CHAPTER 05

PENAL PROVISIONS

5.1 United States Of America

SEC. 301. [21 USC §331] Prohibited acts

Note: revisions were posted to this section in February 2008.

The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 404, 505 or 564.

(e) The refusal to permit access to or copying of any record as required by section 412, 414, 416 417(g), 504, 564, 703, 704(a), 760, or 761; or the failure to establish or maintain any record, or make any report, required under section 412, 414(b), 416, 417, 504, 505(6) or (k), 512(a)(4)(C), 512 (j), (l) or (m), 572(i), 515(f), 519, 564, 760, or 761 or the refusal to permit access to or verification or copying of any such required record.

(f) The refusal to permit entry or inspection as authorized by section 704.

(g) The manufacture, within any Territory of any food, drug, device, or cosmetic that is adulterated or misbranded.

(h) The giving of a guaranty or undertaking referred to in section 303(c)(2), which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, or cosmetic; or the giving of a guaranty or undertaking referred to in section 303(c)(3), which guaranty or undertaking is false.

(i) (1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of section 404 or 721.

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit drug.
(3) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.

(j) The using by any person to his own advantage or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of section 404, 409, 412, 414, 505, 510, 512, 513, 514, 515, 516, 518, 519, 520, 571, 572, 573, 704, 708, or 721 concerning any method or process which as a trade secret is entitled to protection; or the violating of section 408(i)(2) or any regulation issued under that section. This paragraph does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

(l) [Deleted]

(m) The sale or ................................................................................................................ of sections 407(b) or 407(c).

(n) The using, in labeling, advertising or other sales promotion of any reference to any report or analysis furnished in compliance with section 704.

(o) In the case of a prescription drug distributed or offered for sale in interstate commerce, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable State law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved by the Secretary. Nothing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this Act.

(p) The failure to register in accordance with section 510, the failure to provide any information required by section 510(j) or 510(k), 21 USC § 360(j) or (k) or the failure to provide a notice required by section 510(j)(2).

(q)(1) The failure or refusal to

(A) comply with any requirement prescribed under section 518 or 520(g),
(B) furnish any notification or other material or information required by or under section 519 or 520(g),
 or
(C) comply with a requirement under section 522.

(2) With respect to any device,........................................................................................................... in any material respect.

(r) The movement of a device................................................................. to identify the device as detained.

(s) The failure to provide the notice required by section 412(c) or 412(e), the failure to make the reports required by section 412(f)(1)(B), the failure to retain the records required by section 412(b)(4), or the failure to meet the requirements prescribed under section 412(f)(3).
(t) The importation of a drug in violation of section 801(d)(1), the sale, purchase, or trade of a drug or drug sample or the offer to sell, purchase, or trade a drug or drug sample in violation of section 503(c), the sale, purchase, or trade of a coupon, the offer to sell, purchase, or trade such a coupon, or the counterfeiting of such a coupon in violation of section 503(c)(2), the distribution of a drug sample in violation of section 503(d) or the failure to otherwise comply with the requirements of section 503(d), or the distribution of drugs in violation of section 503(e) or the failure to otherwise comply with the requirements of section 503(e).

(u) The failure to comply with any requirements of the provisions of, or any regulations or orders of the Secretary, under section 512(a)(4)(A), 512(a)(4)(D), or 512(a)(5).

(v) The introduction or delivery for introduction into interstate commerce of a dietary supplement that is unsafe under section 413.

(w) The making of a knowingly false statement in any statement, certificate of analysis, record, or report required or requested under section 801(d)(3); the failure to submit a certificate of analysis as required under such section; the failure to maintain records or to submit records or reports as required by such section; the release into interstate commerce of any article or portion thereof imported into the United States under such section or any finished product made from such article or portion, except for export in accordance with section 801(e) or 802, or with section 351(h) of the Public Health Service Act [42 USC § 262(h)] or the failure to so export or to destroy such an article or portions thereof, or such a finished product.

(x) The falsification of a declaration of conformity submitted under section 514(c) or the failure or refusal to provide data or information requested by the Secretary under paragraph (3) of such section.

(y) In the case of a drug, device, or food –

(1) the submission of a report or recommendation by a person accredited under section 523 that is false or misleading in any material respect;

(2) the disclosure by a person accredited under section 523 of confidential commercial information or any trade secret without the express written consent of the person who submitted such information or secret to such person; or

(3) the receipt by a person accredited under section 523 of a bribe in any form or the doing of any corrupt act by such person associated with a responsibility delegated to such person under this Act.

(z) [Terminated]

(aa) The importation of a prescription drug in violation of section 804, the falsification of any record required to be maintained or provided to the Secretary under section, or any other violation of regulations under such section.

(bb) The transfer of an article of food under section 306(b)(3).

(cc) The importing or offering under section 306(b)(3).

(dd) The failure to register in accordance with section 415.

(ee) The importing or under section 801(m).
(ff) The importing or offering for import into the United States of a drug or device with respect to which there is a failure to comply with a request of the Secretary to submit to the Secretary a statement under section 801(o).

(gg) The knowing failure to comply with paragraph (7)(E) of section 704(g); the knowing inclusion by a person accredited under paragraph (2) of such section of false information in an inspection report under paragraph (7)(A) of such section; or the knowing failure of such a person to include material facts in such a report.

(hh) The failure by a shipper... under section 416.

(ii) The falsification of a report of a serious adverse event submitted to a responsible person (as defined under section 760 or 761) or the falsification of a serious adverse event report (as defined under section 760 or 761) submitted to the Secretary.

(jj) (1) The failure to submit the certification required by section 402(j)(5)(B) of the Public Health Service Act [42 USC § 282(j)(5)(B)], or knowingly submitting a false certification under such section.

(2) The failure to submit clinical trial information required under subsection (j) of section 402 of the Public Health Service Act [42 USC § 282].

(3) The submission of clinical trial information under subsection (j) of section 402 of the Public Health Service Act [42 USC § 282] that is false or misleading in any particular under paragraph (5)(D) of such subsection (j).

(kk) [Note: This subsection takes effect 180 days after enactment of Act Sept. 27, 2007, P.L. 110-85, as provided by § 909(a) of such Act, which appears as a note to this section.] The dissemination of a television advertisement without complying with section 503B [21 USC § 353b].

(ll) The introduction or delivery for introduction into interstate commerce of any food to which has been added a drug approved under section 535 [21 USC § 355], a biological product licensed under section 351 of the Public Health Service Act [42 USC § 262], or a drug or a biological product for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, unless-

(1) such drug or such biological product was marketed in food before any approval of the drug under section 505 [21 USC § 355], before licensure of the biological product under such section 351 [42 USC § 262], and before any substantial clinical investigations involving the drug or the biological product have been instituted;

(2) the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, approving the use of such drug or such biological product in the food;

(3) the use of the drug or the biological product in the food is to enhance the safety of the food to which the drug or the biological product is added or applied and not to have independent biological or therapeutic effects on humans, and the use is in conformity with—

(A) a regulation issued under section 409 [21 USC § 348] prescribing conditions of safe use in food

(B) a regulation listing or affirming conditions under which the use of the drug or the biological product in food is generally recognized as safe;
(C) the conditions of use identified in a notification to the Secretary of a claim of exemption from the premarket approval requirements for food additives based on the notifier's determination that the use of the drug or the biological product in food is generally recognized as safe, provided that the Secretary has not questioned the general recognition of safety determination in a letter to the notifier;

(D) a food contact substance notification that is effective under section 409(h) [21 USC § 348(h)]; or

(E) such drug or biological product had been marketed for smoking cessation prior to the date of the enactment of the Food and Drug Administration Amendments Act of 2007 [enacted Sept. 27, 2007]; or

(4) the drug is a new animal drug whose use is not unsafe under section 512 [21 USC § 360b]; (mm) The failure to submit a report or provide a notification required under section 417(j) [21 USC § 350(d)].

(nn) The falsification of a report or notification required under section 417(d) [21 USC § 350(f)(d)].


SEC. 302. [21 USC §332] Injunction proceedings

(a) The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown, to restrain violations of section 301, except paragraphs (h), (i), and (j).

(b) In case of violation of an injunction or restraining order issued under this section, which also constitutes a violation of this Act, trial shall be by the court, or, upon demand of the accused, by a jury.

SEC. 303. [21 USC §333] Penalties

Note: revisions were posted to this section in February 2008.

[a] Note: See prospective amendment note below.

(a) Violation of 21 USC § 331; second violation; intent to defraud or mislead.

(1) Any person who violates a provision of section 301 shall be imprisoned for not more than one year or fined not more than $1,000, or both.

(2) Notwithstanding the provisions of paragraph (1) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000 or both.

(b) Prescription drug market violations

(1) Notwithstanding subsection (a), any person who violates section 301(t) by—

(A) knowingly importing a drug in violation of section 801(d)(1),

(B) knowingly selling, purchasing, or trading a drug or drug sample or knowingly offering to sell, purchase, or trade a drug or drug sample, in violation of section 503(c)(1),

(C) knowingly selling, purchasing, or trading a coupon, knowingly offering to sell, purchase, or trade such a coupon, or knowingly counterfeiting such a coupon, in violation of section 503(c)(2), or

(D) knowingly distributing drugs in violation of section 503(e)(2)(A), shall be imprisoned for not more than 10 years or fined not more than $250,000, or both.
(2) Any manufacturer or distributor who distributes drug samples by means other than the mail or common carrier whose representative, during the course of the representative's employment or association with that manufacturer or distributor, violated section 301(t) because of a violation of section 503(c)(1) or violated any State law prohibiting the sale, purchase, or trade of a drug sample subject to section 503(b) or the offer to sell, purchase, or trade such a drug sample shall, upon conviction of the representative for such violation, be subject to the following civil penalties:

(A) A civil penalty of not more than $50,000 for each of the first two such violations resulting in a conviction of any representative of the manufacturer or distributor in any 10-year period.

(B) A civil penalty of not more than $1,000,000 for each violation resulting in a conviction of any representative after the second conviction in any 10-year period. For the purposes of this paragraph, multiple convictions of one or more persons arising out of the same event or transaction, or a related series of events or transactions, shall be considered as one violation.

(3) Any manufacturer or distributor who violates section 301(t) because of a failure to make a report required by section 503(d)(3)(E) shall be subject to a civil penalty of not more than $100,000.

(4) (A) If a manufacturer or distributor or any representative of such manufacturer or distributor provides information leading to the institution of a criminal proceeding against, and conviction of, any representative of that manufacturer or distributor for a violation of section 301(t) because of a sale, purchase, or trade or offer to purchase, sell, or trade a drug sample in violation of section 503(c)(1) or for a violation of State law prohibiting the sale, purchase, or trade of a drug sample, the conviction of such representative shall not be considered as a violation for purposes of paragraph (2).

(B) If, in an action brought under paragraph (2) against a manufacturer or distributor relating to the conviction of a representative of such manufacturer or distributor for the sale, purchase, or trade of a drug or the offer to sell, purchase, or trade a drug, it is shown, by clear and convincing evidence—

(i) that the manufacturer or distributor conducted, before the institution of a criminal proceeding against such representative for the violation which resulted in such conviction, an investigation of events or transactions which would have led to the reporting of information leading to the institution of a criminal proceeding against, and conviction of, such representative for such purchase, sale, or trade or offer to purchase, sell, or trade, or

(ii) that, except in the case of the conviction of a representative employed in a supervisory function, despite diligent implementation by the manufacturer or distributor of an independent audit and security system designed to detect such a violation, the manufacturer or distributor could not reasonably have been expected to have detected such violation, the conviction of such representative shall not be considered as a conviction for purposes of paragraph (2).

(5) If a person provides information leading to the institution of a criminal proceeding against, and conviction of, a person for a violation of section 301(t) because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample in violation of section 503(c)(1), such person shall be entitled to one-half of the criminal fine imposed and collected for such violation but not more than $125,000.

(6) Notwithstanding subsection (a), any person who is a manufacturer or importer of a prescription drug under section 804(b) and knowingly fails to comply with a requirement of section 804(e) that is applicable to such manufacturer or importer, respectively, shall be imprisoned for not more than 10 years or fined not more than $250,000, or both.
(c) Exceptions in certain cases of good faith, etc. No person shall be subject to the penalties of subsection (a)(1) of this section,

(1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Secretary the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or

(2) for having violated section 301(a) or

(d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 301(a), that such article is not adulterated or misbranded, within the meaning of this Act, designating this Act, or to the effect, in case of an alleged violation of section 301(d), that such article is not an article which may not, under the provisions of section 404 or 505, be introduced into interstate commerce; or

(3) for having violated section 301(a), where the violation exists because the article is adulterated by reason of containing a color additive not from a batch certified in accordance with regulations promulgated by the Secretary under this Act, if such person establishes a guaranty or undertaking signed by, and containing the name and address of, the manufacturer of the color additive, to the effect that such color additive was from a batch certified in accordance with the applicable regulations promulgated by the Secretary under this Act; or

(4) for having violated section 301(b), (c), or (k) by failure to comply with section 502(f) in respect to an article received in interstate commerce to which neither section 503(a) nor section 503(b)(1) is applicable, if the delivery or proffered delivery was made in good faith and the labeling at the time thereof contained the same directions for use and warning statements as were contained in the labeling at the time of such receipt of such article; or

(5) for having violated section 301(i)(2) if such person acted in good faith and had no reason to believe that use of the punch, die, plate, stone, or other thing involved would result in a drug being a counterfeit drug, or for having violated section 301(i)(3) if the person doing the act or causing it to be done acted in good faith and had no reason to believe that the drug was a counterfeit drug.

(d) Exceptions involving misbranded food. because of its advertising.

(e) Prohibited distribution of human growth hormone.

(1) Except as provided in paragraph (2), whoever knowingly distributes, or possesses with intent to distribute, human growth hormone for any use in humans other than the treatment of a disease or other recognized medical condition, where such use has been authorized by the Secretary of Health and Human Services under section 505 and pursuant to the order of a physician, is guilty of an offense punishable by not more than 5 years in prison, such fines as are authorized by title 18, United States Code, or both.

(2) Whoever commits any offense set forth in paragraph (1) and such offense involves an individual under 18 years of age is punishable by not more than 10 years imprisonment, such fines as are authorized by title 18, United States Code, or both.
(3) Any conviction for a violation of paragraphs (1) and (2) of this subsection shall be considered a felony violation of the Controlled Substances Act for the purposes of forfeiture under section 413 of such Act.

(4) As used in this subsection the term “human growth hormone” means somatrem, somatropin, or an analogue of either of them.

(5) The Drug Enforcement Administration is authorized to investigate offenses punishable by this subsection.

(I) Violations related to devices.

(1) (A) Except as provided in subparagraph (B) that relates to devices.

(B) Subparagraph (A) shall not apply—

(i) to any person such requirements, or

(ii) a risk to public health,

(iii) to any person with such section, or

(ii) to violations which are not defective.

(2) (A) Any person who introduces adjudicated in a single proceeding.

(B) This paragraph shall not apply article of food that is adulterated.

(C) In a hearing to assess a investigation under this paragraph.

(3) (A) Any person who violates section 301(jj) [21 USC § 331(jj)] shall be subject to a civil monetary penalty of not more than $10,000 for all violations adjudicated in a single proceeding.

(B) If a violation of section 301(jj) [21 USC § 331(jj)] is not corrected within the 30-day period following notification under section 402(j)(5)(C)(ii) [21 USC § 342(j)(5)(C)(ii)], the person shall, in addition to any penalty under subparagraph (A), be subject to a civil monetary penalty of not more than $10,000 for each day of the violation after such period until the violation is corrected.

(4) [Note: This paragraph takes effect 180 days after enactment of Act Sept. 27, 2007, P.L. 110-85, as provided by § 909(a) of such Act, which appears as 21 USC § 331 note.]

(A) Any responsible person (as such term is used in section 505-1 [21 USC § 355-1]) that violates a requirement of section 505(o), 505(p), or 505-1 [21 USC § 355(o), 355(p), or 355-1] shall be subject to a civil monetary penalty of—

(i) not more than $250,000 per violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding; or

(ii) in the case of a violation that continues after the Secretary provides written notice to the responsible person, the responsible person shall be subject to a civil monetary penalty of $250,000 for the first 30-day period (or any portion thereof) that the responsible person continues to be in violation, and such amount shall double for every 30-day period thereafter that the violation continues, not to exceed $1,000,000 for any 30-day period, and not to exceed $10,000,000 for all such violations adjudicated in a single proceeding.
B) In determining the amount of a civil penalty under subparagraph (A)(ii), the Secretary shall take into consideration whether the responsible person is making efforts toward correcting the violation of the requirement of section 505(o), 505(p), or 505-1 [21 USC § 355(o), 355(p), or 355-1] for which the responsible person is subject to such civil penalty.

(5) (A) A civil penalty under paragraph (1), (2), or (3) shall be assessed by the Secretary by an order made on the record after opportunity for a hearing provided in accordance with this subparagraph and section 554 of title 5, United States Code. Before issuing such an order, the Secretary shall give written notice to the person to be assessed a civil penalty under such order of the Secretary's proposal to issue such order and provide such person an opportunity for a hearing on the order. In the course of any investigation, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

(B) In determining the amount of a civil penalty, the Secretary shall take into account the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require.

(C) The Secretary may compromise, modify, or remit, with or without conditions, any civil penalty which may be assessed under paragraph (1), (2), or (3). The amount of such penalty, when finally determined, or the amount agreed upon in compromise, may be deducted from any sums owing by the United States to the person charged.

(6) Any person who requested, in accordance with paragraph (5)(A), a hearing respecting the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty may file a petition for judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such person resides or transacts business. Such a petition may only be filed within the 60-day period beginning on the date the order making such assessment was issued.

(7) If any person fails to pay an assessment of a civil penalty—

(A) after the order making the assessment becomes final, and if such person does not file a petition for judicial review of the order in accordance with paragraph (6), or

(B) after a court in an action brought under paragraph (6) has entered a final judgment in favor of the Secretary, the Attorney General shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 60-day period referred to in paragraph (6) or the date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.

Penal Provisions in regard to Advertisements:

(g) Note: This subsection takes effect 180 days after enactment of Act Sept. 27, 2007, P.L. 110-85, as provided by § 909(a) of such Act, which appears as 21 USC § 331 note.

(1) With respect to a person who is a holder of an approved application under section 505 [21 USC § 355] for a drug subject to section 503(b) [21 USC § 353(b)] or under section 351 of the Public Health Service Act [42 USC § 262], any such person who disseminates or causes another party to disseminate a direct-to-consumer advertisement that is false or misleading shall be liable to the United States
for a civil penalty in an amount not to exceed $ 250,000 for the first such violation in any 3-year period, and not to exceed $ 500,000 for each subsequent violation in any 3-year period. No other civil monetary penalties in this Act (including the civil penalty in section 303(f)(4) [subsec. (f)(4) of this section]) shall apply to a violation regarding direct-to-consumer advertising. For purposes of this paragraph:

(A) Repeated dissemination of the same or similar advertisement prior to the receipt of the written notice referred to in paragraph (2) for such advertisements shall be considered one violation.

(B) On and after the date of the receipt of such a notice, all violations under this paragraph occurring in a single day shall be considered one violation. With respect to advertisements that appear in magazines or other publications that are published less frequently than daily, each issue date (whether weekly or monthly) shall be treated as a single day for the purpose of calculating the number of violations under this paragraph.

(2) A civil penalty under paragraph (1) shall be assessed by the Secretary by an order made on the record after providing written notice to the person to be assessed a civil penalty and an opportunity for a hearing in accordance with this paragraph and section 554 of title 5, United States Code. If upon receipt of the written notice, the person to be assessed a civil penalty objects and requests a hearing, then in the course of any investigation related to such hearing, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation, including information pertaining to the factors described in paragraph (3).

(3) The Secretary, in determining the amount of the civil penalty under paragraph (1), shall take into account the nature, circumstances, extent, and gravity of the violation or violations, including the following factors:

(A) Whether the person submitted the advertisement or a similar advertisement for review under section 736A [21 USC § 379h-1].

(B) Whether the person submitted the advertisement for review if required under section 503B [21 USC § 353b].

(C) Whether, after submission of the advertisement as described in subparagraph (A) or (B), the person disseminated or caused another party to disseminate the advertisement before the end of the 45-day comment period.

(D) Whether the person incorporated any comments made by the Secretary with regard to the advertisement into the advertisement prior to its dissemination.

(E) Whether the person ceased distribution of the advertisement upon receipt of the written notice referred to in paragraph (2) for such advertisement.

(F) Whether the person had the advertisement reviewed by qualified medical, regulatory, and legal reviewers prior to its dissemination.

(G) Whether the violations were material.

(H) Whether the person who created the advertisement or caused the advertisement to be created acted in good faith.
(I) Whether the person who created the advertisement or caused the advertisement to be created has been assessed a civil penalty under this provision within the previous 1-year period.

(J) The scope and extent of any voluntary, subsequent remedial action by the person.

(K) Such other matters, as justice may require.

(4) (A) Subject to subparagraph (B), no person shall be required to pay a civil penalty under paragraph (1) if the person submitted the advertisement to the Secretary and disseminated or caused another party to disseminate such advertisement after incorporating each comment received from the Secretary.

(B) The Secretary may re retract or modify any prior comments the Secretary has provided to an advertisement submitted to the Secretary based on new information or changed circumstances, so long as the Secretary provides written notice to the person of the new views of the Secretary on the advertisement and provides a reasonable time for modification or correction of the advertisement prior to seeking any civil penalty under paragraph (1).

(5) The Secretary may compromise, modify, or remit, with or without conditions, any civil penalty which may be assessed under paragraph (1). The amount of such penalty, when finally determined, or the amount charged upon in compromise, may be deducted from any sums owed by the United States to the person charged.

(6) Any person who requested, in accordance with paragraph (2), a hearing with respect to the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty, may file a petition for de novo judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such person resides or transacts business. Such a petition may only be filed within the 60-day period beginning on the date the order making such assessments was issued.

(7) If any person fails to pay an assessment of a civil penalty under paragraph (1)--

(A) after the order making the assessment becomes final, and if such person does not file a petition for judicial review of the order in accordance with paragraph (6), or

(B) after a court in an action brought under paragraph (6) has entered a final judgment in favor of the Secretary, the Attorney General of the United States shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 60-day period referred to in paragraph (6) or the date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.

SEC. 304. [21 USC §334] Seizure

(a) Grounds and jurisdiction.

(1) Any article of food, drug, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of section 301(11), 404 or 505, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States or United States court of a Territory within the jurisdiction of which the article is found. No libel for condemnation shall be instituted under this Act, for any alleged misbranding if there is pending in any court a libel for
condemnation proceeding under this Act based upon the same alleged misbranding, and not more than
one such proceeding shall be instituted if no such proceeding is so pending, except that such limitations
shall not apply

(A) when such misbranding has been the basis of a prior judgment in favor of the United States, in a
criminal, injunction, or libel for condemnation proceeding under this Act, or

(B) when the Secretary has probable cause to believe from facts found, without hearing, by him or any
officer or employee of the Department that the misbranded article is dangerous to health, or that the
labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury
or damage of the purchaser or consumer. In any case where the number of libel for condemnation
proceedings is limited as above provided the proceeding pending or instituted shall, on application of the
claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the
parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court
of the district in which the seizure has been made, and such court (after giving the United States attorney
for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the
contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business,
to which the case shall be removed for trial.

(2) The following shall be liable to be proceeded against at any time on libel of information and
condemned in any district court of the United States or United States court of a Territory within the
jurisdiction of which they are found:

(A) Any drug that is a counterfeit drug,
(B) Any container of a counterfeit drug,
(C) Any punch, die, plate, stone, labeling container, or other thing used or designed for use in
making a counterfeit drug or drugs, and
(D) Any adulterated or misbranded device.

(3) (A) Except as provided—

(i) is misbranded advertising, and
(ii) is being held or distributor of the food.

(B) A libel for condemnation subparagraph (A) if—

(i) the food's advertising sale to the ultimate consumer,

(ii) such advertising such establishment, or

(iii) all or part of the operator; and

(ii) the owner or operator sale of the food.

(b) Procedure; Multiplicity of pending proceedings. The article, equipment, or other thing proceeded
against shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this
section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of
either party any issue of fact joined in any such case shall be tried by jury. When libel for condemnation
proceedings under this section, involving the same claimant and the same issues of adulteration or
misbranding, are pending in two or more jurisdictions, such pending proceedings, upon application of the
claimant seasonably made to the court of one such jurisdiction, shall be consolidated for trial by order of
such court, and tried in

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(1) any district selected by the claimant where one of such proceedings is pending; or

(2) a district agreed upon by stipulation between the parties. If no order for consolidation is so made within a reasonable time, the claimant may apply to the court of one such jurisdiction, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant’s principal place of business, in which all such pending proceedings shall be consolidated for trial and tried. Such order of consolidation shall not apply so as to require the removal of any case the date for trial of which has been fixed. The court granting such order shall give prompt notification thereof to the other courts having jurisdiction of the cases covered thereby.

(c) Availability of samples of seized goods prior to trial. The court at any time after seizure up to a reasonable time before trial shall by order allow any party to a condemnation proceeding, his attorney or agent, to obtain a representative sample of the article seized and a true copy of the analysis, if any, on which the proceeding is based and the identifying marks or numbers, if any, of the packages from which the samples analyzed were obtained.

(d) Disposition of goods after decree of condemnation; claims for remission or mitigation of forfeitures.

(1) Any food, drug, device, or cosmetic condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such article shall not be sold under such decree contrary to the provisions of this Act or the laws of the jurisdiction in which sold. After entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article shall not be sold or disposed of contrary to the provisions of this Act or the laws of any State or Territory in which sold, the court may by order direct that such article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this Act, under the supervision of an officer or employee duly designated by the Secretary, and the expenses of such supervision shall be paid by the person obtaining release of the article under bond. If the article was imported into the United States and the person seeking its release establishes

(A) that the adulteration, misbranding, or violation did not occur after the article was imported, and

(B) that he had no cause for believing that it was adulterated, misbranded, or in violation before it was released from customs custody, the court may permit the article to be delivered to the owner for exportation in lieu of destruction upon a showing by the owner that all of the conditions of section 801(e) can and will be met. The provisions of this sentence shall not apply where condemnation is based upon violation of section 402(a)(1), (2), or (6), section 501(a)(3), section 502(ii), or section 601(a) or (d). Where such exportation is made to the original foreign supplier, then subparagraphs (A) and (B) of section 801(e) and the preceding sentence shall not be applicable; and in all cases of exportation the bond shall be conditioned that the article shall not be sold or disposed of until the applicable conditions of section 801(e) have been met. Any person seeking to export an imported article pursuant to any of the provisions of this subsection shall establish that the article was intended for export at the time the article entered commerce. Any article condemned by reason of its being an article which may not, under section 404 or 505, be introduced into interest to commerce, shall be disposed of by destruction.

(2) The provisions of paragraph (1) of this subsection shall, to the extent deemed appropriate by the court, apply to any equipment or other thing which is not otherwise within the scope of such paragraph and which is referred to in paragraph (2) of subsection (a).
(3) Whenever in any proceeding under this section, involving paragraph (2) of subsection (a), the condemnation of any equipment or thing (other than a drug) is decreed, the court shall allow the claim of any claimant, to the extent of such claimant's interest, for remission or mitigation of such forfeiture if such claimant proves to the satisfaction of the court

(i) that he has not committed or caused to be committed any prohibited act referred to in such paragraph (2) and has no interest in any drug referred to therein,
(ii) that he has an interest in such equipment or other thing as owner or lienor or otherwise, acquired by him in good faith, and
(iii) that he at no time had any knowledge or reason to believe that such equipment or other thing was being or would be used in, or to facilitate, the violation of laws of the United States relating to counterfeit drugs.

(e) Costs. When a decree of condemnation is entered against the article, court costs and fees, and storage and other proper expenses, shall be awarded against the person, if any, intervening as claimant of the article.

(f) Removal of case for trial. In the case of removal for trial of any case as provided by subsection (a) or (b)--

(1) The clerk of the court from which removal is made shall promptly transmit to the court in which the case is to be tried all records in the case necessary in order that such court may exercise jurisdiction.

(2) The court to which such case was removed shall have the powers and be subject to the duties, for purposes of such case, which the court from which removal was made would have had, or to which such court would have been subject, if such case had not been removed.

(g) Administrative restraint; detention orders.

(1) If during an inspection conducted under section 704 of a facility or a vehicle, a device......confirm the detention or revoke it.

(2)(A) Except as authorize .................................................................detained until--

(B) A device ................................................................. by the Secretary

(h) Administrative detention of foods.

(1) Detention authority.

(A) In general. An officer or qualified employee of the Food and Drug Administration............. to humans or animals.

(B) Secretary's approval.--An article of 'ood ..............................................to such director.

(2) Period of detention. An article of food .............................................................to perishable foods.

(3) Security of detained article. An order under paragraph (1).............. is subject to the order.
(4) Appeal of detention order.

(A) In general. With respect to an article of food the order is deemed to be terminated.

(B) Effect of instituting court action. The process food involved.


Before any violation of this Act is reported by the Secretary to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.

SEC. 306. [21 USC §336] Debarment, Temporary Denial of Approval, and Suspension

(a) Mandatory Debarment; Certain Drug Applications-

(1) Corporations, Partnerships, And Associations. — If the Secretary finds that a person other than an individual has been convicted, after the date of enactment of this section, of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any abbreviated drug application, the Secretary shall debar such person from submitting, or assisting in the submission of, any such application.

(2) Individuals. If the Secretary finds that an individual has been convicted of a felony under Federal law for conduct –

(A) relating to the development or approval, including the process for development or approval, of any drug product, or

(B) otherwise relating to the regulation of any drug product under this Act, the Secretary shall debar such individual from providing services in any capacity to a person that has an approved or pending drug product application.

(b) Permissive Debarment; Certain Drug Applications; Food Imports.

(1) In General. The Secretary, on the Secretary's own initiative or in response to a petition, may, in accordance with paragraph (2), debar –

(A) a person other than an individual from submitting or assisting in the submission of any abbreviated drug application, or

(B) an individual from providing services in any capacity to a person that has an approved or pending drug product application , or

(C) a person United States .

(2) Persons Subject To Permissive debarment; certain drug applications. -- The following persons are subject to debarment under subparagraph (A) or (B) of paragraph (1):

(A) Corporations, Partnerships, And Associations. Any person other than an individual that the Secretary finds has been convicted –
(i) for conduct that—

(I) relates to the development or approval, including the process for the development or approval, of any abbreviated drug application; and

(II) is a felony under Federal law (if the person was convicted before the date of enactment of this section), a misdemeanor under Federal law, or a felony under State law, or

(ii) of a conspiracy to commit, or aiding or abetting, a criminal offense described in clause (i) or a felony described in subsection (a)(1), if the Secretary finds that the type of conduct which served as the basis for such conviction undermines the process for the regulation of drugs.

(B) Individuals—

(i) Any individual whom the Secretary finds has been convicted of—

(I) a misdemeanor under Federal law or a felony under State law for conduct relating to the development or approval, including the process for development or approval, of any drug product or otherwise relating to the regulation of drug products under this Act, or

(II) a conspiracy to commit, or aiding or abetting, such criminal offense or a felony described in subsection (a)(2), if the Secretary finds that the type of conduct which served as the basis for such conviction undermines the process for the regulation of drugs.

(ii) Any individual whom the Secretary finds has been convicted of—

(I) a felony which is not described in subsection (a)(2) or clause (i) of this subparagraph and which involves bribery, payment of illegal gratuities, fraud, perjury, false statement, racketeering, blackmail, extortion, falsification or destruction of records, or interference with, obstruction of an investigation into, or prosecution of, any criminal offense, or

(II) a conspiracy to commit, or aiding or abetting, such felony, if the Secretary finds, on the basis of the conviction of such individual and other information, that such individual has demonstrated a pattern of conduct sufficient to find that there is reason to believe that such individual may violate requirements under this Act relating to drug products.

(iii) Any individual whom the Secretary finds materially participated in acts that were the basis for a conviction for an offense described in subsection (a) or in clause (i) or (ii) for which a conviction was obtained, if the Secretary finds, on the basis of such participation and other information, that such individual has demonstrated a pattern of conduct sufficient to find that there is reason to believe that such individual may violate requirements under this Act relating to drug products.

(iv) Any high managerial agent whom the Secretary finds—

(I) worked for, or worked as a consultant for, the same person as another individual during the period in which such other individual took actions for which a felony conviction was obtained and which resulted in the debarment under subsection (a)(2), or clause (i), of such other individual,

(II) had actual knowledge of the actions described in subclause (I) of such other individual, or took action to avoid such actual knowledge, or failed to take action for the purpose of avoiding such actual knowledge,
(III) knew that the actions described in subclause (I) were violative of law, and

(IV) did not report such actions, or did not cause such actions to be reported, to an officer, employee, or agent of the Department or to an appropriate law enforcement officer, or failed to take other appropriate action that would have ensured that the process for the regulation of drugs was not undermined, within a reasonable time after such agent first knew of such actions, if the Secretary finds that the type of conduct which served as the basis for such other individual's conviction undermines the process for the regulation of drugs.

(3) Persons subject to permissive debarment; food importation.--A person............. of any food; or

(A) the person................................................. of any food; or

(B) the person ........................................... humans or animals.

(4) Stay Of Certain Orders: An order of the Secretary under clause (iii) or (iv) of paragraph (2)(B) shall not take effect until 30 days after the order has been issued.

(c) Debarment Periods And Considerations –

(1) Effect Of Debarment. -- The Secretary -

(A) shall not accept or review (other than in connection with an audit under this section) any abbreviated drug application submitted by or with the assistance of a person debarred under subsection (a)(1) or (b)(2)(A) during the period such person is debarred,

(B) shall, during the period of a debarment under subsection (a)(2) or (b)(2)(B), debar an individual from providing services in any capacity to a person that has an approved or pending drug product application and shall not accept or review (other than in connection with an audit under this section) an abbreviated drug application from such individual, and

(C) shall, if the Secretary makes the finding described in paragraph (6) or (7) of section 307(a), assess a civil penalty in accordance with section 307.

(2) Debarment Periods. --

(A) In General -- The Secretary shall debar a person under subsection (a) or (b) for the following periods:

(i) The period of debarment of a person (other than an individual) under subsection (a)(1) shall not be less than 1 year or more than 10 years, but if an act leading to a subsequent debarment under subsection (a) occurs within 10 years after such person has been debarred under subsection (a)(1), the period of debarment shall be permanent.

(ii) The debarment of an individual under subsection (a)(2) shall be permanent.

(iii) The period of debarment of any person under paragraph (2) or (3) of subsection (b) shall not be more than 5 years. The Secretary may determine whether debarment periods shall run concurrently or consecutively in the case of a person debarred for multiple offenses.

(B) Notification - Upon a conviction for an offense described in subsection (a) or (b) or upon execution of an agreement with the United States to plead guilty to such an offense, the person involved may notify
the Secretary that the person acquiesces to debarment and such person's debarment shall commence upon such notification.

(3) Considerations -- In determining the appropriateness and the period of a debarment of a person under subsection (b) and any period of debarment beyond the minimum specified in subparagraph (A)(i) of paragraph (2), the Secretary shall consider where applicable -

(A) the nature and seriousness of any offense involved,

(B) the nature and extent of management participation in any offense involved, whether corporate policies and practices encouraged the offense, including whether inadequate institutional controls contributed to the offense,

(C) the nature and extent of voluntary steps to mitigate the impact on the public of any offense involved, including the recall or the discontinuation of the distribution of suspect drugs, full cooperation with any investigations (including the extent of disclosure to appropriate authorities of all wrongdoing), the relinquishing of profits on drug approvals fraudulently obtained, and any other actions taken to substantially limit potential or actual adverse effects on the public health,

(D) whether the extent to which changes in ownership, management, or operations have corrected the causes of any offense involved and provide reasonable assurances that the offense will not occur in the future,

(E) whether the person to be debarred is able to present adequate evidence that current production of drugs subject to abbreviated drug applications and all pending abbreviated drug applications are free of fraud or material false statements, and

(F) prior convictions under this Act or under other Acts involving matters within the jurisdiction of the Food and Drug Administration.

(d) Termination Of Debarment. --

(1) Application -- Any person that is debarred under subsection (a) (other than a person permanently debarred) or any person that is debarred under subsection (b) of this section may apply to the Secretary for termination of the debarment under this subsection. Any information submitted to the Secretary under this paragraph does not constitute an amendment or supplement to pending or approved abbreviated drug applications.

(2) Deadline -- The Secretary shall grant or deny any application respecting a debarment which is submitted under paragraph (1) within 180 days of the date the application is submitted.

(3) Action By The Secretary --

(A) Corporations --

(i) Conviction Reversal -- If the conviction which served as the basis for the debarment of a person under subsection (a)(1) (b) or paragraph (2)(A) or (3) of subsection is reversed, the Secretary shall withdraw the order of debarment.

(ii) Application-- Upon application submitted under paragraph (1), the Secretary shall terminate the debarment of a person if the Secretary finds that --
(I) changes in ownership, management, or operations have fully corrected the causes of the offense involved and provide reasonable assurances that the offense will not occur in the future, and

(II) in applicable cases, sufficient audits, conducted by the Food and Drug Administration or by independent experts acceptable to the Food and Drug Administration, demonstrate that pending applications and the development of drugs being tested before the submission of an application are free of fraud or material false statements. In the case of persons debarred under subsection (a)(1), such termination shall take effect no earlier than the expiration of one year from the date of the debarment.

(B) Individuals –

(i) Conviction Reversal— If the conviction which served as the basis for the debarment of an individual under subsection (a)(2) or clause (i), (ii), (iii), or (iv) of subsection (b)(2)(B) or subsection (a)(3) is reversed, the Secretary shall withdraw the order of debarment.

(ii) Application— Upon application submitted under paragraph (1), the Secretary shall terminate the debarment of an individual who has been debarred under subsection (b)(2)(B) or subsection (b)(3) if such termination serves the interests of justice and adequately protects the integrity of the drug approval process or the food importation process, as the case may be.

(4) Special Termination –

(A) Application. -- Any person that is debarred under subsection (a)(1) (other than a person permanently debarred under subsection (c)(2)(A)(i)) or any individual who is debarred under subsection (a)(2) may apply to the Secretary for special termination of debarment under this subsection. Any information submitted to the Secretary under this subparagraph does not constitute an amendment or supplement to pending or approved abbreviated drug applications.

(B) Corporations — Upon an application submitted under subparagraph (A), the Secretary may take the action described in subparagraph (D) if the Secretary, after an informal hearing, finds that—

(i) the person making the application under subparagraph (A) has demonstrated that the felony conviction which was the basis for such person's debarment involved the commission of an offense which was not authorized, requested, commanded, performed, or recklessly tolerated by the board of directors or by a high managerial agent acting on behalf of the person within the scope of the board's or agent's office or employment,

(ii) all individuals who were involved in the commission of the offense or who knew or should have known of the offense have been removed from employment involving the development or approval of any drug subject to sections 1 505,

(iii) the person fully cooperated with all investigations and promptly disclosed all wrongdoing to the appropriate authorities, and

(iv) the person acted to mitigate any impact on the public of any offense involved, including the recall, or the discontinuation of the distribution, of any drug with respect to which the Secretary requested a recall or discontinuation of distribution due to concerns about the safety or efficacy of the drug.

(C) Individuals — Upon an application submitted under subparagraph (A), the Secretary may take the action described in subparagraph (D) if the Secretary, after an informal hearing, finds that such individual has provided substantial assistance in the investigations or prosecutions of offenses which are described

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in subsection (a) or (b) or which relate to any matter under the jurisdiction of the Food and Drug
Administration.

(D) Secretarial Action - The action referred to in subparagraphs (B) and (C) is –

(i) in the case of a person other than an individual –

(I) terminating the debarment immediately, or

(II) limiting the period of debarment to less than one year, and

(ii) in the case of an individual, limiting the period of debarment to less than permanent but to no less
than 1 year, whichever best serves the interest of justice and protects the integrity of the drug approval
process.

(e) Publication And List Of Debarment Persons. -- The Secretary shall publish in the Federal Register
the name of any person debarred under subsection (a) or (b), the effective date of the debarment, and
the period of the debarment. The Secretary shall also maintain and make available to the public a list,
updated no less often than quarterly, of such persons, of the effective dates and minimum periods of such
debarments, and of the termination of debarments.

(f) Temporary Denial Of Approval. –

(1) In General -- The Secretary, on the Secretary’s own initiative or in response to a petition, may, in
accordance with paragraph (3), refuse by order, for the period prescribed by paragraph (2), to approve
any abbreviated drug application submitted by any person –

(A) if such person is under an active Federal criminal investigation in connection with an action described
in subparagraph (B),

(B) if the Secretary finds that such person –

(i) has bribed or attempted to bribe, has paid or attempted to pay an illegal gratuity, or has induced or
attempted to induce another person to bribe or pay an illegal gratuity to any officer, employee, or agent of
the Department of Health and Human Services or to any other Federal, State, or local official in
connection with any abbreviated drug application, or has conspired to commit, or aided or abetted, such
actions, or

(ii) has knowingly made or caused to be made a pattern or practice of false statements or
misrepresentations with respect to material facts relating to any abbreviated drug application, or the
production of any drug subject to an abbreviated drug application, to any officer, employee, or agent of
the Department of Health and Human Services, or has conspired to commit, or aided or abetted, such
actions, and

(C) if a significant question has been raised regarding –

(i) the integrity of the approval process with respect to such abbreviated drug application, or

(ii) the reliability of data in or concerning such person’s abbreviated drug application.
Such an order may be modified or terminated at any time.
(2) Applicable Period --

(A) In General -- Except as provided in subparagraph (B), a denial of approval of an application of a person under paragraph (1) shall be in effect for a period determined by the Secretary but not to exceed 18 months beginning on the date the Secretary finds that the conditions described in subparagraphs (A), (B), and (C) of paragraph (1) exist. The Secretary shall terminate such denial --

(i) if the investigation with respect to which the finding was made does not result in a criminal charge against such person, if criminal charges have been brought and the charges have been dismissed, or if a judgment of acquittal has been entered, or

(ii) if the Secretary determines that such finding was in error.

(B) Extension -- If, at the end of the period described in subparagraph (A), the Secretary determines that a person has been criminally charged for an action described in subparagraph (B) of paragraph (1), the Secretary may extend the period of denial of approval of an application for a period not to exceed 18 months. The Secretary shall terminate such extension if the charges have been dismissed, if a judgment of acquittal has been entered, or if the Secretary determines that the finding described in subparagraph (A) was in error.

(3) Informal Hearing. -- Within 10 days of the date an order is issued under paragraph (1), the Secretary shall provide such person with an opportunity for an informal hearing, to be held within such 10 days, on the decision of the Secretary to refuse approval of an abbreviated drug application. Within 60 days of the date on which such hearing is held, the Secretary shall notify the person given such hearing whether the Secretary's refusal of approval will be continued, terminated, or otherwise modified. Such notification shall be final agency action.

(g) Suspension Authority --

(1) In General -- If --

(A) the Secretary finds --

(i) that a person has engaged in conduct described in subparagraph (B) of subsection (f)(1) in connection with 2 or more drugs under abbreviated drug applications, or

(ii) that a person has engaged in flagrant and repeated, material violations of good manufacturing practice or good laboratory practice in connection with the development, manufacturing, or distribution of one or more drugs approved under an abbreviated drug application during a 2-year period, and -

(I) such violations may undermine the safety and efficacy of such drugs, and

(II) the causes of such violations have not been corrected within a reasonable period of time following notice of such violations by the Secretary, and

(B) such person is under an active investigation by a Federal authority in connection with a civil or criminal action involving conduct described in subparagraph (A), the Secretary shall issue an order suspending the distribution of all drugs the development or approval of which was related to such conduct described in subparagraph (A) or suspending the distribution of all drugs approved under abbreviated drug applications of such person if the Secretary finds that such conduct may have affected the development or approval of a significant number of drugs which the Secretary is unable to identify. The

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Secretary shall exclude a drug from such order if the Secretary determines that such conduct was not likely to have influenced the safety or efficacy of such drug.

(2) **Public Health Waiver** -- The Secretary shall, on the Secretary's own initiative or in response to a petition, waive the suspension under paragraph (1) (involving an action described in paragraph (1)(A)(i)) with respect to any drug if the Secretary finds that such waiver is necessary to protect the public health because sufficient quantities of the drug would not otherwise be available. The Secretary shall act on any petition seeking action under this paragraph within 180 days of the date the petition is submitted to the Secretary.

(h) **Termination Of Suspension** -- The Secretary shall withdraw an order of suspension of the distribution of a drug under subsection (g) if the person with respect to whom the order was issued demonstrates in a petition to the Secretary—

(1)(A) on the basis of an audit by the Food and Drug Administration or by experts acceptable to the Food and Drug Administration, or on the basis of other information, that the development, approval, manufacturing, and distribution of such drug is in substantial compliance with the applicable requirements of this Act, and

(B) changes in ownership, management, or operations—

(i) fully remedy the patterns or practices with respect to which the order was issued, and

(ii) provide reasonable assurances that such actions will not occur in the future, or

(2) the initial determination was in error.

The Secretary shall act on a submission of a petition under this subsection within 180 days of the date of its submission and the Secretary may consider the petition concurrently with the suspension proceeding. Any information submitted to the Secretary under this subsection does not constitute an amendment or supplement to a pending or approved abbreviated drug application.

(i) **Procedure** -- The Secretary may not take any action under subsection (a), (b), (c), (d)(3), (g), or (h) with respect to any person unless the Secretary has issued an order for such action made on the record after opportunity for an agency hearing on disputed issues of material fact. In the course of any investigation or hearing under this subsection, the Secretary may administer oaths and affirmations, examine witnesses, receive evidence, and issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

(j) **Judicial Review**

(1) **In General** -- Except as provided in paragraph (2), any person that is the subject of an adverse decision under subsection (a), (b), (c), (d), (f), (g), or (h) may obtain a review of such decision by the United States Court of Appeals for the District of Columbia or for the circuit in which the person resides, by filing in such court (within 60 days following the date the person is notified of the Secretary's decision) a petition requesting that the decision be modified or set aside.

(2) **Exception** -- Any person that is the subject of an adverse decision under clause (iii) or (iv) of subsection (b)(2)(B) may obtain a review of such decision by the United States District Court for the District of Columbia or a district court of the United States for the district in which the person resides, by filing in such court (within 30 days following the date the person is notified of the Secretary's decision) a
complaint requesting that the decision be modified or set aside. In such an action, the court shall determine the matter de novo.

(k) Certification -- Any application for approval of a drug product shall include -

(1) a certification that the applicant did not and will not use in any capacity the services of any person debarred under subsection (a) or (b), in connection with such application, and

(2) if such application is an abbreviated drug application, a list of all convictions, described in subsections (a) and (b) which occurred within the previous 5 years, of the applicant and affiliated persons responsible for the development or submission of such application.

(l) Applicability--

(1) Conviction -- For purposes of this section, a person is considered to have been convicted of a criminal offense -

(A) when a judgment of conviction has been entered against the person by a Federal or State court, regardless of whether there is an appeal pending,

(B) when a plea of guilty or nolo contendere by the person has been accepted by a Federal or State court, or

(C) when the person has entered into participation in a first offender, deferred adjudication, or other similar arrangement or program where judgment of conviction has been withheld.

(2) Effective Dates -- Subsection (a), subparagraph (A) of subsection (b)(2), and subsection (b)(3)(A) clauses (i) and (ii) of subsection (b)(2)(B) shall not apply to a conviction which occurred more than 5 years before the initiation of an agency action proposed to be taken under subsection (a) or (b). Clauses (iii) and (iv) of subsection (b)(2)(B), subsection (b)(3)(B) and subsections (f) and (g) shall not apply to an act or action which occurred more than 5 years before the initiation of an agency action proposed to be taken under subsection (b), (f), or (g). Clause (iv) of subsection (b)(2)(B) shall not apply to an action which occurred before June 1, 1992. Subsection (k) shall not apply to applications submitted to the Secretary before June 1, 1992.

(m) Devices; Mandatory Debarment Regarding Third-Party Inspections and Reviews.—

(1) In general.--If the Secretary finds .....................................................described in section 803(b).

(2) Debarment period.--The Secretary .........for the following periods:

(A) The period of debarment .................................................................debarment shall be permanent.

(B) The debarment .................................................................permanent.

(3) Termination of debarment; judicial review; other matters.--Subsections (c)(3), (d), .........respectively.

SEC. 307. [21 USC §337] Civil Penalties

(a) In General—Any person that the Secretary finds—

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(1) knowingly made or caused to be made, to any officer, employee, or agent of the Department of Health and Human Services, a false statement or misrepresentation of a material fact in connection with an abbreviated drug application,

(2) bribed or attempted to bribe or paid or attempted to pay an illegal gratuity to any officer, employee, or agent of the Department of Health and Human Services in connection with an abbreviated drug application,

(3) destroyed, altered, removed, or secreted, or procured the destruction, alteration, removal, or secretion of, any material document or other material evidence which was the property of or in the possession of the Department of Health and Human Services for the purpose of interfering with that Department's discharge of its responsibilities in connection with an abbreviated drug application,

(4) knowingly failed to disclose, to an officer or employee of the Department of Health and Human Services, a material fact which such person had an obligation to disclose relating to any drug subject to an abbreviated drug application,

(5) knowingly obstructed an investigation of the Department of Health and Human Services into any drug subject to an abbreviated drug application,

(6) is a person that has an approved or pending drug product application and has knowingly—

(A) employed or retained as a consultant or contractor, or

(B) otherwise used in any capacity the services of, a person who was debarred under section 306, or

(7) is an individual debarred under section 306 and, during the period of debarment, provided services in any capacity to a person that had an approved or pending drug product application, shall be liable to the United States for a civil penalty for each such violation in an amount not to exceed $250,000 in the case of an individual and $1,000,000 in the case of any other person.

(b) Procedure—

(1) In General—

(A) Action By The Secretary—A civil penalty under subsection (a) shall be assessed by the Secretary on a person by an order made on the record after an opportunity for an agency hearing on disputed issues of material fact and the amount of the penalty. In the course of any investigation or hearing under this subparagraph, the Secretary may administer oaths and affirmations, examine witnesses, receive evidence, and issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

(B) Action By The Attorney General—In lieu of a proceeding under subparagraph (A), the Attorney General may, upon request of the Secretary, institute a civil action to recover a civil money penalty in the amount and for any of the acts set forth in subsection (a). Such an action may be instituted separately from or in connection with any other claim, civil or criminal, initiated by the Attorney General under this Act.

(2) Amount—In determining the amount of a civil penalty under paragraph (1), the Secretary or the court shall take into account the nature, circumstances, extent, and gravity of the act subject to penalty, the person's ability to pay, the effect on the person's ability to continue to do business, any history of prior similar acts, and such other matters as justice may require.

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(3) Limitation On Actions—No action may be initiated under this section—
(A) with respect to any act described in subsection (a) that occurred before the date of the enactment of this section, or
(B) more than 6 years after the date when facts material to the act are known or reasonably should have been known by the Secretary but in no event more than 10 years after the date the act took place.

(c) Judicial Review—Any person that is the subject of an adverse decision under subsection (b)(1)(A) may obtain a review of such decision by the United States Court of Appeals for the District of Columbia or for the circuit in which the person resides, by filing in such court (within 60 days following the date the person is notified of the Secretary's decision) a petition requesting that the decision be modified or set aside.

(d) Recovery Of Penalties—The Attorney General may recover any civil penalty (plus interest at the currently prevailing rates from the date the penalty became final) assessed under subsection (b)(1)(A) in an action brought in the name of the United States. The amount of such penalty may be deducted, when the penalty has become final, from any sums then or later owing by the United States to the person against whom the penalty has been assessed. In an action brought under this subsection, the validity, amount, and appropriateness of the penalty shall not be subject to judicial review.

(e) Informants—The Secretary may award to any individual (other than an officer or employee of the Federal Government or a person who materially participated in any conduct described in subsection (a)) who provides information leading to the imposition of a civil penalty under this section an amount not to exceed—
(1) $250,000, or
(2) one-half of the penalty so imposed and collected, whichever is less. The decision of the Secretary on such award shall not be reviewable.

SEC. 308. [21 USC §338] Authority to Withdraw Approval of Abbreviated Drug Applications

(a) In General—The Secretary—

(1) shall withdraw approval of an abbreviated drug application if the Secretary finds that the approval was obtained, expedited, or otherwise facilitated through bribery, payment of an illegal gratuity, or fraud or material false statement, and

(2) may withdraw approval of an abbreviated drug application if the Secretary finds that the applicant has repeatedly demonstrated a lack of ability to produce the drug for which the application was submitted in accordance with the formulations or manufacturing practice set forth in the abbreviated drug application and has introduced, or attempted to introduce, such adulterated or misbranded drug into commerce.

(b) Procedure—The Secretary may not take any action under subsection (a) with respect to any person unless the Secretary has issued an order for such action made on the record after opportunity for an agency hearing on disputed issues of material fact. In the course of any investigation or hearing under this subsection, the Secretary may administer oaths and affirmations, examine witnesses, receive evidence, and issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.
(c) **Applicability**—Subsection (a) shall apply with respect to offenses or acts regardless of when such offenses or acts occurred.

(d) **Judicial Review**—Any person that is the subject of an adverse decision under subsection (a) may obtain a review of such decision by the United States Court of Appeals for the District of Columbia or for the circuit in which the person resides, by filing in such court (within 60 days following the date the person is notified of the Secretary's decision) a petition requesting that the decision be modified or set aside.


Nothing in this Act shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this Act whenever he believes that the public interest will be adequately served by a suitable written notice or warning.

SEC. 310. [21 USC §337] Proceedings in Name of United States; Provision As To Subpoenas

(a) Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this Act shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section.

(b)(1) A State may bring ...........................................................................................................

(2) No proceeding ................................................................................................................

(A) before 30 days ........................................................................................................

(B) before 90 days ...........................................................................................................

(C) if the Secretary ...........................................................................................................


**CRIMINAL INVESTIGATIONS**

**Mission**

As the criminal investigative arm of the Food and Drug Administration (FDA), the mission of the Office of Criminal Investigations (OCI) is to conduct and coordinate investigations of suspected criminal violations of the Federal Food, Drug, and Cosmetic Act (FDCA) and other related Acts and to collect evidence to support successful prosecutions through the federal or state court systems as appropriate.

**What OCI Investigates:** The Office of Criminal Investigations (OCI) was established to provide the Food and Drug Administration (FDA) with a specific Office to conduct and coordinate criminal investigations. OCI special agents employ customary federal law enforcement methods and techniques in the investigation of suspected criminal violations of the Federal Food, Drug, and Cosmetic Act and other related federal statutes. OCI investigations concentrate on significant violations of these laws, with a priority on conduct that may present a danger to the public health.

The FDA regulates approximately 25 cents of every dollar spent annually by American consumers. FDA is responsible for regulating products to ensure the safety of foods, drugs, biological products, medical
devices, cosmetics, radiation-emitting devices, and more. As the law enforcement arm of FDA, the Office of Criminal Investigations conducts and coordinates criminal investigations regarding possible violations of the laws which regulate these products. Such violations include:

- Manufacture and sale of counterfeit or unapproved drugs
- Illegal diversion of pharmaceuticals and other regulated products
- Prescription Drug Marketing Act violations
- Off-Label promotion of FDA approved drugs and medical devices
- Health fraud - schemes involving fraudulent treatments/cures/devices
- New drug application fraud
- Clinical investigator fraud
- Product substitution crimes
- Product tampering
- Crimes affecting the safety/integrity of the nation's blood supply
- Crimes involving the adulteration and/or misbranding of food
- Internet facilitated criminal violations involving FDA regulated products
- Illegal importation of FDA regulated products
- Crimes involving the manufacture, sale or distribution of unapproved FDA regulated products

Pursuant to its investigative mission, OCI maintains liaison and cooperative investigative efforts with various federal, state, local, and international law enforcement agencies. OCI is designated by the Commissioner as the Agency's point of contact with the U.S. intelligence community as it relates to the Agency's counter-terrorism mission. OCI has representation at the Interpol U.S. National Central Bureau in Washington, DC.

(http://www.fda.gov/ICECI/CriminalInvestigations/ucm123062.htm)

Recalls

Definition of Class I, II and III

**Class I recall**: situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.

**Class II recall**: situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

**Class III recall**: situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.
Types of FDA Regulatory Actions: The objective of FDA regulatory programs is to assure compliance with the Federal Food, Drug, and Cosmetic Act (the Act). Specific enforcement activities include actions to correct and prevent violations, remove violative products or goods from the market, and punish offenders. The type of enforcement activity FDA uses will depend on the nature of the violation. The range of enforcement activities include issuing a letter notifying the individual or firm of a violation and requesting correction, to criminal prosecution of the individual or firm. Adulteration or misbranding is usually the result of an individual failing to take steps to assure compliance with the law. Such an individual may be liable for a violation of the Act and, if found guilty, be subject to the penalties specified by the law.

COMPLIANCE ACHIEVEMENT: The observed repair, modification, or adjustment of a violative condition, or the repair, modification, adjustment, relabeling, or destruction of a violative product when either the product or condition does not comply with the Acts enforced by the Agency.

CIVIL MONEY PENALTY: A monetary penalty for a non-criminal action that is assessed by FDA or the courts for violations of the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act.

INDICTMENT: A formal accusation by a grand jury that sets forth charges against a defendant and states when the alleged crime occurred. An indictment is not a finding of guilt.

INJUNCTION: A civil action taken against an individual or firm seeking to stop continued production or distribution of a violative product.

NOTICE OF INSPECTIONAL OBSERVATIONS (FDA-483): The document lists observations made by the FDA representative(s) during an inspection of a facility.

PROSECUTION: A criminal action taken against a company or individual charging violation of the law.

RECALL AND FIELD CORRECTION: An action taken by a firm to either remove a violative product from the market or to conduct a field correction. Recalls may be conducted on a firm’s own initiative, by FDA request, or by FDA order under statutory authority. A Class I recall is a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death. A Class II recall is a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. A Class III recall is a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.

SEIZURE: An action taken to remove a product from commerce because it is in violation of the law. FDA initiates a seizure by filing a complaint with the U.S. District Court where the product is located. A U.S. Marshal is then directed by the court to take possession of the goods until the matter is resolved.

WARNING LETTER: An informal advisory to a firm communicating the Agency’s Enforcement Statistics Fiscal Year 2008 10-20 position on a matter but does not commit FDA to taking enforcement action. The Agency’s policy is that Warning Letters should be issued for violations which are of regulatory significance in that failure to adequately and promptly take corrections may be expected to result in enforcement action should the violation(s) continue. In FY08 FDA conducted 14,298 domestic inspections and performed 947 inspections of foreign facilities and 24,260 import sample collections, reflecting the focus on the global environment, precipitated by findings of public health issues in infant formula, heparin and others. Criminal investigations conducted in FY08 resulted in more than $860 million in fines and restitution, as well as a record number of convictions. In civil cases, we have seen an increase in seizures.
from last year, while the number of injunctions has declined. (http://www.fda.gov/downloads/ICECI/EnforcementActions/EnforcementStory/UCM129823.pdf)

Criminal Fines for Food Drug and Cosmetic Act Violations

Misdemeanor fines under the Act may reach $500,000 under some circumstances. The Criminal Fine Enforcement Act of 1994 (Public Law 98-596) provides for fines for violations of Federal law. Although it is not part of the Act, the Criminal Fine Enforcement Act of 1994 applies to all fines levied under the Act, as well as other statutes that contain provisions enforced by FDA. The following fines are applicable for each offense:

- Up to $100,000 for a misdemeanor by an individual that does not result in death.
- Up to $200,000 for a misdemeanor by a corporation that does not result in death.
- Up to $250,000 for a misdemeanor by an individual that results in death, or a felony.
- Up to $500,000 for a misdemeanor by a corporation that results in death, or a felony.

The maximum imprisonment for a misdemeanor under the Act remains a year for each offense. (http://www.fda.gov/AnimalVeterinary/ResourcesforYou/FDAandtheVeterinarian/ucm077392.htm)

5.2 EUROPEAN UNION

What is a Directive? :

A Directive is a legal instrument which is binding, as to the result to be achieved, upon each Member State to whom it is addressed. However, the national authorities are left the choice of form and methods to achieve their objectives. Directives may be addressed to individual, several or all Member States. In order to ensure that the objectives laid down in directives become applicable to individual citizens, an act of transposition by national legislators is required, whereby national law is adapted to the objectives laid down in directives. Individual citizens are given rights and bound by the legal act when the directive is incorporated into national law.

Since the Member States are only bound by the objectives laid down in directives, they have some discretion, in transposing them into national law, in taking account of specific national circumstances. Transposition must be effected within the period laid down in a directive. In transposing directives, the Member States must select the national forms which are best suited to ensure the effectiveness of Community law (Article 10 (5) ECT, 'effet utile'). Directives must be transposed in the form of binding national legislation which fulfills the requirements of legal security and legal clarity and establishes an actionable legal position for individuals. Legislation which has been adapted to EC directives may not subsequently be amended contrary to the objectives of those directives (blocking effect of directives).

What is a Regulation? :

A Regulation is a legal instrument which has a general application, it is binding in its entirety and is directly applicable in all Member States. As ‘Community laws’, regulations must be complied with fully by those to whom they are addressed (individuals, Member States, Community Institutions). Regulations
apply directly in all the Member States, without requiring a national act to transpose them, on the basis of their publication in the Official Journal of the European Community.

Regulations serve to ensure the uniform application of Community law in all the Member States. At the same time, they prevent the application of national rules the substance of which is incompatible with their own regulatory purpose. National laws, regulations and administrative provisions are permissible only in so far as they are provided for in regulations or are otherwise necessary for their effective implementation. National implementing provisions may not amend or amplify the scope and effectiveness of regulations (Article 5 (10) ECT).

**What is a guideline in the pharmaceutical legislative framework?:**

A guideline is a Community document, which is either referred to in the legislative framework as intended to fulfil a legal obligation laid down in the Community pharmaceutical legislation or considered to provide advice to applicants or marketing authorisation holders, competent authorities and/or other interested parties on the best or most appropriate way to fulfil an obligation laid down in the Community pharmaceutical legislation. In the case of scientific guidelines, these may relate to specific scientific issues reflecting a harmonised EU approach and based on the most up-to-date scientific knowledge.

**What is the legal status of guidelines?:**

Most guidelines within the framework of the pharmaceutical legislation do not have legal force and the definitive legal requirements are those outlined in the relevant Community legislative framework (Directives, Regulations, Decisions etc.) as well as appropriate national rules.

However, guidelines are to be considered as a harmonised Community position, which if followed by relevant parties such as the applicants, marketing authorisation holders, sponsors, manufacturers and regulators will facilitate the assessment, approval and control of medicinal products in the European Union. Nevertheless, alternative approaches may be taken, provided that these are appropriately justified.

**DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 November 2001 on the Community code relating to medicinal products for human use**

*Article 25; Authorization shall not affect the civil and criminal liability of the manufacturer and, where applicable, of the marketing authorization holder. (http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol1/dir_2001_83_cons/dir2001_83_cons_2008_1230_en.pdf)*

*Article 26; 1 The marketing authorisation shall be refused if, after verification of the particulars and documents listed in Articles 8, 10, 10a, 1Cb and 10c, it is clear that:*

(a) the risk-benefit balance is not considered to be favourable; or

(b) its therapeutic efficacy is insufficiently substantiated by the applicant; or

(c) its qualitative and quantitative composition is not as declared.

2. Authorisation shall likewise be refused if any particulars or documents submitted in support of the application do not comply with Articles 8, 10, 10a, 10b and 10c.

3. The applicant or the holder of a marketing authorisation shall be responsible for the accuracy of the documents and the data submitted.
**Article 36:** Where a Member State considers that the variation of a marketing authorization which has been granted in accordance with the provisions of this Chapter or its suspension or withdrawal is necessary for the protection of public health, the Member State concerned shall forthwith refer the matter to the Agency for the application of the procedures laid down in Articles 32, 33 and 34.

2. Without prejudice to the provisions of Article 31, in exceptional cases, where urgent action is essential to protect public health, until a definitive decision is adopted a Member State may suspend the marketing and the use of the medicinal product concerned on its territory. It shall inform the Commission and the other Member States no later than the following working day of the reasons for its action.

**Inspections - Product Defects and Recalls**

**Instructions on Notifying Quality Defects or Recalls of Centrally Authorised Products to the EMEA**

**Step 1.** Download the Defective Product Report Form from the EMEA Website (Annex 1 to SOP/EMEA/007).

**Step 2.** Complete the Defective Product Report Form ensuring that all of section 1 and as much as possible of sections 2 and 3 are complete.

**Step 3.** Send the form by email to qdefect@emea.europa.eu.

**Step 4.** Immediately telephone the EMEA to confirm that the Defective Product Report Form has been received and to provide additional information as required. The telephone numbers to use are:

**Step 5.** Investigate the product defect (with the urgency indicated by the nature of the defect) and send a report to the EMEA, which includes at least the following information:

a. Background information (e.g. information about the product, its manufacturing process and/or use)

b. History of the incident with specific dates when it occurred and/or was observed

c. Potential root cause:

i. If the problem is due to the presence of a foreign object, describe the foreign object’s size and composition.

ii. If the problem is due to the presence of a contaminant (i.e. cleaning fluid, machine oil, paint vapours), the level of contamination should be given and the Material Safety Data Sheet for the contaminant should be provided.

iii. If the problem is due to failure of the product to meet product specifications, provide the specifications and report all test results.

iv. If the problem is due to a label or formulation issue, provide and identify the correct and incorrect label(s), description(s) and formulation(s)

d. Describe the corrective and preventive actions taken or to be taken to eliminate the root cause.

e. Review of complaint records for reports of similar defects.
f. Review of all associated batch manufacturing, packaging, testing, release and distribution records for anomalies which may explain the suspected defect

g. Examination, and retesting, if appropriate, of retained samples.

h. Estimation of stock under the manufacturer’s control.

i. Distribution and parallel distribution of the batches affected

j. Recommendation on whether a recall is necessary, and if so, to what level

k. If recall is recommended, assessment of the classification of the defect

l. If recall is recommended, explain whether the problem affects ALL units subject to recall or just a portion of the units. Explain why the problem is restricted only to those products/lots identified.

m. Overall conclusions

Step 6: Provide a report outlining the risks associated with the suspected quality defect in particular the impact on the safety and/or efficacy of the medicinal product concerned. Outline any risk mitigation measures.

If any delay is expected in making the report of steps 5 and 6, interim reports should be sent not more than 48 hours after the original notification in step 3.

Step 7: Keep the EMEA informed immediately of any changes or additional information.

Annex 1

Crisis Management regarding Defects of Centrally Authorised Products

Defective Product Report

1. Origin of Report

<table>
<thead>
<tr>
<th>Information required</th>
<th>Information Obtained</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of person / organisation reporting problem.</td>
<td></td>
</tr>
<tr>
<td>Organisation</td>
<td></td>
</tr>
<tr>
<td>Address</td>
<td></td>
</tr>
<tr>
<td>Telephone number.</td>
<td></td>
</tr>
<tr>
<td>Facsimile number.</td>
<td></td>
</tr>
<tr>
<td>E-mail address.</td>
<td></td>
</tr>
</tbody>
</table>

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2 Product Details

<table>
<thead>
<tr>
<th>Information required</th>
<th>Information Obtained</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name(s) of product(s) affected by the problem.</td>
<td></td>
</tr>
<tr>
<td>Community authorisation number or other reference number.</td>
<td></td>
</tr>
<tr>
<td>Pharmaceutical form.</td>
<td></td>
</tr>
<tr>
<td>Strength.</td>
<td></td>
</tr>
<tr>
<td>Pack size and type.</td>
<td></td>
</tr>
<tr>
<td>Language on pack</td>
<td></td>
</tr>
<tr>
<td>Marketing Authorisation Holders name and address.</td>
<td></td>
</tr>
</tbody>
</table>

Nature of defect(s)

<table>
<thead>
<tr>
<th>Information required</th>
<th>Information Obtained</th>
</tr>
</thead>
<tbody>
<tr>
<td>Details of defect or problem.</td>
<td></td>
</tr>
<tr>
<td>Is the problem associated with any adverse event? (If so specify).</td>
<td></td>
</tr>
<tr>
<td>Is there any evidence or suspicion of a risk to public health (adverse effects or inefficacy)?</td>
<td></td>
</tr>
</tbody>
</table>
### Extent of the problem (e.g., how many batches how many patients).

<table>
<thead>
<tr>
<th>0. Extent of distribution of the product / batch(es).</th>
</tr>
</thead>
</table>

### Name and address of any regulatory authority notified of the problem.

<table>
<thead>
<tr>
<th>1. Name and address of any regulatory authority notified of the problem.</th>
</tr>
</thead>
</table>

### Action taken so far (if any).

<table>
<thead>
<tr>
<th>2. Action taken so far (if any).</th>
</tr>
</thead>
</table>

### Action planned or proposed.

<table>
<thead>
<tr>
<th>3. Action planned or proposed.</th>
</tr>
</thead>
</table>

### Other relevant information.

<table>
<thead>
<tr>
<th>4. Other relevant information.</th>
</tr>
</thead>
</table>

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### Action taken by EMEA

<table>
<thead>
<tr>
<th>Information required</th>
<th>Information Obtained</th>
</tr>
</thead>
<tbody>
<tr>
<td>referred to - name and position in EMEA and time</td>
<td></td>
</tr>
<tr>
<td>decision on next action (none/refer to CMT/Exec Director) and time</td>
<td></td>
</tr>
</tbody>
</table>

### 5. Record of all contacts (Names/Organisations/Dates/Times/Contact numbers)

<table>
<thead>
<tr>
<th>Date &amp; Time</th>
<th>Organisation</th>
<th>Name</th>
<th>phone &amp; fax</th>
</tr>
</thead>
</table>

---

### Annex 4

### Crisis Management regarding Defects of Centrally Authorised Products

#### Class 1: Defects, which are potentially life-threatening or could cause serious risk to health.

**Examples:**

1.1: Wrong product (label and contents are different products).
1.2: Correct product but wrong strength, with serious medical consequences.
1.3: Microbial contamination of sterile injectable or ophthalmic product.
1.4: Chemical contamination with serious medical consequences.

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1.5: Mix up of some products ("rogues") with more than one container involved.
1.6: Wrong active ingredient in a multi-component product with serious medical consequences

Class 2: Defects, which could cause illness or mistreatment but are not Class 1.

Examples:
2.1: Mislabelling: e.g. wrong or missing text or figures.
2.2: Missing or incorrect information - leaflets or inserts.
2.3: Microbial contamination of non-injectable, non-ophtalmic sterile product with medical consequences.
2.4: Chemical/physical contamination (significant impurities, cross-contamination, particulates).
2.5: Mix up of products in containers ("rogues").
2.6: Non-compliance with specification (e.g. assay, stability, fill/weight).
2.7: Insecure closure with serious medical consequences (e.g. cytotoxics, child-resistant containers, potent products).

Class 3: Defects which may not pose a significant hazard to health but where a recall has been initiated (perhaps not required by the competent authority) for other reasons, but are not Class 1 or 2.

Examples:
3.1: Faulty packaging: e.g. wrong or missing batch number or expiry date.
3.2: Faulty closure
3.3: Contamination
   - microbial spoilage
   - dirt or detritus
   - particulate matter
   (http://www.emea.europa.eu/inspections/GMPCompproc.html)

HAS ADOPTED THIS REGULATION:

CHAPTER I GENERAL PROVISIONS

Article 1

Subject-matter and scope: This Regulation lays down rules concerning the application of financial penalties to the holders of marketing authorisations, granted under Regulation (EC) No 726/2004, in respect of infringements of the following obligations, in cases where the infringement concerned may have significant public health implications in the Community, or where it has a Community dimension by taking place or having its effects in more than one Member State, or where interests of the Community are involved:

Article 2

Complementarity of procedures: For the purposes of the initiation and conduct of the infringement procedure provided for in Chapter II, the Agency and the Commission shall take into account any
infringement procedure by a Member State against the same marketing authorization holder and based on the same legal grounds and the same facts.

**Article 3**

Cooperation by the competent authorities of the Member States: 1. The competent authorities of the Member States shall cooperate with the Agency and the Commission to enable them to carry out their duties under this Regulation.

2. Information provided by the national competent authorities in response to a request from the Agency or the Commission under this Regulation shall be used by the Agency and the Commission only for the following purposes:

(a) as evidence for the purposes of applying this Regulation;

(b) for carrying out the tasks entrusted to them for the authorization and supervision of medicinal products under Regulation (EC) No 726/2004.

**Article 4**

Burden of proof: In any infringement procedure under this Regulation, the burden of proving an infringement shall rest on the Commission.

CHAPTER II INFRINGEMENT PROCEDURE

SECTION 1: Inquiry

Subsection 1: Initiation of procedure

**Article 5**

Initiation of the infringement procedure: 1. The Agency may initiate the infringement procedure on its own initiative or following a request from the Commission or a Member State. The Agency shall inform the Commission that it intends to initiate the infringement procedure.

2. The Agency shall initiate the infringement procedure only after informing the Member States.

**Article 6**

Request for information

Prior to initiating an infringement procedure, the Agency may request from the marketing authorisation holder concerned any information relating to the alleged infringement. The Agency shall state the purpose of the request and the fact that it is made under this Regulation, and indicate a time-limit for the submission of the reply by the marketing authorization holder, which shall be at least four weeks. Where the request is in response to a request from a Member State under Article 5(1), that Member State shall be informed by the Agency.

**Article 7**

Notification: The Agency shall send written notification of the initiation of an infringement procedure to the marketing authorization holder concerned, to the Member States and to the Commission. The
notification shall set out the allegations against the marketing authorisation holder, specifying the provision allegedly infringed, and the evidence on which those allegations are founded. It shall give notice to the marketing authorisation holder that fines or periodic penalty payments may be imposed.

Subsection 2 Measures of inquiry

Article 8

Requests by the Agency

1. The Agency may request the marketing authorization holder to provide written or oral explanations, or particulars or documents. Requests shall be addressed in writing to the marketing authorization holder. The Agency shall state the legal basis and the purpose of the request, fix a time-limit by which the information is to be provided, which shall be at least four weeks, and inform the marketing authorization holder of the fines provided for in Article 19(1)(a) and (b) for failing to comply with the request or for supplying incorrect or misleading information.

2. The Agency may request national competent authorities to cooperate in the investigation in the following ways:

(a) by performing any of the tasks entrusted to the supervisory authorities by Articles 19(1) and 44(1) of Regulation (EC) No 726/2004;

(b) by performing inspections or other supervisory measures in accordance with Articles 111 to 115 of Directive 2001/83/EC and Articles 80, 81 and 82 of Directive 2001/82/EC. Requests shall be addressed in writing and shall state the legal basis and the purpose of the request. The time-limit for the submission of the reply or the conduct of the measure of inquiry shall be determined by agreement between the Agency and the national competent authority to which the request is addressed, having regard to the specific circumstances of the case.

3. The Agency may ask any natural or legal persons to provide information relating to the alleged infringement. Requests shall be addressed in writing and shall state the legal basis and the purpose of the request, and shall fix a time-limit by which the information should be provided, which shall be at least four weeks.

Article 9

Right to be heard: Before adoption of the report provided for in Article 10, the Agency shall invite the marketing authorisation holder to submit written observations. It shall do so in writing, indicating a time-limit for the submission of those observations, which shall be at least four weeks.

Subsection 3 Report

Article 10

Content and time-limits: 1 The Agency shall provide the Commission, the Member States and the marketing authorisation holder with a report summarising its findings in the light of the inquiry carried out in accordance with this Section.

2. Where the Agency considers that the marketing authorization holder has committed an infringement as referred to in Article 1, the report shall also include an assessment of the circumstances of the specific
case in accordance with the criteria set out in Article 18(2) and a request to the Commission for application of financial penalties.

3. The Agency shall adopt its report no later than 18 months after notification of initiation of the procedure in accordance with Article 7 or one year after notification by the Commission of the return of the file in accordance with Article 15.

SECTION 2 Decision-making stage

Subsection 1 Procedure

Article 11

Statement of objections: 1 Where, following a request from the Agency pursuant to Article 10(2), the Commission decides to continue with the infringement procedure, it shall notify in writing to the marketing authorisation holder a statement of objections containing the following:

(a) the allegations against the marketing authorisation holder, including a precise indication of which provision has allegedly been infringed, and the evidence on which those allegations are founded;

(b) notice that fines or periodic penalty payments may be imposed.

2. Where, within 18 months of receiving the request from the Agency, the Commission has not notified a statement of objections, it shall provide the marketing authorisation holder with an explanatory statement.

Article 12

Right to reply: 1 When notifying the statement of objections, the Commission shall set a time-limit within which the marketing authorisation holder may submit to the Commission his written observations on the statement of objections. That time-limit shall be at least four weeks. The Commission shall not be obliged to take into account written observations received after the expiry of that time-limit.

2. The marketing authorisation holder may annex to his written observations, statements from other persons who may corroborate any aspect of those written observations. L 155/14 EN Official Journal of the European Union 15.6.2007

Article 13

Oral hearing: 1 Where the marketing authorisation holder so requests in his written observations, the Commission shall give him an opportunity to develop his arguments at an oral hearing. The date for the oral hearing shall be set by the Commission.

2. Where necessary, the Commission may invite the national competent authorities or any other persons to take part in the oral hearing.

3. The oral hearing shall not be public. Each person may be heard separately or in the presence of other persons invited to attend, having regard to the legitimate interest of marketing authorisation holders and other persons in the protection of their business secrets and other confidential information.

Article 14
Requests for information: 1 After receipt of a request from the Agency pursuant to Article 10(2) and before adoption of the decision referred to in Article 16, the Commission may at any time request the marketing authorisation holder to provide written or oral explanations, or particulars or documents, relating to the alleged infringement. Requests shall be addressed in writing to the marketing authorisation holder. The Commission shall state the legal basis and the purpose of the request, fix a time-limit by which the information is to be provided, which shall be at least four weeks, and inform the marketing authorisation holder of the fines provided for in Article 13(1)(c) and (d) for failing to comply with the request or supplying incorrect or misleading information.

2. The Commission may request the Agency, the national competent authorities or any other natural or legal persons to provide information relating to the alleged infringement. Requests shall be addressed in writing and shall state the legal basis and the purpose of the request. Where the request is addressed to the Agency or a national competent authority, the time-limit by which the information is to be provided shall be determined by the Commission after consultation of the Agency or the national competent authority to which the request is addressed, having regard to the specific circumstances of the case. Where the request is addressed to other natural or legal persons, it shall fix a time-limit by which the information is to be provided, which shall be at least four weeks.

Article 15

New period of inquiry: 1 Where, having regard to the report of the Agency, the observations of the marketing authorisation holder and, as the case may be, other information submitted to it, the Commission considers that additional information is needed in order to continue the procedure, it may return the case-file to the Agency for a new period of inquiry. The Commission shall clearly indicate to the Agency the points of fact which it should further examine and, if appropriate, suggest possible measures of inquiry to that effect.

2. Subsections 2 and 3 of Section 1 shall apply to the conduct of the new period of inquiry.

Subsection 2 Decision and financial penalties

Article 16

Forms of financial penalty and maximum amounts: 1 Where, following the procedure provided for in Subsection 1, the Commission finds that the marketing authorization holder has committed, intentionally or negligently, an infringement as referred to in Article 1, it may adopt a decision imposing a fine not exceeding 5 % of the holder’s Community turnover in the preceding business year.

2. Where the marketing authorisation holder has not terminated the infringement, the Commission may, in the decision referred to in paragraph 1, impose periodic penalty payments per day not exceeding 2.5 % of the holder’s average daily Community turnover in the preceding business year. Periodic penalty payments may be imposed for a period running from the date of notification of that decision until the infringement has been brought to an end.

3. For the purposes of paragraphs 1 and 2, the preceding business year refers to the business year preceding the date of the decision referred to in paragraph 1.

Article 17

Decision: 1 The decision provided for in Article 16 shall be based exclusively on grounds on which the marketing authorization holder has been able to comment. 15.6.2007 EN Official Journal of the European Union L 155/15
2. The Commission shall inform the marketing authorization holder of the judicial remedies available.

3. The Commission shall communicate the adoption of the decision to the Agency and to the Member States.

4. When publishing details of its decision in accordance with the second subparagraph of Article 84(3) of Regulation (EC) No 726/2004, the Commission shall have regard to the legitimate interest of marketing authorisation holders and other persons in the protection of their business secrets.

**Article 18**

**Principles governing the application and quantification of financial penalties:**

1. In determining whether to impose a financial penalty and in determining the appropriate financial penalty, the Commission shall be guided by the principles of effectiveness, proportionality and dissuasiveness.

2. In each case, the Commission shall take into consideration, where relevant, the following circumstances:

   (a) the seriousness and the effects of the infringement, and, in particular, the following:

      (i) the way in which the infringement adversely affects the rights, safety or well-being of patients;

      (ii) its effects on animal health and welfare and the impact on animal owners;

      (iii) whether it poses or could pose a risk to public health, animal health or the environment;

      (iv) the gravity of the infringement in relation to public health, animal health and the environment;

   (b) on the one hand, the good faith of the marketing authorization holder in the interpretation and fulfilment of the obligations connected with marketing authorizations granted in accordance with Regulation (EC) No 726/2004 or, on the other hand, any evidence of wilful deceit on the part of the marketing authorisation holder;

   (c) on the one hand, the degree of diligence and cooperation shown by the marketing authorisation holder in the detection of the infringement and the application of corrective action, or during the course of the infringement procedure or, on the other hand, any obstruction by the marketing authorisation holder of the detection of an infringement and the conduct of an infringement procedure, or any non-compliance by the marketing authorisation holder with requests made by the Agency, the Commission or a national competent authority in application of this Regulation;

   (d) the turnover of the medicinal product concerned;

   (e) the need to adopt provisional measures by the Commission or urgent action by a Member State in accordance with Articles 20 or 45 of Regulation (EC) No 726/2004 as a result of an infringement;

   (f) the repetition, frequency or duration of the infringement by that marketing authorisation holder;

   (g) prior sanctions, including penalties, imposed on the same marketing authorisation holder.
In determining the amount of the financial penalty, the Commission shall take into account any penalties already imposed on the marketing authorisation holder at national level on the basis of the same legal grounds and the same facts.

SECTION 3 Non-cooperation

Article 19

Financial penalties: 1 The Commission may by decision impose on marketing authorisation holders fines not exceeding 0.5% of their Community turnover in the preceding business year where, intentionally or negligently:

(a) they do not comply with a measure of inquiry adopted pursuant to Article 8(1);

(b) they supply incorrect or misleading information in response to a measure of inquiry adopted pursuant to Article 8(1); L 155/16 EN Official Journal of the European Union 15.6.2007

(c) they do not comply with a request for information pursuant to Article 14;

(d) they supply incorrect or misleading information in response to a request for information pursuant to Article 14.

2. Where the non-cooperation of the marketing authorisation holder continues, the Commission may, in the decision referred to in paragraph 1, impose periodic penalty payments per day not exceeding 0.5% of the holder's average daily Community turnover in the preceding business year. Periodic penalty payments may be imposed for a period running from the date of notification of that decision until the non-cooperation has ceased.

3. For the purposes of paragraphs 1 and 2, the preceding business year refers to the business year preceding the date of the decision referred to in paragraph 1.

Article 20

Procedure: When the Commission intends to adopt a decision as referred to in Article 19(1), it shall first notify in writing the marketing authorisation holder, setting a time-limit within which the marketing authorisation holder may submit to the Commission his written observations. That time-limit shall be at least four weeks. The Commission shall not be obliged to take into account written observations received after the expiry of that time-limit.

CHAPTER III: ACCESS TO THE FILE, REPRESENTATION, CONFIDENTIALITY AND TEMPORAL PROVISIONS

Article 21

Access to the file: Following notification under Article 7, the marketing authorization holder shall have the right, on request, to access the documents and other materials compiled by the Agency and the Commission which serve as evidence of an alleged infringement. Documents obtained through access to the file shall be used only for the purposes of judicial or administrative proceedings for the application of this Regulation.

Article 22
Legal representation: The marketing authorisation holder shall have the right to legal representation during the infringement procedure.

Article 23

Confidentiality and professional secrecy: Without prejudice to the exchange and the use of information foreseen in Article 3, an infringement procedure shall be carried out subject to the principles of confidentiality and professional secrecy. The Agency and the Commission, their officials, servants and other persons working under their supervision shall not disclose information acquired or exchanged by them pursuant to this Regulation and of the kind covered by the obligation of professional secrecy and confidentiality.

2. Without prejudice to the right to access the case-file, the marketing authorisation holder shall not have access to business secrets, confidential information or internal documents held by the Agency, the Commission or a Member State.

3. Any person who submits information or observations pursuant to Articles 8, 9, 12 or 14 shall clearly identify any material considered to be confidential, giving reasons, and provide a separate non-confidential version by the date set by the Agency or the Commission.

4. Without prejudice to paragraph 3, the Agency and the Commission may require persons who submit information or observations pursuant to this Regulation to identify the documents or parts of documents which they consider to contain business secrets or other confidential information belonging to them. The Agency and the Commission may also require marketing authorisation holders and other persons to identify any part of a report by the Agency, of a statement of objections or of a decision adopted by the Commission which in their view contains business secrets. The Agency and Commission may set a time-limit within which the marketing authorisation holder and other persons are to:

(a) substantiate their claim for confidentiality with regard to each individual document or part of document;

(b) provide the Commission with a non-confidential version of the documents, in which the confidential passages are deleted;

(c) provide a concise description of each piece of deleted information. The time-limit referred to in the third subparagraph shall be at least two weeks.

5. If the marketing authorisation holder or other persons fail to comply with paragraphs 3 and 4, the Commission may assume that the information or observations concerned do not contain confidential information.

Article 24

Application of time-limits: The time-limits laid down in this Regulation shall run from the day following receipt of a communication or delivery thereof by hand. In the case of a communication from the marketing authorization holder, it shall be sufficient for the purposes of the relevant time-limits for the communication to have been dispatched by registered post before the relevant time-limit has expired.

2. Where the time-limit falls to expire on a Saturday, Sunday or public holiday, it shall be extended up to the end of the following working day.
3. In setting the time-limits provided for in Articles 6, 8(1), 12(1) and 14(1), the Agency and the Commission, as the case may be, shall have regard both to the time required for preparation of the submission and to the urgency of the case.

4. Where appropriate and upon reasoned request made before the expiry of the original time-limit, time-limits may be extended.

**Article 25**

**Limitation periods for the imposition of financial penalties:**
1. The right of the Commission to adopt a decision imposing a financial penalty pursuant to Article 16 shall expire after five years. In the case of the financial penalties provided for in Article 19, the right of the Commission to adopt a decision imposing such a penalty shall expire after three years. Time shall begin to run on the day on which the infringement is committed. However, in the case of continuing or repeated infringements, time shall begin to run on the day on which the infringement ceases.

2. Any action taken by the Agency or the Commission for the purpose of the investigation or infringement procedure shall interrupt the limitation periods laid down in paragraph 1. The limitation period shall be interrupted with effect from the date on which the action is notified to the marketing authorization holder.

3. Each interruption shall start time running afresh. However, the limitation period shall expire at the latest on the day on which a period equal to twice the limitation period has elapsed without the Commission having imposed a financial penalty. The period shall be extended by the time during which limitation is suspended pursuant to paragraph 4.

4. The limitation period for the imposition of financial penalties shall be suspended for as long as the decision of the Commission is the subject of proceedings pending before the Court of Justice of the European Communities.

**Article 26**

**Limitation periods for the collection of financial penalties:**
1. The right to start a recovery procedure shall expire one year after the decision pursuant to Article 16 or Article 19 has become final.

2. The limitation period for the recovery of financial penalties shall be interrupted by any action of the Commission or of a Member State, acting at the request of the Commission, designed to enforce payment of the penalty.

3. Each interruption shall start time running afresh.

4. The limitation period for the recovery of financial penalties shall be suspended for so long as:
   
   (a) time to pay is allowed;

   (b) enforcement of payment is suspended pursuant to a decision of the Court of Justice of the European Communities.
CHAPTER IV FINAL PROVISIONS

Article 27

Transitional provision: In the case of infringements which began before its entry into force, this Regulation shall apply to the part of the infringement which takes place after that date.

Article 28

Entry into force: This Regulation shall enter into force on the 20th day following its publication in the Official Journal of the European Union. This Regulation shall be binding in its entirety and directly applicable in all Member States. (www.emea.europa.uk)

5.2.1 UNITED KINGDOM

Enforcing the law

The MHRA Enforcement & Intelligence Group (E & I) has responsibility for enforcing medicines legislation in England and does so in Scotland and Wales on behalf of the Scottish Parliament and Welsh Assembly. The E&I Group is based at the MHRA’s headquarters in London. In this section information regarding the working of the Group, its responsibilities and powers as well as details of examples of prosecutions brought by the Group are available.

What does the Group do?: Investigates cases and where appropriate, brings criminal prosecutions. Civil action is rarely used. Department of Health lawyers (as opposed to the Crown Prosecution Service) usually conduct prosecutions, instructing Counsel as necessary. Intelligence officers and analysts back up the work of the investigators by providing strategic and operational advice and information in relation to on-going investigations.

What powers does the Group have?: Officers have their own powers conferred by the Medicines Act 1968 and subordinate legislation applying the Act. These include the right to enter any premises to inspect, to take samples and to require production of any books or documents, to take copies of, or of any entry in, any such book or document for the purposes specified in sections 111 and 112 of that Act, or in subordinate legislation applying those sections. Officers are bound by the Police and Criminal Evidence Act (PACE) and PACE codes of practice. It is a criminal offence to obstruct an enforcement officer.

What sort of cases does the Group handle?: Any illegal activities involving medicines and their availability, manufacture, import, sale, supply and administration: from sale and supply of unlicensed products to manufacture and distribution of licensed products. Cases also can involve administration of medicines by doctors, dentists, other health service professionals, hospital and pharmacy services.

Prosecutions under Medicines legislation are usually tried in the Crown Court. Prosecutions are also brought under other legislation where appropriate. Details of examples of prosecutions brought by the Group are available in this section.

Who does the Group report to?: Through the Management Board of the MHRA to the Secretary of State for Health.

Who is the Group in contact with?: The Group is in close liaison with UK Police Forces, HM Revenue & Customs, Prescription Pricing Authority, Association of Port Health Officers, Trading Standards and Environmental Health Units, Royal Pharmaceutical Society of Great Britain, General Medical Council, US
Food and Drug Administration (FDA), US Drug Enforcement Agency, Police, Customs and regulatory authorities throughout Europe and elsewhere in the world.

How can I help the Enforcement & Intelligence Group?: By reporting any information you may have regarding premises with suspicious activities related to medicines, advertisements or sales of medicines.

Medicines Act 1968
1968 CHAPTER 67

Suspension, revocation and variation of licences

28 General power to suspend, revoke or vary licences: (1) Subject to the following provisions of this Part of this Act, the licensing authority may suspend a licence under this Part of this Act for such period as the authority may determine, or may revoke, or vary the provisions of, any such licence.

http://www.opsi.gov.uk/RevisedStatutes/Acts/ukpga/1968/cukpga_19680067_en_1

(2) The suspension or revocation of a licence under this section may be total or may be limited to medicinal products of one or more descriptions or to medicinal products manufactured, assembled or stored on any particular premises or in a particular part of any premises.

(3) Subject to subsection (3A) of this section, the powers conferred by this section shall not be exercisable by the licensing authority in relation to a product licence except on one or more of the following grounds, that is to say—

a) that the matters stated in the application on which the licence was granted were false or incomplete in a material particular;

b) that any of the provisions of the licence has to a material extent been contravened by the holder of the licence or by a person procured by him to manufacture or assemble medicinal products of a description to which the licence relates;

(c) that medicinal products of any such description, as sold, supplied, exported, imported, manufactured or assembled in pursuance of the licence, fail to a material extent to correspond to the characteristics by reference to which the licence was granted;

d) that the holder of the licence has without reasonable excuse failed to comply with a requirement imposed on him under section 44(2) of this Act to furnish information to the licensing authority with respect to medicinal products of any such description;

(e) that any premises on which, or in part of which, medicinal products of any such description are manufactured, assembled or stored by or on behalf of the holder of the licence are unsuitable;

(f) in the case of a licence other than a licence of right, that the holder of the licence has not, within two years after the grant of the licence, notified to the licensing authority, in relation to each description of medicinal products to which the licence relates, a date on which medicinal products of that description were effectively on the market in the United Kingdom;

g) that medicinal products of any description to which the licence relates can no longer be regarded as products which can safely be administered for the purposes indicated in the licence, or can no longer be regarded as efficacious for those purposes;

(h) that the specification and standards to which medicinal products of any such description are manufactured can no longer be regarded as satisfactory.
(3A) Where a product licence relates to a product to which the 2001 Directive applies, the power conferred by this section to suspend a licence shall be exercisable in relation to the licence on the ground that—

(a) any of the provisions contained in regulations made under section 85 (labelling and marking of containers and packages) or 86 (leaflets) of this Act, or (b) section 86(4), has to a material extent been contravened in relation to the product by the holder of the licence or by a person procured by him to manufacture or assemble the product.

(4) Subject to the following provisions of this section, the powers conferred by this section shall not be exercisable in relation to a manufacturer's licence or a wholesale dealer's licence except on one or more of the following grounds, that is to say—

(a) that the matters stated in the application on which the licence was granted were false or incomplete in a material particular;

(b) that a material change of circumstances has occurred in relation to any of those matters;

(c) that any of the provisions of the licence has to a material extent been contravened by the holder of the licence;

(d) that the holder of the licence has without reasonable excuse failed to comply with a requirement imposed on him under section 44(2) of this Act to furnish information to the licensing authority with respect to medicinal products of a description to which the licence relates.

(5) In relation to a manufacturer's licence, the powers conferred by this section shall be exercisable on either of the following grounds, in addition to those specified in subsection (4) of this section, that is to say—

(a) that the holder of the manufacturer's licence has carried out processes of manufacture or assembly to the order of another person who is the holder of a product licence, and has habitually failed to comply with the provisions of that product licence;

(b) that the holder of the manufacturer's licence does not have the requisite facilities for carrying out properly processes of manufacture or assembly authorised by the licence.

(6) In relation to a wholesale dealer's licence, the powers conferred by this section shall be exercisable on the following grounds, in addition to those specified in subsection (4) of this section, that is to say, that the equipment and facilities for storing or distributing medicinal products which are available to the holder of the licence are inadequate to maintain the quality of medicinal products of one or more descriptions to which the application for the licence related.

(7) The preceding provisions of this section shall have effect subject to the next following section.

29 Procedure where licensing authority propose to suspend, revoke or vary licence under s. 28

(1) The provisions of Schedule 2 to this Act shall have effect where the licensing authority propose to exercise any power conferred by section 28 of this Act.

(2) Without prejudice to any requirement of that Schedule as to the service of notices, where in the exercise of any such power the licensing authority suspend, revoke or vary a licence, they shall serve on
the holder of the licence a notice giving particulars of the suspension, revocation or variation and of the reasons for their decision to suspend, revoke or vary the licence

45 Offences under Part II

(1) Subject to the next following section, any person who contravenes any of the provisions of section 7, section 8, section 31, section 32, section 34 or section 40 of this Act, or who is in possession of any medicinal product or animal feeding stuff for the purpose of selling, supplying or exporting it in contravention of any of those sections, shall be guilty of an offence.

(2) Where any medicinal product or animal feeding stuff is imported in contravention of section 7, section 31, section 32 or section 40 of this Act, any person who, otherwise than for the purpose of performing or exercising a duty or power imposed or conferred by or under this Act or any other enactment, is in possession of the product or feeding stuff knowing or having reasonable cause to suspect that it was so imported shall be guilty of an offence.

(3) Any person who, being the holder of a product licence or of a clinical trial certificate or animal test certificate, procures another person to carry out a process in the manufacture or assembly of medicinal products of a description to which the licence or certificate relates, and—

(a) does not communicate to that person the provisions of the licence or certificate which are applicable to medicinal products of that description, or

(b) in a case where any of those provisions has been varied by a decision of the licensing authority, does not communicate the variation to that person within fourteen days after notice of the decision has been served on him, shall be guilty of an offence.

(4) Any person who, being the holder of a product licence or of an animal test certificate, sells or supplies a substance or article to which the licence or certificate relates to another person for the purpose of its being incorporated in any animal feeding stuff, and does not communicate to that person any provisions of the licence or certificate which relate to the incorporation of that substance or article in animal feeding stuffs, or any instructions required by the licence to be communicated by him to persons to whom the substance or article is sold or supplied for that purpose, shall be guilty of an offence.

(5) Where any such provisions of a product licence or animal test certificate as are mentioned in subsection (4) of this section are varied by the licensing authority, and on varying those provisions the licensing authority serve on the holder of the licence or certificate a notice requiring him, within such time (not being less than fourteen days from the date of service of the notice) as may be specified in the notice, to take such steps as may be so specified for making the variation known, either generally or to persons or classes of persons specified in the notice, then if the holder of the licence or certificate does not comply with the requirements of that notice he shall be guilty of an offence.

(6) Any person who, in giving any information which he is required to give under section 44 of this Act, makes a statement which he knows to be false in a material particular shall be guilty of an offence.

(7) Any person who without reasonable excuse fails to comply with a requirement imposed on him by a notice under section 44(2) of this Act shall be guilty of an offence.

(8) Any person guilty of an offence under any of subsections (1) to (6) of this section shall be liable—

(a) on summary conviction, to a fine not exceeding £400;

(b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.
(9) Any person guilty of an offence under subsection (7) of this section shall be liable on summary conviction to a fine not exceeding

62 Prohibition of sale or supply, or importation, of medicinal products of specified description, or of animal feeding stuffs incorporating such products

(1) Subject to the following provisions of this section, the appropriate Ministers, where it appears to them to be necessary to do so in the interests of safety, may by order—

(a) prohibit the sale or supply, or the importation, of medicinal products of any description, or falling within any class, specified in the order, or in such manner as may appear to them to be sufficient to identify the products in question) designate particular medicinal products and prohibit the sale or supply, or the importation, of those particular products;

(b) prohibit the sale or supply, or the importation, of animal feeding stuffs in which medicinal products of any description, or falling within any class, specified in the order have been incorporated, or in such manner as may appear to them to be sufficient to identify the feeding stuffs in question) designate particular animal feeding stuffs in which medicinal products have been incorporated and prohibit the sale or supply, or the importation, of those particular feeding stuffs.

(2) A prohibition imposed by order under this section may be a total prohibition or may be imposed subject to such exceptions as may be specified in the order.

(3) Before making an order under this section the appropriate Ministers, unless in their opinion it is essential to make the order with immediate effect to avoid serious danger to health, whether of human beings or of animals, shall consult the appropriate committee, or if for the time being there is no such committee, shall consult the Commission.

(4) Where an order is made under this section without prior consultation with the appropriate committee or the Commission in accordance with subsection (3) of this section, the prohibition imposed by the order shall not have effect after the end of such period, not exceeding three months from the date on which it comes into operation, as may be specified in the order, but without prejudice to the making of any further order in accordance with the provisions of this section (including this subsection).

(5) If any organisation consulted in pursuance of section 129(6) of this Act with respect to a proposal to make an order under this section have given notice to the appropriate Ministers of their desire to be heard under this subsection, or have made representations in writing to those Ministers with respect to that proposal, then before making the order—

(a) if the organisation have given notice of their desire to be heard, the appropriate Ministers shall arrange for them to have an opportunity of appearing before, and being heard by, the Commission, or

(b) if they have made representations in writing, the appropriate Ministers shall refer those representations to the Commission, and, where the organisation have availed themselves of the opportunity of being heard, or after considering the representations, as the case may be, the Commission shall report their findings and conclusions to the appropriate Ministers and those Ministers shall take that report into account in determining whether to make the order.

(6) Subsection (5) of this section shall not have effect where in the opinion of the appropriate Ministers it is essential to make the order with immediate effect as mentioned in subsection (3) of this section.

(7) If an order is made under this section in circumstances where either—
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(a) neither the appropriate committee (if any) nor the Commission have considered the proposal to make the order (whether on being consulted under subsection (3) of this section or, in the case of the Commission, in pursuance of subsection (5) of this section), or

(b) the order is made contrary to the advice of the Commission or, in a case where the Commission have not, but the appropriate committee have, considered the proposal to make the order, is made contrary to the advice of that committee, the order shall include a statement of the fact that it has been so made.

63 Adulteration of medicinal products

No person shall—

(a) add any substance to, or abstract any substance from, a medicinal product so as to affect injuriously the composition of the product, with intent that the product shall be sold or supplied in that state, or

(b) sell or supply, or offer or expose for sale or supply, or have in his possession for the purpose of sale or supply, any medicinal product whose composition has been injuriously affected by the addition or abstraction of any substance.

(\text{http://www.opsi.gov.uk/RevisedStatutes/Acts/ukpga/1968/cukpga_19680067_en_1})

64 Protection of purchasers of medicinal products

(1) No person shall, to the prejudice of the purchaser, sell any medicinal product which is not of the nature or quality demanded by the purchaser.

(2) For the purposes of this section the sale of a medicinal product shall not be taken to be otherwise than to the prejudice of the purchaser by reason only that the purchaser buys the product for the purpose of analysis or examination.

(3) Subsection (1) of this section shall not be taken to be contravened by reason only that a medicinal product contains some extraneous matter, if it is proved that the presence of that matter was an inevitable consequence of the process of manufacture of the product.

(4) Subsection (1) of this section shall not be taken to be contravened by reason only that a substance has been added to, or abstracted from, the medicinal product, if it is proved that—

(a) the addition or abstraction was not carried out fraudulently, and did not injuriously affect the composition of the product, and

(b) the product was sold having attached to it, or to a container or package in which it was sold, a conspicuous notice of adequate size and legibly printed, specifying the substance added or abstracted.

(5) Where a medicinal product is sold or supplied in pursuance of a prescription given by a practitioner, the preceding provisions of this section shall have effect as if—

(a) in those provisions any reference to sale included a reference to supply and (except as provided by the following paragraph) any reference to the purchaser included a reference to the person (if any) for whom the product was prescribed by the practitioner, and

(b) in subsection (1) of this section, for the words "demanded by the purchaser", there were substituted the words "specified in the prescription".

Devi Ahilya Vishwavidyalaya Indore
65 Compliance with standards specified in monographs in certain publications

(1) No person shall, in the course of a business carried on by him,—

(a) sell a medicinal product which has been demanded by the purchaser by, or by express reference to, a particular name, or

(b) sell or supply a medicinal product in pursuance of a prescription given by a practitioner in which the product required is described by, or by express reference, to a particular name, if that name is a name at the head of the relevant monograph and the product does not comply with the standard specified in that monograph.

(2) No person shall, in the course of a business carried on by him sell or supply a medicinal product which, in the course of that business, has been offered or exposed for sale and has been so offered or exposed for sale by, or by express reference to, a particular name, if that name is a name at the head of the relevant monograph and the product does not comply with the standard specified in that monograph.

(3) Where a medicinal product is sold or supplied in the circumstances specified in subsection (1) or subsection (2) of this section, and the name in question is the name, not of the product itself, but of an active ingredient of the product, then for the purposes of the subsection in question the product shall be taken not to comply with the standard specified in the relevant monograph if, in so far as it consists of that ingredient, it does not comply with the standard so specified.

(4) Subject to subsection (7) of this section, in this section “publication” means one of the following, that is to say, the British Pharmacopoeia, the British Pharmaceutical Codex, the British Veterinary Codex and any compendium published under Part VII of this Act; “the relevant monograph”, in relation to the sale or supply of a medicinal product which has been demanded, described in a prescription, or offered or exposed for sale, by or by express reference to a particular name—

(a) if, together with that name, there was specified a particular edition of a particular publication, means the monograph (if any) headed by that name in that edition of that publication, or, if there is no such monograph in that edition, means the appropriate current monograph (if any) headed by that name;

(b) if, together with that name, there was specified a particular publication, but not a particular edition of that publication, means the monograph (if any) headed by that name in the current edition of that publication, or, if there is no such monograph in that edition, means the appropriate current monograph (if any) headed by that name, or, in default of such a monograph, means the monograph headed by that name in the latest edition of the specified publication which contained a monograph so headed;

(c) if no publication was specified together with that name, means the appropriate current monograph (if any); and “current” means current at the time when the medicinal product in question is demanded, described in a prescription, or offered or exposed for sale as mentioned in subsection (1) or subsection (2) of this section.

(5) In this section “the appropriate current monograph”, in relation to a particular name, means—

(a) the monograph (if any) headed by that name in the current edition of the British Pharmacopoeia, or

(b) if there is no such monograph, then the monograph (if any) headed by that name in the current edition of a compendium published under Part VII of this Act, or
(c) if there is no such monograph, then the monograph (if any) headed by that name in the current edition of the British Pharmaceutical Codex or the British Veterinary Codex.

(6) Subject to subsection (8) of this section, for the purposes of this section an edition of a publication—

(a) if it is the current edition of that publication, shall be taken as it is for the time being in force (that is to say, together with any amendments, additions and deletions made to it up to the time referred to in subsection (4) of this section), or

(b) if it is an edition previous to the current edition of that publication, shall be taken as it was immediately before the time when it was superseded by a subsequent edition of that publication (that is to say, together with any amendments, additions and deletions made to it up to that time), and any monograph in an edition of a publication shall be construed in accordance with any general monograph or notice or any appendix, note or other explanatory material which is contained in that edition and is applicable to that monograph, and any reference in this section to compliance with the standard specified in a monograph shall be construed accordingly.

(7) In relation to any time on or after the date on which, by notice published in the Gazette by or on behalf of the Health Ministers, it is declared that the European Pharmacopoeia prepared in pursuance of the Convention in that behalf done at Strasbourg on 22nd July 1364 is to have effect for the purposes of this section, subsections (1) and (2) of this section shall have effect as if, after the words "that name is", in each place where those words occur, there were inserted the words "or is an approved synonym for", subsection (4) of this section shall have effect as if, before the words "the British Pharmacopoeia", there were inserted the words "the European Pharmacopoeia", and after the words "headed by that name", in each place where those words occur, there were inserted the words "or by a name for which it is an approved synonym", and subsection (5) of this section shall have effect as if for paragraph (a) of that subsection there were substituted the following paragraphs:

"(a) the monograph (if any) headed by that name, or by a name for which it is an approved synonym, in the current edition of the European Pharmacopoeia, or

(aa) if there is no such monograph, then the monograph (if any) headed by that name in the current edition of the British Pharmacopoeia, or".

(8) For the purposes of this section, an edition of the European Pharmacopoeia—

(a) if it is the current edition of that Pharmacopoeia at the time in question, shall be taken as it is for the time being in force in the United Kingdom (that is to say, together with any amendments, additions and deletions made to it up to the time by notice published as mentioned in subsection (7) of this section before the time referred to in subsection (4) of this section, have been declared to have effect for the purposes of this section), and

(b) if it is an edition previous to the current edition of that Pharmacopoeia, shall be taken as it was immediately before the time when it was superseded by a subsequent edition of that Pharmacopoeia in force in the United Kingdom (that is to say, together with any amendments, additions and deletions made to it which, by notice so published before that time, had been declared to have effect), and a name shall be taken to be approved synonym for a name at the head of a monograph in the European Pharmacopoeia if, by a notice so published and not withdrawn by any subsequent notice so published, it has been declared to be approved by the Medicines Commission as a synonym for that name.
66 Further powers to regulate dealings with medicinal products

(1) The appropriate Ministers may by regulations prescribe such requirements as they may consider necessary or expedient with respect to any of the following matters, that is to say:

(a) the manner in which, or persons under whose supervision, medicinal products may be prepared or may be dispensed;

(b) the amount of space to be provided in any premises for persons preparing or dispensing medicinal products, the separation of any such space from the remainder of the premises, and the facilities to be provided in any premises for such persons;

(c) the amount of space to be provided in any premises for the sale or supply of medicinal products;

(d) the accommodation (including the amount of space) to be provided in any premises for members of the public to whom medicinal products are sold or supplied or for whom medicinal products are being prepared or assembled;

(e) the amount of space to be provided in any premises for the storage of medicinal products;

(f) the safekeeping of medicinal products;

(g) the disposal of medicinal products which have become unusable or otherwise unwanted;

(h) precautions to be observed before medicinal products are sold or supplied;

(i) the keeping of records relating to the sale or supply of medicinal products;

(j) the supply of medicinal products distributed as samples;

(k) sanitation, cleanliness, temperature, humidity or other factors relating to the risks of deterioration or contamination in connection with the manufacture, storage, transportation, sale or supply of medicinal products;

(l) the construction, location and use of automatic machines for the sale of medicinal products.

(2) Without prejudice to the generality of the preceding subsection, regulations made under subsection (1) of this section may prescribe requirements in respect of—

(a) the construction, lay-out, drainage, equipment, maintenance, ventilation, lighting and water supply of premises at or from which medicinal products are manufactured, stored, transported, sold or supplied;

(b) the disposal of refuse at or from any such premises, and

(c) any apparatus, equipment, furnishings or utensils used at any such premises.

Offences, and provision for disqualification

67 Offences under Part III

(1) The following provisions of this section shall have effect subject to sections 121 and 122 of this Act.
(1A) Any person who gives a prescription or directions or administers a medicinal product in contravention of a condition imposed by an order under section 58 of this Act by virtue of subsection (4A) of that section shall be guilty of an offence.

(1B) Any person who—

(a) is an appropriate practitioner by virtue of provision made under section 58(1) of this Act; and

(b) gives a prescription or directions in respect of a medicinal product of a description or class in relation to which he is not an appropriate practitioner, shall be guilty of an offence.

(2) Any person who contravenes any of the following provisions of this Part of this Act, that is to say, sections 52, 58, 63, 64 and 65, or who contravenes any regulations made under section 60 or section 61 or any order made under section 62 of this Act, shall be guilty of an offence.

(3) Where a medicinal product is sold, supplied or imported in contravention of an order made under section 62 of this Act, any person who, otherwise than for the purpose of performing or exercising a duty or power imposed or conferred by or under this Act or any other enactment, is in possession of the medicinal product, knowing or having reasonable cause to suspect that it was sold, supplied or imported in contravention of the order, shall be guilty of an offence.

(4) Any person guilty of an offence under subsection (1A), (1B), subsection (2) or subsection (3) of this section shall be liable—

(a) on summary conviction, to a fine not exceeding £400;

(b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.

(5) Any person who contravenes section 53 or section 54(1) or an order made under section 54(2) of this Act shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 3 on the standard scale.

(6) Any regulations made under section 66 of this Act may provide that any person who contravenes the regulations shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the standard scale or such lesser sum as may be specified in the regulations.

68 Disqualification on conviction of certain offences

(1) Where in proceedings brought by an enforcement authority a person is convicted of an offence under section 67(6) of this Act in respect of any premises used for carrying on a retail pharmacy business, then on the application of that authority the court by or before which he was convicted may (subject to the following provisions of this section) make an order disqualifying him from using those premises for the purposes of such a business for such period, not exceeding two years, as may be specified in the order.

(2) The court shall not make an order under this section disqualifying a person in respect of any premises unless the court thinks it expedient to do so having regard—

(a) to the gravity of the offence of which he has been convicted as mentioned in the preceding subsection, or

(b) to the unsatisfactory nature of the premises, or
(c) to any offences under section 67(6) of this Act of which he has previously been convicted.

(3) No order under this section shall be made against a person on the application of an enforcement authority unless the authority have, not less than fourteen days before the date of the hearing, given him notice in writing of their intention to apply for such an order to be made against him.

(4) If, while an order under this section disqualifying a person in respect of any premises is in force, the premises are used for the purposes of a retail pharmacy business carried on by him, he shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the standard scale.

(5) Subject to the next following subsection, at any time after the end of the period of six months from the date on which an order under this section comes into force, the person to whom the order relates may apply to the court by which the order was made to revoke the order or to vary it by reducing the period of disqualification.

(6) On any application made under subsection (5) of this section the court may revoke or vary the order as mentioned in that subsection if it thinks it proper to do so having regard to all the circumstances of the case, including in particular the conduct of the applicant and any improvement in the state of the premises to which the order relates; but, if on any such application the court refuses to revoke or vary the order, no further application made by the applicant under that subsection shall be entertained if it is made within three months from the date of the refusal.

(7) The court to which an application under subsection (5) of this section is made shall have power to order the applicant to pay the whole or any part of the costs of the application.

(8) In the application of this section to Scotland, for references to an enforcement authority and to costs there shall be substituted respectively references to the procurator fiscal and to expenses.

91 Offences under Part V, and supplementary provisions

(1) Subject to sections 121 and 122 of this Act, any person who contravenes the provisions of section 85(5), section 86(3) or (4) or section 90(2) of this Act shall be guilty of an offence and liable—

(a) on summary conviction, to a fine not exceeding £400;

(b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.

(2) Any regulations made under this Part of this Act may provide that any person who contravenes the regulations, or who contravenes the provisions of section 85(3), section 86(2) or section 87(2) of this Act or any of those provisions as applied by section 90(1) of this Act, shall be guilty of an offence and—

(a) shall be liable on summary conviction to a fine not exceeding £400 or such lesser sum as may be specified in the regulations, and

(b) if the regulations so provide, shall be liable on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both.

(3) Without prejudice to the application of section 129(5) of this Act, any power to make regulations conferred by sections 85 to 87 of this Act may be exercised so as to impose requirements either in relation to medicinal products generally or in relation to medicinal products of a particular description, or falling within a particular class, specified in the regulations, and any power to make regulations conferred by those sections as applied by section 90(1) of this Act shall be exercisable in a corresponding way.
(4) In this Part of this Act "requirements" includes restrictions

111 Rights of entry

(1) Subject to the following provisions of this section, any person duly authorised in writing by an enforcement authority shall, on production, if required, of his credentials, have a right at any reasonable time to enter any premises—

(a) for the purpose of ascertaining whether there is or has been, on or in connection with those premises, any contravention of any provisions of this Act or of any regulations or order made under this Act which, by or under any provisions of sections 108 to 110 of this Act, that authority is required or empowered to enforce, or

(b) generally for the purposes of the performance by the authority of their functions under this Act or under any such regulations or order.

114 Supplementary provisions as to rights of entry and related rights

(1) Any person entering any property (that is to say, any premises, ship, aircraft, vehicle, stall or place) by virtue of section 111 of this Act (whether in pursuance of a warrant or not) may take with him such other persons and such equipment as may appear to him to be necessary; and on leaving any such property which he has entered in pursuance of a warrant under that section he shall, if the property is unoccupied or the occupier (or, in the case of a ship, aircraft, vehicle, stall or place, the master, commander or other person in charge of it) is temporarily absent, leave it as effectively secured against trespass as he found it.

(2) Any person who—

(a) wilfully obstructs a person acting in pursuance of this Act and duly authorised so to act by an enforcement authority, or

(b) wilfully fails to comply with any requirement properly made to him by a person so acting under section 112 of this Act, or

(c) without reasonable cause fails to give to a person so acting any other assistance or information which that person may reasonably require of him for the purpose of the performance of his functions under this Act, shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding level 3 on the standard scale.

116 Liability to forfeiture under Customs and Excise Act 1952

(1) For the purposes of section 49 of the Customs and Excise Management Act 1979 (forfeiture of goods improperly imported) any imported goods shall be deemed to be imported contrary to a restriction for the time being in force with respect to them under this Act.

118 Restrictions on disclosure of information

(1) If any person discloses to any other person—

(a) any information with respect to any manufacturing process or trade secret obtained by him in premises which he has entered by virtue of section 111 of this Act, or

(b) any information obtained by or furnished to him in pursuance of this Act,
he shall, unless the disclosure was made in the performance of his duty, be guilty of an offence.

(2) Any person guilty of an offence under this section shall be liable—

(a) on summary conviction, to a fine not exceeding £400;

(b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.

121 Contravention due to default of other person

(1) Where a contravention by any person of any provision to which this section applies constitutes an offence under this Act, and is due to an act or default of another person, then, whether proceedings are taken against the first-mentioned person or not, that other person may be charged with and convicted of that offence, and shall be liable on conviction to the same punishment as might have been imposed on the first-mentioned person if he had been convicted of the offence.

(2) Where a person who is charged with an offence under this Act in respect of a contravention of a provision to which this section applies proves to the satisfaction of the court—

(a) that he exercised all due diligence to secure that the provision in question would not be contravened, and

(b) that the contravention was due to the act or default of another person,

the first-mentioned person shall, subject to the next following subsection, be acquitted of the offence.

(3) A person shall not, without the leave of the court, be entitled to rely on the defence provided by subsection (2) of this section unless, not later than seven clear days before the date of the hearing, he has served on the prosecutor a notice in writing giving such information identifying, or assisting in the identification of, the other person in question as was then in his possession.

(4) This section applies to the following provisions, that is to say, sections 63 to 65, 85 to 90, and 93 to 96, and the provisions of any regulations made under any of those sections.

122 Warranty as defence

(1) Subject to the following provisions of this section, in any proceedings for an offence under this Act in respect of a contravention of a provision to which this section applies, it shall be a defence for the defendant to prove—

(a) that he purchased the substance or article to which the contravention relates in the United Kingdom as being a substance or article which could be lawfully sold, supplied, or offered or exposed for sale, or could be lawfully sold, supplied, or offered or exposed for sale under the name or description or for the purpose under or for which he sold, supplied or offered or exposed it for sale, and with a written warranty to that effect;

(b) that at the time of the commission of the alleged offence he had no reason to believe that it was otherwise; and

(c) that the substance or article was then in the same state as when he purchased it.

(2) This section applies to the following provisions, that is to say, section 63(b), sections 64 and 65, sections 85 to 88 and section 90 and the provisions of any regulations made under any of those sections.
(3) A warranty shall not be a defence by virtue of this section unless the defendant has, not later than three clear days before the date of the hearing, sent to the prosecutor a copy of the warranty with a notice stating that he intends to rely on it and specifying the name and address of the person from whom he received it, and has also sent a like notice to that person.

(4) Where the defendant is a servant of the person who purchased the substance or article under the warranty, he shall be entitled to rely on the provisions of this section in the same way as his employer would have been entitled to do if he had been the defendant.

(5) The person by whom the warranty is alleged to have been given shall be entitled to appear at the hearing and to give evidence, and the court may, if it thinks fit, adjourn the hearing to enable him to do so.

(6) For the purposes of this section a name or description entered in an invoice shall be deemed to be a written warranty that the article or substance to which the name or description applies can be sold, supplied, or offered or exposed for sale under that name or description by any person without contravening any provision to which this section applies.

(7) In the application of this and the next following section to Scotland, any reference to the defendant shall be construed as a reference to the accused

123 Offences in relation to warranties and certificates of analysis

(1) If a defendant in any such proceedings as are mentioned in section 122(1) of this Act wilfully applies to any substance or article—

(a) a warranty given in relation to a different substance or article, or

(b) a certificate issued under section 115 of this Act, or under paragraph 19 of Schedule 3 to this Act, which relates to a sample of a different substance or article, he shall be guilty of an offence.

(2) A person who, in respect of any substance or article sold by him in respect of which a warranty might be pleaded under section 122 of this Act, gives to the purchaser a false warranty in writing shall be guilty of an offence, unless he proves that when he gave the warranty he had reason to believe that the statement or description contained in it was accurate.

(3) Where the defendant in any such proceedings as are mentioned in section 122(1) of this Act relies successfully on a warranty given to him or to his employer, any proceedings for an offence under subsection (2) of this section in respect of the warranty may, at the option of the prosecutor, be taken either before a court having jurisdiction in the place where a sample of the substance or article to which the warranty relates was procured, or before a court having jurisdiction in the place where the warranty was given.

(4) Any person guilty of an offence under this section shall be liable—

(a) on summary conviction, to a fine not exceeding £400;

(b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.

124 Offences by bodies corporate

(1) Where an offence under this Act which is committed by a body corporate is proved to have been committed with the consent and connivance of, or to be attributable to any neglect on the part of, any director, manager, secretary or other similar officer of the body corporate, or any person who was
purporting to act in any such capacity, he as well as the body corporate shall be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

(2) In relation to a body corporate carrying on a retail pharmacy business as mentioned in subsection (1) of section 71 of this Act, the preceding subsection shall have effect in relation to a person who (not being such an officer of the body corporate as is mentioned in the preceding subsection)—

(a) is the superintendent referred to in subsection (1) of that section, or
(b) at any premises where the business is carried on, is the pharmacist referred to in subsection

(1)(a) of that section who acts under the directions of the superintendent, as if he were such an officer of the body corporate as is mentioned in the preceding subsection.

(3) In this section "director", in relation to a body corporate established by or under any enactment for the purpose of carrying on under national ownership any industry or part of an industry or undertaking, being a body corporate whose affairs are managed by its members, means a member of that body corporate.

125 Prosecutions

(1) Notwithstanding anything in section 127(1) of the Magistrates' Courts Act 1980], a magistrates' court in England or Wales may try an information for an offence under this Act if the information was laid at any time within twelve months from the commission of the offence.

(2) Notwithstanding anything in section 331 of the Criminal Procedure (Scotland) Act 1975] (limitation of time for proceedings in statutory offences) summary proceedings in Scotland for an offence under this Act may be commenced at any time within twelve months from the time when the offence was committed, and subsection 3 of the said section 331 shall apply for the purposes of this subsection as it applies for the purposes of that section.

(3) Notwithstanding anything in section 34 of the Magistrates' Courts Act (Northern Ireland) 1964] Article 19(1) of the Magistrates' Courts (Northern Ireland) Order 1981, a magistrates' court in Northern Ireland may hear and determine a complaint for an offence punishable under this Act upon summary conviction other than an offence which is also triable upon indictment if the complaint was made at any time within twelve months from the commission of the offence.

(4) Neither the Pharmaceutical Society nor any other body referred to in subsection (2) or subsection (8) of section 108 of this Act shall institute proceedings for an offence under this Act in respect of a contravention of a provision which, by virtue of either of those subsections, that Society or body have a power or duty to enforce, unless they have given to the appropriate Minister not less than twenty-eight days’ notice of their intention to institute proceedings, together with a summary of the facts upon which the charges are founded.

(5) For the purposes of subsection (4) of this section the appropriate Minister, in relation to a contravention of any provision, is the Minister who in accordance with section 108 of this Act has a concurrent duty to enforce that provision.

(6) A district council (as defined by section 110 of this Act) shall not prosecute for an offence under this Act in respect of a contravention of any provision which, by virtue of subsection (2) of that section, the authority have a power or duty to enforce, unless the authority have given to the Minister of Health and Social Services for Northern Ireland not less than twenty-eight days’ notice of their intention to begin the prosecution, together with a summary of the facts upon which the charges are founded.
(7) A certificate of the Minister who is the appropriate Minister for the purposes of subsection (4) of this section that the requirements of that subsection have been complied with in relation to any proceedings, and a certificate of the Minister of Health and Social Services for Northern Ireland that the requirements of subsection (6) of this section have been complied with in relation to any prosecution, shall be conclusive evidence that those requirements have been so complied with; and any document purporting to be such a certificate and to be signed by or on behalf of that Minister shall be presumed to be such a certificate unless the contrary is proved.

126 Presumptions

(1) For the purposes of any proceedings under this Act for an offence consisting of—

(a) offering any animal feeding stuff for sale in contravention of section [F140] of this Act, or

(b) offering a medicinal product for sale by retail in contravention of section 52 or section 53 of this Act, or

(c) offering a medicinal product for sale in contravention of section 63(b) of this Act, where it is proved that the animal feeding stuff or medicinal product in question was found on a vehicle from which animal feeding stuffs or medicinal products are sold, it shall be presumed, unless the contrary is proved, that the person in charge of the vehicle offered that animal feeding stuff or medicinal product for sale and, in a case falling within paragraph (b) of this subsection, that he offered it for sale by retail.

(2) For the purposes of any proceedings under this Act for an offence consisting of a contravention of so much of any provision to which this subsection applies as relates to a person's having any medicinal product or animal feeding stuff in his possession for the purpose of sale or supply, where it is proved that the medicinal product or animal feeding stuff in question was found on premises at which the person charged with the offence carries on a business consisting of or including the sale or supply of medicinal products or of animal feeding stuffs in which medicinal products have been incorporated, it shall be presumed, unless the contrary is proved, that he had that medicinal product or animal feeding stuff in his possession for the purpose of sale or supply.

(3) Subsection (2) of this section applies to the following provisions of this Act, that is to say, section 63(b), subsections (3) and (5) of section 85, subsection (2) of section 87 and subsection (3) of section 88, to any of those provisions as applied by subsection (1) of section 90, and to subsection (2) of section 90 except in so far as it relates to leaflets.

(4) For the purposes of any proceedings under this Act for an offence consisting of a contravention of subsection (2) or subsection (3) of section 86 of this Act, or of so much of subsection (2) of section 90 of this Act as relates to leaflets, where it is proved that the leaflet in question was found on premises at which the person charged with the offence carries on a business consisting of or including the sale or supply of medicinal products or of animal feeding stuffs in which medicinal products have been incorporated, it shall be presumed, unless the contrary is proved, that he had the leaflet in his possession—

(a) where the offence charged relates to section 86 of this Act, for the purpose of supplying it with a medicinal product, or

(b) where the offence charged relates to section 90 of this Act, for the purpose of supplying it with animal feeding stuff in which a medicinal product has been incorporated.


Medicines - Enforcement and Intelligence (E & I) Group
The Enforcement group at the MHRA comprises of an Intelligence, Investigations, Prosecutions and Support unit of 42 staff based in London, Welwyn Garden City and York.

The Group has responsibility for the investigation of breaches of the Medicines Act and associated legislation, including the MHRA response to counterfeit medicines available through the regulated and unregulated supply chain.

Enforcement group staff have statutory powers under the Medicines Act 1968 to enter business and private property in the furtherance of their duties and seize articles suspected of being concerned in breaches of the Act and associated legislation.

The Group conduct investigations in accordance with all relevant legislation and submit recommendations for prosecution to Department of Work and Pensions solicitors.

The MHRA are usually engaged in approximately 30 prosecutions at any one time for a range of offences, in addition to this the Agency provide support to the Police for any prosecutions they are conducting which also include breaches of the Medicines Act.

Prosecutions can range from cases relating to illegal advertising or sale of unlicensed products heard at Magistrates Courts, through to large Crown court trials concerning global conspiracies to supply counterfeit medicines.

Investigations concerning counterfeit medicine are usually complex, involving networks of companies and bank accounts, often overseas. The individuals concerned have a thorough knowledge of the markets and different countries supply arrangements, procedures and laws. They will often try to exploit perceived weaknesses in supply chain arrangements. The extent of this type of criminal activity is serious and these types of cases are invariably referred to DWP solicitors recommending prosecution.

The MHRA has had to adapt to this rising challenge. The Enforcement and Intelligence group now employs specialists in conducting International investigations, financial investigations, crime analysts, internet investigators, disclosure officers, test purchasers, and specialists in the use of the Regulation of Investigatory Powers Act 2000.

The Enforcement and Intelligence Group principally rely upon the offences contained within the Medicines Act 1968, these carry a maximum two year sentence and/or unlimited fine. Cases involving counterfeit medicines are also prosecuted using the Trademarks Act 1994 carrying a maximum sentence of 10 years imprisonment and the Proceeds of Crime Act 2002 with a maximum sentence of 14 years. Consideration will now be given to using the Fraud Act 2006 for these types of cases. Civil injunctions have also been relied upon where appropriate. (http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Adviceandinformationforc onsumers/Counterfeitmedicinesanddevices/index.htm)

Prosecutions under medicines legislation are usually tried in the Crown Court. Prosecutions are also brought under other legislation, where appropriate.

Lastest convictions

Kishore Jain

On 10 September 2010 Kishore Bharat Jain of 76 Roseneath Avenue, Leicester pleaded guilty to four offences relating to the sale of an unlicensed medicinal product and the sale of a Prescription only medicine not in accordance with prescription at Leicester Magistrates’ Court.
The MHRA investigation arose as a result of a 'yellow card' report by a member of the public. The member of the public who reported Mr Jain visited his business premises at Herbs and Yoga, 8 Briton Street, Leicester, LE3 0AA with a minor skin complaint. Following the visit on 30 November 2008 and after a brief consultation Jain sold the complainant two pots of cream at a cost of £331, one for day and one for night time use. After using the creams as instructed the victim started to suffer adverse reactions developing inflamed spots on their face, some leaving dark scars. Following an online consultation with Mr Jain as result of the reactions the victim bought another two treatments at a cost of £265, which had no positive impact on the worsening condition of the victim.

It was after the adverse reactions started that the victim asked Jain to confirm that the ingredients were 100% natural. Jain provided a handwritten list in Hindi of the ingredients of the creams confirming that they were made from natural ingredients. It was during this time that the victim made a complaint to their local Trading Standards office who subsequently provided details of the case to the MHRA.

Following correspondence with the MHRA the victim sent the creams that had been purchased from Mr Jain to the MHRA for analysis. These were subsequently analysed and were found to contain steroids namely Miconazole, Clobestosol and Betamethasone.

Following the execution of search warrants during December 2009 Mr Jain was contacted by an MHRA investigator to request that he attend an interview under caution. After initially agreeing to attend the interview the MHRA investigator was informed by Mr Jain's solicitors that he would be unable to attend the interview due to ill health. After failing to attend numerous interviews the matter was submitted for prosecution.

A summons was issued to Mr Jain on 23 July 2010 informing him that he had to attend court on 10 September 2010 for offences relating to the sale and supply of prescription only medicines. At the first appearance on 10 September 2010 Mr Jain pleaded guilty to four offences and was sentenced as follows:

- Fined £300 for each offence
- Pay costs of £2355 to the MHRA
- Ordered to pay £1000 to the victim
- Victim surcharge of £15
- All to be paid within 28 days

**John Henry Atkinson**

On 6 September 2010, 61-year-old, John Henry Atkinson of 24 Weymouth Drive Sutton Coldfield, B74 4LF was sentenced at Birmingham Crown Court for the sale and supply of unlicensed medicines and money laundering offences.

Following information received by the MHRA relating to the supply of erectile dysfunctional products including Kamagra, Apcalis and the prescription only medicine Viagra; an investigation was commenced into the business affairs of Libido Centre Europe, a business linked to John Henry Atkinson.

Warrants were executed on addresses in the West Midlands including 24 Weymouth Drive, Sutton Coldfield on 16 September 2009. It was during the inspection of the premises that a quantity of unlicensed medicinal products, namely Kamagra and Savitra, along with correspondence relating to Libido Centre Europe was discovered. The value of the seized medicines totalled £35,000. John Henry Atkinson was subsequently arrested and taken to Sutton Coldfield police station where he was interviewed under caution.
Following further investigation by the MHRA, John Atkinson was formally charged on 29 March 2010 with seven offences relating to the sale and supply of unlicensed medicinal products and one offence of money laundering contrary to section 329(1)(a) of the Proceeds of Crime Act 2002. At a hearing on 21 July before Birmingham Crown Court, John Henry Atkinson pleaded guilty to five of the eight offences he was charged with, four offences relating to the sale and supply of unlicensed medicines and one relating to money laundering.

Following the completion of pre-sentence reports John Henry Atkinson was sentenced, on 6 September 2010, to nine months imprisonment suspended for two years to be supervised for 12 months. The remaining charges were ordered to lie on file and the forfeited drugs were ordered to be destroyed. The case is now proceeding to confiscation.

5.3 CANADA

Suspension of Establishment Licence The Inspectorate may suspend an establishment licence under the authority provided in the Food and Drug Regulations and Medical Device Regulations where there are reasonable grounds to believe that any provisions of the Acts and Regulations have been contravened or that the licence has made a false or misleading statement in its application for an establishment licence.

Drugs All Canadian drug establishments as of January 1, 1998 must hold an establishment licence to fabricate, package, label, distribute, import, wholesale, or test a drug. This licensing requirement applies to all Canadian drug establishments except those solely dealing with natural health products, for which prescriptions are not required, and that are for human use in dosage form. These natural health products include traditional medicines (i.e. traditional herbal medicines as well as traditional medicines such as Chinese, ayurvedic (East Indian) and aboriginal (North American medicines), homeopathic preparations and vitamin and mineral supplements. The Inspectorate may amend the terms and conditions of a drug establishment licence if it is believed on reasonable grounds that it is necessary to do so to prevent injury to the health of the consumer.

Prosecutions, Injunctions, Forfeitures Prosecution and injunctions are options available to the Health Products and Food Branch Inspectorate (Inspectorate) to respond to a company's noncompliance with legislative requirements. The Inspectorate recognizes that these enforcement options may not be appropriate to address all situations of noncompliance; for example, an immediate health hazard. However, a prosecution or an injunction can be an effective component of the Inspectorate compliance and enforcement strategy. They may be used as a last resort or they may be used in conjunction with other measures, such as a seizure or recall.

Prosecution is a legal proceeding in which a court determines whether there has been a contravention of the applicable statute or regulation and if so, the appropriate penalty.

Injunction is a formal order from a court which usually requires that a company and/or an individual cease and desist a particular activity.

Forfeiture is an action taken after a conviction, which allow to seize in her majesty in right of Canada name, the object which had given rise to a violation perpetrated. Once charges have been laid and the information has been confirmed by a Justice, subject to an Order of the Court to the contrary, it is available to the public. The Inspectorate may advise other interested regulatory agencies or parties of the identity of the accused and the alleged contravention of the legislation. Inspectorate personnel should not normally provide any further information while the matter is before the court.
On obtaining a conviction, the Inspectorate may publicize the disposition of the Court, in published or electronic communications, in order to inform the public and to act as a deterrent to other companies.

It is possible to obtain information on compliance and enforcement activities in accordance with the requirements of the Access to Information and Privacy Acts.

Recalls

C.01.051. Where a manufacturer who sells a drug in dosage form or a person who imports into and sells in Canada a drug in dosage form commences a recall of the drug, the manufacturer or importer shall forthwith submit to the Director the following information:

(a) the proper name of the drug, the common name of the drug if there is no proper name, the brand name of the drug and the lot number;
(b) in the case of an imported drug, the names of the manufacturer and importer;
(c) the quantity of the drug manufactured or imported;
(d) the quantity of the drug distributed;
(e) the quantity of the drug remaining on the premises of the manufacturer or importer;
(f) the reasons for initiating the recall; and
(g) a description of any other action taken by the manufacturer or importer with respect to the recall.

Prohibition

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.

Refusal to Issue

C.01A.010. (1) The Minister may refuse to issue or amend an establishment licence in respect of any or all matters indicated in subsection C.01A.008(2) if

(a) the applicant has made a false or misleading statement in relation to the application for the licence; or
(b) the applicant has had an establishment licence suspended in respect of the matter.

(2) The Minister shall refuse to issue or amend an establishment licence in respect of any or all matters indicated in subsection C.01A.008(2) if the Minister has reasonable grounds to believe that issuing or amending an establishment licence in respect of the matter would constitute a risk to the health of the consumer.

(3) Where the Minister refuses to issue or amend an establishment licence, the Minister shall

(a) notify the applicant in writing of the reasons for the refusal; and
(b) give the applicant an opportunity to be heard.

Suspension
C.01A.016. (1) Subject to subsection (3), the Minister may suspend an establishment licence in respect of any or all matters indicated in subsection C.01A.008(2) if the Minister has reasonable grounds to believe that
(a) the licensee has contravened any provision of the Act or these Regulations; or
(b) the licensee has made a false or misleading statement in the application for the establishment licence.
(2) Before suspending an establishment licence, the Minister shall consider
(a) the licensee's history of compliance with the Act and these Regulations; and
(b) the risk that allowing the licence to continue in force would constitute a health hazard for the consumer.
(3) Subject to subsection C.01A.017(1), the Minister shall not suspend an establishment licence until
(a) an inspector has sent the licensee a written notice that states the reason for the proposed suspension, any corrective action required to be taken and the time within which it must be taken;
(b) if corrective action is required, the time set out in the notice has passed without the action having been taken; and
(c) the licensee has been given an opportunity to be heard in respect of the suspension.

INSPECTION, SEIZURE AND FORFEITURE
Inspectors
22. (1) The Minister may designate any person as an inspector for the purpose of the enforcement of this Act.

Powers of inspectors
23. (1) Subject to subsection (1.1), an inspector may at any reasonable time enter any place where the inspector believes on reasonable grounds any article to which this Act or the regulations apply is manufactured, prepared, preserved, packaged or stored, and may
(a) examine any such article and take samples thereof, and examine anything that the inspector believes on reasonable grounds is used or capable of being used for that manufacture, preparation, preservation, packaging or storing;
(a.1) enter any conveyance that the inspector believes on reasonable grounds is used to carry any article to which section 6 or 6.1 applies and examine any such article found therein and take samples thereof;
(b) open and examine any receptacle or package that the inspector believes on reasonable grounds contains any article to which this Act or the regulations apply;
(c) examine and make copies of, or extracts from, any books, documents or other records found in any place referred to in this subsection that the inspector believes on reasonable grounds contain any information relevant to the enforcement of this Act with respect to any article to which this Act or the regulations apply; and
(d) seize and detain for such time as may be necessary any article by means of or in relation to which the inspector believes on reasonable grounds any provision of this Act or the regulations has been contravened.

Warrant required to enter dwelling-house
(1.1) Where any place mentioned in subsection (1) is a dwelling-house, an inspector may not enter that dwelling-house without the consent of the occupant except under the authority of a warrant issued under subsection (1.2).

Authority to issue warrant
(1.2) Where on ex parte application a justice of the peace is satisfied by information on oath
(a) that the conditions for entry described in subsection (1) exist in relation to a dwelling-house,
(b) that entry to the dwelling-house is necessary for any purpose relating to the administration or enforcement of this Act, and
(c) that entry to the dwelling-house has been refused or that there are reasonable grounds for believing that entry thereto will be refused, the justice of the peace may issue a warrant under his hand authorizing the inspector named therein to enter that dwelling-house subject to such conditions as may be specified in the warrant.
Use of force
(1.3) In executing a warrant issued under subsection (1.2), the inspector named therein shall not use force unless the inspector is accompanied by a peace officer and the use of force has been specifically authorized in the warrant.

Definition of “article to which this Act or the regulations apply”
(2) In subsection (1), “article to which this Act or the regulations apply” includes
(a) any food, drug, cosmetic or device;
(b) anything used for the manufacture, preparation, preservation, packaging or storing thereof; and
(c) any labelling or advertising material.

26. An inspector who has seized any article under this Part shall release it when he is satisfied that all the provisions of this Act and the regulations with respect thereto have been complied with.

Destruction with consent
27. (1) Where an inspector has seized an article under this Part and its owner or the person in whose possession the article was at the time of seizure consents to its destruction, the article is thereupon forfeited to Her Majesty and may be destroyed or otherwise disposed of as the Minister or the Minister of Agriculture and Agri-Food may direct.

Forfeiture
(2) Where a person has been convicted of a contravention of this Act or the regulations, the court or judge may order that any article by means of or in relation to which the offence was committed, and any thing of a similar nature belonging to or in the possession of the person or found with the article, be forfeited. On the making of the order, the article and thing are forfeited to Her Majesty and may be disposed of as the Minister or the Minister of Agriculture and Agri-Food may direct.

Order for forfeiture on application of inspector
(3) Without prejudice to subsection (2), a judge of a superior court of the province in which any article is seized under this Part may, on the application of an inspector and on such notice to such persons as the judge directs, order that the article and any thing of a similar nature found with it be forfeited to Her Majesty, if the judge finds, after making such inquiry as the judge considers necessary, that the article is one by means of or in relation to which any of the provisions of this Act or the regulations have been contravened. On the making of the order, the article or thing may be disposed of as the Minister or the Minister of Agriculture and Agri-Food may direct.

Contravention of unpublished order
(3) No person shall be convicted of an offence consisting of a contravention of an interim order that, at the time of the alleged contravention, had not been published in the Canada Gazette unless it is proved that, at the time of the alleged contravention, the person had been notified of the interim order or reasonable steps had been taken to bring the purport of the interim order to the notice of those persons likely to be affected by it.

REGULATIONS
(1) The Governor in Council may make regulations for carrying the purposes and provisions of this Act into effect, and, in particular, but without restricting the generality of the foregoing, may make regulations...
(a) declaring that any food or drug or class of food or drugs is adulterated if any prescribed substance or class of substances is present therein or has been added thereto or extracted or omitted therefrom;

(b) respecting

(i) the labelling and packaging and the offering, exposing and advertising for sale of food, drugs, cosmetics and devices,
(ii) the size, dimensions, fill and other specifications of packages of food, drugs, cosmetics and devices,
(iii) the sale or the conditions of sale of any food, drug, cosmetic or device, and
(iv) the use of any substance as an ingredient in any food, drug, cosmetic or device, to prevent the purchaser or consumer thereof from being deceived or misled in respect of the design, construction, performance, intended use, quantity, character, value, composition, merit or safety thereof, or to prevent injury to the health of the purchaser or consumer;

(c) prescribing standards of composition, strength, potency, purity, quality or other property of any article of food, drug, cosmetic or device;

(d) respecting the importation of foods, drugs, cosmetics and devices in order to ensure compliance with this Act and the regulations;

(e) respecting the method of manufacture, preparation, preserving, packing, storing and testing of any food, drug, cosmetic or device in the interest of, or for the prevention of injury to, the health of the purchaser or consumer;

(f) requiring persons who sell food, drugs, cosmetics or devices to maintain such books and records as the Governor in Council considers necessary for the proper enforcement and administration of this Act and the regulations;

(g) respecting the form and manner of the Minister’s indication under section 12, including the fees payable therefor, and prescribing what premises or what processes or conditions of manufacture, including qualifications of technical staff, shall or shall not be deemed to be suitable for the purposes of that section;

(h) requiring manufacturers of any drugs described in Schedule E to submit test portions of any batch of those drugs and respecting the form and manner of the Minister’s indication under section 13, including the fees payable therefor;

(i) respecting the powers and duties of inspectors and analysts and the taking of samples and the seizure, detention, forfeiture and disposition of articles;

(j) exempting any food, drug, cosmetic or device from all or any of the provisions of this Act and prescribing the conditions of the exemption;

(k) prescribing forms for the purposes of this Act and the regulations;

(l) providing for the analysis of food, drugs or cosmetics other than for the purposes of this Act and prescribing a tariff of fees to be paid for that analysis;

(ll) respecting the assessment of the effect on the environment or on human life and health of the release into the environment of any food, drug, cosmetic or device, and the measures to take before importing or selling any such food, drug, cosmetic or device;

(m) adding anything to any of the schedules, in the interest of, or for the prevention of injury to, the health of the purchaser or consumer, or deleting anything therefrom;
(n) respecting the distribution or the conditions of distribution of samples of any drug;

(o) respecting

(i) the method of manufacture, preparation, preserving, packing, labelling, storing and testing of any new drug, and

(ii) the sale or the conditions of sale of any new drug, and defining for the purposes of this Act the expression “new drug”;

(p) authorizing the advertising to the general public of contraceptive devices and drugs manufactured, sold or represented for use in the prevention of conception and prescribing the circumstances and conditions under which, and the persons by whom, those devices and drugs may be so advertised;

(q) defining “agricultural chemical”, “food additive”, “mineral nutrient”, “veterinary drug” and “vitamin” for the purposes of this Act; and

(r) respecting interim marketing authorizations, including applications for authorizations.

**Regulations respecting drugs manufactured outside Canada**

(2) Without limiting or restricting the authority conferred by any other provisions of this Act or any Part thereof for carrying into effect the purposes and provisions of this Act or any Part thereof, the Governor in Council may make such regulations governing, regulating or prohibiting

(a) the importation into Canada of any drug or class of drugs manufactured outside Canada, or

(b) the distribution or sale in Canada, or the offering, exposing or having in possession for sale in Canada, of any drug or class of drugs manufactured outside Canada, as the Governor in Council deems necessary for the protection of the public in relation to the safety and quality of any such drug or class of drugs.

**Contravention of Act or regulations**

31. Subject to section 31.1, every person who contravenes any of the provisions of this Act or of the regulations made under this Part is guilty of an offence and liable –

(a) on summary conviction for a first offence to a fine not exceeding five hundred dollars or to imprisonment for a term not exceeding three months or to both and, for a subsequent offence, to a fine not exceeding one thousand dollars or to imprisonment for a term not exceeding six months or to both; and

(b) on conviction on indictment to a fine not exceeding five thousand dollars or to imprisonment for a term not exceeding three years or to both.

**Limitation period**

32. (1) A prosecution for a summary conviction offence under this Act may be instituted at any time within two years after the time the subject-matter of the prosecution becomes known to the Minister.

**Certificate of analyst**

Devi Ahilya Vishwavidyalaya Indore
35. (1) Subject to this section, in any prosecution for an offence under section 31, a certificate purporting to be signed by an analyst and stating that an article, sample or substance has been submitted to, and analysed or examined by, the analyst and stating the results of the analysis or examination is admissible in evidence and, in the absence of evidence to the contrary, is proof of the statements contained in the certificate without proof of the signature or official character of the person appearing to have signed it.

Proof as to manufacturer or packager

36. (1) In a prosecution for a contravention of this Act or of the regulations made under this Part, proof that a package containing any article to which this Act or the regulations apply bore a name or address purporting to be the name or address of the person by whom it was manufactured or packaged is, in the absence of evidence to the contrary, proof that the article was manufactured or packaged, as the case may be, by the person whose name or address appeared on the package.

Offence by employee or agent

(2) In a prosecution for a contravention described in subsection (1), it is sufficient proof of the offence to establish that it was committed by an employee or agent of the accused whether or not the employee or agent is identified or has been prosecuted for the offence.

Certified copies and extracts

(3) In a prosecution for a contravention described in subsection (1), a copy of a record or an extract therefrom certified to be a true copy by the inspector who made it pursuant to paragraph 23(1)(c) is admissible in evidence and is, in the absence of evidence to the contrary, proof of its contents.

Where accused had adulterating substances

(4) Where a person is prosecuted under this Part for having manufactured an adulterated food or drug for sale, and it is established that the person had in his possession or on his premises any substance the addition of which to that food or drug has been declared by regulation to cause the adulteration of the food or drug, the onus of proving that the food or drug was not adulterated by the addition of that substance lies on the accused (http://laws.justice.gc.ca/en/F-27/C.R.C.-c.870)

5.4 AUSTRALIA

Enforcement Guidelines
Therapeutic Goods Amendment Act (No. 1) 2006 Implementation - General Principles

2 September 2008

1. GENERAL PRINCIPLES
   Civil Proceedings versus Criminal Prosecutions

1.1 Background

The 2006 Act included provisions that inserted a number of parallel civil penalty and criminal offence provisions in relation to substantially the same conduct. The introduction of new civil penalties for dealing with breaches of existing regulatory requirements was based on a recognition that civil penalties are often more appropriate for sanctioning corporate wrongdoing. Also, where criminal culpability is
absent but serious breaches of critical regulatory requirements has occurred civil action rather than criminal prosecution may be more appropriate. Higher pecuniary penalties, which are a main feature of civil sanctions, may also be a more effective deterrent for regulating commercial activities to cancel any financial gains obtained through corporate non compliance. General guidelines are outlined below to provide guidance on how the TGA may choose to either prosecute a person for committing an offence under the Act, or take civil action by applying to the Federal Court for a civil penalty order for a breach of a civil penalty provision.

In deciding to take a matter to court, the TGA will continue its current approach in choosing court action as a last resort for securing compliance with regulatory requirements. The sanctions package introduced by the 2006 Act enables the TGA to choose to take a person who breaches a relevant provision to the Federal Court seeking a civil penalty order instead of prosecuting a person before a criminal court.

1.2 Scope

The sanctions regime introduced by the 2006 Act built on existing offences previously present in the legislation and, with the exception of two new offences, did not add any new offences or regulatory requirements that industry members must meet.

Those two new offences introduced by the 2006 Act are contained in sections 42YE (Gathering information for application for pecuniary penalty), and 54B (Application of the Act to an executive officer of a body corporate) of the Act.

Subsection 42YE(2) provides that if the Secretary, on reasonable grounds, suspects that a person other than the wrongdoer can give information relevant to an application for a civil penalty order in relation to the contravention, whether or not such an application has been made, the Secretary may, by writing given to the person, require the person to give all reasonable assistance in connection with such an application. Subsection 42YE(5) provides that if a person fails to give assistance as required under subsection 42YE(2), the person commits an offence against subsection 42YE(5), which attracts a maximum penalty of 30 penalty units.

Section 54B sets out a criminal offence and a civil penalty in relation to an executive officer of a body corporate if certain conditions are present. Those conditions are that: the body corporate commits an offence against the Act or contravenes a civil penalty provision; the officer know that the offence would be committed or the contravention would occur; that the officer was in a position to influence the conduct of the body in relation to the commission of the offence or the contravention; and the officer failed to take all reasonable steps to prevent the commission of the offence or contravention. The maximum criminal or civil penalty under section 54B is the maximum penalty that a Court could impose in respect of an individual for the offence committed.

An “executive officer” of a body corporate is defined in subsection 54B(5) of the Act as, for the purposes of section 54B, “a person, by whatever name called and whether or not a director of the body, who is concerned in, or takes part in, the management of the body”. Section 54C of the Act deals with establishing whether an executive officer took reasonable steps to prevent the commission of an offence or the contravention of a civil penalty provision for the purposes of section 54B of the Act. Subsection 54C(3) of the Act makes it clear that executive officer has the same meaning in section 54B, a definition which is broadly consistent with the definition of “officer” of a corporation in section 9 of the Corporations Act 2001.
Other than sections 42YE and 54B, no new offences or regulatory requirements have been introduced as part of the 2006 Act. It is also important to note that the enforcement provisions of the 2006 Act will have no effect on those industry members who are compliant with the Act and the Regulations or who are genuinely seeking to be compliant.

In cases where there has been a breach of the Act or the Regulations, the entity liable for sanction under the legislation will depend on who is required under the legislation to comply with a relevant requirement. Most of the requirements under the legislation attach or relate to a particular type of person. In most cases this will be the sponsor or manufacturer, however in some situations individuals or corporate entities generally may be liable if they have acted in a manner that constitutes a breach or breaches of the legislation.

For example, in the case of offences or civil breaches relating to the importation into, exportation from, or supply in, Australia, of therapeutic goods for use in humans under section 20(1) of the Act, the entity liable would be the sponsor of the therapeutic goods in question, because it is only upon sponsors that the legislation places obligations to include goods in the Register. In the case of offences or civil breaches relating to the manufacture in Australia of therapeutic goods without a licence as required under section 35 of the Act, the entity liable would be the manufacturer of the therapeutic goods in question, as the legal obligations apply to manufacturers.

To establish whether you are a sponsor, check the definition of ‘sponsor’ in the Act, which is available on the TGA website at http://www.tga.gov.au/legis/index.htm. Note that the definition of ‘sponsor’ may include persons who do not have goods included in the Australian Register of Therapeutic Goods (the Register) because, for example, they are importing or manufacturing goods illegally.

Section 42YE of the Act, introduced by the 2006 Act, however, would be an example of where an individual or a corporate entity generally rather than necessarily a sponsor or manufacturer of therapeutic goods, may be liable for a breach of the Act. Section 42YE deals with gathering of information in relation to the application of a civil penalty provision.

1.3 Criminal Prosecution

The Australian Law Reform Commission (ALRC) Report No 95 at paragraph 2.41 described criminal penalties as:

"The main criminal penalties used in Australian legislation are fines and imprisonment. Other criminal penalties include forfeiture of property; and criminal conviction may also result in ‘follow on’ penalties such as cancellation of licences. The most serious sanctions, like imprisonment, are likely to be reserved for very serious breaches of the law or may be invoked where the court or Parliament seeks to focus on the immorality of the offence".

A criminal offence conviction is considered to be the ultimate sanction for breaching the law. According to the ALRC Report No 95 at paragraph 2.9:

"The main purpose of criminal law is traditionally considered to be deterrence and punishment. Central to the concept of criminality is the notation of individual culpability and the criminal intention for one’s actions."

Where the regulated conduct involves actual harm or injury to the public, or could pose considerable harm to the public, and the requisite mental elements relating to the conduct can be established, the TGA
will generally pursue a criminal prosecution. This is particularly the case where the level of culpability of the person warrants criminal sanction.

The need to show a mental element (an intention to commit the offence) in order to successfully prosecute someone for a criminal offence against the Act will apply to all criminal offences in the Act that are not noted as being offences of strict liability. A criminal prosecution will generally be pursued where:

-- there is a significant degree of criminality or culpability on the part of the alleged offender; previous administrative sanctions or other enforcement measures have not resulted in compliance;

-- where the Australian Government or the Australian public expects that a crime will be dealt with by way of a prosecution;

-- the conduct in question will result, is very likely to result or has resulted in harm or injury to the public;

-- the alleged crime is of such a nature or magnitude that it is important to deter potential offenders and prosecution will act as a very effective deterrent.

For the purposes of establishing whether a corporation may be liable to prosecution for a breach of a regulatory requirement, section 55 of the Act deals with the matter of establishing a mental element or intention on the part of a body corporate. Section 55(1) of the Act provides that:

-- “Where, in proceedings for an offence against this Act, it is necessary to establish the state of mind of a body corporate in relation to particular conduct, it is sufficient to show:

(a) that the conduct was engaged in by a director, servant or agent of the body corporate within the scope of his or her actual or apparent authority; and

(b) that the director, servant or agent had the state of mind”

Where culpability and criminality of the conduct are not apparent but there is a need to address breaches of the Act and effectively deter future non-compliance, particularly by a body corporate, it may well be appropriate for the TGA to apply for a civil penalty order

1.4 Civil Penalties

Civil Penalties have become a recognised means of enforcement under various regulatory frameworks in Australia as well as other countries including the United States and New Zealand.

A civil penalty is a punitive sanction of a financial nature, with no aggravating element and no fault element, imposed through a civil court procedure rather than through the criminal court process. It takes the form of a monetary penalty only, and does not result in any criminal conviction.

The ALRC Report No. 95 described civil penalties as:

“A civil penalty is one imposed by courts applying civil rather than criminal court processes.

Civil penalties may be broadly defined as punitive sanctions that are imposed otherwise than through the normal criminal process. These sanctions are often financial in nature, and closely resemble fines and other punishments imposed on criminal offenders ... the process by which these penalties are imposed is decidedly non-criminal"
The focus of a civil penalty is generally the regulation of commercial activity, and is directed against corporate or white-collar wrongdoing. Civil penalties are appropriate in regulating commercial activities involving the manufacture and supply of therapeutic products, particularly where the activities are undertaken in the main by incorporated bodies, including subsidiaries of multinational companies engaged in commercial operations. The financial disincentive that a civil penalty regime provides to address and deter breaches of the Act is considered most likely to be more effective in appropriate circumstances.

To quote from paragraph 26.14 of the ALRC Report No. 95, *Principled Regulation Report – Federal Civil & Administrative Penalties in Australia*, “The emphasis in deterrence theory is both on pricing the illegal behaviour and having a penalty large enough to deter a well-resourced corporate offender”.

Civil penalties are an alternative sanction for activity or conduct that underpins requirements designed to ensure that therapeutic goods used by the community meet acceptable standards of safety, quality, and efficacy. These requirements include compliance with standards applicable to the goods themselves, and compliance with standards in relation to the way these goods are manufactured.

Civil penalty provisions also apply in relation to breaches of requirements relating to breaches of requirements relating to the inclusion of therapeutic goods in the Australian Register of Therapeutic Goods (the Register), or compliance with conditions applying to exemptions from the need to include goods in the Register.

A decision to pursue a civil action may take into account one or more of the following factors, being whether: there has been a blatant disregard for, or a significant degree of indifference to, the regulatory requirements under the Act or Regulations; the Australian Government or the community expects that the matter will be dealt with by way of a serious enforcement action; the relevant conduct is of such a nature or magnitude that it is important to deter future non-compliance by the same wrongdoer; the relevant conduct is of such a nature or magnitude that it is important to deter non-compliance by other potential wrongdoers; and/or the conduct in question was driven by anticipated commercial benefit for the person at the expense of public health and safety.

1.5 Double jeopardy

The ALRC Report No.95 notes at paragraph 11.20 that the rule against double jeopardy in criminal law prevents a person being prosecuted for an offence when that person has previously been prosecuted for ‘substantially the same’ offence.

1.6 Criteria for undertaking court action

The ALRC Report No. 95 notes at paragraph 10.12 that the factors that influence a regulator’s enforcement strategy include the nature of the contravention (whether one-off or persistent), the seriousness of the contravention, and whether the contravention was careless, negligent or deliberate.

The ALRC Report No. 95 also notes at paragraph 10.13 that prosecutions are most likely to be pursued where a contravention gives rise to an immediate risk, a direct harm has already resulted, or breaches are flagrant, repeated or extreme in their culpability. Whether a one-off contravention will be regarded as an accident or a deliberate contravention will depend on the regulator’s assessment. This assessment is in turn likely to be influenced by the regulator’s overall characterisation of the relevant conduct, and whether or not the regulated party has been a persistent offender. If the contravention is regarded as an accident, and the regulated party is not a persistent offender, it is less likely that a punitive approach will be used unless the contravention is severe in nature.
14 Compliance with standards

(1) Except with the consent in writing of the Secretary, a person must not:

(a) import therapeutic goods into Australia; or

(b) supply therapeutic goods for use in Australia; if the goods do not conform with a standard applicable to the goods.

Maximum penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(2) Paragraph (1)(a) does not apply to goods that do not conform with a standard applicable to the goods by reason only of matters relating to labelling or packaging.

(3) Except in exceptional circumstances and with the consent in writing of the Secretary, a person must not export therapeutic goods from Australia if the goods do not conform with a standard applicable to the goods (other than a standard relating to the labelling of the goods for supply in Australia).

Maximum penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(4) Where:

(a) the importation or exportation of goods is prohibited under subsection (1) or (3); and

(b) the Secretary notifies the Comptroller-General in writing that the Secretary wishes the Customs Act 1901 to apply to that importation or exportation; the Customs Act 1901 has effect as if the goods included in that importation or exportation were goods described as forfeited to the Crown under section 229 of that Act because they were:

(c) prohibited imports within the meaning of that Act; or

(d) prohibited exports within the meaning of that Act; as the case requires.

(5) The Secretary must, as soon as practicable after making a decision to give a consent under this section, cause particulars of the decision to be published in the Gazette.

(6) The Secretary must, within 28 days after making a decision to refuse to give a consent under this section, notify the applicant in writing of the decision and of the reasons for the decision.

15 Consent may be subject to conditions etc.

(1) The consent of the Secretary under section 14 may be given:

(a) unconditionally or subject to conditions; or

(b) in respect of particular goods or classes of goods.

(2) A person is guilty of an offence if:
(a) the person engages in conduct; and

(b) the conduct breaches a condition of such a consent.

Penalty: 120 penalty units.

(2A) In subsection (2):

engage in conduct means:

(a) do an act; or

(b) omit to perform an

20 Offences relating to importation, exportation, manufacture and supply of therapeutic goods

(1) A person is guilty of an offence if

(a) the person:

(i) imports into Australia therapeutic goods for use in humans; or

(ii) exports from Australia therapeutic goods for use in humans; or

(iii) manufactures in Australia therapeutic goods for use in humans; or

(iv) supplies in Australia therapeutic goods for use in humans; and

(b) none of the following subparagraphs applies in relation to the goods:

(i) the goods are registered goods or listed goods in relation to the person;

(ii) the goods are exempt goods;

(iia) the goods are exempt under section 18A;

(iii) the goods are the subject of an approval or authority under section 19;

(iv) the goods are the subject of an approval under section 19A.

Note: A person may commit an offence against subsection (2A) or (2C) by importing into Australia therapeutic goods that are exempt under section 18A.

(1AA) An offence against subsection (1) is punishable on conviction by imprisonment for 12 months or a fine not more than 1,000 penalty units, or both.

(1A) It is a defence to a prosecution under subsection (1) if the defendant proves that the defendant was not the sponsor of the goods at the time of the importation, export, manufacture or supply, as the case may be.

(1B) A person is guilty of an offence if:

(a) the person is the sponsor of therapeutic goods for use in humans; and

(b) the person:

(i) imports the goods into Australia; or

(ii) exports the goods from Australia; or

(iii) manufactures the goods in Australia; or

(iv) supplies the goods in Australia; and

(c) the person has not, at the time of the importation, export, manufacture or supply, properly notified to the Secretary either or both of the following:

(i) the manufacturer of the goods;
(ii) premises used in the manufacture of the goods. Maximum penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(1C) For the purposes of paragraph (1B)(c):

(a) a manufacturer is **properly notified** to the Secretary if:

(i) the manufacturer was nominated, as a manufacturer of the goods, in an application for the registration or listing of the goods; or
(ii) the Secretary was subsequently informed in writing that the manufacturer is a manufacturer of the goods; and

(b) premises are **properly notified** to the Secretary if:

(i) the premises were nominated, as premises used in the manufacture of the goods, in an application for the registration or listing of the goods; or
(ii) the Secretary was subsequently informed in writing that the premises are used in the manufacture of the goods.

(2) A person in relation to whom therapeutic goods are registered or listed must not import those goods into Australia, or supply those goods in Australia, unless:

(a) the registration number or listing number of the goods is set out on the label of the goods in the prescribed manner or, in the case of an importation, that number is so set out, or is to be so set out before the goods are supplied in Australia; or
(b) the goods are devices that are listed goods.

Maximum penalty: 60 penalty units.

(2A) A person commits an offence if:

(a) the person imports therapeutic goods into Australia; and
(b) the goods are exempt under section 18A; and
(c) the importation breaches a condition of the exemption

Maximum penalty: Imprisonment for 4 years or 240 penalty units, or both.

(2B) Strict liability applies to paragraph (2A)(b)

(2C) A person commits an offence if:

(a) the person imports therapeutic goods into Australia; and
(b) the goods are exempt under section 18A; and
(c) the importation breaches a condition of the exemption.

Maximum penalty: 60 penalty units.

(2D) An offence under subsection (2C) is an offence of strict liability.

(3) Where:

(a) the importation or exportation of goods is prohibited under subsection (1); and
(b) the Secretary notifies the Comptroller-General in writing that the Secretary wishes the Customs Act 1901 to apply to that importation or exportation; the Customs Act 1901 has effect as if the goods included in that importation or exportation were goods described as forfeited to the Crown under section 229 of that Act because they were:
(c) prohibited imports within the meaning of that Act; or
(d) prohibited exports within the meaning of that Act; as the case requires.

21 Offence relating to wholesale supply

A person must not supply in Australia therapeutic goods for use in humans (other than listable devices), being goods of which the person is not a sponsor, to another person who is not the ultimate consumer of the goods unless:

(a) the goods are registered goods or listed goods; or
(b) the goods are exempt goods; or
(ba) the goods are exempt under section 18A; or
(c) the goods are the subject of an approval or authority under section 19; or
(d) the goods are the subject of an approval under section 19A.

Maximum penalty: 120 penalty units.

22 General offences relating to this Part

(1) A person must not set out or cause to be set out, on a container or package that contains therapeutic goods or on a label of goods of that kind, a number that purports to be the registration number or listing number of the goods in relation to a particular person if the number is not that number.

Maximum penalty: 60 penalty units.

(2A) A person must not, in or in connection with a certification of any matter under subsection 26A(2), make a statement that is false or misleading in a material particular.

Maximum penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(3) A person is guilty of an offence if:

(a) therapeutic goods are registered or listed in relation to the person; and
(b) the person engages in conduct; and
(c) the conduct breaches a condition of the registration or listing of the goods. Penalty: 60 penalty units.

(3A) In subsection (3):

engage in conduct means:

(a) do an act; or
(b) omit to perform an act.

(4) A person must not:

(a) represent therapeutic goods that are not included in the Register as being so included; or
(b) represent therapeutic goods that are not exempt goods as being exempt goods; or

(ba) represent therapeutic goods that are not goods exempt under section 18A as being goods exempt under that section; or

(c) represent therapeutic goods that are included in one part of the Register as being included in the other part of the Register; or

(d) represent therapeutic goods that are not the subject of an approval or authority under section 19 as being the subject of such an approval or authority; or

(e) represent therapeutic goods that are not the subject of an approval under section 19A as being the subject of such an approval.

Maximum penalty: 60 penalty units.

(5) A person, being the sponsor of therapeutic goods that are included in the Register, must not, by any means, advertise the goods for an indication other than those accepted in relation to the inclusion of the goods in the Register.

Maximum penalty: 60 penalty units.

(6) A person must not make a claim, by any means, that the person or another person can arrange the supply of therapeutic goods (not being exempt goods or goods exempt under section 18A) that are not registered goods or listed goods Maximum penalty: 60 penalty units.

(7) A person is guilty of an offence if:

(a) the person does an act or omits to do an act; and
(b) the act or omission results in the breach of:

(i) a condition of an exemption applicable under regulations made for the purposes of subsection 18(1); or
(ii) a condition of an approval under section 19; or
(iii) a condition applicable under regulations made for the purposes of subsection 19(4A); or
(iv) a condition of an approval under section 19A.

(7AA) An offence against subsection (7) is punishable on conviction by a fine of not more than 60 penalty units

(7AB) A person commits an offence if:

(a) the person does an act or omits to do an act in relation to therapeutic goods; and
(b) the goods are exempt under section 18A; and
(c) the act or omission results in the breach of a condition of the exemption; and
(d) the act or omission is likely to cause a serious risk to public health.

Maximum penalty: Imprisonment for 5 years or 300 penalty units, or both.

Note 1: A person may commit an offence against subsection 20(2A) or (2C) by breaching a condition of an exemption of therapeutic goods under section 18A that relates to the importation of the goods.
Note 2: A person may commit an offence against subsection 30H(1) or (3) by breaching a condition of an exemption of therapeutic goods under section 18A that relates to records about the goods.

(7AC) Strict liability applies to paragraph (7AB)(b).

(7AD) A person commits an offence if:

(a) the person does an act or omits to do an act in relation to therapeutic goods; and
(b) the goods are exempt under section 18A; and
(c) the act or omission results in the breach of a condition of the exemption.

Maximum penalty: Imprisonment for 4 years or 240 penalty units, or both.

(7AE) Strict liability applies to paragraph (7AD)(b).

(7A) A person to whom an authority under subsection 19(5) has been granted must not supply the therapeutic goods to which the authority relates except in accordance with:

(a) the authority; and
(aa) the conditions (if any) to which the authority is subject; and
(b) any regulations made for the purpose of subsection 19(7).

Maximum penalty: 60 penalty units.

(8) A person must not use therapeutic goods, other than exempt goods, listed goods, registered goods, goods exempt under section 18A or goods that are the subject of an approval under section 19A:

(a) for use in the treatment of another person; or
(b) for use solely for experimental purposes in humans; except in accordance with an approval or authority under section 19 or a condition applicable under regulations made for the purposes of subsection 19(4A).

Maximum penalty: 60 penalty units

22A False statements in applications for registration

A person must not, in or in connection with an application for registration of therapeutic goods, make a statement that is false or misleading in a material particular.

Maximum penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

30 Cancellation of registration or listing

(1) The Secretary may, by notice in writing given to a person in relation to whom therapeutic goods are included in the Register, cancel the registration or listing of the goods if:

(a) it appears to the Secretary that failure to cancel the registration or listing would create an imminent risk of death, serious illness or serious injury; or
(b) the goods become exempt goods; or
(c) the person requests in writing the cancellation of the registration or listing; or
(d) the goods contain substances that are prohibited imports for the purposes of the *Customs Act 1901*; or

(da) the person has refused or failed to comply with the condition to which the inclusion of the goods is subject under paragraph 28(5)(d):

(i) if the person was requested under that paragraph to make the record in question available at or before a requested time—before the end of the period of 24 hours after that time; or

(ii) if the person was requested under that paragraph to make the record in question available immediately—within 24 hours after the request was made; or

(e) in the case of a medicine listed under section 26A, it appears to the Secretary that any of the certifications under paragraph 26A(2)(a), (e) or (g) are incorrect or (if applicable) the requirements under subsection 26A(3) are not fulfilled; or

(f) both of the following apply:

(i) under the regulations, an authority constituted by or under the regulations gives a direction to, or makes a requirement of, the person in relation to an advertisement of the goods to ensure that advertising complies with the Therapeutic Goods Advertising Code;

(ii) the person does not comply with the direction or requirement.

(1A) The Secretary may, by notice in writing given to a person in relation to whom a medicine is listed under section 26A, cancel the listing of the medicine if:

(a) the medicine is not eligible for listing; or

(b) the medicine is exempt; or

(c) there is a serious breach, involving the medicine, of the requirements relating to advertising applicable under Part 5-1 or under the regulations, and the Secretary is satisfied that:

(i) the breach is significant; and

(ii) as a result of the breach, the presentation of the medicine is misleading to a significant extent.

(1B) However, paragraph (1A)(c) does not apply to medicines that are manufactured in Australia for export only, or are imported into Australia for export only. Medicines

(1C) The Secretary may, by notice in writing given to a person in relation to whom a medicine is listed under section 26A, cancel the listing of the medicine if:

(a) the Secretary, under section 31, gives to the person a notice requiring the person to give to the Secretary information or documents relating to the medicine; and

(b) the notice is given for the purposes of ascertaining whether the medicine should have been listed; and

(c) the person fails to comply with the notice within 20 working days after the notice is given.

(2) Subject to subsection (3), the Secretary may, by notice in writing given to a person in relation to whom therapeutic goods are included in the Register, cancel the registration or listing of the goods if:
(a) it appears to the Secretary that the quality, safety or efficacy of the goods is unacceptable; or
(b) the goods have changed so that they have become separate and distinct from the goods as so
   included; or

(ba) in the case of a medicine listed under section 26A, it appears to the Secretary that any of the
   certifications under paragraph 26A(2)(b), (c), (d), (f), (h), (i), (j) or (k) are incorrect; or

(c) the sponsor has refused or failed to comply with a condition to which the inclusion of the goods is
   subject (other than the condition under paragraph 28(5)(d)); or

(ca) the person has contravened subsection 29A(1) in relation to the goods; or

(d) the goods become required to be included in the other part of the Register; or

(e) the goods do not conform to a standard applicable to the goods or to a requirement relating to
   advertising applicable to the goods under Part 5-1 or under the regulations; or

(f) the annual registration or listing charge is not paid within 28 days after it becomes payable.

(3) Where the Secretary proposes to cancel the registration or listing of goods in relation to a person
   under subsection (2) otherwise than as a result of a failure to pay the annual registration or listing charge,
   the Secretary must:

(a) inform the person in writing that the Secretary proposes to cancel that registration or listing and set out
   the reasons for that proposed action; and

(b) give the person a reasonable opportunity to make submissions to the Secretary in relation to the
   proposed action.

(4) Where a person makes submissions in accordance with paragraph (3)(b), the Secretary is not to make
   a decision relating to the cancellation until the Secretary has taken the submissions into account.

(4A) The Secretary must, by notice in writing given to a person in relation to whom therapeutic goods are
   included in the Register, cancel the registration of the goods if the Secretary becomes aware that
   protected information was used when evaluating the goods for registration.

(5) Where the Secretary cancels the registration or listing of goods in relation to a person, the goods
   cease to be registered or listed:

(a) if the cancellation is effected under subsection (1), (1A) or

(1C)—on the day on which the notice of cancellation is given to the person; or

(b) in any other case—on such later day as is specified in the notice.

30EC Non-compliance with requirements

A person is guilty of an offence if:

(a) the person does an act, or omits to do an act; and

(b) the act or omission constitutes a contravention of a requirement imposed on the person under section
    30EA.
Maximum penalty: 60 penalty units

31D False or misleading information

(1) A person to whom a notice is given under section 31A, 31AA or 31B is guilty of an offence if:

(a) the person gives information to the Secretary in compliance or purported compliance with subsection 31C(1); and

(b) the person does so knowing that the information:

(i) is false or misleading; or
(ii) omits any matter or thing without which the information is misleading.

Maximum penalty: Imprisonment for 12 months.

(2) Subsection (1) does not apply as a result of subparagraph (1)(b)(i) if the information is not false or misleading in a material particular.

Note: A defendant bears an evidential burden in relation to the matter in subsection (2).

(3) Subsection (1) does not apply as a result of subparagraph (1)(b)(ii) if the information did not omit any matter or thing without which the information is misleading in a material particular.

Note: A defendant bears an evidential burden in relation to the matter in subsection (3).

31E False or misleading documents

(1) A person is guilty of an offence if:

(a) the person produces a document to the Secretary; and
(b) the person does so knowing that the document is false or misleading; and
(c) the document is produced in compliance or purported compliance with subsection 31C(1).

Maximum penalty: Imprisonment for 12 months.

(2) Subsection (1) does not apply if the document is not false or misleading in a material particular.

Note: A defendant bears an evidential burden in relation to the matter in subsection (2).

(3) Subsection (1) does not apply to a person who produces a document if the document is accompanied by a written statement signed by the person or, in the case of a body corporate, by a competent officer of the body corporate:

(a) stating that the document is, to the knowledge of the first-mentioned person, false or misleading in a material particular; and
(b) setting out, or referring to, the material particular in which the document is, to the knowledge of the first-mentioned person, false or misleading.

Note: A defendant bears an evidential burden in relation to the matter in subsection (3).
35 Offences relating to manufacturing and licences

(1) A person must not, at premises in Australia, carry out a step in the manufacture of therapeutic goods (other than goods exempt under section 18A) for supply for use in humans unless:

(a) the goods are exempt goods or the person is an exempt person in relation to the manufacture of the goods; or
(b) the person is the holder of a licence that is in force that authorises the carrying out of that step in relation to the goods at those premises. Maximum penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(2) A person is guilty of an offence if:

(a) the person holds a licence; and
(b) the person engages in conduct; and
(c) the conduct breaches a condition of the licence.

Maximum penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(3) In subsection (2):

engage in conduct means:

(a) do an act; or
(b) omit to perform an act.

(4) A person commits an offence if:

(a) the person, at premises in Australia, carries out a step in the manufacture of therapeutic goods for supply for use in humans; and
(b) the goods are exempt under section 18A; and
(c) the person is not the holder of a licence that:

(i) is in force; and
(ii) authorises the carrying out of that step in relation to the goods at those premises.

Maximum penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(5) Strict liability applies to paragraph (4)(b).

Note: For strict liability, see section 6.1 of the Crim

41 Revocation and suspension of licences

(1) Subject to subsection (2), the Secretary may, by notice in writing given to the holder of a licence, revoke the licence, or suspend the licence for a period specified in the notice, if:

(a) the holder has been convicted of an offence against this Act; or
(aa) the holder controls another person (whether directly, or indirectly through one or more interposed entities) that has been convicted of an offence against this Act or a law of a State or Territory relating to therapeutic goods; or
(ab) the holder controlled another person (whether directly, or indirectly through one or more interposed entities) when the other person committed an offence against this Act or a law of a State or Territory relating to therapeutic goods, and the other person has been convicted of that offence; or

(ac) the holder is controlled by another person (whether directly, or indirectly through one or more interposed entities) and that other person has been convicted of an offence against this Act or a law of a State or Territory relating to therapeutic goods; or

(b) the holder has breached a condition of the licence; or

(c) the holder is controlled by another person (whether directly, or indirectly through one or more interposed entities) and that other person has breached a condition of a licence; or

(ca) the holder controls another person (whether directly, or indirectly through one or more interposed entities) and that other person has, while controlled by the holder, breached a condition of a licence; or

(cb) the holder is not a fit and proper person to hold a licence; or

(cc) a person who is participating in managing the holder's affairs is not a fit and proper person to participate in the management of the affairs of a holder of a licence; or

(cd) a person who has effective control over the holder is not a fit and proper person to have effective control over a holder of a licence; or

(d) the holder requests in writing that the licence be revoked or suspended, as the case may be; or

(e) the holder ceases to carry on the business of manufacturing the goods to which the licence relates; or

(f) the annual licensing charge, or any applicable prescribed inspection fees, have not been paid within 28 days after they become payable; or

(g) the goods are exempt under section 18A and the holder has breached a condition of the exemption in relation to those goods.

(1A) Without limiting the matters to which the Secretary may have regard in considering whether the holder or another person is not a fit and proper person for the purposes of paragraph (1)(cb), (cc) or (cd), the Secretary must have regard to the matters set out in paragraphs 38(1A)(a), (b) and (c).

(2) Where the Secretary proposes to revoke a licence or suspend a licence otherwise than at the request of the holder, the Secretary must, unless the Secretary considers that failure to revoke or suspend the licence immediately would create an imminent risk of death, serious illness or serious injury:

(a) by notice in writing given to the holder, inform the holder of the action that the Secretary proposes to take and of the reasons for that proposed action; and

(b) except where the proposed action is to be taken as a result of a failure to pay the annual licensing charge or an applicable prescribed inspection fee—give the holder an opportunity to make, within such reasonable time as is specified in the notice, submissions to the Secretary in relation to the proposed action.
(3) Where the holder makes submissions in accordance with paragraph (2)(b), the Secretary is not to make a decision relating to the revocation or suspension of the licence before taking into account the submissions.

(4) A licence may be revoked notwithstanding that the licence is suspended.

(5) Where a licence is suspended, the Secretary may, by notice in writing given to the holder of the licence, revoke the suspension.

(6) Where the Secretary revokes or suspends a licence, the Secretary must cause particulars of the decision to be published in the Gazette as soon as is practicable after the decision is made.

Chapter 4—Medical devices

41BK Application of the Criminal Code

Chapter 2 of the Criminal Code applies to all offences against this Chapter.

Note: Chapter 2 of the Criminal Code sets out the general principles of criminal responsibility.

Part 5-2—Counterfeit therapeutic goods

42E Offence of dealing with counterfeit therapeutic goods

(1) A person is guilty of an offence if:

(a) the person intentionally:

(i) manufactures goods in Australia; or
(ii) supplies goods in Australia; or
(iii) imports goods into Australia; or
(iv) exports goods from Australia; and

(b) the goods are therapeutic goods; and

(c) the goods are counterfeit and the person knows that fact or is reckless as to whether that fact exists.

(2) Goods are counterfeit if any of the following contain a false representation of a matter listed in subsection (3):

(a) the label or presentation of the goods;
(b) any document or record relating to the goods or their manufacture;
(c) any advertisement for the goods

(3) The matters are as follows:

(a) the identity or name of the goods;
(b) the formulation, composition or design specification of the goods or of any ingredient or component of them;
(c) the presence or absence of any ingredient or component of the goods;
(d) the strength or size of the goods (other than the size of any pack in which the goods are contained);
(e) the strength or size of any ingredient or component of the goods;
(f) the sponsor, source, manufacturer or place of manufacture of the goods.
(4) An offence against this section is punishable on conviction by imprisonment for not more than 5 years, a fine not more than 2,000 penalty units or both.

Note: Subsection 4B(3) of the Crimes Act 1914 lets a court fine a body corporate up to 5 times the maximum amount the court can fine an individual.

(5) To avoid doubt, a term that is defined in subsection 3(1) in relation to therapeutic goods and used in this section in relation to goods has in this section the meaning given by subsection 3(1).

42F Customs treatment of counterfeit therapeutic goods

Imported counterfeit therapeutic goods

(1) If the Secretary notifies the Chief Executive Officer of Customs in writing that the Secretary wishes the Customs Act 1901 to apply to an import of counterfeit therapeutic goods, that Act has effect as if the goods included in the import were goods described as forfeited to the Crown under section 229 of that Act because they were prohibited imports within the meaning of that Act.

Exported counterfeit therapeutic goods

(2) If the Secretary notifies the Chief Executive Officer of Customs in writing that the Secretary wishes the Customs Act 1901 to apply to an export of counterfeit therapeutic goods, that Act has effect as if the goods included in the export were goods described as forfeited to the Crown under section 229 of that Act because they were prohibited exports within the meaning of that Act.

Part 5-3—Product tampering

42T Notifying of actual or potential tampering

(1) A person is guilty of an offence if:

(a) the person supplies, manufactures or is a sponsor of, or proposes to supply, manufacture or become a sponsor of, therapeutic goods; and
(b) either:

(i) the person knows that some or all of those therapeutic goods, or any other therapeutic goods, are or have been subject to actual or potential tampering; or
(ii) some or all of those therapeutic goods, or any other therapeutic goods, are or have been subject to actual or potential tampering, and the person is reckless as to that fact; and

(c) the person fails, within 24 hours after becoming aware of, or becoming aware of a substantial risk of, the actual or potential tampering, to notify the Secretary or the National Manager of the Therapeutic Goods Administration.

Maximum penalty: 400 penalty units.

(2) A person is guilty of an offence if:

(a) the person supplies, manufactures or is a sponsor of, or proposes to supply, manufacture or become a sponsor of, therapeutic goods; and
(b) the person receives information or a demand; and
(c) either:
(i) the person knows that the information or demand relates (either expressly or by implication) to actual or potential tampering with some or all of those therapeutic goods, or any other therapeutic goods; or

(ii) the information or demand relates (either expressly or by implication) to actual or potential tampering with some or all of those therapeutic goods, or any other therapeutic goods, and the person is negligent as to that fact; and

(d) the person fails to notify the Secretary or the National Manager of the Therapeutic Goods Administration of the information or demand within 24 hours after receiving it.

Maximum penalty: 240 penalty units.

(3) For the purposes of subparagraph (2)(c)(ii), the person is only taken to be negligent as to the fact that the information or demand is of the kind referred to in that subparagraph if:

(a) the person's acts or omissions involve such a great falling short of the standard of care that a reasonable person would exercise in the circumstances; and

(b) there is such a high risk that the information or demand is of that kind; that the acts or omissions merit criminal punishment.

(4) For the purposes of this section, it does not matter whether, at the time of receipt of the information or demand:

(a) the person has possession or control of the therapeutic goods to which the information or demand relates; or

(b) the therapeutic goods are in existence.

42U Meaning of actual or potential tampering etc.

**Actual or potential tampering**, in relation to therapeutic goods, means:

(a) tampering with the therapeutic goods; or

(b) causing the therapeutic goods to be tampered with; or

(c) proposing to tamper with the therapeutic goods; or

(d) proposing to cause the therapeutic goods to be tampered with.

42V Recovery of therapeutic goods because of actual or potential Tampering

(1) The Secretary may, in writing, impose requirements under this section on a person if:

(a) the person supplies or has supplied therapeutic goods of a particular kind, or a particular batch of therapeutic goods of that kind; and

(b) the Secretary is satisfied that therapeutic goods of that kind, or included in that batch, are, have been or could possibly be, subject to actual or potential tampering.

(2) The requirements may be one or more of the following:

(a) to take specified steps, in the specified manner and within such reasonable period as is specified, to recover therapeutic goods of that kind, or included in that batch, that the person has supplied;
(b) to inform the public or a specified class of persons, in the specified manner and within such reasonable period as is specified, that therapeutic goods of that kind, or included in that batch, are, or have been, subject to actual or potential tampering;

(c) to inform the public or a specified class of persons, in the specified manner and within such reasonable period as is specified, that therapeutic goods of that kind, or included in that batch, could possibly be subject to actual or potential tampering.

(3) Requirements referred to in paragraph (2)(a) do not apply to therapeutic goods that cannot be recovered because they have been administered to, or applied in the treatment of, a person or animal.

(4) The Secretary must cause to be published in the Gazette, as soon as practicable after imposing such requirements, a notice setting out particulars of the requirements.

(5) The Secretary may impose requirements under this section whether or not the Secretary has been notified under section 42T.

(6) A person who intentionally refuses or fails to comply with a requirement under subsection (1) is guilty of an offence. Maximum penalty: 240 penalty units.

(7) This section does not prevent the Secretary from taking action under section 30 or Division 1 or 2 of Part 4-6.

42W Supply etc. of therapeutic goods that are subject to recovery Requirements

(1) A person is guilty of an offence if:

(a) the person supplies therapeutic goods in Australia; and

(b) either:

(i) the person knows that the therapeutic goods are of a kind, or are included in a batch, in respect of which requirements have been imposed under section 42V, on that person or another person, to recover therapeutic goods; or

(ii) the therapeutic goods are of such a kind, or are included in such a batch, and the person is reckless as to that fact; and

(c) the Secretary has not consented in writing to the supply.

Maximum penalty: 240 penalty units.

(2) A person is guilty of an offence if:

(a) the person exports therapeutic goods from Australia; and

(b) either:

(i) the person knows that the therapeutic goods are of a kind, or are included in a batch, in respect of which requirements have been imposed under section 42V, on that person or another person, to recover therapeutic goods; or
(ii) the therapeutic goods are of such a kind, or are included in such a batch, and the person is reckless as to that fact; and

(c) the Secretary has not consented in writing to the exportation.

Maximum penalty: 240 penalty units.

(3) The Secretary must not give consent relating to an exportation unless satisfied that there are exceptional circumstances that justify giving the consent.

42X Saving of other laws

This Part is not intended to exclude or limit the operation of any other law of the Commonwealth or any law of a State or Territory

54 Indictable offences and forfeiture

(1) An offence against section 22A, 29A, 29B, 41FE, 41MP or 41MQ is an indictable offence.

(3) Where a court convicts a person of an offence against this Act in relation to any therapeutic goods, the court may order that the goods be forfeited to the Commonwealth and, where such an order is made, the goods become the property of the Commonwealth.

(4) Where goods are so forfeited, the Secretary may cause notice of the forfeiture to be published in the Gazette.

(5) Goods forfeited under an order referred to in subsection (3) are to be disposed of in such manner as the Secretary directs.

54AA Offences for contravening conditions or requirements imposed under the regulations

(1) If:

(a) a person holds a licence or a permission to import or export therapeutic goods; and

(b) the person engages in conduct; and

(c) the conduct breaches a condition or a requirement to which the licence or permission is subject under the regulations; the person is guilty of an offence punishable on conviction by a fine of no more than the number of penalty units specified in whichever of n or (3) applies whichever of subsection (2) or (3) applies.

(1A) In subsection

(1) engage in conduct means:

(a) do an act; or

(b) omit to perform an act.

(2) If:
(a) the condition or requirement relates to the possession, custody, transport, use or disposal of the goods; or

(b) the regulation providing for the condition or requirement states that the purpose of the condition or requirement is to protect the safety of the public; the number of penalty units for the contravention is 240 penalty units.

(3) If subsection (2) does not apply, the number of penalty units for the contravention is 50 penalty units.

54AB Damage etc. to documents

(1) A person is guilty of an offence if:

(a) the person damages, destroys, alters, conceals or falsifies a document; and

(b) the document is created, retained or issued for the purposes of this Act, or for purposes that include the purposes of this Act. Maximum penalty: Imprisonment for 5 years or 2,000 penalty units, or both.

(2) Strict liability applies to paragraph (1)(b). Note: For strict liability, see section 6.1 of the Criminal Code

54A Time for bringing prosecutions

A prosecution for an offence against this Act may be commenced at any time within 3 years after the commission of the offence.

55 Conduct by directors, servants and agents

(1) Where, in proceedings for an offence against this Act, it is necessary to establish the state of mind of a body corporate in relation to particular conduct, it is sufficient to show:

(a) that the conduct was engaged in by a director, servant or agent of the body corporate within the scope of his or her actual or apparent authority; and

(b) that the director, servant or agent had the state of mind.

(2) Any conduct engaged in on behalf of a body corporate by a director, servant or agent of the body corporate within the scope of his or her actual or apparent authority is to be taken, for the purposes of a prosecution for an offence against this Act, to have been engaged in also by the body corporate unless the body corporate establishes that the body corporate took reasonable precautions and exercised due diligence to avoid the conduct.

(3) Where, in proceedings for an offence against this Act, it is necessary to establish the state of mind of a person other than a body corporate in relation to particular conduct, it is sufficient to show that:

(a) the conduct was engaged in by a servant or agent of the person within the scope of his or her actual or apparent authority; and

(b) the servant or agent had the state of mind.

(4) Any conduct engaged in on behalf of a person other than a body corporate (in this subsection called the employer) by a servant or agent of the employer within the scope of his or her actual or apparent authority is to be taken, for the purposes of a prosecution for an offence against this Act, to have been
engaged in also by the employer unless the employer establishes that he or she took reasonable precautions and exercised due diligence to avoid the conduct.

(5) Where:

(a) a person other than a body corporate is convicted of an offence; and
(b) the person would not have been convicted of the offence if subsections (3) and (4) had not been enacted; the person is not liable to be punished by imprisonment for that offence.

(6) A reference in subsection (1) or (3) to the state of mind of a person includes a reference to:

(a) the knowledge, intention, opinion, belief or purpose of the person; and
(b) the person's reasons for the intention, opinion, belief or purpose.

(7) A reference in this section to a director of a body corporate includes a reference to a constituent member of a body corporate incorporated for a public purpose by a law of the Commonwealth, of a State or of a Territory.

(8) A reference in this section to engaging in conduct includes a reference to failing or refusing to engage in conduct.

56 Judicial notice

All courts (except in proceedings under Chapter 4) are to take judicial notice of the British Pharmacopoeia and of the British Pharmacopoeia (Veterinary).


Commonwealth Government settlement with Pan Pharmaceuticals and its former Chief Executive

14 August 2008
The Commonwealth Government today agreed to settle a civil claim which had been lodged in the Federal Court in Sydney by Pan Pharmaceuticals and its former Chief Executive.

The claim which was part heard in the Federal Court during the past month, related to the Therapeutic Goods Administration's decision in 2003 to suspend Pan's manufacturing licence and recall the medicines it manufactured.

The agreed settlement amount of $50 million plus legal costs is considerably less than the $234 million claimed. The settlement involves a judgement for the claimant, but does not involve the Commonwealth conceding any of the specific allegations in the proceedings.

Background

The TGA took regulatory action against Pan in 2003 after investigating a series of adverse drug reaction reports related to the Pan manufactured "Travacalm" medicine. Deficiencies in Pan's manufacturing of Travacalm were associated with 19 people being hospitalised for serious side effects and more than 100 reports of additional adverse reactions.

Devi Ahilya Vishwavidyalaya Indore
Pan Pharmaceuticals subsequently pleaded guilty to a number of criminal charges including inflicting grievous bodily harm and manufacturing counterfeit medicines, and was fined $3 million.

5.5 INDIA

CHAPTER III

IMPORT OF DRUGS AND COSMETICS

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 or cosmetic which is not of standard quality;
(b) any misbranded drug or misbranded or spurious cosmetic;
(bb) any adulterated or spurious drug;
(c) any drug or cosmetic for the import of which a licence is prescribed, 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) any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended;
(f) any drug 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.

13. Offences.—(f) 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.

14. Confiscation.—Where any offence punishable under section 13 has been committed, the consignment of the drugs or cosmetics 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] shall try an offence punishable under section 13.

CHAPTER IV

MANUFACTURE, SALE AND DISTRIBUTION OF DRUGS AND COSMETICS

16. 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 7[the Second Schedule], and

(b) in relation to a cosmetic, that the cosmetic complies with such standard as may be prescribed.]

(2) The Central Government, after consultation with the Board and after giving by notification in the Official Gazette not less than three months’ notice of its intention so to do, may by a like notification add to or otherwise amend the Second Schedule for the purposes of this Chapter, and thereupon the Second Schedule shall be deemed to be amended accordingly.

17. 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 betaputic value than it really is; or

(b) if it is not labelled in the prescribed manner; or

(c) if its label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular.

17A. 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 the 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.

17B. Spurious drugs.—For the purposes of this Chapter, a drug shall be deemed to be spurious,—

(a) if it is manufactured 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 not truly a product.

17C. Misbranded cosmetics.—For the purposes of this Chapter, a cosmetic shall be deemed to be misbranded,—

(a) if it contains a colour which is not prescribed; or

(b) if it is not labelled in the prescribed manner; or

(c) if the label or container or anything accompanying the cosmetic bears any statement which is false or misleading in any particular.

17D. Spurious cosmetics.—For the purposes of this Chapter, a cosmetic shall be deemed to be spurious,—

(a) if it is manufactured under a name which belongs to another cosmetic; or

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

(c) if the label or container bears the name of an individual or a company purporting to be the manufacturer of the cosmetic which individual or company is fictitious or does not exist; or

(d) if it purports to be the product of a manufacturer of whom it is not truly a product.

18. Prohibition of manufacture and sale of certain drugs and cosmetics.—From such date as may be fixed by the State Government by notification in the Official Gazette in this behalf, no person shall himself or by any other person on his behalf—

(a) manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale or distribute—

(i) any drug which is not of a standard quality, or is misbranded, adulterated or spurious

(ii) any cosmetic which is not of a standard quality or is misbranded or spurious;
(iii) 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;

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

(v) any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended;

(vi) any drug or cosmetic in contravention of any of the provisions of this Chapter or any rule made thereunder;

(b) sell, or stock or exhibit or offer for sale, or distribute any drug or cosmetic which has been imported or manufactured in contravention of any of the provisions of this Act or any rule made thereunder;

(c) manufacture or distribute, or sell, or stock or exhibit or offer for sale, or distribute any drug or cosmetic except under, and in accordance with the conditions of, a licence issued for such purpose under this Chapter

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

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 [manufacture for sale, or for distribution, sale, stocking or exhibiting or offering for sale] or distribution of any drug or class of drugs not being of standard quality.

18A. Disclosure of the name of the manufacturer, etc.—Every person, not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof, shall, if so required, disclose to the Inspector the name, address and other particulars of the person from whom he acquired the drug or cosmetic.

18B. Maintenance of records and furnishing of information.—Every person holding a licence under clause (c) of section 18 shall keep and maintain such records, registers and other documents as may be prescribed and shall furnish to any officer or authority exercising any power or discharging any function under this Act such information as is required by such officer or authority for carrying out the purposes of this Act.

19. Pleas.—(1) Save as hereinafter provided in this section, it shall be no defence in a prosecution under this Chapter to prove merely that the accused was ignorant of the nature, substance or quality of the drug or cosmetic or of the circumstances of its manufacture or import, or that a purchaser, having bought only for the purpose of test or analysis, has not been prejudiced by the sale.

(2) For the purposes of section 18 a drug shall not be deemed to be misbranded or adulterated or spurious or to be below standard quality nor shall a cosmetic be deemed to be misbranded or to be below standard quality only by reason of the fact that—

(a) there has been added thereto some innocuous substance or ingredient because the same is required for manufacture or preparation of the drug or cosmetic as an article of commerce in a state fit for carriage
or consumption, and not to increase the bulk, weight or measure of the drug [or cosmetic] or to conceal its inferior quality or other defects; or

(b) in the process of manufacture, preparation or conveyance some extraneous substance has unavoidably become intermixed with it: Provided that this clause shall not apply in relation to any sale or distribution of the drug or cosmetic occurring after the vendor or distributor became aware of such intermixture.

(3) A person, not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof, shall not be liable for a contravention of section 18 if he proves—

(a) that he acquired the drug or cosmetic from a duly licensed manufacturer, distributor or dealer thereof;

(b) that he did not know and could not, with reasonable diligence, have ascertained that the drug or cosmetic in any way contravened the provisions of that section; and

(c) that the drug or cosmetic, while in his possession, was properly stored and remained in the same state as when he acquired it.

23. Procedure of Inspectors.—(1) Where an Inspector takes any sample of a drug or cosmetic under this Chapter, he shall tender the fair price thereof and may require a written acknowledgment therefor.

(2) Where the price tendered under sub-section (1) is refused, or where the Inspector seizes the stock of any drug [or cosmetic] under clause (c) of section 22, he shall tender a receipt therefor in the prescribed form.

(3) Where an Inspector takes a sample of a drug [or cosmetic] for the purpose of test or analysis, he shall intimate such purpose in writing in the prescribed form to the person from whom he takes it and, in the presence of such person unless he wilfully absents himself, shall divide the sample into four portions and effectively seal and suitably mark the same and permit such person to add his own seal and mark to all or any of the portions so sealed and marked:

Provided that where the sample is taken from premises whereon the drug or cosmetic is being manufactured, it shall be necessary to divide the sample into three portions only:

Provided further that where the drug [or cosmetic] is made up in containers of small volume, instead of dividing a sample as aforesaid, the Inspector may, and if the drug [or cosmetic] be such that it is likely to deteriorate or be otherwise damaged by exposure shall, take three or four, as the case may be, of the said containers after suitably marking the same and, where necessary, sealing them.

(4) The Inspector shall restore one portion of a sample so divided or one container, as the case may be, to the person from whom he takes it, and shall retain the remainder and dispose of the same as follows:—

(i) one portion or container he shall forthwith send to the Government Analyst for test or analysis;

(ii) the second he shall produce to the Court before which proceedings, if any, are instituted in respect of the drug [or cosmetic]:

(iii) the third, where taken, he shall send to the person, if any, whose name, address and other particulars have been disclosed under section 18A.
(5) Where an Inspector takes any action under clause (c) of section 22,—

(a) he shall use all despatch in ascertaining whether or not the drug or cosmetic contravenes any of the provisions of the section 18 and, if it is ascertained that the drug [or cosmetic] does not so contravene, forthwith revoke the order passed under the said clause or, as the case may be, take such action as may be necessary for the return of the stock seized;

(b) if he seizes the stock of the drug or cosmetic, he shall as soon as may be inform a Judicial Magistrate and take his orders as to the custody thereof;

(c) without prejudice to the institution of any prosecution, if the alleged contravention be such that the defect may be remedied by the possessor of the drug [or cosmetic], he shall, on being satisfied that the defect has been so remedied, forthwith revoke his order under the said clause.

(6) Where an Inspector seizes any record, register, document or any other material object under clause (cc) of sub-section (1) of section 22, he shall, as soon as may be, inform [a Judicial Magistrate] and take his orders as to the custody thereof.

24. Persons bound to disclose place where drugs or cosmetics are manufactured or kept. — Every person for the time being in charge of any premises whereon any drug [or cosmetic] is being manufactured or is kept for sale or distribution shall, on being required by an Inspector so to do, be legally bound to disclose to the Inspector the place where the drug [or cosmetic] is being manufactured or is kept, as the case may be.

26. Purchaser of drug or cosmetic enabled to obtain test or analysis.—Any person [or any recognised consumer association, whether such person is a member of that association or not,] shall, on application in the prescribed manner and on payment of the prescribed fee, be entitled to submit for test or analysis to a Government Analyst any drug [or cosmetic] [purchased by him or it] and to receive a report of such test or analysis signed by the Government Analyst.

Explanation.—For the purposes of this section and section 32, “recognised consumer association” means a voluntary consumer association registered under the Companies Act, 1956 (1 of 1956) or any other law for the time being in force.

27. Penalty for manufacture, sale, etc., of drugs in contravention of this Chapter.—Whoever, himself or by any other person on his behalf, manufactures for sale or for distribution, or sells, or stocks or exhibits or offers for sale or distributes, —

(a) any drug deemed to be adulterated under section 17A or spurious under section 17B and which when used by any person for or in the diagnosis, treatment, mitigation, or prevention of any disease or disorder is likely to cause his death or is likely to cause such harm on his body as would amount to grievous hurt within the meaning of section 320 of the Indian Penal Code (45 of 1860), solely on account of such drug being adulterated or spurious or not of standard quality, as the case may be, shall be punishable with imprisonment for a term which shall not be less than ten years but which may extend to imprisonment for life and shall also be liable to fine which shall not be less than ten lakhs rupees or three times value of the drugs confiscated, whichever is more;

Provided that the fine imposed on and released from, the person convicted under this clause shall be paid, by way of compensation, to the person who had used the adulterated or spurious drugs referred to in this clause;
Provided further that where the use of the adulterated or spurious drugs referred to in this clause has caused the death of a person who used such drugs, the fine imposed on and realized from, the person convicted under this clause, shall be paid to the relative of the person who had died due to the use of the adulterated or spurious drugs referred to in this clause. (The term 'relative' has been defined in the explanation)

(b) any drug—

(i) deemed to be adulterated under section 17A, but not being a drug referred to in clause (a), or

(ii) without a valid licence as required under clause (c) of section 18,

shall be punishable with imprisonment for a term which shall not be less than three years but which may extend to five years and with fine which shall not be less than one lakh rupees or three times the value of the drugs confiscated, whichever is more:

Provided that the Court may, for any adequate and special reasons to be recorded in the judgment, impose a sentence of imprisonment for a term of less than three years and of fine of less than one lakh rupees;

(c) any drug deemed to be spurious under section 17B, but not being a drug referred to in clause (a) shall be punishable with imprisonment for a term which shall not be less than seven years but which may extend to imprisonment for life and with fine which shall not be less than three lakh rupees or three times the value of the drugs confiscated, whichever is more:

Provided that the Court may, for any adequate and special reasons, to be recorded in the judgment, impose a sentence of imprisonment for a term of less than seven years but not less than three years and of fine of not less than one lakh rupees;

(d) any drug, other than a drug referred to in clause (a) or clause (b) or clause (c), in contravention of any other provision of this Chapter or any rule made thereunder, shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to two years and with fine which shall not be less than twenty thousand rupees:

Provided that the Court may, for any adequate and special reasons, to be recorded in the judgment impose a sentence of imprisonment for a term of less than one year.

State Amendments
Uttar Pradesh
Section 27 of the Act

In its application to the State of Uttar Pradesh, for Section 27, substitute as under:

Section 27. Penalty for manufacture, sale, etc., of drugs in contravention of this Chapter. —
Whoever himself or by any other person on his behalf manufactures for sale, sells, stocks or exhibits for sale, or distributes,—

(a) any drug —

(i) deemed to be misbranded under Clause (a), Clause (b), Clause (c), Clause (d), Clause (f) or Clause (g) of Section 17 or adulterated under Section 17-b, or...
(ii) without a valid licence as required under Clause (c) of Section 18, or
(b) any drug other than drug referred to in Clause (a) in contravention of the provisions of this Chapter or
any rule made thereunder, shall be punished with imprisonment for life:

Provided that the Court may, for any special reasons to be recorded in writing impose a sentence of imprisonment which is less than imprisonment for life."
[U.P. Act 47 of 1975]

West Bengal

In its application to the State of West Bengal, in Clause (a) of Section 27, for the words, "for a term which shall not be less than one year but which may extend to ten years" words "for life" substituted; in the proviso, for the words "imprisonment for less than one year" words "less than imprisonment for life" substituted; and in Clause (b), the words "for a term which may extend to three years" words "for life" substituted

[West Bengal Act 42 of 1973]

30. Penalty for subsequent offences

In its application to the State of Uttar Pradesh, for Section 27-A substitute as under:

27-A. Penalty for manufacture, sale, etc., of cosmetics in contravention of this Chapter. —
Whoever himself or by any other person on his behalf manufactures for sale, sells, stocks or exhibits for sale, or distributes any cosmetics in contravention of any of the provisions of this Chapter or any rule made thereunder, shall be punishable with imprisonment for life and shall also be liable to fine:

Provided that the Court may, for adequate and special reasons to be mentioned in the judgment, impose a sentence of imprisonment which is less than imprisonment for life."
[U.P. Act 45 of 1975]

West Bengal

In its application to the State of West Bengal, in Section 27-A for the words "a term which may extend to one year, or with fine which may extend to five hundred rupees." words "life or with fine," substituted.
[West Bengal Act 42 of 1973]

Uttar Pradesh

In its application to the State of Uttar Pradesh for Section 30 substitute as under:

“30. All offences punishable under this Chapter shall be cognizable and non-bailable."[U.P. Act 45 of 1975]

West Bengal

In its application to the State of Uttar Pradesh for Section 30 substitute as under:

30. All offences punishable under this Chapter shall be cognizable and non-bailable."[U.P. Act 45 of 1975]
West Bengal

In its application to the State of West Bengal, —

(a) in Section 30 (1)(a), for the words “ten years”, the words “imprisonment for life” shall be substituted;
(b) in Section 30 (1)(b), for the words “may extend to ten years or with fine, or with both”, the words “shall but be less than two years but which may extend to imprisonment for life and shall also be liable to fine”, shall be substituted;
(c) under Section 30(1-A) for the words “may extend to two years, or with fine which may extend to one thousand rupees, or with both”, the words “shall also be liable to fine” shall be substituted. [W.B. Act 42 of 1973]

Haryana

Section 32 of the Act
Same as in Punjab.
[Haryana A.L.O. 1968]

Punjab

For the words “a Magistrate” in sub-section (2), substitute the words “a Judicial Magistrate”.
[Punjab Act 25 of 1964]

West Bengal

For Section 32 substitute as under:

32. Cognizance of offence and arrest without warrant. — [1] (1) All offences punishable under this Act shall be cognizable and non-bailable.

(2) Any Police Officer not below the rank of a Sub-Inspector of Police may arrest without warrant any person against whom a reasonable complaint has been made or credible information has been received of his having been concerned in any of the offences punishable under this Act”. [W.B. Act 42 of 1973]

27A. Penalty for manufacture, sale, etc., of cosmetics in contravention of this Chapter.—Whoever himself or by any other person on his behalf manufactures for sale or for distribution, or sells, or stocks or exhibits or offers for sale—

(I) any cosmetic deemed to be spurious under section 17D or adulterated under section 17E shall be punishable with imprisonment for a term which may extend to three years and with fine which shall not be less than fifty thousand rupees or three times the value of the cosmetics contravened, whichever is more;

(ii) any cosmetic other than a cosmetic referred to in clause (i) in contravention of any provisions of this chapter or any rule made thereunder shall be punishable with imprisonment for a term which may extend to one year and with fine which may extend to twenty thousand rupees, or with both”

28. Penalty for non-disclosure of the name of the manufacturer, etc.—Whoever contravenes the provisions of section 18A [or section 24] shall be punishable with imprisonment for a term which may extend to one year, or with fine which shall not be less than twenty thousand rupees or with both.

28A. Penalty for not keeping documents, etc., and for non-disclosure of information.—Whoever without reasonable cause or excuse, contravenes the provisions of section 18B shall be punishable with
imprisonment for a term which may extend to one year or with fine which shall not be less than twenty thousand rupees or with both.

28B. Penalty for manufacture, etc., of drugs or cosmetics in contravention of section 26A.—Whoever himself or by any other person on his behalf manufactures or sells or distributes any drug or cosmetic in contravention of the provisions of any notification issued under section 26A, shall be punishable with imprisonment for a term which may extend to three years and shall also be liable to fine which may extend to five thousand rupees.

29. Penalty for use of Government Analyst’s report ‘or advertising.—Whoever uses any report of a test or analysis made by the Central Drugs Laboratory or by a Government Analyst, or any extract from such report, for the purpose of advertising any drug or cosmetic, shall be punishable with fine, which may extend to five thousand rupees.

30. Penalty for subsequent offences.—(1) Whoever having been convicted of an offence—

(a) under clause (b) of section 27 is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which shall not be less than seven years but which may extend to ten years and with fine which shall not be less than two lakh rupees:

Provided that the Court may, for any adequate and special reasons to be mentioned in the judgment, impose a sentence of imprisonment for a term of less than seven years and of fine of less than one lakh rupees;

(b) under clause (c) of section 27, is again convicted of an offence under that clause shall be punishable with imprisonment for a term which shall not be less than ten years but which may extend to imprisonment for life and with fine which shall not be less than three lakh rupees;

(c) under clause (d) of section 27, is again convicted of an offence under that clause shall be punishable with imprisonment for a term which shall not be less than two years but which may extend to four years or with fine which shall not be less than fifty thousand rupees, or with both.

(1A) Whoever, having been convicted of an offence under section 27A is again convicted under that section, shall be punishable with imprisonment for a term which may extend to two years, or with fine which may extend to two thousand rupees, or with both.

(2) Whoever, having been convicted of an offence under section 29 is again convicted of an offence under the same section shall be punishable with imprisonment which may extend to two years or with fine which shall not be less than ten thousand rupees or with both.

31. Confiscation.—(1) Where any person has been convicted under this Chapter for contravening any such provision of this Chapter or any rule made thereunder as may be specified by rule made in this behalf, the stock of the drug or cosmetic in respect of which the contravention has been made shall be liable to confiscation and if such contravention is in respect of—

(i) manufacture of any drug deemed to be misbranded under section 17, adulterated under section 17A or spurious under section 17B; or

(ii) manufacture for sale, or for distribution, sale, or stocking or exhibiting or offering for sale, or distribution of any drug without a valid licence as required under clause (c) of section 18; any implements or machinery used in such manufacture, sale or distribution and any receptacles, packages or coverings
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in which such drug is contained and the animals, vehicles, vessels or other conveyances used in carrying such drug shall also be liable to confiscation.

(2) Without prejudice to the provisions contained in sub-section (1) where the Court is satisfied, on the application of an Inspector or otherwise and after such inquiry as may be necessary that the drug or cosmetic is not of standard quality or misbranded, adulterated or spurious drug or misbranded or spurious cosmetic, such drug or, as the case may be, such cosmetic shall be liable to confiscation.

31A. Application of provisions to Government departments.—The provisions of this Chapter except those contained in section 31 shall apply in relation to the manufacture, sale or distribution of drugs of any department of Government as they apply in relation to the manufacture, sale or distribution of drugs by any other person.

32. Cognizance of offence

(a) No prosecution under this Chapter shall be instituted except by—

(b) an Inspector; or

(c) any gazetted officer of the Central Government or a State Government Authorized in writing in this behalf by the Central Government or a State Government by a general or special order made in this behalf by that Government; or

(c) the person aggrieved; or

(d) a recognised consumer association whether such person is a member of that association or not.

(2) Save as otherwise provided in this Act, no court inferior to that of a Court of Session shall try an offence punishable under this Chapter

(3) Nothing contained in this Chapter shall be deemed to prevent any person from being prosecuted under any other law for any act or omission which constitutes an offence against this Chapter.

32A. Power of Court to implead the manufacturer, etc.—Where, at any time during the trial of any offence under this Chapter alleged to have been committed by any person, not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof, the Court is satisfied, on the evidence adduced before it, that such manufacturer or agent is also concerned in that offence, then, the Court may, notwithstanding anything contained in sub-sections (1), (2) and (3) of section 319 of the Code of Criminal Procedure, 1973 (2 of 1974) proceed against him as though a prosecution had been instituted against him under section 32.

32B. (1) Notwithstanding anything contained in the Code of Criminal Procedure, 1973, any offence punishable under clause (b) of sub-section (1) of section 13 of section 28 and section 28A of this Act (whether committed by a company or any officer thereof), not being an offence punishable with imprisonment only, or with imprisonment and also with fine, may, either before or after the institution of any prosecution, be compounded by the Central Government or by any State Government or any officer authorised in this behalf by the Central Government or a State Government, on payment for credit to the Government of such sum as that Government may, by rules made in this behalf, specify:

Provided that such sum shall not, in any case, exceed the maximum amount of the fine which may be imposed under this Act for the offence so compounded:

Provided further that in cases of subsequent offences, the same shall not be compoundable.
(2) When the accused has been committed for trial or when he has been convicted and an appeal is pending, no composition for the offence shall be allowed without the leave of the court to which he is committed or, as the case may be, before which the appeal is to be heard.

(3) Where an offence is compounded under sub-section (1), no proceeding or further proceeding, as the case may be, shall be taken against the offender in respect of the offence so compounded and the offender, if in custody, shall be released forthwith.

33-I. Penalty for manufacture, sale, etc., of Ayurvedic, Siddha or Unani drug in contravention of this Chapter —

Whoever himself or by any other person on his behalf—

(1) manufactures for sale or for distribution,—

(a) any Ayurvedic, Siddha or Unani drug—

(i) deemed to be misbranded under section 33E,
(ii) deemed to be adulterated under section 33EE, or
(iii) without a valid licence or in violation of any of the conditions thereof, as required under section 33EEC,

shall be punishable with imprisonment for a term which may extend to one year and with fine which shall not be less than twenty thousand rupees or three times the value of the drugs confiscated, whichever is more;

(b) any Ayurvedic, Siddha or Unani drug deemed to be spurious under section 33EEA, shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to three years and with fine which shall not be less than fifty thousand rupees or three times the value of the drugs confiscated, whichever is more;

(c) any Ayurvedic, Siddha or Unani drug in contravention of the provisions of any notification issued under section 33EED shall be punishable with imprisonment for a term which may extend to three years and with fine which may extend to fifty thousand rupees or three times the value of the drugs confiscate, whichever is more.

Provided that the Court may, for any adequate and special reasons to be mentioned in the judgment, impose a sentence of imprisonment for a term of less than one year and of fine of less than five thousand rupees; or

(2) contravenes any other provisions of this Chapter or of section 24 as applied by section 33H or any rule made under this Chapter, shall be punishable with imprisonment for a term which may extend to six months and with fine which shall not be less than ten thousand rupees.

33J. Penalty for subsequent offences.—Whoever having being convicted of an offence,—

(a) under clause (a) of sub-section (1) of section 33-I is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which may extend to two years and with fine which shall not be less than fifty thousand rupees or three times the value of the drugs confiscated whichever is more;
(b) under clause (b) of sub-section (1) of section 33-I is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which shall not be less than two years but which may extend to six years and with fine which shall not be less than one lakh rupees or three times the value of the drugs confiscated, whichever is more:

Provided that the Court may, for any adequate and special reasons to be mentioned in the judgment, impose a sentence of imprisonment for a term of less than two years and of fine which shall not be less than one lakh rupees or three time the value of the drugs confiscated, whichever is more;

(c) under sub-section (2) of section 33-I is again convicted of an offence under that sub-section, shall be punishable with imprisonment for a term which may extend to one year and with fine which shall not be less than twenty thousand rupees or three times the value of drugs confiscated, whichever is more.

33K. Confiscation.—Where any person has been convicted under this Chapter, the stock of the 1[Ayurvedic, Siddha or Unani] drug, in respect of which the contravention has been made, shall be liable to confiscation.

33P. Power to give directions.—The Central Government may give such directions to any State Government as may appear to the Central Government to be necessary for carrying into execution in the State any of the provisions of this Act or of any rule or order made thereunder.

34. Offences by companies.—(1) Where an offence under this Act has been committed by a company, every person who at the time the offence was committed, was in charge of, and was responsible to the company for the conduct of the business of the company, as well as the company shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly:

Provided that nothing contained in this sub-section shall render any such person liable to any punishment provided in this Act if he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence.

(2) Notwithstanding anything contained in sub-section (1), where an offence under this Act has been committed by a company and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any director, manager, secretary or other officer of the company, such director, manager, secretary or other officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly:

Explanation.—For the purposes of this section—

(a) "company" means a body corporate, and includes a firm or other association of individuals; and

(b) "director" in relation to a firm means a partner in the firm.

34A. Offences by Government Departments.—Where an offence under Chapter 1V or Chapter 1VA has been committed by any department of Government, such authority as is specified by the Central Government to be in charge of manufacture, sale or distribution of drugs or where no authority is specified, the head of the department, shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly:

Provided that nothing contained in this section shall render any such authority or person liable to any punishment provided in Chapter 1V or Chapter 1VA, as the case may be, if such authority or person...
proves that the offence was committed without its or his knowledge or that such authority or person exercised all due diligence to prevent the commission of such offence.

34AA. Penalty for vexatious search or seizure.—Any Inspector exercising powers under this Act or the rules made thereunder, who,—

(a) without reasonable ground of suspicion searches any place, vehicle, vessel or other conveyance; or
(b) vexatiously and unnecessarily searches any person; or
(c) vexatiously and unnecessarily seizes any drug or cosmetic, or any substance or article, or any record, register, document or other material object; or
(d) commits, as such Inspector, any other act, to the injury of any person without having reason to believe that such act is required for the execution of his duty, shall be punishable with fine which may extend to one thousand rupees.

35. Publication of sentences passed under this Act.—(1) If any person is convicted of an offence under this Act, the Court before which the conviction takes place shall, on application made to it by the Inspector, cause the offender’s name, place of residence, the offence of which he has been convicted and the penalty which has been inflicted upon him, to be published at the expense of such person in such newspapers or in such other manner as the Court may direct.

(2) The expenses of such publication shall be deemed to form part of the cost relating to the conviction and shall be recoverable in the same manner as those costs are recoverable.

36. Magistrate’s power to impose enhanced penalties.—Notwithstanding anything contained in 4. the Code of Criminal Procedure, 1973 (2 of 1974) it shall be lawful for any Metropolitan Magistrate or any Judicial Magistrate of the first class to pass any sentence authorised by this Act in excess of his powers under 4. the said Code.

36A. Certain offences to be tried summarily.—Notwithstanding anything contained in the Code of Criminal Procedure, 1973 (2 of 1974), all offences (except the offences triable by the Special Court under section 36AB or Court of Session) under this Act, punishable with imprisonment for a term not exceeding three years, other than an offence under clause (b) of sub-section (1) of section 33-I, shall be tried in a summary way by a Judicial Magistrate of the first class specially empowered in this behalf by the State Government or by a Metropolitan Magistrate and the provisions of sections 262 to 265 (both inclusive) of the said Code shall, as far as may be, apply to such trial:

Provided that, in the case of any conviction in a summary trial under this section, it shall be lawful for the Magistrate to pass a sentence of imprisonment for a term not exceeding one year. Provided further that when at the commencement of, or in the course of, a summary trial under this section it appears to the Magistrate that the nature of the case is such that a sentence of imprisonment for a term exceeding one year may have to be passed or that it is, for any other reason, undesirable to try the case summarily, the Magistrate shall, after hearing the parties, record an order to that effect and thereafter recall any witness who has been examined and proceed to hear or rehear the case in the manner provided by the said Code.

(b) no person accused of an offence punishable under clauses (a) and (c) of sub-section (1) of section 13, clause (a) of sub-section (2) of section 13, subsection (3) of section 22, clauses (a) and (c) of sub-section 27, section 28, section 28A, section 28B, and subsections (1) and (2) of section 30, and other offences relating to adulterated drugs or spurious drugs, shall be released on bail or on his own bond unless:

(i) the Public Prosecutor has been given an opportunity to oppose the application for such release; and
(ii) where the Public Prosecutor opposes the application the court is satisfied that there are reasonable
grounds for believing that he is not guilty of such offence and that he is not likely to commit any offence
while on bail;

Provided that a person, who, is under the age of sixteen years, or is a woman or is sick or infirm, may be
released on bail, if the Special court so directs. 36AB (1) The Central Government, or the State
Government, in consultation with the Chief Justice of the High Court, shall, for trial of offences relating to
adulterated drugs or spurious drugs and punishable under clauses (a) and (b) of section 13, sub-
section (3) of section 22, clauses (a) and (c) of section 27, section 28, section 28A, section 28B and clause (b) of
sub-section (1) of section 30 and other offences relating to adulterated drugs or spurious drugs, by
notification, designate one or more Courts of Session as a Special Court or Special Courts for such area
or areas or for such case or class or group of cases as may be specified in the notification.

Explanation. - In this sub-section, "High Court" means the High Court of the State in which a Court of
Session designated as Special Court was functioning immediately before such designation.

(2) While trying an offence under this Act, a Special court shall also try an offence, other than an offence
referred to in sub-section (1), with which the accused may, under the Code of Criminal Procedure, 1973,
be charged at the same trial.

36AC. (1) Notwithstanding anything contained in the Code of Criminal Procedure, 1973-

(a) every offence, relating to adulterated or spurious drug and punishable certain cases under clauses (a)
and (c) of sub-section (1) of section 13, clause (a) of subsection (2) of section 13, sub-section (1) of
section 27, clauses (a) and (c) of section 27, section 28, section 28A, section 28B and sub-sections (1)
and (2) of section 30 and other offences relating to adulterated drugs or spurious drugs, shall be
cognizable.

(2) The limitation on granting of bail specified in clause (b) of sub-section (1) is in addition to the
limitations under the Code of Criminal Procedure, 1973 or any other law for the time being in force on
granting of bail

(3) Nothing contained in this section shall be deemed to affect the special powers of the High Court
regarding bail under section 439 of the code of Criminal Procedure, 1973 and the High Court exercise
such powers including the power

under clause (b) of sub-section (1) of that section as if the reference to "Magistrate" in that section
includes also a reference to a "Special Court" designated under section 36AB

36AD. (1) Save as otherwise provided in this Act, the provisions of the Code of Criminal Procedure, 1973
(including the provisions as to bails or bonds), shall apply to 2. of 1974 the proceedings before a Special
Court and for the purposes of the said provisions, the Special Court shall be deemed to be a Court of
Session and the person conducting the prosecution before the Special Court, shall be deemed to be a
Public Prosecutor.

37. Protection of action taken in good faith — No suit, prosecution or other legal proceeding shall lie
against any person for anything which is in good faith done or intended to be done under this Act.

38. Rules to be laid before Parliament — Every rule made under this Act shall be laid as soon as may
be after it is made before each House of Parliament while it is in session for a total period of thirty days
which may be comprised in one session or in two or more successive sessions, 2(and if, before the expiry

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of the session immediately following the session or the successive sessions aforesaid], both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified from or be of no effect, as the case may be; so however that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.

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:

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.

29A. 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.

PART VII

MANUFACTURE FOR SALE [OR FOR DISTRIBUTION] OF DRUGS OTHER THAN HOMOEOPATHIC MEDICINES

85. Cancellation and suspension of licences. — (1) The Central Licence Approving Authority may, after giving the licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, cancel a licence issued under this Part, or suspend it for such period as he thinks fit either wholly or in respect of any of the drugs to which it relates [or direct the licensee to stop manufacture, sale or distribution of the said drugs and [thereupon order the destruction of drugs and] the stock thereof in the presence of an Inspector], if in his opinion, the licensee has failed to comply with any of the conditions of the licensee or with any provisions of the Act or rules made thereunder.

(2) The Licensing Authority may, for such licences granted or renewed by him, after giving the licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, cancel a licence issued under this Part or suspend it for such period as he thinks fit, either wholly or in respect of some of the substances to which it relates, [or direct the licensee to stop manufacture, sale or distribution of the said drugs and thereupon order the destruction of drugs and] the stock thereof in the presence of an Inspector], if in his opinion, the licensee has failed to comply with any of the conditions of the licence or with any provisions of the Act or rules made thereunder.
(3) A licensee whose licence has been suspended or cancelled by the Central Licence Approving Authority or Licensing Authority under sub-rule (1) or sub-rule (2), as the case may be, may within ninety days of the receipt of a copy of the order by him prefer an appeal to the Central Government or the State Government, as the case may be, and the Central Government or the State Government may after giving the licensee an opportunity of being heard, confirm, reverse or modify such order. (www.cdsco.nic.in)

5.6 CHINA

Drug Administration Law of the People’s Republic of China

Article 64 Drug regulatory departments shall have the power to supervise and inspect, according to law and administrative regulations, matters related to drug research and development, which it has given approval, to drug production and distribution, and to the use of drugs by medical institutions. No institutions or individuals concerned may resist the supervision and inspection or conceal any facts.

Article 65 Drug regulatory departments may conduct selective testing of drug quality in light of the need of supervision and inspection. The drug regulatory department shall take administrative enforcement measures to seal or seize the drugs and related materials that are proved to be potentially harmful to human health and shall, within seven days, make an administrative decision on the matter in question. Where it is necessary to test such drugs, it shall, within 15 days from the date the testing report is issued, make the administrative decision.

Article 66 The drug regulatory department under the State Council and the drug regulatory departments of the people’s governments of provinces, autonomous regions and municipalities directly under the Central Government shall regularly announce the results of selective testing of drug quality. Where the announcement is improper, it shall be corrected within the scope in which the original announcement is made.

Article 67 Where the party has objection to the results of testing conducted by the drug testing institution, it may, within seven days from the date it receives the testing results, apply for re-testing to the said drug testing institution, or to such an institution established or designated by the drug regulatory department at the next higher level, and it may also directly apply to the drug testing institution established or designated by the drug regulatory department under the State Council. The drug testing institution that accepts the application shall, within the time limit specified by the drug regulatory department under the State Council, draw a conclusion from the re-test.

Article 68 Drug regulatory departments shall, in accordance with regulations and on the basis of the GMP and GSP, make follow-up inspections on the certified drug manufacturers and distributors.

Article 69 With regard to the drugs produced according to the provisions of this Law by drug manufacturers not located in the region, no local people’s government or drug regulatory department may, by means of demanding drug testing or approval, restrict or deny their access to the region.

Article 70 No drug regulatory department, or drug testing institution established by the department, or the institution specially engaged in drug testing designated by the department may be involved in production or distribution of drugs, or recommend drugs in its name or have the supervisor for drug production or sale named after it.

No staff members of drug regulatory departments, of drug testing institutions established by the departments or of institutions specially engaged in drug testing designated by the departments may be involved in drug production or distribution.
**Article 71** The State applies a system of report on adverse drug reaction. Drug manufacturers, drug distributors and medical institutions shall make constant investigations into quality, therapeutic efficacy and reactions of the drugs produced, distributed and used by them. When serious adverse drug reactions possibly induced by drug use are discovered, they shall, without delay, report the matter to the local drug regulatory departments and administrative departments for health of the people's governments of provinces, autonomous regions and municipalities directly under the Central Government. Specific measures shall be formulated by the drug regulatory department under the State Council together with the administrative department for health under the State Council.

With regard to drugs with confirmed serious adverse reactions, the drug regulatory department under the State Council or the drug regulatory department of the people's government of province, autonomous region or municipality directly under the Central Government may take urgent control measures to suspend their production, distribution and use, and it shall, within five days, arrange for assessment and, within 15 days from the date the conclusion is drawn, make an administrative decision on how to deal with the case.

**Article 72** Drug testing sections of the drug manufacturers, drug distributors and medical institutions and their staff members shall accept technical instructions given by drug testing institutions set up by the local drug regulatory departments.

**Chapter IX**

**Legal Liabilities**

**Article 73** Any drug manufacturer or distributor that, without obtaining Drug Manufacturing Certificate, Drug Supply Certificate or Pharmaceutical Preparation Certificate for Medical Institution, manufactures or distributes drugs shall be banned, the drugs illegally produced or sold and the illegal gains there from shall be confiscated, and they shall also be fined not less than two times but not more than five times the value of the drugs (including the drugs sold and not sold, the same below). If a crime is constituted, criminal liabilities shall be investigated in accordance with law.

**Article 74** Where counterfeit drugs are produced or sold, the drugs illegally produced or sold and the illegal gains shall be confiscated, and a fine not less than two times but not more than five times the value of the said drugs shall be imposed. The approval documents, if any, shall be withdrawn and an order shall be given to suspend production or business operation for rectification. If the circumstances are serious, the Drug Manufacturing Certificate, Drug Supply Certificate or Pharmaceutical Preparation Certificate for Medical Institution shall be revoked. If a crime is constituted, criminal liabilities shall be investigated in accordance with law.

**Article 75** Where substandard drugs are produced or sold, the drugs illegally produced or sold and the illegal gains shall be confiscated, and a fine not less than, but not more than three times, the value of the said drugs shall also be imposed. If the circumstances are serious, an order shall be given to suspend production or business operation for rectification, or the drug approval documents shall be withdrawn and the Drug Manufacturing Certificate, the Drug supply Certificate, or the Pharmaceutical Preparation Certificate for Medical Institution shall be revoked. If a crime is constituted, criminal liabilities shall be investigated in accordance with law.

**Article 76** Where enterprises or other institutions are engaged in production or sale of counterfeit or substandard drugs, if the circumstances are serious, the persons directly in charge and the other persons directly responsible shall be prohibited from engaging in the drug production or distribution within 10 years.
The drug substances, excipients, packaging materials and manufacturing equipment specially used for producing counterfeit or substandard drugs by any producer shall be confiscated.

**Article 77** Anyone who knows or should know that the drugs are counterfeit or substandard drugs provides conveniences such as transportation, keeping or storage of the drugs, all the earnings therefrom shall be confiscated, and a fine not less than 50 per cent of, but not more than 3 times, the amount of the illegal earnings shall also be imposed. If a crime is constituted, criminal liabilities shall be investigated in accordance with law.

**Article 78** The quality testing results provided by the drug testing institution shall be contained in the penalty notification regarding counterfeit and substandard drugs, except in cases specified in the provisions of Subparagraphs (1), (2), (5) and (6) of the third paragraph of Article 48 and the third paragraph of Article 49 of this Law.

**Article 79** Any drug manufacturer, drug distributor, institution for non-clinical safety study, or institution for drug clinical trial that does not implement the GMP, GSP, GLP or GCP according to regulations shall be given a disciplinary warning and shall be instructed to rectify within a time limit. If it fails to do so, it shall be instructed to suspend production or business operation or other work for rectification and shall also be fined not less than RMB5,000 yuan but not more than RMB20,000 yuan. If the circumstances are serious, the Drug Manufacturing Certificate, Drug Supply Certificate or the qualifications of the institution for drug clinical trial shall be annulled.

**Article 80** Any drug manufacturer, drug distributor or medical institution that, in violation of the provisions of Article 34 of this Law, purchases drugs from the enterprises without Drug Manufacturing Certificate or Drug Supply Certificate shall be instructed to rectify, the drugs illegally purchased shall be confiscated, and it shall be fined not less than two times but not more than five times the value of the drugs purchased; the illegal gains, if any, shall be confiscated. If the circumstances are serious, the Drug Manufacturing Certificate, Drug Supply Certificate or the license for the medical institution shall be revoked.

**Article 81** If any enterprise that imports drugs to which import drug license has been granted fails to register, in accordance with the provisions of this Law, for the record with the drug regulatory department in the place where the port is located and drug importation is permitted, it shall be given a disciplinary warning and be instructed to rectify within a time limit; if it fails to do so, the import drug license shall be revoked.

**Article 82** If anyone falsifies, alters, alters, trades in, rents out or lends the certificates or drug approval documents, the illegal gains shall be confiscated and a fine not less than, but not more than three times, the amount of the illegal gains shall be imposed; if there are no illegal gains, a fine not less than RMB 20,000 yuan but not more than RMB 100,000 yuan shall be imposed. If the circumstances are serious, the Drug Manufacturing Certificate, Drug Supply Certificate or Pharmaceutical Preparation Certificate for Medical Institution of the party that sells, rents out or lends it shall be revoked. If a crime is constituted, criminal liabilities shall be investigated in accordance with law.

**Article 83** If anyone, in violation of the provisions of this Law, obtains the Drug Manufacturing Certificate, Drug Distribution Certificate, Pharmaceutical Preparation Certificate for Medical Institution, or drug approval documents by providing false certificates, documents and data, or samples, or by other fraudulent means, the said certificates shall be revoked and the documents shall be withdrawn, his applications for such certificates or approval documents shall be rejected within five years, and a fine not less than RMB 10,000 yuan but more than RMB 30,000 yuan shall also be imposed.
**Article 84** Any medical institution that sells its own dispensed pharmaceutical preparations on the market shall be instructed to rectify, the preparations for illegal sale shall be confiscated, and a fine not less than, but not more than three times, the value of the said preparations shall be imposed, and the illegal gains, if any, shall be confiscated.

**Article 85** Any drug distributor that violates the provisions of Article 18 and 19 of this Law shall be instructed to rectify and be given a disciplinary warning. If the circumstances are serious, the Drug Supply Certificate shall be revoked.

**Article 86** Where the drugs with labels or marks are not in conformity with the provisions of Article 54 of this Law, except for those treated as counterfeit or substandard drugs, an instruction for rectification and a disciplinary warning shall be given. If the circumstances are serious, the approval documents for the drugs shall be withdrawn.

**Article 87** Where a drug testing institution issues a false testing report, if it constitutes a crime, criminal liabilities shall be investigated in accordance with law; if it does not constitute a crime, the institution shall be instructed to rectify and be given a disciplinary warning, and also be fined not less than RMB30, 000 yuan but not more than RMB 50, 000 yuan. The persons directly in charge and the other person directly responsible shall, in accordance with law, be punished with demotion, dismissal, or exulsion and also be fined not more than RMB 30, 000 yuan. The illegal gains, if any, shall be confiscated. If the circumstances are serious, the qualification for testing shall be annulled. If the testing result issued by the drug testing institution is not true to fact and losses are thus occasioned, the institution shall bear corresponding liability of compensation for losses.

**Article 88** The administrative sanctions prescribed in Article 73 through Article 87 of this Law shall be determined by the drug regulatory departments at or above the county level according to the division of responsibility defined by the drug regulatory department under the State Council. Revocation of the Drug Manufacturing Certificate, Drug Supply Certificate and Pharmaceutical Preparation Certificate for Medical Institution or withdrawal of the drug approval documents shall be determined by the department that issued the certificate or the approval documents.

**Article 89** Any violation of the provision of Article 55, 56 or 57 of this Law governing the control over drug pricing shall be punished pursuant to the provisions of the Pricing Law of the People's Republic of China.

**Article 90** Drug manufacturers, drug distributors or medical institutions that offer or accept, in private, the rake-offs or other benefits in the course of purchasing and selling drugs or drug manufacturers, drug distributors or their agents that offer money or things of value or other benefits to leading members, drug purchasers, physicians, or other related persons of the medical institutions where their drugs are used shall be fined not less than RMB 10, 000 yuan but not more than RMB 200, 000 yuan by the administrative department for industry and commerce, and the illegal gains, if any, shall be confiscated. If the circumstances are serious, the said department shall revoke the business licenses of the drug manufacturers or drug distributors and inform the drug regulatory department of the matter, which shall revoke their Drug Manufacturing Certificate, or Drug Distribution Certificate. If a crime is constituted, criminal liabilities shall be investigated in accordance with law.

**Article 91** Any leading members, purchasers or other related persons of drug manufacturers or distributors that, in the course of drug purchasing or selling, accept money or things of value or other benefits offered by other manufacturers, distributors or their agents shall be given sanctions according to law, and the illegal gains shall be confiscated. If a crime is constituted, criminal liabilities shall be investigated in accordance with law.
Leading members, drug purchasers, physicians or other related persons of medical institutions who accept money or things of value or other benefits offered by drug manufacturers, drug distributors or their agents shall be given sanctions by the administrative department for health or the institutions to which they belong, and the illegal gains shall be confiscated. With regard to licensed physicians who seriously violate laws, the administrative department for health shall revoke their licenses for medical practice. If a crime is constituted, criminal liabilities shall be investigated in accordance with law.

Article 92 Any violation of the provisions of this Law related to the control over drug advertising shall be punished pursuant to the provisions of the Advertisement Law of the People’s Republic of China, the drug regulatory department that issues the advertisement approval number shall withdraw it and shall, within one year, reject any application for approval of advertising for the drug in question. If a crime is constituted, criminal liabilities shall be investigated in accordance with law.

Where a drug regulatory department does not perform its duty of drug advertisement examination in accordance with law and the advertisement approved for issuance contains false information or other content violating laws or administrative regulations, administrative sanctions shall, in accordance with law, be given to the persons directly in charge and the other persons directly responsible. If a crime is constituted, criminal liabilities shall be investigated in accordance with law.

Article 93 Drug manufacturers, drug distributors or medical institutions that violate the provisions of this Law and thus cause harm and losses to users of drugs shall bear the liability of compensation in accordance with law.

Article 94 Any drug regulatory department that violates the provisions of this Law and commits one of the following acts shall be instructed by the competent authority at the next higher level or the supervisory body to recall the certificates unlawfully issued or to withdraw the drug approval documents, and administrative sanctions shall be given to the persons directly in charge and the other persons directly responsible in accordance with law. If a crime is constituted, criminal liabilities shall be investigated in accordance with law.

1) issuing the GMP and GSP certificates to the enterprises that do not comply with the corresponding requirements, failing to perform, in accordance with regulations, the duty of follow-up inspections in respect of the enterprises that have obtained the certificates, or failing to instruct, in accordance with law, the enterprises not complying with the requirements to rectify or withdraw their certificates;

2) issuing the Drug Manufacturing Certificate, Drug Supply Certificate or Pharmaceutical Preparation Certificate for Medical Institution to the enterprises or institutions that do not comply with the statutory requirements;

3) issuing an Import Drug License to the drug that does not comply with the requirements for import; or

5) granting approval for conducting a clinical trial, issuing a New Drug Certificate or a drug approval number, where the requirements for clinical trial or drug production are not fulfilled.

Article 95 If any drug regulatory department, drug testing institution established by the department or institutions specially engaged in drug testing designated by the department is involved in drug production or distribution, it shall be instructed by the authority at the next high level or the supervisory body to rectify, and the illegal gains, if any, shall be confiscated. 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. Any staff member of the drug regulatory department, drug testing institution established by the department or institution specially engaged in drug testing designated by the
department who is involved in drug production or distribution shall be given an administrative sanction in accordance with law.

**Article 96** If any drug regulatory department or drug testing institution established or designated by the department, in violation of law, collects testing fees for supervision over drug testing shall be instructed by the relevant government department to return the fees, and administrative sanctions shall be given to the persons directly in charge and the other persons directly responsible in accordance with law. Any drug testing institution that collects testing fees in violation of law, if the circumstances are serious, shall be disqualified for drug testing.

**Article 97** Drug regulatory departments shall, in accordance with law, perform their duties of supervision and inspection and shall see to it that the enterprises holding the Drug Manufacturing Certificate or Drug Supply Certificate engage in drug production or drug distribution in accordance with the provisions of this Law.

Where enterprises holding the Drug Manufacturing Certificate or Drug Supply Certificate produce or sell counterfeit or substandard drugs, the legal liabilities of such enterprises shall be investigated and, in addition, the persons directly in charge and the other persons directly responsible of the drug regulatory departments who neglect their duty or commit dereliction of duty shall be given administrative sanctions in accordance with law. If a crime is constituted, criminal liabilities shall be investigated in accordance with law.

**Article 98** The drug regulatory department shall instruct the drug regulatory department at a lower level to put right, within a time limit, the administrative action taken in violation of this Law, and it shall have the power to alter or annul the action which is not put right within the time limit.

**Article 99** Anyone responsible for drug regulation who abuses his power, engages in malpractice for personal gain or neglects his duty, if it constitutes a crime, shall be investigated for criminal liabilities in accordance with law; if it is not serious enough to constitute a crime, he shall be given administrative sanctions in accordance with law.

**Article 100** Where a Drug Manufacturing Certificate or Drug Distribution Certificate is revoked in accordance with this Law, the drug regulatory department shall notify the administrative department for industry and commerce to alter or cancel the registration.

**Article 101** The value of products mentioned in this Chapter shall be calculated on the basis of the marked prices of the drugs illegally produced or sold; where there is no marked price, the value shall be calculated according to the market prices of drugs of the same kind.

(http://eng.sfda.gov.cn/cms/web/webportal/W45649037/A48335975.ntml#01)

### 5.7 NEW ZEALAND

**Revocation and suspension of consents**

The Minister may at any time, by notice in the Gazette, revoke, or suspend for such period as he may determine, any consent given under section 20 or section 23 of this Act, if he is of the opinion that—

(a) The medicine can no longer be regarded as a medicine that can be administered or used safely for the purposes indicated in the application for consent, or in a notice deposited under section 24 of this Act; or
(b) The specifications and standards with respect to the manufacture of the medicine that were included in the terms of a consent can no longer be regarded as satisfactory; or

(c) The efficacy of the medicine can no longer be regarded as satisfactory.

(2) Where a consent is suspended under this section, it shall be deemed for the purposes of subsections (2) and (4) of section 20 of this Act not to have been granted.

Control of established medicines

(1) Without limiting subsection (5) of section 24 of this Act, if the Director-General has reason to believe that any medicine, not being a new medicine, may be unsafe or ineffective for the therapeutic purpose for which it is sold, he may, by notice in writing to an importer or manufacturer in New Zealand, state the reasons for his belief and require the importer or manufacturer to satisfy him of the safety or efficacy of that medicine.

(2) If the Director-General is not satisfied, by evidence supplied to him pursuant to a notice under subsection (1) of this section or otherwise, of the safety and efficacy of a medicine to which that notice relates, he may at any time after the expiration of 60 days from the date of that notice refer a description of the medicine to the appropriate committee, and shall forthwith by notice in writing inform the importer or manufacturer that he has done so.

(3) In any case to which this section applies, the Minister may, by notice in writing to the importer or manufacturer,—

(a) Prohibit the importer or manufacturer, either indefinitely or for such period as may be specified in the notice, from selling or supplying the medicine; or

(b) Impose such conditions as may be specified in the notice on the sale or supply of the medicine by the importer or manufacturer.

(4) The Minister may at any time, by a like notice, revoke any notice given under subsection (3) of this section, or vary, revoke, or add to any conditions imposed in any such notice.

(5) Every person commits an offence and is liable to imprisonment for a term not exceeding 6 months or a fine not exceeding $5,000 who sells or supplies any medicine in contravention of a notice given under subsection (3) of this section, or of a condition imposed in any such notice or in a notice given under subsection (4) of this section.

Adulteration of medicines

(1) No person shall—

(a) Add any substance to, or abstract any substance from, a medicine so as to affect injuriously the composition of the medicine, with intent that the medicine shall be sold or supplied in that state:

(b) Sell or supply any medicine the composition of which has been injuriously affected by the addition or abstraction of any substance.

(2) Every person commits an offence against this Act who contravenes subsection (1) of this sec

Compliance with standards
(1) If a standard is prescribed in respect of a medicine, or a medical device, or the ingredient of a medicine, no person shall, in the course of any business, sell or supply any substance or article under a name that is likely to cause the person to whom the substance or article is sold or supplied to believe that that person is purchasing or otherwise acquiring that medicine, or that medical device, or a substance containing that ingredient, unless the substance or article, or the ingredient of the substance or article, complies with the standard.

(2) If a person sells an article to a purchaser in response to a request for a medicine or a medical device of a kind for which a standard is prescribed, he shall be deemed to sell a medicine or medical device of that kind and under such a description as is specified in subsection (1) of this section unless he clearly notifies the purchaser at the time of sale that the article is not of that kind.

(3) Notwithstanding that a medicine, or a medical device, or an ingredient of a medicine, otherwise conforms with the standard prescribed for that medicine, medical device, or ingredient, it shall be deemed not to conform with that standard if anything has been added to it—

(a) The addition of which is not expressly required or permitted by regulations made under this Act; or

(b) In a quantity or proportion greater or lesser than that so required or permitted; or

(c) That does not comply with the standard (if any) prescribed for that kind of thing.

(4) Every person commits an offence against this Act who contravenes subsection (1) of this section.

Duty of importer or manufacturer to report untoward effects of medicines

(1) If at any time the importer or manufacturer in New Zealand of any medicine has reason to believe that any substantial untoward effects have arisen from the use of the medicine whether in New Zealand or elsewhere, the importer or manufacturer shall forthwith notify the Director-General of the nature of those effects and the circumstances in which they have arisen, so far as they are known to him.

(2) Every person commits an offence against this Act who fails to comply with subsection (1) of this section.

Duty of importer and manufacturer to have and produce specifications of medicines

(1) No importer or manufacturer shall sell, or distribute by way of gift or loan or sample or in any other way, or advertise for sale, or advertise the availability of, any medicine other than a herbal remedy unless he is in possession of—

(a) Details of the specifications for testing the quality of that medicine; and

(b) A certificate of the results of testing in respect of every batch of that medicine distributed or to be distributed in New Zealand.

(2) Every importer or manufacturer in New Zealand shall, on demand, supply to an officer the details and certificates referred to in subsection (1) of this section.

(3) A person who contravenes this section commits an offence, and is liable on conviction—
Drug Enforcement Laws – Globalization, Vis-à-Vis, Indian Drug Laws

(a) In the case of an individual, to imprisonment for a term not exceeding 3 months or a fine not exceeding $10,000:

(b) In the case of a body corporate, to a fine not exceeding $100,000. Subsection (3) was substituted, as from 19 May 1998, by section 13 Copyright (Removal of Prohibition on Parallel Importing) Amendment Act 1998 (1998 No 20).

Powers of officers

(1) In this section the expression article to which this section applies means—

(a) Any medicine; and
(b) Any medical device; and
(c) Any cosmetic; and
(d) Any equipment used or intended to be used in connection with the manufacture, packing, or labelling of anything referred to in any of paragraphs (a) to (c) of this subsection; and
(e) Any package or container, and any advertising material or labelling material, used or intended to be used in any such connection.

(2) An officer, and any other person assisting him and acting under his direct supervision, may at any reasonable time—

(a) Enter and inspect any premises (not being a dwellinghouse) or vehicle (including any fixtures, fittings, or appliances in the premises or vehicle) where the officer reasonably believes that any article to which this section applies is manufactured, packed, stored, or kept for sale:

(b) Enter any premises (not being a dwellinghouse) or vehicle where the officer reasonably believes that any books, documents, or other records are kept relating to any such manufacture, packing, storage, or keeping for sale:

(c) Open and examine any package or container that the officer reasonably believes contains any article to which this section applies:

(d) Examine any article to which this section applies:

(e) Examine any process of manufacture or packing of any article to which this section applies, and the means employed at any stage in the processes of manufacture or packing for testing the materials after they have been subjected to those processes:

(f) Subject to section 69 of this Act, purchase or take samples of any medicine or medical device or cosmetic that the officer reasonably believes to be intended for sale or to have been sold:

(g) Purchase or take—

(i) Any package or container in which the officer reasonably believes any medicine or medical device is intended to be packed for sale; or

(ii) Any advertising material or labelling material that the officer reasonably believes is intended for use in connection with the sale of any medicine or medical device, or to have been used for such purpose:
(h) Examine any books, documents, or other records that the officer reasonably believes contain information relevant to the enforcement of this Act or any regulations made under this Act, and make copies of or take extracts from any such records:

(i) Seize and detain any article to which this section applies, not being equipment, by means of or in relation to which the officer reasonably believes an offence against this Act or against any regulations made under this Act has been committed:

(j) Seize and detain any advertising material or labelling material that contravenes or does not comply with the requirements of this Act or any regulations made under this Act:

(k) Take photographs of any premises or vehicle, or any article to which this section applies, or any other thing, where or by means of or in relation to which the officer reasonably believes an offence against this Act or against any regulations made under this Act has been committed.

(3) On demand by any person in any premises or vehicle, or claiming any interest in any article, in or in respect of which any power is exercised under this section, the officer exercising the power shall identify himself and produce evidence that he is an officer.

(4) [Repealed]

Further provisions relating to seizure and detention of articles

(1) If any officer seizes any article under section 63 of this Act in any premises or vehicle that is not in the occupation or use of the owner of the article, he shall forthwith give notice in writing of the seizure to the owner, or to the consignor or consignee, or to the agent of the owner, of the article, if his name and address are on or attached to the article or are otherwise known to the officer, and the address is that of a place in New Zealand.

(2) Subject to subsection (3) of this section, where any article is seized under paragraph (i) or paragraph (j) of section 63(2) of this Act, it may, at the option of the officer concerned, be detained in the premises or vehicle where it was ordered to be seized, or removed to another place and detained there, at the expense of the owner at the time of the seizure.

(3) An officer shall release any article seized by him under section 63 of this Act when he is satisfied—

(a) That all the provisions of this Act and of any regulations made under this Act, to the extent that they are material, have been complied with in respect of the article; and

(b) That the article is fit for the purpose for which it is intended to be sold or used.

(4) If, within the time limited by section 65(1) of this Act, the seized article has not been released and no application for disallowance of that seizure has been made under that section or any such application has been dismissed, the article shall become the property of the Crown; and the owner of the article at the time of the seizure shall be liable for any costs or expenses incurred in the disposition of that article.

(5) Without prejudice to the owner's liability under subsections (2) and (4) of this section, where the article was, at the time of the seizure, in the possession of a person who was not the owner and the identity of the owner is not known to the officer, the person in whose possession the article was at that time shall be liable for any costs and expenses incurred in the detention, removal, or disposition of that article.
(6) If any article seized under section 63 of this Act is not destroyed or otherwise disposed of under this section, it shall be returned to the person from whom it was seized when the officer concerned is satisfied of the matters referred to in subsection (3) of this section.

**District Court may order return of property or compensation**

(1) Any person claiming an interest in any substance or article seized under section 63(2)(i) of this Act, may, within 7 days thereafter, apply to a District Court for an order—

(a) That the seizure be disallowed and that the article be returned or otherwise made available to him:

(b) That the Crown shall pay to him such sum by way of compensation for any depreciation in the value of the substance or article resulting from its seizure, detention, or removal as the Court thinks fit.

(2) On any such application, the Court may dismiss it, or, subject to subsections (3) and (4) of this section, order—

(a) That the seizure be disallowed in whole or in part; or

(b) That the detention of the substance or article be terminated in whole or in part; or

(c) That compensation be paid by the Crown for any depreciation in the value of the substance or article resulting from its seizure, detention, or removal, and any transport and storage costs,—

and any such order may be made upon and subject to such terms and conditions as the Court thinks fit.

(3) No order that the seizure of the substance or article be disallowed or that the detention of the substance or article be terminated in whole or in part shall be made if the Court is of the opinion that the purpose to which that substance or article or that part is intended to be put will probably involve the commission of an offence against this Act, or any regulation made under this Act, or that the continued detention of that substance or article or that part is expedient for the purpose of its production in any pending proceedings under this Act.

(4) No order for the payment of compensation shall be made except in respect of a substance or article or part that, in the opinion of the Court, ought not to have been seized or continued to be detained, as the case may be, and except to the extent that the Court disallows the seizure or terminates the detention.

(5) Where the Court makes an order for the payment of any sum by way of compensation to any person under this section, the sum so awarded shall be recoverable by that person as a debt due from the Crown.

(6) Every application to the Court under this section shall be made and dealt with by way of originating application filed in the office of the Court nearest to the place where the substance or article in dispute was seized or ordered to be detained.

(7) The applicant shall serve notice of his application on the respondent on or before the date on which he files it in the Court.

(8) Except as modified by subsections (6) and (7) of this section, the rules of procedure for the time being in force under the District Courts Act 1947 shall apply with respect to every application to the Court under this section.

(9) Every order made by the Court under this section shall be final and binding on all parties.
(10) Nothing in this section shall limit or affect the Customs and Excise Act 1996 or any other enactment.

Powers to require information

(1) Without limiting section 63 of this Act, where the Director-General or a Medical Officer of Health reasonably suspects that any person is in possession—

(a) Of any medicine or medical device for the purpose of sale; or
(b) Of any substance or article for the purpose of the manufacture, packing, sale, or supply of any medicine or medical device; or
(c) Of any advertising material or labelling material for use as an advertisement or label,—

in breach of this Act or of any regulations made under this Act, he may require that person to produce for his inspection, or to produce to any officer specially authorised by him for the purpose, any books, documents, or other records dealing with the importation, purchase, reception, manufacture, packing, storage, carriage, delivery, sale, or supply of any such medicine, medical device, substance, article, or material.

(2) The Director-General or the Medical Officer of Health may make or cause to be made copies of or extracts from any such books, documents, or other records, and the copies of extracts, certified as such by him or by any specially authorised officer, shall be deemed to be true and correct copies or extracts, unless the contrary is proved.

(3) Every person commits an offence against this Act who refuses or fails to comply with any requisition made pursuant to this section.

(4) [Repealed]

(5) For the purposes of this section, any goods that have been seized or ordered to be detained, whether pursuant to this Act or any other enactment, shall be deemed to be still in the possession of the person who had them in his possession when they were seized or ordered to be detained.

Obstruction of officers

(1) Every person commits an offence against this Act who willfully obstructs, hinders, resists, or deceives any officer in the execution of any powers conferred on that officer by or under this Act.

(2) Without limiting subsection (1) of this section, every person shall be deemed to have obstructed an officer if—

(a) Except with the authority of an officer or under an order of a Court, he removes, alters, or interferes in any way with any article seized or detained under this Act; or

(b) Except with the authority of an officer or of an analyst or under an order of a Court, he erases, alters, opens, breaks, or removes any mark, seal, or fastening placed by an officer under this Act on any sample or part of a sample procured under this Act, other than a part of a sample or bottle or container left with the owner of the medicine from which the sample was taken or the person from whom the sample was procured; or
(c) He refuses to sell to an officer, or to allow an officer to take, in the quantity that the officer reasonably requires as a sample, any medicine that appears to the officer to be intended for sale or to have been sold, or any advertising material or labelling material, that appears to the officer to be intended for use in connection with the sale of any article to which section 63 of this Act applies or to have been so used; or

(d) He refuses or fails to give an officer any assistance that that officer may reasonably require him to give, or to give to an officer any information, or to produce or permit an officer to examine and make copies of and extracts from any books, documents, or other records, that that officer is expressly authorised by this Act to require to be given or produced or to examine or make, or may reasonably require to be given or produced or to examine or make, or when required to give any such information or to produce any such books, documents, or other records, knowingly makes any false statement in respect thereof.

Penalty for false statement

(1) Every person commits an offence against this Act who, for the purpose of obtaining, whether for himself or for any other person, the grant of any licence under this Act, or for any other purposes in relation to this Act,—

(a) Make any declaration or statement that he knows is false in any particular; or

(b) Utters, produces, or makes use of any such declaration or statement, or any document containing the same; or

(c) Utters, produces, or makes use of any document that he knows is not genuine.

(2) Every person who commits an offence against this section is liable to imprisonment for a term not exceeding 6 months or a fine not exceeding $1,000.

Offences in relation to authorised prescribers

Every pharmacist, person licensed to operate a pharmacy, or operator or manager of a pharmacy commits an offence against this Act who gives, offers, or agrees to give to any authorised prescriber or to any other person any money or other consideration as a commission on prescriptions.

Jurisdiction of District Courts

(1) Every offence against this Act or against any regulations made under this Act shall be punishable on summary conviction.

(2) Notwithstanding anything in section 14 of the Summary Proceedings Act 1957, any information in respect of any offence against this Act or against any regulations made under this Act may be laid at any time within 1 year after the time when the matter of the information arose.

(3) The summons in any such proceedings shall not be made returnable in less than 14 days from the day on which it is served.

(4) There shall be served with the summons in any such proceedings a copy of the analyst's certificate or report (if any) relating to the prosecution.
General penalty

Every person who commits any offence against this Act for which no penalty is provided elsewhere than in this section is liable to imprisonment for a term not exceeding 3 months or a fine not exceeding $500, and, if the offence is a continuing one, to a further fine not exceeding $50 for every day or part of a day during which the offence has continued.

Liability of principal for acts of agents, etc

(1) Where an offence is committed against this Act or against any regulations made under this Act by any person acting as the agent or employee of another person, that other person shall, without prejudice to the liability of the first-mentioned person, be liable under this Act in the same manner and to the same extent as if he had personally committed the offence.

(2) Notwithstanding anything in subsection (1) of this section, where any proceedings are brought by virtue of that subsection it shall be a good defence to the charge if the defendant proves that the offence was committed without his knowledge and that he took all reasonable steps to prevent the commission of the offence.

(3) Where any body corporate is convicted of an offence against this Act or against any regulations made under this Act, every director and every person concerned in the management of the body corporate shall be guilty of a like offence if it is proved that the act that constituted the offence took place with his authority, permission, or consent, or that he knew the offence was to be or was being committed and failed to take all reasonable steps to prevent or stop it.

Strict liability

(1) In any prosecution for selling a medicine or medical device contrary to any provision of this Act or of any regulation made under this Act, it shall not be necessary for the prosecution to prove that the defendant intended to commit an offence.

(2) Subject to subsection (3) of this section, it shall be a good defence in any such prosecution if the defendant proves—

(a) That he did not intend to commit an offence against this Act or any regulations made under this Act; and
(b) That he took all reasonable steps to ensure that the sale of the article would not constitute any such offence.

(3) Except as provided in subsection (4) of this section, subsection (2) of this section shall not apply unless, within 7 days after the service of the summons, or within such further time as the Court may allow, the defendant has delivered to the prosecutor a written notice—

(a) Stating that he intends to rely on subsection (2) of this section; and
(b) Specifying the reasonable steps that he will claim to have taken.

(4) In any such prosecution, evidence that the defendant took a step not specified in the written notice required by subsection (3) of this section shall not, except with the leave of the Court, be admissible for the purpose of supporting a defence under subsection (2) of this section.
Further defences

(1) Subject to subsections (2) and (4) of this section, it shall be a good defence in a prosecution for selling or supplying any medicine or medical device contrary to any provision of this Act or any regulations made under this Act if the defendant proves—

(a) That he purchased the article sold or supplied by him in reliance on a written warranty or other written statement as to the nature of the article purchased, signed by or on behalf of the person from whom the defendant purchased the article; and

(b) That if the article had truly conformed to the warranty or statement, the sale or supply of the article by the defendant would not have constituted the offence charged against him; and

(c) That he had no reason to believe or suspect that the article sold or supplied by him did not conform to the warranty or statement; and

(d) That at the time of the commission of the alleged offence, the article was in the same state as it was when he purchased it.

(2) No warranty or statement shall be any defence under this section unless—

Liability of persons named on labels

(1) If any medicine or medical device is sold or supplied in the container in which it was enclosed when purchased by the person who sells or supplies the substance or article, and which has not since that purchase been opened by that person or any agent or employee of that person, every person who appears from any statement or label on or attached to the container to be—

(a) The person who has manufactured, imported, or packed the medicine or medical device; or
(b) The person who is the owner of the rights of manufacture of the medicine or medical device, or who has packed it; or
(c) The agent of any such person,—

shall, unless he proves the contrary, be deemed to have so manufactured, imported, or packed the medicine or medical device, or, as the case may require, to be the agent of such a person, and shall be liable in the same manner and to the same extent as if he had actually sold or supplied the medicine or medical device at the time and place at which the sale or supply was made, and, if that sale or supply involved the commission of an offence against this Act, he shall be deemed to be a party to that offence.

(2) Subject to subsection (3) of this section, it shall be a defence in a prosecution under subsection (1) of this section if the defendant proves—

(a) In the case of a prosecution relating to the condition of a medicine or medical device, that when the container left his possession, the medicine or medical device was in such a condition that its sale or supply then would not have involved the commission of the offence with which he is charged; or

(b) In the case of a prosecution relating to manufacture, packing, or labelling, that the offence with which he is charged arises from an alteration made to the container or labelling since the container left his possession.
(3) Subsection (2) of this section shall not apply unless, within 7 days after the service of the summons, or within such further time as the Court may allow, the defendant has delivered to the prosecutor a written notice—

(a) Stating that he intends to rely on subsection (2) of this section; and
(b) Identifying the person to whom the defendant consigned or delivered the medicine or medical device or explaining why the defendant is unable to identify that person.

(4) Nothing in subsection (1) of this section shall apply in respect of any offence against section 17 or section 18 of this Act.

(a) It was given or made by or on behalf of a person resident in New Zealand or a company having a registered office in New Zealand or a firm having a place of business in New Zealand; and

(b) The signature to the warranty or statement is written by hand; and

(c) The defendant proves that at the time he received the warranty or statement he took reasonable steps to ascertain, and did in fact believe, that the signature was that of the person from whom he purchased the article, or, as the case may be, of some person purporting to sign on behalf of the person from whom the defendant purchased the article.

(3) Subject to subsection (4) of this section, it shall be a good defence in a prosecution for selling or supplying any medicine or medical device contrary to any provision of this Act or of any regulations made under this Act if the defendant proves—

(a) That he purchased the article sold or supplied by him in a container and sold or supplied in the same container and in the same condition as the article was in at the time when he purchased it; and

(b) That he could not with reasonable diligence have ascertained that the sale or supply of the article would constitute the offence charged against him.

(4) Neither subsection (1) nor subsection (3) of this section shall apply unless, within 7 days after the service of the summons, or within such further time as the Court may allow, the defendant has delivered to the prosecutor a copy of the warranty or statement, if any, and a written notice to the effect that he intends to rely on it or on subsection (3) of this section, as the case may require, and specifying the name and address of the person from whom he received the warranty or statement or container, and has also, within the same time, sent by post a like notice of his intention to that person.

(4) Where the defendant is an agent or employee of the person who purchased the article under such a warranty or statement or in such a container, he shall be entitled to the benefit of this section in the same manner and to the same extent as his principal or employer would have been if he had been the defendant.

Cancellation of licence

(1) In any case where a licensee is convicted of an offence against this Act, or against any regulations made under this Act, the Court may, in addition to or instead of imposing any other penalty,—

(a) Cancel the licence, either forthwith or with effect from such future date as may be specified by the Court;

(b) Disqualify the licensee from obtaining any new licence for such period as the Court may specify:
(c) Cause particulars of the conviction, and of any order made under paragraph (a) or paragraph (b) of this subsection to be endorsed on the licence.

(2) When a Court cancels a licence pursuant to subsection (1) of this section, the licence shall cease to have effect either forthwith or on the date specified by the Court, as the case may require.

(3) When a Court, pursuant to subsection (1) of this section, disqualifies a person from obtaining a new licence, no licence shall be issued to that person during the period specified by the Court.

(4) Any licence cancelled or required by the Court for endorsement under this section shall be produced by the licensee in such manner and within such time as the Court directs.

(5) Every person commits an offence against this Act who, without reasonable excuse, fails to produce any licence in accordance with subsection (4) of this section.

(6) For the purposes of Part 4 of the Summary Proceedings Act 1957, the cancellation or endorsement of a licence, or a disqualification, under this section shall be deemed to be a sentence or part of a sentence, as the case may be.

(7) The particulars of any cancellation, disqualification, or endorsement under this section, and the particulars of the conviction relating thereto, shall be notified in writing to the Director-General by the Registrar of the Court.

Payment of expenses of analysis on conviction

(1) Where any person is convicted of an offence against this Act or any regulations made under this Act, the Court may order that all fees and other expenses incidental to the analysis of any medicine in respect of which the conviction is obtained shall be paid by the defendant.

(2) All such fees and expenses shall be deemed to be part of the costs attending the conviction, and shall be recoverable accordingly.

Forfeiture on conviction

(1) Where any person is convicted of an offence against this Act or any regulations made under this Act, the Court may order that any medicine or medical device, or any advertising material or labelling material, to which the conviction relates, and any similar medicine, medical device, or material found on the premises of the defendant or in the defendant's possession at the time of the offence, together with all packages or containers containing the medicine, medical device, or material, shall be forfeited to the Crown.

(2) Everything so forfeited to the Crown shall be disposed of as the Minister directs.

Courts may order withdrawal of goods from circulation

(1) If any person who manufactures, packs, or imports medicines of any description, or medical devices of any kind, is convicted of an offence against section 61 of this Act in respect of medicines of that description, or medical devices of that kind, the Court may in its discretion order that person to withdraw from sale all medicines of that description, or medical devices of that kind, until the matter in relation to which the offence was committed has been remedied.
(2) If the Court makes an order under subsection (1) of this section, the Director-General shall cause particulars of the order and of the offence in relation to which the order was made to be published in the Gazette; and thereupon every distributor, wholesaler, or retailer who has possession of any medicines of the same description, or medical devices of the same kind, that are packed and labelled in the same way as the medicines or medical devices in relation to which the offence was committed shall withdraw them from sale, and may—

(a) Return them to the person who supplied them; or

(b) Remedy the matter in relation to which the offence was committed.

(3) Every distributor, wholesaler, or retailer who takes action in accordance with paragraph (a) or paragraph (b) of subsection (2) of this section may recover all the costs and expenses incurred in so acting (including, if action is taken under the said paragraph (a), the purchase price of the medicines or medical devices) from the person who supplied them as a debt due by that person to the distributor, wholesaler, or retailer.

(4) Without limiting subsection (1) of this section, if any person referred to in that subsection is convicted of an offence against any of the provisions of sections 57, 58, and 61 of this Act in respect of any container, or of any advertising material or labelling material, the Court may in its discretion order that person to withdraw from use all containers or material of the same description until the matter in relation to which the offence was committed has been remedied; and in any such case subsections (2) and (3) of this section shall apply with any necessary modifications.

(5) Where any person referred to in subsection (1) of this section is convicted of an offence against any of sections 57, 58, and 61 of this Act, the Director-General may cause particulars of the offence and a description of the substances or articles in relation to which the offence was committed to be published in the Gazette.

Right of appeal to High Court

(1) Subject to subsections (2) and (3) of this section, any person who is aggrieved by—

(a) A decision of the Minister refusing, revoking, or suspending any consent or approval, or imposing, varying, or adding to any conditions, under any of sections 20, 23, 24, and 35 of this Act; or

(b) A decision to issue a notice under section 36(3) or section 37(1) of this Act, or the imposition, variation, or addition of conditions under that section; or

(c) A decision of the Medicines Review Committee made under section 88 of this Act,—

may appeal to the High Court.

(2) The grounds on which an appeal may be brought under subsection (1) of this section are—

(a) That any relevant requirement of this Act or of any regulations made under this Act has not been complied with:

(b) That the decision that is the subject of the appeal is unreasonable.
(3) Every appeal under subsection (1) of this section shall be commenced **within 28 days** after the date on which notice of the decision that is the subject of the appeal has been given to the person seeking to bring the appeal, or within such extended time as the Court may allow.

(4) [Repealed]

(5) Subject to subsection (6) of this section, on any appeal under subsection (1) of this section, the Court may—

(a) By interim order, suspend the operation of the decision to which the appeal relates until the final determination of the proceedings;

(b) Dismiss the appeal, or make such modifications in the decision to which the appeal relates as it thinks fit, or quash the decision with or without substituting a new decision in its place.

(6) The Court shall not quash or modify the decision to which the appeal relates on any ground other than a ground specified in subsection (2) of this section.

**Proceedings before Court**

(1) At the hearing of an appeal under section 89 of this Act, the Court shall hear all evidence tendered and representations made by or on behalf of the parties that the Court considers relevant to the subject-matter of the appeal.

(2) The Court may, at any such hearing, receive as evidence any statement, document, information, or matter that may, in its opinion assist it to deal effectually with the matters before it, whether or not it would be otherwise admissible in a Court of law.

(3) For the purpose of modifying any decision of the Medicines Review Committee, or substituting a new decision, the Court shall have all the powers and discretions that the Medicines Review Committee had in respect of the same matter.

(4) The Court in its discretion may, having regard to the interests of all parties concerned and to the public interest, order that the hearing or any part of it shall be held in private.

(5) Subject to the provision of this Act, the procedure in respect of any appeal under section 89 of this Act shall be in accordance with rules of Court.

**Power of Court to restrict publication of name of medicine**

(1) Where, in the course of proceedings in any Court or before a Coroner, reference is made to any medicine, the Court or Coroner may, in its or his discretion, order that the name of that medicine shall not be published in relation to those proceedings at any time before the expiration of a 5 years from the date of the final disposal of those proceedings.

(2) Notwithstanding anything in subsection (1) of this section, no order made under that subsection shall apply to the publication of that name to scientists or to members of the legal, medical, dental, veterinary, nursing, or pharmaceutical professions, or to persons studying to become scientists or members of those professions, or to designated prescribers, or in any publication of a scientific or technical character intended solely or principally for circulation among scientists or members of those professions or persons so studying.
(3) Where the publication of the name of a medicine is prohibited under this section in relation to any proceedings, no person shall, within the said period of 5 years, publish the name of that medicine or any name or particulars likely to lead to the identification of the description or class of medicine as the description or class of medicine to which the medicine referred to in those proceedings belonged.

(4) Nothing in this section shall limit the provisions of any other enactment relating to the prohibition or regulation of the publication of reports or particulars relating to any judicial proceedings.

(5) Every person commits an offence against this Act who contravenes subsection (3) of this section.

(3) Where the publication of the name of a medicine is prohibited under this section in relation to any proceedings, no person shall, within the said period of 5 years, publish the name of that medicine or any name or particulars likely to lead to the identification of the description or class of medicine as the description or class of medicine to which the medicine referred to in those proceedings belonged.

(4) Nothing in this section shall limit the provisions of any other enactment relating to the prohibition or regulation of the publication of reports or particulars relating to any judicial proceedings.

(5) Every person commits an offence against this Act who contravenes subsection (3) of this section.

(3) Where the publication of the name of a medicine is prohibited under this section in relation to any proceedings, no person shall, within the said period of 5 years, publish the name of that medicine or any name or particulars likely to lead to the identification of the description or class of medicine as the description or class of medicine to which the medicine referred to in those proceedings belonged.

(4) Nothing in this section shall limit the provisions of any other enactment relating to the prohibition or regulation of the publication of reports or particulars relating to any judicial proceedings.

(5) Every person commits an offence against this Act who contravenes subsection (3) of this section.


5.8 SOUTH AFRICA

GENERAL REGULATIONS MADE IN TERMS OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT NO. 101 OF 1965), AS AMENDED

32. SEIZURE OF MEDICINES

32.1 A medicine may be seized if it-
(a) is unregistered and sold in contravention of the Act;
(b) is suspected counterfeit;
(c) is misbranded;
(d) has expired;
(e) is suspected stolen;
(f) is Scheduled and is possessed by an unauthorised person or by an authorised person but in unauthorised quantities;
(g) has been declared undesirable in terms of the Act;
(h) belongs to the State and is found possessed by an unauthorised person; or
(i) is used in unauthorised clinical trial.

32.2 An inspector seizing any item in terms of section 28 (1) (c) of the Act shall as soon as possible and at the scene of seizure make a written inventory of all items seized and the inventory shall include:

(a) the date, place and time of seizure;
(b) the name and personal details of the person from whom the items were seized;
(c) the name and quantity of every item seized; and
(d) the name of the inspector conducting the seizure.

32.3 An item contemplated in section 28 (1) (c) of the Act may be used as evidence in any criminal proceedings in terms of this Act.

32.4 An inspector taking any sample in terms of section 28 (1) (d) shall make a written inventory of all samples taken which shall include:

(a) the date on which, the place where and time when the sample was taken;
(b) a description of nature and size of each sample taken;
(c) the personal details of the person in whose presence the samples were taken; and
(e) the name of the inspector taking the sample.

39. INVESTIGATIONS

39.1 The Council may conduct an investigation with regard to a medicine if-
(a) such a medicine is recalled in South Africa or any other country;
(b) adverse reaction is reported;
(c) the medicine is suspected or found not to comply with the requirements of the Act;
(d) there is an international alert with regard to such a medicine; or
(e) for any other reason, the Council deems it fit to conduct an investigation on the medicine

42. OFFENCES AND PENALTIES

42.1 Any person who fails to comply with, contravenes the provisions of or wilfully furnishes incorrect information in respect of -

(a) Regulation 7(1)(c) or (d) with regard to the parallel importation of medicines;
(b) Regulation 8 with regard to the labelling of medicines for human use;
(c) Regulation 9 with regard to the package inserts;
(d) Regulation 10 with regard to the patient information leaflet;
(e) Regulation 11 with regard to the prescription book;
(f) Regulations 12 or 13 with regard to the importation or transmission of medicines;
(g) Regulation 14 with regard to the permits issued in terms of section 22A(9) of the Act;
(h) Regulation 15 with regard to the importation or exportation of specified Schedule 5, Schedules 6, or 8 substances;
(i) Regulation 16 with regard to the possession of specified quantities of Schedule substances for personal medicinal use by persons entering or departing from the Republic;
(j) Regulation 17 with regard to the information to be furnished annually to the Registrar by the holder of a permit to import or export Schedules 6 & 7 substances;
(k) Regulation 18 with regard to the licence to compound and dispense medicines;

(l) Regulation 19 with regard to the licence to manufacture, act as a wholesaler or distributor of medicines;
(m) Regulation 27 with regard to the destruction of medicines;
(n) Regulation 28 with regard to the particulars which must appear on a prescription or order for medicine;
(o) Regulation 29 with regard to the returns to be furnished in respect of specified Schedule 5, Schedules 6, 7 and 8 medicines and specified substances;
(p) Regulation 30 with regard to the register of schedule 5 & 6 medicines
(q) Regulation 34 with regard to the conduct of clinical trials;
(r) Regulation 40 with regard to the package inserts for veterinary medicines;
(s) Regulation 45 with regard to the advertising of medicines; or
(t) Regulation 48 with regard to the labelling of veterinary medicines; or sells a medicine that has expired, shall be guilty of an offence and upon conviction be liable to a fine, or to imprisonment for a period not exceeding 10 years.

43. COMPLIANCE WITH REQUIREMENTS

43.1 Every medicine shall comply with the standards and specifications which were furnished to the Council on the form prescribed by regulation 22 and which have been accepted by the Council in regard to such medicine.

43.2 Any proposed deviation from accepted standards and specifications as intended in subregulation (1) shall be submitted to the Council for prior approval and such deviation shall not be introduced before the said approval has been granted

Devi Ahilya Vishwavidyalaya Indore
MEDICINE AND RELATED SUBSTANCES ACT 101 OF 1965

22E Suspension and cancellation of licence

1. If the holder of a licence under section 22C-

(a) has in or in connection with an application for a licence or renewal of a licence furnished the Director-General or the council, as the case may be, with any information which to the knowledge of such holder is untrue or misleading in any material respect;

(b) has contravened or failed to comply with a condition upon which the licence was issued;

(c) has contravened or failed to comply with a provision of this Act;

(d) has, in the case of a licence issued in terms of section 22C(1)(a), at any time been convicted of an offence which is of such a nature that, in the opinion of the Director-General, it renders him or her unsuitable to compound or dispense medicines, the Director-General or the council, as the case may be, may by way of a notice in writing call upon him or her to show cause within the period specified in the notice, which period shall not be less than 20 days as from the date of the notice, why the licence in question should not be suspended or revoked.

2. The Director-General or the council, as the case may be, may after considering the reasons furnished to him or her in terms of subsection (1)-

(a) suspend the licence in question for such period as he or she or the council may determine; or

(b) revoke the licence in question.

3. No person shall be entitled to the repayment of any prescribed fee in respect of any application for the granting or renewal of a licence if such application has been refused or if the licence has been suspended or revoked.

29. Offences

Any person who-

(a) obstructs or hinders any inspector in the exercise of his or her powers or the performance of his or her duties under this Act; or

(b) contravenes or fails to comply with the provisions of section 14(1), 18, 18A or 18B; or

(c) contravenes the provisions of section 19(1) or fails to comply with a notice issued under section 19(2); or

(d) contravenes the provisions of section 20(1); or

(e) contravenes or fails to comply with any condition imposed under section 15(7); or

(f) fails to comply with any direction given under section 23 or contravenes the provisions of section 23(3); or

(g) with fraudulent intent tampers with any sample taken in terms of this Act; or

(h) makes any false or misleading statement in connection with any medicine or Scheduled substance-

(i) in an application for the registration thereof; or
(ii) in the course of the sale thereof; or
(i) sells any medicine or Scheduled substance upon the container of which a false or misleading statement in connection with the contents is written; or
(l) for purposes of business or trade makes use of any report or certificate made or issued by an inspector, analyst, pharmacologist or pathologist under this Act; or
(k) contravenes any provision of section 22A, 22C (5) and (6), 22F, 22G or 22H or contravenes or fails to comply with any condition imposed thereunder;
(l) contravenes or fails to comply with the provisions of section 34;
(m) manufactures, sells or uses a veterinary medicine in contravention of a prohibition referred to in section 36A, or contravenes, or fails to comply with, a condition imposed in terms of the said section, shall be guilty of an offence.

30. Penalties

1. Any person who is convicted of an offence referred to in section 29 shall be liable to a fine, or to imprisonment for a period not exceeding 10 years.

2. The court convicting any person of an offence under this Act may, upon the application of the prosecutor, declare any medicine or Scheduled substance in respect of which the offence has been committed to be forfeited to the State.

3. Any medicine or Scheduled substance forfeited under this Act shall be destroyed or otherwise dealt with as the Director-General may direct.

4. Notwithstanding anything to the contrary in any law contained, a magistrate's court shall be competent to impose any penalty provided for in this section.

31. Procedure and evidence

1. In any criminal proceedings under this Act-

(a) any quantity of a medicine or Scheduled substance in or upon any premises, place, vehicle, vessel or aircraft at the time a sample thereof is taken pursuant to the provisions of this Act shall, unless the contrary is proved, be deemed to possess the same properties as such sample;

(b) ... ........

(c) a certificate stating the result of a test, examination or analysis carried out in terms of the provisions of section twenty-eight and purporting to be signed by the analyst, pharmacologist or pathologist who carried out such test, examination or analysis, shall be accepted as prima facie proof of the facts stated therein;

(d) any statement or entry contained in any book, record or document kept by any owner of a medicine or Scheduled substance, or by the manager, agent or employee of such owner or found upon or in any premises occupied by, or any vehicle used in the business of, such owner, shall be admissible in evidence against him as an admission of the facts set forth in that statement or entry, unless it is proved that that statement or entry was not made by such owner, or by any manager, agent or employee of such owner in the course of his work as manager, or in the course of his agency or employment.

2. ..........

3. The court in which any such certificate is adduced in evidence may in its discretion cause the person who signed such certificate to be summoned to give oral evidence in the proceedings in question or may
cause written interrogatories to be submitted to him for reply, and such interrogatories and any reply thereto, purporting to be a reply from such person, shall be admissible in evidence in such proceedings.

32. Special defences in case of prosecutions

33. Act or omission by manager, agent or employee

1. Whenever any manager, agent or employee of any person (hereinafter called the employer) does or omits to do any act which it would be an offence under this Act for the employer to do or omit to do, then unless it is proved that-

(a) in doing or omitting to do that act the manager, agent or employee was acting without the connivance or the permission of the employer; and

(b) all reasonable steps were taken by the employer to prevent any act or omission of the kind in question; and

(c) it was not under any condition or in any circumstances within the scope of the authority or in the course of the employment of the manager, agent or employee to do or omit to do acts, whether lawful or unlawful, of the character of the act or omission charged, the employer shall be presumed himself to have done or omitted to do that act and shall be liable to be convicted and sentenced in respect thereof; and the fact that he issued instructions forbidding any act or omission of the kind in question shall not, of itself, be accepted as sufficient proof that he took all reasonable steps to prevent the act or omission.

2. Whenever any manager, agent or employee of any such employer does or omits to do an act which it would be an offence under this Act for the employer to do or omit to do, he shall be liable to be convicted and sentenced in respect thereof as if he were the employer.

3. Any such manager, agent or employee may be so convicted and sentenced in addition to the employer

Medicines Control Council recommends suspension of the sale of the medicine: Simply Slim

Issued by the Department of Health

5 February 2010

It has come to the attention of the Medicines Control Council that the weight loss product SIMPLY SLIM may pose significant risks to the South African public. For this reason the Medicines Control Council (MCC) resolved to immediately suspend the sale of SIMPLY SLIM weight loss products in the country until further investigations and review can be completed. This decision was made during its meeting on 27 January 2010.

SIMPLY SLIM is a weight loss product that is not registered as a medicine by the MCC as it is being promoted and sold as a complementary herbal weight loss product. It is being sold at various retail outlets including health shops and pharmacies and is being actively marketed to consumers as a weight loss product.
5.9 NIGERIA

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL ACT (AS AMENDED)
DRAFT CHEMICAL AND CHEMICAL PRODUCTS REGULATIONS

In exercise of the powers conferred on the Governing Council of the National Agency for Food And Drug Administration and Control (NAFDAC) by sections 5 and 29 of the National Agency for Food And Drug Administration and Control Act as amended and of all the powers enabling it in that behalf, the Governing Council of the NAFDAC with the approval of the Honourable Minister of Health hereby makes the following Regulations:-

Penalty

10(a) A person who contravenes a provision of these regulations is guilty of an offence and liable on conviction:

(b) In the case of an individual, to a fine not exceeding N 50,000.00 or to imprisonment for a term not exceeding two years or to both fine and imprisonment.

(ii) In the case of body corporate, to a fine not exceeding N 100,000.00

(c) Where an offence under this regulation is committed by a corporate or firm or other association of individuals:

(i) every director, manager, secretary or other similar officer of the body corporate; or
(ii) every partner or officer of the firm; or
(iii) every trustee of the body concerned; or
(iv) every person concerned in the management of the affairs of the association; or
(v) every person who was purporting to act in a capacity referred to in this paragraph, is severally guilty of that offence and liable to be proceeded against and punished for that offence in the same manner as if he had himself committed the offence unless he proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

Forfeiture

11. In addition to the penalty specified in paragraph 10 of these regulations, a person convicted of an offence under these regulations shall forfeit to the Agency the malt products and whatever is used in connection with the commission of the offence. (www.nafdacnigeria.org)

END OF CHAPTER 05

And

V O L U M E 01