supposedly established through a certificate from 'China Council of Pharma Industry and Trade or CCPIT' which by the port offices is treated as an authentication of invoice, whereas the CCPIT only authenticates the annexed paper and commit nothing for genuineness of the material. More so, many times this vital link too is missed, the item however is not held-up and generally cleared. According to Author there is no will to check such illegal imports which he termed as SMUGGLING.

For quality checking of imported drugs regulatory supervision and a guarantee to be given by regulatory officials that only assured quality drugs are imported in our country is another aspect. As against this, compromises do exist and number of GMP aspects is overlooked at various ports of the country. Further our laboratories, under Government control, including the appellate one, CDL, are not adequately equipped to test items that are imported in the country.

At present for export regulatory controls are not clearly prescribed in Drug Rules. In simple terms an item is to be manufactured under a valid manufacturing licence, it is packed and labelled according to requirement of importing country and exported.
The "export NOC check list" appearing on the website of CDSCO does not bear its date of implementation. The idea of this check list could be ensuring safety while permitting exports and ensuring that any wrong product is not exported.

Another check list also appears on CDSCO website i.e Check list for Bioequivalence Study for Export. Application in Form-44 as per schedule 'Y' of Drug Rules for BE NOC for export together with specified documents and Treasury chalan of prescribed fee is required to be submitted.

(Mr. Kapil Bhargava, Ex Dy. Drugs Controller (India) CDSCO, published in Vol. 41-No. 8-August 2009 of Pharma Times an Official Publication of The Indian Pharmaceutical Association)

2.6 THAILAND

Pre-marketing Control: Licensing

The Drug Act requires that any person who wishes to sell, manufacture or import drugs into the Kingdom must obtain a licence from the licensing authorities. The Drug Control Division is the licensing and registration authority for manufacturing, import and sale of drugs within Bangkok metropolis and its territories. Provincial Public Health Offices are the licensing authorities for manufacture and import of traditional drugs and sale of drugs in other provinces.

Applications for licences must be submitted to the licensing authority. The buildings and facility shall then be inspected. A licence will be issued after the inspection has confirmed that the applicant has adequate capabilities of doing such business and he/she can secure appropriate facilities and personnel for that purpose. Licences are issued according to the business of the applicant in the different categories.

The procedure of generic drugs registration is divided into 2 main steps:

Step 1: Application for the permission to import or manufacture drug sample intended to be registered.

The following documents are required:

1) Application form to be completely filled by authorized licensee
2) Drug formula [ active ingredients(s) only ]
3) Drug literature
4) Drug labeling and packaging

Step 2: Application for the approval of granted credential certificate

The following documents are required:

1. Application form to be completely filled by authorized licensee
2. Permit to manufacture or import drug sample
3. Drug sample
4. Pharmacological and toxicological study (if any)
5. Clinical trials, safety and efficacy study (if any)
6. Complete drug formula
7. Drug literature
8. Labeling and packaging should consist of name of the drug, registration number, quantity of drug per packaging, formula which shows active ingredient (s) and quantity of strength, lot no, batch control number, name of manufacturer and address, manufacturing date, the words

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“dangerous drug”/ “specially controlled”/ “for external use”/ “for topical use” written in Thai and in red color if the drug is considered to be of them, the word “household remedy drug” written in Thai if the drug is considered to be, the word “for veterinary use” written in Thai if the drug is considered to be, and the expire date.

9. Certificate of Free sale (in case of imported drug)
10. Manufacturing method
11. In-process control with the relevant acceptable limits
12. Raw material specifications of active(s) and inert ingredients with the corresponding control methods in details
13. Finished product specification with the corresponding control methods in details
14. Certificate of analysis of active ingredient(s) (raw material) (To be required in case of that active substance dose not conform to official pharmacopoeias (USP, NF, BP, .......ect)
15. Drug analytical control method
16. Packaging
17. Storage condition
18. Stability studies of finished product
19. Certificate of GMP (in case of imported drug)

(www.fda.moph.go.th)

2.7 CHINA

Guiding Principles in Registration Test of Import Drugs issued by SFDA

On June 25, 2004, the State Food and Drug Administration issued the “Guiding Principles in Registration Test of Import Drugs” to the port institutes for drug control. The purpose was to strengthen the registration of import drugs, and standardize the testing of import drug registration.

Application and Approval of Import Drugs

Section 1

Registration of Import Drugs

Article 84 A drug being applied for importation shall have already obtained the drug marketing authorization in the producing country or region where the overseas pharmaceutical manufacturer is located; those not yet obtained marketing authorization in the producing country or region. The production of a drug applied for importation shall comply with the GMP requirements of both the producing country or region where the drug manufacturer is located and China.

Article 85 To apply for import drug registration, the applicant shall fill the Application Form for Drug Registration, submit relevant dossiers and samples provide relevant approval documents, and submit the application to the State Food and Drug Administration.

Article 86 The State Food and Drug Administration shall conduct the preliminary review of the application dossiers, and issue an acceptance notice of drug registration application and notify the National Institute for the Control of Pharmaceutical and Biological Products to conduct testing for registration of samples from three batches if requirements are met; or issue a non-acceptance notice of drug registration application with reasons if requirements are not met.

The State Food and Drug Administration may organize to conduct on-site inspection of development and production conditions, and take samples.
Article 87 The National Institute for the Control of Pharmaceutical and Biological Products shall organize to conduct the testing for drug registration within five days from the date it receives the dossiers and samples.

Article 88 The drug testing institutes undertaking the import drug testing shall complete the testing for registration and submit the certificate of analysis for drug registration to the National Institute for the Control of Pharmaceutical and Biological Products within 60 days from the date they receive the documents, samples and relevant reference standards.

Sample testing and verification of specifications for controlled drugs or vaccines shall be completed within 90 days.

Article 89 The National Institute for the Control of Pharmaceutical and Biological Products shall organize experts to conduct technical review within 20 days from the date it receives the certificate of analysis for drug registration and the verified import specifications, and if necessary, conduct further verification according to the review opinions.

Article 90 After completing the testing for import drug registration, the National Institute for the Control of Pharmaceutical and Biological Products shall give the verified specifications, certificate of analysis and opinions thereof to the Center for Drug Evaluation of the State Food and Drug Administration, and copy the applicants.

Article 91 The Center for Drug Evaluation of the State Food and Drug Administration shall organize pharmaceutical, medical and other technical personnel to conduct technical review of the submitted dossiers within the specified timeline, and may request, with reasons, applicants to provide supplementary materials when necessary.

Article 92 The Center for Drug Evaluation of the State Food and Drug Administration shall make a general opinion based on the technical review opinions and sample testing results, and report the general opinion together with relevant documents to the State Food and Drug Administration. The State Food and Drug Administration shall make a review and approval decision based on the general opinion. Where the regulations are conformed to, a Clinical Trial Approval shall be issued; where the regulations are not conformed to, a Disapproval Notice shall be issued with reasons.

Article 93 After a clinical trial application is approved, the applicant shall conduct the trial in accordance with the requirements in Chapter III of the Provisions and the other relevant requirements.

After a clinical trial is completed, the applicant shall fill the Application Form for Drug Registration, submit the clinical trial data, other altered and supplementary data in accordance with regulations, give in detail the basis and reasons, and provide relevant approved documents.

Article 94 The Center for Drug Evaluation of the State Food and Drug Administration shall organize pharmaceutical, medical and other technical personnel to conduct comprehensive review of the submitted clinical trial data within the specified timeline, and may request, with reasons, applicants to provide supplementary materials when necessary.

The State Food and Drug Administration shall make a review and approval decision based on the general opinion. An Import Drug License shall be issued if regulations are conformed to. For a drug applied for registration by a drug manufacturer in Hong Kong, Macao or Taiwan of China, its application shall be handled in reference to the application procedures for import drug registration. If requirements are met, a Pharmaceutical Product License shall be issued; if requirements are not met, a Disapproval Notice shall be issued with reasons.
Article 95 To apply for importation of pharmaceutical preparations, approved documents for the lawful sources of the immediate packaging materials and containers and those of the drug substances and the excipients used for the pharmaceutical preparations shall be provided. Where drug substances and excipients are not yet approved by the State Food and Drug Administration, relevant data of manufacturing processes, specifications and testing methods, etc. shall be submitted.

Section 2
Registration of Import Drug Repackaging

Article 96 The import drug repackaging refers to dividing a large pack into small ones in China or adding outer-package to a drug with inner-package, placing insert sheets and attaching labels, etc., after the production process of the finished pharmaceutical preparations for the drug are completed overseas.

Article 97 To apply for import drug repackaging, the following requirements shall be met:

1. the Import Drug License or Pharmaceutical Product License of the drug is already obtained;
2. the drug shall be one that is not produced within the territory of China, or is produced in China but unable to meet clinical needs;
3. one drug produced by a drug manufacturer shall be repackaged by only one drug manufacturer. The term allowed for repackaging shall not exceed the expiry date of the Import Drug License or Pharmaceutical Product License;
4. the inner-packaging of a drug in any dosage form for repackaging, except tablets and capsules, shall be completed overseas;
5. a drug manufacturer that conducts repackaging shall hold the Drug Manufacturing Certificate. To apply for repackaging of import unpackaged tablets and capsules, the manufacturer shall also hold the GMP certificate covering the dosage forms for repackaging; and
6. An application for drug repackaging shall be made one year prior to the expiration of the Import Drug License or the Pharmaceutical Product License.

Article 98 An overseas drug manufacturer shall sign a contract for import drug repackaging with a domestic drug manufacturer, and fill in the Drug Supplementary Application Form.

Article 99 To apply for the repackaging of an import drug, the drug manufacturer entrusted with repackaging of the drug shall submit an application to the drug regulatory department of the province, autonomous region, or municipality directly under the Central Government where it is located. The trustee shall submit the Supplementary Drug Application Form filled in by the trustor, the relevant data and samples as well as the contract of entrustment, etc. The drug regulatory department shall conduct the preliminary review of the submitted documents. Where requirements are met, it shall issue a notice of acceptance; where requirements are not met, it shall issue a notice of non-acceptance with reasons.

The drug regulatory department shall make review opinions, then submit the application documents and review opinions to the State Food and Drug Administration and inform the applicant at the same time.
Article 100 The State Food and Drug Administration shall review the submitted documents. Where the regulations are conformed to, it shall issue an Approval for Supplementary Drug Application and a drug approval number; where the regulations are not conformed to, it shall issue a Disapproval Notice with reasons.

Article 101 The repackaged import drugs shall comply with the registration specifications for import drugs.

Article 102 The insert sheets and labels of a repackaged import drug shall be in conformity with those of the import drug, and shall be indicated with the approval number of the repackaging drug and the name of drug manufacturer.

Article 103 The testing for import of overseas pharmaceutical preparation in large package shall be conducted according to the State Food and Drug Administration regulations. The same specifications shall be used for the testing of both repackaged and import products.

Article 104 The overseas drug manufacturer providing the drug shall be responsible for the quality of the repackaged drug. If there is any quality problem, the State Food and Drug Administration may withdraw the approval number of the repackaged drug, revoke the Import Drug License or the Pharmaceutical Product License when necessary according to the requirements of Article 42 of the Drug Administration Law.

Chapter VII

Application of Non-Prescription Drugs

Article 105 Where the applied generic drug is regulated as a non-prescription drug, the applicant shall indicate the item of non-prescription drug in the “additional application items” of the Application Form for Drug Registration.

Article 106 Where the applied generic drug is regulated as both a prescription and non-prescription drug, the applicant may submit an application for either a prescription or non-prescription drug according to the respective requirements.

Article 107 For any of the following circumstances, the applicant may indicate the item of non-prescription drug in the “additional application items” of the Application Form for Drug Registration. If relevant requirements for non-prescription drugs apply, the drug shall be reviewed and approved, and regulated as a non-prescription drug; if relevant requirements for non-prescription drugs do not apply, it shall be reviewed and approved, and regulated as a prescription drug:

(1) To alter the dosage form of a non-prescription drug determined by the State Food and Drug Administration without changing the indications or functions, dosage and route of administration; or

(2) To formulate a new fixed dose combination using active ingredients of non-prescription drugs determined by the State Food and Drug Administration.

Article 108 For the registration application of a non-prescription drug, the insert sheet and package label shall comply with the relevant regulations on non-prescription drugs.

Article 109 For the registration application of an import drug categorized as non-prescription drug, the application, review and approval procedures for import drugs shall apply, and the technological requirements shall be the same as those for the domestically produced non-prescription drugs.
Chapter VIII
Submission, Review and Approval of Supplementary Application

Article 110 For the variation of the items specified in the approval document and its attachment for approved new drug development, drug production and import drug, supplementary applications shall be made.

The applicant shall assess the implications of the variation to the safety, efficacy and quality of the drug, and conduct corresponding technical studies in reference to relevant technical guidelines.

Article 111 The applicant shall fill in Supplementary Drug Application Form and submit relevant dossier and explanation to the drug regulatory department of the province, autonomous region, or municipality directly under the Central Government where the applicant is located. Drug regulatory departments of provinces, autonomous regions, or municipalities directly under the Central Government shall conduct the preliminary review of the application dossiers, and issue an acceptance notice of drug registration application if requirements are met, or issue a non-acceptance notice, with reasons, of drug registration application if requirements are not met.

Article 112 For the supplementary application of an import drug, the applicant shall submit relevant dossier and explanations to the State Food and Drug Administration, and provide documents approving the variation issued by the drug regulatory department of the producing country or region. The State Food and Drug Administration shall conduct the preliminary review of the application dossiers, and issue an acceptance notice of drug registration application if requirements are met, or issue a non-acceptance notice, in which reasons shall be given, of drug registration application if requirements are not met.

Article 113 For any supplementary application to amend the drug registration specifications, change excipients for pharmaceutical use in the drug formulation, or modify the manufacturing process that affects the drug quality, etc., the drug regulatory department of the province, autonomous region, or municipality directly under the Central Government shall provide a review opinion, report it to the State Food and Drug Administration for review and approval, and inform the applicant at the same time. For supplementary application to amend the drug registration specifications, the drug testing institute shall verify the specifications when necessary.

Article 114 For any supplementary application to change the name of a domestic drug manufacturer, the shelf-life of a domestically produced drug, or the production site by a domestic drug manufacturer internally, etc., the drug regulatory departments of the provinces, autonomous regions, or municipalities directly under the Central Government shall conduct the acceptance, review and approval. Where the regulations are conformed to, it shall issue an Approval for Supplementary Drug Application, and report to the State Food and Drug Administration for record; where the regulations are not conformed to, it shall issue a Disapproval Notice with reasons.

Article 115 Any supplementary application to alter drug packaging label in accordance with regulations, or amend the insert sheet as required by the State Food and Drug Administration, etc. shall be filed to the drug regulatory department of the province, autonomous region, or municipality directly under the Central Government for record.

Article 116 Supplementary applications of import drugs shall be reviewed and approved by the State Food and Drug Administration. Those supplementary applications to change the place of production of the drug substance used for any import drug preparation, change the appearance of an import drug not
resulting in specification changes, amend the insert sheet of an import drug according to the national specifications or the requirements of the State Food and Drug Administration, update the safety information in the insert sheet of an import drug, alter drug packaging label in accordance with regulations, or change the registration agent shall be filed to the State Food and Drug Administration for record.

Article 117 For supplementary applications of drug manufacturing technology transfer, altering formula or manufacturing process that may affect product quality, etc., the drug regulatory department of the province, autonomous region, or municipality directly under the Central Government shall organize production site inspection, according to the attachment of the Letter of Approval for Drug Registration or the verified manufacturing process. Drug testing institutes shall conduct testing on samples of three batches of product.

Article 118 While reviewing drug supplementary applications, the State Food and Drug Administration may require, with reasons, the applicants to submit additional documents when necessary. Where the regulations are conformed to, it shall issue an Approval for Supplementary Drug Application and a drug approval number; where the regulations are not conformed to, it shall issue a Disapproval Notice with reasons.

Article 119 After the supplementary application is approved, if a drug approval document is to be renewed, the original one shall be cancelled by the State Food and Drug Administration; if an additional drug approval certificate is to be issued, the original one shall remain valid.

Chapter IX
Drug Re-Registration

Article 120 The valid term of a drug approval number, Import Drug License or Pharmaceutical Product License issued by the State Food and Drug Administration is five years. To continue its drug production or importation, the applicant shall submit a re-registration application six months prior to the expiry date.

Article 121 Within the valid term of a drug approval number, Import Drug License or Pharmaceutical Product License, the applicant shall conduct systematic assessment on the safety, efficacy and quality control of the drug such as relevant research results in the observation period, adverse reaction monitoring, production control and product quality consistency, etc.

Article 122 Where applying for drug re-registration, the holder of a drug approval number shall submit the application to the drug regulatory department of the province, autonomous region, or municipality directly under the Central Government, fill in the Application Form for Drug Re-registration, and provide relevant data. Where applying for an import drug re-registration, the applicant shall submit the application to the State Food and Drug Administration.

Article 123 Drug regulatory departments of provinces, autonomous regions, or municipalities directly under the Central Government shall review the application dossiers, and issue a acceptance notice of drug re-registration application if requirements are met, or issue a non-acceptance notice, in which reasons shall be given, of drug re-registration application if requirements are not met.

Article 124 Drug regulatory departments of provinces, autonomous regions, or municipalities directly under the Central Government shall review the application dossiers within six months starting from the...
date of acceptance, and approve the re-registration application if regulations are conformed to, or report to the State Food and Drug Administration if regulations are not conformed to.

Article 125 The State Food and Drug Administration shall deal with import drug re-registration applications, complete the review within six months, and approve the re-registration application if regulations are conformed to, or issue a non-acceptance notice, in which reasons shall be given, if regulations are not conformed to.

Article 126 In any of the following circumstances, a drug shall not be re-registered:

1. the application for re-registration is not made prior to the expiry date;
2. the relevant requirements set by the State Food and Drug Administration when approved for marketing are not met;
3. the phase IV clinical trial is not completed as required;
4. the adverse drug reaction monitoring is not conducted in accordance with regulations;
5. there are uncertain therapeutic efficacy, serious adverse reaction or other factors harmful to human health upon re-evaluation by the State Food and Drug Administration;
6. the drug approval documents shall be withdrawn in accordance with the provisions of the Drug Administration Law;
7. the production conditions prescribed in the Drug Administration Law are not met;
8. the obligation of observation period is not fulfilled in accordance with regulations; or
9. there are other circumstances not in conformity with relevant regulations.

Article 127 After receiving the opinions from the drug regulatory departments of the provinces, autonomous regions, or municipalities directly under the Central Government, the State Food and Drug Administration shall review the application. Where the regulations on drug re-registration are not conformed to, a notice of rejection for re-registration shall be issued with reasons.

Where a re-registration application has been rejected, except where the drug approval document is withdrawn due to lawfully defined reasons, the drug approval number, Drug Import License or Pharmaceutical Production Certificate shall be withdrawn on the expiry date.

Chapter X

Testing for Drug Registration

Article 128 Testing for drug registration consists of sample testing and verification of specifications.

Sample testing refers to the testing of samples conducted by a drug testing institute according to the specifications submitted by an applicant or checked by the State Food and Drug Administration.

Verification of specifications refers to the laboratory testing and review conducted by a drug testing institute on the feasibility and scientific basis of the testing methods and the controllability of the set items and indicators of drug quality in the submitted specifications.
Article 129 The National Institute for the Control of Pharmaceutical and Biological Products or the drug testing institutes of the provinces, autonomous regions, and municipalities directly under the Central Government shall take charge of the testing for drug registration. The National Institute for the Control of Pharmaceutical and Biological Products shall arrange testing for import drug registration.

Article 130 The testing for registration of the following drugs shall be conducted by the National Institute for the Control of Pharmaceutical and Biological Products or the drug testing institutes designated by the State Food and Drug Administration:

1. drugs prescribed in subparagraph (1) and (2) of Article 45 of the Provisions;
2. biological products and radioactive pharmaceuticals; and
3. other drugs specified by the State Food and Drug Administration.

Article 131 Where a drug is permitted entering a special review and approval procedure, the drug testing institute shall give priority to sample testing and specification verification.

Article 132 A drug testing institute engaged in testing for drug registration shall, in compliance with the requirements set forth by the Good Laboratory Practice of drug testing institute and national metrology accreditation, have qualified personnel and adequate equipment, and comply with the quality assurance system and technical requirements of the testing for drug registration.

Article 133 An applicant shall provide the relevant data, samples and reference standards, or assist in sampling, which are required for the testing for drug registration. The amount of samples shall be three times the amount used for testing and, for biological products, manufacturing record for the relevant batches of products shall also be provided.

Article 134 While verifying the specifications of a new drug, the drug testing institute shall, in addition to sample testing, give verification opinions in respect of the specifications and test items, etc., of the drug referring to the study data, the specifications of the same kind of products at home and abroad and relevant requirements.

Article 135 Where the specifications are required to be reestablished, the applicant shall not entrust the drug testing institute that gave verification opinions to conduct the specification study of the drug; and the drug testing institute shall not accept such entrustment.

Chapter XI

Drug Registration Specifications and Insert Sheet

Section 1

Drug Registration Specifications

Article 136 National drug standards refer to the Pharmacopoeia of the People's Republic of China, drug registration specifications, etc. published by the State Food and Drug Administration, including the technical requirements such as specifications, testing methods and manufacturing processes, etc.

Drug registration specifications refer to the specified specifications of the applied drug approved by the State Food and Drug Administration to the applicant. The specifications shall be implemented by the drug manufacturer producing the drug.
Drug registration specifications shall not be lower than those required by the Chinese Pharmacopoeia.

**Article 137** The establishment of items and the testing methods for drug registration specifications shall be in conformity with the basic requirements of the Chinese Pharmacopoeia, the technical guidelines and rules for compiling the national drug standards published by the State Food and Drug Administration.

**Article 138** An applicant shall select representative samples for drug registration specifications study.

**Section 2**

**Drug Reference Standards**

**Article 139** Drug reference standards refer to the materials used in physical, chemical or biological testing specified in specifications and have assigned values of a quantity, and are used for equipment calibration, method validation or value assignment of drugs to be tested, and include reference standards, reference substances, reference crude drugs and reference reagents.

**Article 140** The National Institute for the Control of Pharmaceutical and Biological Products shall be responsible for the characterization of national reference standards. The National Institute for the Control of Pharmaceutical and Biological Products may organize relevant drug testing institute of provinces, autonomous regions, and municipalities directly under the Central Government, drug research institutions or drug manufacturers to undertake collaborative assays of such standards.

**Article 141** The National Institute for the Control of Pharmaceutical and Biological Products shall be responsible for the overall technical evaluation of the characterized reference standards in respect of the data of source material selection, preparation methods, testing methods and results, accuracy of value assignment, traceability, stability, filling and packaging conditions, etc. and shall conclude whether or not the candidate materials can be used as national reference standards.

**Section 3**

**Drug Name, Insert Sheet and Label**

**Article 142** The name, insert sheet and label of any drug for which the registration is applied, shall comply with the provisions of the State Food and Drug Administration.

**Article 143** The drug insert sheet and label shall be provided by the applicant. The Center for Drug Evaluation of the State Food and Drug Administration shall review the contents thereof except the manufacturer information, and the State Food and Drug Administration shall review and approve the data when approving the drug production. The applicant shall be responsible for making the drug insert sheet and label scientific, standard and accurate.

**Article 144** The applicant shall monitor the safety and efficacy of a marketed drug, and submit supplementary application to modify the drug insert sheet n time.

**Article 145** The applicant shall print the insert sheets and labels according to the format and requirements established by the State Food and Drug Administration, and in conformity with the contents approved.
Chapter XII

Timeline

Article 146 The drug regulatory department shall follow the provisions on the timeline for drug registration set forth in the Drug Administration Law, the Administrative Permission Law and the Regulations for Implementation of the Drug Administration Law. The timeline for drug registration in the Provisions refers to the maximum time for acceptance, review and approval of drug registration. The time for the suspension of the review and approval prescribed in laws and regulations or for the applicant to supplement data is not included.

The time for the testing for drug registration and for the review shall be kept in accordance with the Provisions. Where there is a need for time extension in particular situation, it, with reasons provided, shall be reported to the State Food and Drug Administration for approval, and the applicant shall be informed thereof.

Article 147 Drug regulatory departments shall conduct preliminary review on applications, and proceed according to the following circumstances respectively:

(1) Where no administrative approval is needed for any application item by law, the non-acceptance of the application thereof shall be informed to the applicant in time;

(2) Where an application item is not subject to the jurisdiction of the concerned departments by law, it shall be decided not to accept the application in time and informed to the applicant to apply to the relevant administrative departments;

(3) Where there is an error that can be corrected on-site in the dossier, the on-site correction shall be allowed;

(4) Where the dossier is incomplete or not conformed with the defined format, the applicant shall be informed on-site or within five days at once of what to be supplemented or corrected; if it is not informed to the applicant within the timeline, the application is regarded as accepted on the date the dossier is received; and

(5) Where the application item is subject to the jurisdiction of the concerned departments, and the dossier is complete and conformed with the defined format or the applicant has submitted all the required supplementary or corrected data, the application of drug registration shall be accepted.

Where a drug regulatory department accepts or rejects a drug registration application, it shall issue a written receipt on which there shall be a stamp of registration and date.

Article 148 The drug regulatory department of a province, autonomous region, or municipality directly under the Central Government shall complete the check of drug development conditions and raw data, the review of application dossiers, sampling, the notice to drug testing institutes for conducting testing for drug registration, the submission of review opinions, inspection report and application dossiers to the State Food and Drug Administration, and the notice to the applicant of the review opinions within 30 days starting from the date an application is accepted.

Article 149 The time for the testing for drug registration shall be kept in accordance with the following provisions:

(1) Sample testing: 30 days; sample testing and specifications verification: 60 days; and
(2) sample testing of a controlled drug or vaccine: 60 days; sample testing and specifications verification: 90 days.

The sample testing for a drug used for clinical trial conducted by a drug testing institute, as prescribed in Article 36 of the Provisions, shall be completed within the time for sample testing in the previous clause.

Article 150 The time for technical review shall be kept in accordance with the following provisions:

(1) new drug application for clinical trial: 90 days; any drug permitted to enter the special review and approval procedures: 80 days;

(2) new drug application for production: 150 days; any drug permitted to enter the special review and approval procedures: 120 days;

(3) the application for changing the dosage form of a marketed drug or for a generic drug: 160 days; and

(4) the supplementary application subject to technical review: 40 days.

The time for the technical review of an import drug registration application shall be kept in accordance with the previous clause.

Article 151 Where the applicant is required to supplement data in the process of technical review, a Deficiency Notice should be issued at one time. Where the applicant disagrees on the contents of the Deficiency Notice, the opinions of the applicant may be heard vis-à-vis. The applicant shall provide supplementary data at one time according to the requirements in the notice within four months; where an application enters the special review and approval procedures, it shall be handled in conformity with the requirements of the relevant procedures.

After receiving the supplementing data, the technical review shall be completed in no more than one third of the original time; for applications entering the special review and approval procedures, the review shall be completed in no more than one fourth of the original time.

Where an application is recalled by the applicant in the process of drug registration, the review and approval procedure is terminated henceforth.

Article 152 The State Food and Drug Administration shall make the review and approval decision within 20 days; where a decision cannot be made within 20 days, another ten days may be extended with the approval of the State Food and Drug Administration head in charge, and the applicant shall be informed of the reason of the time extended.

Article 153 The State Food and Drug Administration shall issue and deliver relevant administrative licensing certificates within ten days from the date the review and approval decision is made.

Chapter XIII

Second Review

Article 154 Where there is any of the following circumstances, the State Food and Drug Administration shall not approve the application:
(1) different applicants submit the same or almost the same research data without justified reasons;

(2) when the application dossier is found false in the process of registration, and the applicant cannot prove the authenticity thereof;

(3) the design and performance of the research project are not able to support to evaluate the safety, efficacy and quality of the drug applied for registration;

(4) there are critical defects regarding the safety, efficacy and quality in the submitted dossier of the drug applied for registration;

(5) an applicant fails to provide supplementary data within the prescribed timeline;

(6) the source of drug substances does not meet the requirements;

(7) the result of production site inspection or sample testing does not meet the requirements;

(8) other circumstances in which applications shall not be approved according to laws and regulations.

**Article 155** The written non-acceptance or unapproval decision made by drug regulatory departments by law shall provide the reasons thereof, and inform the applicant of the right to apply for administrative reconsideration or to bring an administrative suit by law.

**Article 156** If holding any dispute on the unapproval decision made by the State Food and Drug Administration, an applicant may, within 60 days after receiving the decision, fill in the Application Form for Drug Registration Second Review, and submit the application to the State Food and Drug Administration and provide reasons.

The content of second review shall not exceed the originally applied items and the original application dossier.

**Article 157** The State Food and Drug Administration shall make a second review decision, and notify the applicant the decision within 50 days after receiving an application for second review. Where the original decision is affirmed, the State Food and Drug Administration shall not accept any further application for second review thereof.

**Article 158** Where there is any need for technical review in second review, the State Food and Drug Administration shall organize relevant technical personnel to conduct review within the timeline as that for the original application.

**Chapter XIV**

**Legal Liabilities**

**Article 159** In any of the circumstances prescribed in Article 69 of the Administrative Permission Law, the State Food and Drug Administration may withdraw the relevant drug approval documents upon the request of any interest party or according to its responsibilities and authorities.

**Article 160** Any drug regulatory department or its staff members that violate the provisions of this Provisions and constitute any of the circumstances below shall be instructed by its superior administrative department or supervisory departments to make rectification. If the circumstances are
serious, administrative sanctions shall be given to the persons directly in charge and the other persons directly responsible in accordance with law:

(1) not accepting a drug registration application that is in conformity with regulatory requirements;

(2) not publicizing at the acceptance place the information that shall be publicized by law;

(3) in the process of acceptance, review and approval, not fulfilling the regulatory informing obligation to the applicant or interest party;

(4) not informing the applicant at once of all the contents needed to be supplemented or corrected, where the drug application dossier submitted is incomplete or not conformed with the required format;

(5) not stating the reasons of non-acceptance or unapproval of a drug registration application by law; and

(6) not holding hearings that shall be held by law.

Article 161 If any drug regulatory department and its staff members request for or accept money or valuable articles from others, or pursue other interests in the process of drug registrations, where a crime is committed, criminal liabilities shall be investigated by law; where a crime is not committed, administrative sanctions shall be given by law.

Article 162 Any drug regulatory department that constitutes any of the following circumstances in the process of drug registration shall be instructed by its superior administrative department or supervisory departments to make rectification, and administrative sanctions shall be given to the persons directly in charge and the other persons directly responsible by law; if a crime is committed, criminal liabilities shall be investigated by law:

(1) making a decision to approve any registration application that does not meet the regulatory requirements prescribed in the Provisions or acting beyond regulatory responsibilities and authorities to make such a decision;

(2) making a decision to disapprove a registration application conformed with the regulatory requirements, or failing to make a decision to approve a registration application within the regulatory timeline; and

(3) failing to perform the confidentiality obligation in violating the requirements prescribed in Article Nine of the Provisions.

Article 163 When undertaking testing for drug review and approval, a drug testing institute that issues a false certificate of analysis shall be punished in accordance with the provisions in Article 87 of the Drug Administration Law.

Article 164 Any drug regulatory department that charges fees without permission or does not charge fees according to set items and rates shall be instructed by its superior administrative department or supervisory departments to return the illegal charges; and administrative sanctions shall be given to the persons directly in charge and the other persons directly responsible by law.

Article 165 Where the Good Laboratory Practice for Non-Clinical Laboratory Studies or the Good Clinical Practice is not executed in the process of drug registration according to regulations,
punishments shall be given in accordance with the provisions in Article 79 of the Drug Administration Law.

**Article 166** Where an applicant submits false drug registration dossier and samples when applying for clinical trial, the drug regulatory department shall not accept the application or disapprove the applied clinical trial, give a disciplinary warning to the applicant, and not accept any further application for clinical trial of the drug made by the applicant within one year; where clinical trial of the drug is already approved, the Drug Clinical Trial Approval shall be withdrawn, a fine of no less than 10,000 yuan but no more than 30,000 yuan shall also be imposed, and no further application for clinical trial of the drug made by the applicant shall be accepted within three years. The State Food and Drug Administration shall keep records of the fraud acts of applicants that submit false dossier and samples, and publicize such records.

**Article 167** Where an applicant submits false drug registration dossier and samples when applying for drug production or importation, the State Food and Drug Administration shall not accept or disapprove the application, give a disciplinary warning to the applicant, and not accept any further application made by the applicant within one year; where the production or importation of the drug is already approved, the drug approval documents shall be withdrawn, no further application made by the applicant shall be accepted within five years, and a fine of no less than 10,000 yuan but no more than 30,000 yuan shall also be imposed.

**Article 168** According to the provisions in Article 27 of the Provisions, where a drug testing needs to be repeated but the applicant refuses to do so, the State Food and Drug Administration shall: give a warning and instruct to make rectification; if the applicant refuses to make rectification, the application thereof shall not be approved.

**Article 169** Where there is any of the following circumstances, the State Food and Drug Administration shall withdraw the drug approval number, and announce to the public:

1. the applicant requests to annul its own drug approval number before the drug approval document expires;

2. the re-registration is not allowed according to provisions in Article 126 of the Provisions;

3. the Drug Manufacturing Certificate is revoked or withdrawn by law;

4. according to provisions in Article 42 of the Drug Administration Law or Article 41 of the Regulations for Implementation of the Drug Administration Law, the drug approval document is withdrawn for any drug with serious adverse reactions or other factors harmful to human health;

5. a decision is made to give an administrative sanction of revoking the drug approval document by law; and

6. other circumstances in which the drug approval documents shall be withdrawn or recalled by law.

(https://eng.sfda.gov.cn/WS03/CL0768/61645)

2.8 JAPAN

Accreditation of Overseas Manufacturers

Persons wishing to manufacture drugs, quasi-drugs, cosmetics, or medical devices exported to Japan from overseas (overseas manufacturers) must receive accreditation from the Minister (enforced from
April 1, 2005). The specifications for accreditation are the same as those for manufacturing licenses for domestic manufacturers. The following items are taken from the "Q&A on Accreditation of Overseas Manufacturers" in an office communication of the Evaluation and Licensing Division, PFSB dated February 14, 2006. Refer to the PMDA homepage for reference. 

(1) Applicants for accreditation of overseas manufacturers and their agents

- When the applicant is a corporation, the representative (director with representative authority) makes the application.

- The marketer, etc. who acts as the agent for the application files the application after confirming from the applicant the type of corporation of the applicant, name, address, and agent. The contact information for the agent, and whether the agent is a marketing authorization holder or a manufacturer is entered in the Remarks section of the application form.

(2) Timing of applications for accreditation of overseas manufacturers The application should be submitted by the time of the marketing approval application. When accreditation is not obtained beforehand, "under application" should be entered in the marketing approval application form (Marketing approval can not be obtained without accreditation approval).

(3) Outline of the structure and facilities of the manufacturing plant required for accreditation of overseas manufacturers and attached documentation

- The outline of the structure and facilities of the manufacturing plant should be based on that in the manufacturing business license application in Japan. A list of the structures and facilities must be included.

- When Japanese can not be used as the language in the attached documentation under special circumstances, a foreign language can be used, but a Japanese translation must be attached n such cases. If the foreign language is not English, certification of the translator must be attached.

- A medical certificate from a physician must be submitted when the applicant is a corporation of the executives involved in the business, namely the executive with representative authority and executives involved in the business without representative authority, and a table showing the duties of the executives must be attached. When it is difficult to submit medical certificates for physicians for unavoidable reasons in countries where the overseas manufacturer has received authorization, it is possible to submit documents verifying that the executives involved do not correspond to the provisions of Article 5, Item 3(d) (excluding the part related to adult wards) and (e) in place of the medical certificates for physicians.

(4) On-site surveys for accreditation of overseas manufacturers When a GMP compliance survey is performed simultaneously with the accreditation, the structures and facilities are required for accreditation to be confirmed in the GMP compliance survey, as a rule.

2.9 PHILIPPINES

The act is known as 'Food, Drug and Cosmetic Act' created under Republic Act no. 3720. Chapter XII deals with provisions of Imports and Exports.
Section 30: (a) The Commissioner of Customs shall cause to be delivered to the Food and Drug Administration samples taken at random from every incoming shipment of Food, Drugs, Devices and Cosmetics which are being imported or offered for import into the Philippines giving notice thereof to the owner or consignee. The quantity of such samples shall be fixed by regulation issued by the Secretary. If it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed or packed under insanitary conditions, or (2) such article is forbidden or restricted from sale in the country in which it was produced or from which it was exported, or (3) such article is adulterated, misbranded, or in violation of section twenty one, then the food and drug administrator shall so inform the Commissioner of Customs who shall then cause the destruction of any such article refuse admission unless such article is exported, under regulations prescribed by the Commissioner of Customs, within 90 days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulation.

(b) Pending decision as to the admission of an article being imported or offered for import, the Commissioner of Customs may authorize deliver of such article to the owner or consignee upon execution by him a good and sufficient bond providing for the payment of such liquidated damages in the event of default as may be required pursuant to regulations of the Commissioner of Customs. If it appears to the Secretary that an article included within the provisions of clause (3) of subsection (a) of this section can, by relabelling or other action, be brought into compliance of the Act or rendered other than a food, drug, device or cosmetic, final determination as to admission of such article may be deferred, and upon filing of timely written application by the owner or consignee and the execution by him of a bond as provided in the preceding provisions of this subsection, the Secretary may, in accordance with regulations, authorize the applicant to perform such relabelling or other actions specified in such authorization with regulations (including destruction or export of rejected articles or portions thereof as may be specified in the Secretary's authorization). All such relabelling or other action pursuant to such authorization shall be in accordance with regulations and be under the supervision of an official or employee of the Commissioner of Customs and a duly authorized representative of the Food and Drug Administrator.

(c) All expenses (including travel per diem or subsistence, and salaries) of officers or employees of the Philippines in connection with the destruction provided for in subsection (a) of this section and the supervision of the relabelling or other action authorized under the provisions of subsection (b) of this section, the amount of such expenses to be determined in accordance with regulations, and all expenses in connection with the storage, cargo, or labor with respect to any article refused admission under subsection (a) of this section, shall be paid by the owner or consignee, and a default of such payment, shall constitute a lien against any future importations made by such owner or consignee.

(d) A food, drug, device or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this Act if it (1) conforms with the specifications of the foreign purchaser, (2) is not in conflict with laws of the country to which it is intended for export. But if such article is sold or offered for sale in domestic commerce, this subsection shall not exempt it from any of the provisions of this Act. (www.doh.gov.ph)

2.10 KOREA: ADMINISTRATION KOREA FOOD AND DRUGS

KFDA Notification no. 2004-20, March 25, 2004

Article 34 (licensing etc. of drug import) ( Entirely amended in December 31, 1991)
1. Any one who intends to import drugs (hereinafter referred to as “importer”) shall get a license from and notify the Commissioner of the KFDA for each product in accordance with an ordinance of the Ministry of Health and Welfare. Same procedure shall be followed when the importer intends to change the approved or notified label, <Amended on December 3, 1997, and February 28, 1998>

2. In case any one intends to urgently import drugs not manufactured in the country for military affairs in spite of the provision of the Article (1), the Minister of the National Defense can import them by discussing items and quantity with the Commissioner of the KFDA in advance <Newly established on December 31, 1994, December 13, 1997 and February 28, 1998>

3. Importer shall establish the necessary facilities in accordance with the standards of facilities as provided by the Presidential Degree <Amended on January 12, 2000>

4. Provisions of paragraph (2), (3),(6)-(8) of Article 25, Article 29-31 and Article 63 shall apply this with respect to drugs imported in accordance with the provisions of Article 1 of their importers. In this case ‘manufacturing’ or ‘production’ is regarded as ‘import’ and ‘manufacture’ as ‘importer’ <Amended on January 12, 2000>

5. In the approval of imported items including drugs according to the provisions of Article 1, necessary details with respect to the subject, standard, condition and management of the approval are decided in accordance with an ordinance of the Ministry of Health and Welfare <Newly established on January 7, 1994 and December 12, 1997> Article 5 (Review Process)

6. The KFDA Commissioner shall handle the submitted “Registration of Drug Substances Manufacturing or Import” application for the designated items as specified in the following. A site inspection (in case of any imported items, at the foreign manufacturing site) may be considered if necessary. In such cases, the schedule of the site inspection shall be notified to an applicant 20 days before inspection.

7. After a company submits the application for the registration of drug substances (manufacturing or import) under the provisions of paragraph 3 of Article 24 of the Enforcement Rule, appropriateness of submitted data shall be reviewed within 17 weeks (within 13 weeks provided that a site inspection is considered to be unnecessary). Then the KFDA Commissioner shall issue a registration certificate and notify publicly on the website provided that the submitted data and the result of the site inspection are deemed appropriate.

8. In case of any imbalance in supply and demand of drugs is concerned, the KFDA Commissioner may withhold issuance of the registration certificate and the public notification on the website until such circumstances do not persist any longer.

9. The site inspection will be made in accordance with the “Criteria of Evaluation of Inspection at the API Manufacturing Site” (Annexure 2) and the inspection relating to the submitted data, including the manufacturing processes, etc., shall be conducted, depending upon the drug properties.

10. Any one who intends to register the drug substances shall bear the expenses for the inspection made hereunder.

• In principle, site inspection will be done for every drug substance, except the drug substance of which manufacturing site of the same company in the same country has already been
inspected and registered by KFDA. The KFDA Commissioner may decide site inspection considering drug substance’s properties, characteristics of manufacturing type, observations from prior inspection, the period from the prior inspection etc.

- Pre-approval site inspection will be done for every sterile drug substances and, for other drug substances, the KFDA Commissioner may notify registration of the drug substance on the web and inspect the site later, depending on credibility and appropriateness of submitted data Letter of Declaration of Willingness to KFDA Inspection shall be submitted for post-approval inspection.

- Workflow and review period of Drug Substance Manufacture Import Registration (Including Drug Substance Registration submitted at New Drug Application for finished products) ([www.kfda.go.kr](http://www.kfda.go.kr))

2.11 NIGERIA

A. Application:

1. (a) An application for registration of a drug product shall be made by the manufacturer.

(b) In case of a manufacturer outside Nigeria such shall be represented in Nigeria by a duly registered pharmaceutical company.

(c) An applicant for a manufacturer outside Nigeria must file an evidence of Power Of Attorney from the manufacturer which authorizes him to speak for his principal on all matters relating to the latter’s specialties. The original Power Of Attorney be notarized and submitted to NAFDAC.

NOTE: The representative in Nigeria, whether a corporate body or an individual with the power of attorney, will be held responsible for ensuring that the competent authority in the country is informed of any serious hazard newly associated with a product imported under the provisions of the decree or any criminal abuse of the certificate in particular to the importation of falsely labeled, spurious, counterfeited or sub-standard medicinal products.

(a) The manufacturer, in the case of imported products, must show evidence that he or she is licensed to manufacture drugs for sale in the country of origin (Manufacturer’s Certificate). Such evidence must be by the competent Health Authority of the country of manufacture, and shall be authenticated by the Nigerian Mission in that country.

2.(a) The applicant must submit to the office of the Director (Registration and Regulatory Affairs) NAFDAC, a written application, stating name of the manufacturer, generic name, (brand name where applicable) strength, indications and obtain the prescribed application form which must be properly filled with all informations required. This form, labeled “FORM-D-REG/001” shall be obtained on payment of applicable fee per product by Bank Draft (MICR) issued in favour of NATIONAL AGENCY FOR FOOD & DRUG ADMINISTRATION & CONTROL (NAFDAC). Lagos.

(a) A separate application form shall be submitted for each drug product. In this context, a drug product means a separate drug formulation. However the application for registration of one dosage form with different strengths may be made on a different application form.

PRODUCT

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Devi Ahilya Vishwavidyalaya Indore
1. A drug product is issued by NAFDAC.

2. In case of imported products:
   a. There must be evidence of registration of such product by the competent Health Authority of the country of manufacture i.e. product license/Certificate of Registration.
   b. There must be evidence by the competent Health Authority, that the sale of the product does not constitute a contravention of the drug laws of that country i.e. Certificate of Pharmaceutical Product (COPP) that conforms to WHO format.
   c. The documents in respect of (a) and (b) shall be authenticated by the Nigerian Mission in that country.

3. In the case of imported new drug substance, there must be evidence that limited local clinical trials have been undertaken, and that such product is registered in the country of origin and also, in at least two more developed countries.

4. No combination drug product shall be registered or considered for registration unless there is proven evidence that such a product has clinical advantage over the single drug available from the same indication(s).

5. Identification mark must be embossed on all tablets and capsule shell.

6. The application should indicate the class or type of registration required- whether it is prescription only product.

7. Product found to be doubtful, little or no therapeutic value and those which are some times rather harmful and subject to misuse shall not be considered for registration.

8. An applicant shall not be allowed to register a formulation in more than one brand name even where different doses of the active ingredient(s) are used.

9. The product information must in two copies with hard covers per product (dossiers) made out in accordance with application format (the content of the dossier must be in compliance with the item on the format).

10. All dosage forms of a particular brand name must contain the same active ingredient(s) or at least the major active ingredient(s).

11. Evidence of Trade Mark Approval from Federal Ministry of Commerce in Nigeria.

12. Notarized declaration to be notarized by the Notary Public.

13. Comprehensive certificate of analysis of the batch of the product to be registered.


15. Annual license for the Superintendent Pharmacist.


LABELING: Labeling shall be informative, accurate and must comply with the 'DRUG LABELING REGULATIONS 2004'
**BANNED PRODUCTS:** These are products which have been prohibited from importation into Nigeria by Federal Government therefore, not accepted for registration or renewal of registration.

- Paracetamol tablets and syrups
- Cotrimoxazole tablets and syrups
- Metronidazole tablets and syrups
- Chloroquine tablets and syrups
- Haemeticin formulations
- Ferrous sulphate and ferrous gluconate tablets
- Folic acid
- Vitamin B Complex tablets (except modified release formulations)
- Multivitamin tablets, capsules and syrups (except special formulations)
- Aspirin tablets (except modified formulations and soluble aspirin)
- Magnesium trisilicate tablets and suspensions
- Piperazine tablets and syrups
- Levamisole tablets and syrups
- Clotrimazole cream
- Ampicillin/Cloxacillin combination capsules
- Ointments- Penicillin/Gentamycin
- Pyrantel pamoate tablets and syrups
- Intravenous fluids (Dextrose, Normal saline etc.)
- Disinfectants, and Germicides [www.nafdacnigeria.org/bannedsubstances.html](http://www.nafdacnigeria.org/bannedsubstances.html)

**CEILED PRODUCTS:** Products no longer accepted by NAFDAC for registration:

- Paracetamol tablet & syrups (now banned)
- Ampicillin capsules
- Ciprofloxacin tablets
- Amoxycillin capsules
- Piroxicam capsules
- Ibuprofen tablets
- Tetracycline capsules
- Cotrimoxazole tablets (tablets and syrups now banned)
- Ampicillin/Cloxacillin capsules (capsules are now banned)
- Metronidazole tablets (tablets and syrups now banned)
- Cyproheptadine tablets
- Sulphadoxine/Pyrimethamine tablets
- Chloroquine tablets (tablets and syrups now banned)
- Diclofenac sodium tablets
- Nimesulide tablets and syrups (administrative ban on health grounds)
- Haemeticin tablets: (ferrous sulphate and ferrous gluconate tablet, folic acid tablets, Vitamin B complex tablets except special formulations)
- Multivitamin capsules and syrups (tablets, capsules and syrups are now banned except special formulations)
- Anti-inflammatory agent+Paracetamol combinations
- Aspirin tablets (excluding enteric coated) (now banned except modified release formulations and soluble aspirin)
- Magnesium trisilicate tablets and syrups (now banned)
- Levamisole tablets and syrups (tablets and syrups now banned)
• Piperazine tablets and syrups (now banned)
• Mebendazole tablets and syrups
• Pseudoephedrine+paracetamol+caffeine, tablets/syrups (www.nafdacnigeria.org/ceiled.html)

End of Chapter 02