LAWS OF KENYA

FOOD, DRUGS AND CHEMICAL SUBSTANCES ACT

CHAPTER 254

Published by the National Council for Law Reporting
with the Authority of the Attorney-General
www.kenyalaw.org
CHAPTER 254

FOOD, DRUGS AND CHEMICAL SUBSTANCES ACT

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PART I – PRELIMINARY

1. Short title

This Act may be cited as the Food, Drugs and Chemical Substances Act.

2. Interpretation

In this Act, except where the context otherwise requires—

“advertisement” includes any representation by any means whatsoever for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic, device or chemical substance;

“article” includes—

(a) any food, drug, cosmetic, device or chemical substance and any labelling or advertising materials in respect thereof;

(b) anything used for the preparation, preservation, packing or storing of any food, drug, cosmetic, device or chemical substance;

“authorized officer” means a medical officer of health, a public health officer or any suitably qualified person authorized in writing by a municipal council for the purposes of this Act, and—

(a) for the purpose of any provision of this Act relating to the taking of samples, includes a police officer of or above the rank of sub-inspector;

(b) for the purpose of section 29, includes a Veterinary Surgeon registered or licensed under the Veterinary Surgeons Act (Cap. 366);

(c) for the purpose of any proceedings under section 35 of this Act, includes the clerk of a municipal council;

“Board” means the Public Health (Standards) Board established by section 27;

“chemical substance” means any substance or mixture of substances prepared, sold or represented for use as—

(a) a germicide;

(b) an antiseptic;

(c) a disinfectant;
(d) a pesticide;
(e) an insecticide;
(f) a rodenticide;
(g) a vermicide; or
(h) a detergent,

or any other substance or mixture or substances which the Minister may, after consultation with the Board, declare to be a chemical substance;

“container” includes any basket, pail, tray, package or receptacle of any kind, whether open or closed;

“cosmetic” includes any substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair, eyes or teeth, and includes deodorants and perfumes;

“device” means any instrument, apparatus or contrivance, including components, parts and accessories thereof, manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or the symptoms thereof, in man or animal;

“drug” includes—
(a) any substance included in any publication mentioned in the Schedule; and
(b) any substance or mixture of substances prepared, sold or represented for use in—
   (i) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or the symptoms thereof, in man or animal; or
   (ii) restoring, correcting or modifying organic functions in man or animal;

“food” includes any article manufactured, sold or represented for use as food or drink for human consumption, chewing gum, and any ingredient of such food, drink or chewing gum;

“insanitary conditions” means such conditions or circumstances as might contaminate food, a drug or a cosmetic with dirt or filth or might render the same injurious or dangerous to health;

“label” includes any legend, work or mark attached to, included in, belonging to or accompanying any food, drug, cosmetic, device or chemical substance;

“medical officer of health” means a person appointed as a medical officer of health in accordance with the Public Health Act (Cap. 242), and includes a deputy medical officer of health and an assistant medical officer of health so appointed;

“package” includes anything in which any food, drug, cosmetic, device or chemical substance is wholly or partly placed or packed;
“premises” includes any building or tent together with the land on which the same is situated and any adjoining land used in connection therewith, and includes any vehicle, conveyance or vessel;

“preparation” includes manufactured and any form of treatment, and “prepared” shall be construed accordingly;

“public analyst” means a person appointed by the Minister, or by a municipal council with the approval of the Minister, to act as an analyst for the purposes of this Act:

Provided that no person shall be appointed a public analyst for any area in which he is engaged directly in any trade or business connected with the sale of food, drugs, cosmetics, devices or chemical substances;

“public health officer” means any person for the time being lawfully appointed as such by the Minister or by a municipal council to be a public health officer;

“sell” includes offer, advertise, keep, expose, transmit, convey, deliver or prepare for sale or exchange, dispose of for any consideration whatsoever, or transmit, convey or deliver in pursuance of a sale, exchange or disposal as aforesaid;

“ship” includes any boat or craft;

“substance” includes liquid.

[Rev. 2012]
[Issue 1]

PART II – GENERAL PROVISIONS

A – Food

3. Prohibition against sale of unwholesome, poisonous or adulterated food

Any person who sells any food that—

(a) has in or upon it any poisonous or harmful substance; or

(b) is unwholesome or unfit for human consumption; or

(c) consists in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased substance or foreign matter; or

(d) is adulterated,

shall be guilty of an offence.

4. Deception

Any person who labels, packages, treats, processes, sells or advertises any food in contravention of any regulations made under this Act, or in a manner that is false, misleading or deceptive as regards its character, nature, value, substance, quality, composition, merit or safety, shall be guilty of an offence.

5. Standards of foods

Where a standard has been prescribed for any food, any person who labels, packages, sells or advertises any food which does not comply with that standard, in such a manner that it is likely to be mistaken for food of the prescribed standard, shall be guilty of an offence.
6. Prohibition against sale of food not of nature, substance or quality demanded

Any person who sells to the prejudice of the purchaser any food which is not of the nature, or is not of the substance, or is not of the quality, of the article demanded by the purchaser shall be guilty of an offence.

7. Preparation of food under insanitary conditions

Any person who sells, prepares, packages, conveys, stores or displays for sale any food under insanitary conditions shall be guilty of an offence.

8. Prohibited sale of drugs

Any person who sells any drug that—

(a) is adulterated; or

(b) consists in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased substance or foreign matter,

shall be guilty of an offence.

9. Deception

Any person who labels, packages, treats, processes, sells or advertises any drug in contravention of any regulations made under this Act, or in a manner that is false, misleading or deceptive as regards its character, constitution, value, potency, quality, composition, merit or safety, shall be guilty of an offence.

10. Standards of drugs

(1) Where a standard has been prescribed for a drug, any person who labels, packages, sells or advertises any substance in such a manner that it is likely to be mistaken for that drug shall be guilty of an offence unless the substance is the drug in question and complies with the prescribed standard.

(2) Where a standard has not been prescribed for a drug but a standard for the drug is contained in any of the publications specified in the Schedule, any person who labels, packages, sells or advertises any other substance or article in such a manner that it is likely to be mistaken for such drug shall be guilty of an offence.

(3) Any person who labels, packages, sells or advertises any drug for which no standard has been prescribed, or for which no standard is contained in any of the publications specified in the Schedule, shall be guilty of an offence unless such drug—

(a) is in accordance with the professed standard under which it is labelled, packaged, sold or advertised; and

(b) does not resemble, in a manner likely to deceive, any drug for which a standard has been prescribed or which is contained in any of the publications specified in the Schedule.
11. Prohibition against sale of drugs not of nature, substance or quality demanded

Any person who sells to the prejudice of the purchaser any drug which is not of the nature, or is not of the substance, or is not of the quality, of the article demanded by the purchaser shall be guilty of an offence.

12. Preparation of drug under insanitary conditions

Any person who sells, prepares, preserves, packages, stores or conveys for sale any drug under insanitary conditions shall be guilty of an offence.

C – Cosmetics

13. Prohibited sale of cosmetics

Any person who sells any cosmetic that—

(a) has in or upon it any substance that may cause injury to the health of the user when the cosmetic is used—

(i) according to the directions on the label of or accompanying such cosmetic; or

(ii) for such purposes and by such methods of use as are customary or usual therefor; or

(b) consists in whole or in part of any filthy, disgusting, rotten, decomposed or diseased substance or of any injurious foreign matter; or

(c) was prepared, preserved, packed or stored under insanitary conditions,

shall be guilty of an offence.

14. Standards of cosmetics

Where a standard has been prescribed for a cosmetic, any person who labels, packages, sells or advertises any article in such a manner that it is likely to be mistaken for a cosmetic of the prescribed standard shall be guilty of an offence unless the article complies with the prescribed standard.

15. Preparation of cosmetic under insanitary conditions

Any person who sells, prepares, preserves, packages, conveys, stores or displays for sale any cosmetic under insanitary conditions shall be guilty of an offence.

D – Devices

16. Prohibited sale of devices

Any person who sells any device that, when used according to directions on the label or contained in a separate document delivered with the device or under such conditions as are customary or usual, may cause injury to the health of the purchaser or user thereof shall be guilty of an offence.
17. Deception

Any person who labels, packages, treats, processes, sells or advertises any device in contravention of any regulations made under this Act, or in a manner that is false, misleading or deceptive as regards its character, value, composition, merit or safety, shall be guilty of an offence.

18. Standards of devices

Where a standard has been prescribed for a device, any person who labels, packages, sells or advertises any article in such a manner that it is likely to be mistaken for that device shall be guilty of an offence unless the article complies with the prescribed standard.

19. Preparation of device under insanitary conditions

Any person who sells, prepares, preserves, packages, stores or conveys for sale any device under insanitary conditions shall be guilty of an offence.

20. Adulteration of chemical substances

Any person who sells any chemical substance that—

(a) is adulterated; or

(b) consists in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased substance or foreign matter,

shall be guilty of an offence.

21. Deception

Any person who labels, packages, treats, processes, sells or advertises any chemical substance in contravention of any regulations made under this Act, or in a manner that is false, misleading or deceptive as regards its character, value, quality, composition, merit or safety, shall be guilty of an offence.

22. Standards of chemical substances

Where a standard has been prescribed for a chemical substance, any person who labels, packages, sells or advertises any other substance in such a manner that it is likely to be mistaken for that chemical substance shall be guilty of an offence unless the substance complies with the prescribed standard for such chemical substance.

23. Professed standards

Any person who sells any chemical substance which—

(a) is not in accordance with the professed standard under which it is sold; and

(b) resembles in a manner likely to deceive any branded chemical substance sold under a professed standard,

shall be guilty of an offence.
24. Disposal of chemical substances in certain manner prohibited

Any person who uses or disposes of any chemical substance in a manner likely to cause contamination of food or water for human consumption or in a manner liable to be injurious or dangerous to the health of any person shall be guilty of an offence.

25. Prohibited sales of chemical substances

Any person who sells any chemical substance which, when used according to the instructions of the manufacturer or under such conditions as are customary or usual, might cause injury to the health of any person shall be guilty of an offence.

26. Preparation of chemical substances under insanitary conditions

Any person who sells, prepares, preserves, packages, stores or conveys for sale any chemical substance under insanitary conditions shall be guilty of an offence.

PART III – ADMINISTRATION AND ENFORCEMENT

27. Establishment of Board

(1) There is hereby established a Board, to be known as the Public Health (Standards) Board, which shall consist of ten members appointed by the Minister unless otherwise provided.

(2) The members of the Board shall be—

(a) a chairman, who shall be the Director of Medical Services, or a person deputed by him in writing for the purposes of this Act;

(b) a vice-chairman, who shall be the Chief Public Health Officer of the Ministry of Health and Housing, or a person deputed by him in writing for the purposes of this Act;

(c) four members appointed to represent the Government;

(d) one member with special knowledge of the food-packing industry;

(e) one member representing municipal councils;

(f) one member nominated by the Pharmaceutical Society of Kenya; and

(g) one member representing the National Assembly.

(3) All appointments made under this section shall be notified in the Gazette.

(4) The members of the Board appointed under paragraphs (d), (e), (f) and (g) of subsection (2)—

(a) shall each hold office for a period of three years, and shall then retire but shall be eligible for reappointment;

(b) may at any time resign by instrument in writing addressed to the chairman.

(5) The quorum of the Board shall be four.
(6) The Board may invite any person to attend any particular meeting for the purpose of assisting or advising the Board, but no such person shall have any right to vote at such meeting.

(7) Subject to this Act, and to any general or special directions in writing by the Minister, the Board shall regulate its own proceedings.


28. Regulations

(1) The Minister, after consultation with the Board, may make regulations—

(a) declaring that any food, drug or chemical substance or class of food, drugs or chemical substances is adulterated if any prescribed substances or class of substances is present therein or has been added thereto or extracted or omitted therefrom;

(b) respecting—

(i) the labelling and packing and the offering, exposing and advertising for sale of food, drugs, chemical substances, cosmetics and devices;

(ii) the size, dimensions and other specifications of packages of food, drugs, chemical substances, cosmetics and devices;

(iii) the sale or the conditions of sale of any food, drug, chemical substance, or cosmetic or device; and

(iv) the use of any substance as an ingredient in any food, drug, chemical substance or cosmetic or device, to prevent the consumer or purchaser thereof from being deceived or misled as to its quality, quantity, character, value, composition, effect, merit or safety or to prevent injury to the health of the consumer or to purchaser;

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

(d) respecting the importation or exportation of food, drugs, chemical substances, cosmetics and devices in order to ensure compliance with this Act and any regulations made thereunder;

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

(f) respecting the carriage of goods subject to the provisions of this Act, including the licensing of vehicles used in such carriage;

(g) requiring person who sell food, drugs, chemical substances, cosmetics or devices to maintain such books and records as the Board considers necessary for the proper enforcement and administration of this Act and any regulations made thereunder;

(h) requiring manufacturers of any drugs or chemical substances to submit test portions of any batch of such drugs or chemical substances;
(i) providing for the analysis of food, drugs, chemical substances, cosmetics or devices for the purposes of this Act or to for any other purpose and prescribing a tariff of fees to be paid for such analysis and for prescribing methods of analysis;

(j) providing for the taking of samples of any article for the purposes of this Act or for any other purpose;

(k) exempting any food, drug, cosmetic, chemical substance or device from all or any of the provisions of this Act and prescribing the conditions of such exemption.

(2) Where any regulations made under this Act or under the Public Health Act (Cap. 242) prohibit or restrict the addition of any preservative or other ingredient or material to any food, the addition of such preservative, ingredient or material, if made in contravention of the regulations, shall, for the purposes of this Act, be deemed to render the food injurious to health.

(3) Where any regulations made under this Act or under the Public Health Act (Cap. 242) prescribes the composition of any article of food intended for sale, or prohibit or restrict the addition of any preservative or other ingredient or material to any such article, the purchaser of such article shall, unless the contrary is proved, be deemed for the purposes of this section to have demanded an article complying with the provisions of the regulations as regards the presence or amount of any constituent, ingredient or material specified in the regulations.

(4) The Minister, after consultation with the Board, may make regulations generally for carrying any of the purposes or provisions of this Act into effect.

29. Inspection of animals by authorized officers

An authorized officer may, for the purposes of this Act, inspect any animal intended for slaughter and may seize and examine any meat which he considers to be unfit for consumption.

30. Powers of authorized officers

(1) An authorised officer may, at any hour reasonable for the proper performance of his duty—

(a) enter any premises where he believes any article to which this Act or any regulations made hereunder apply is prepared, preserved, packaged, stored or conveyed, examine any such article and take samples thereof, and examine anything that he believes is used or capable of being used for such preparation, preservation, packaging or storing or conveying;

(b) stop or search or detain any aircraft, ship or vehicle in which he believes that any article subject to the provisions of this Act is being conveyed and to examine any such article and take samples thereof for the purposes of this Act;

(c) open and examine any receptacle or package which he believes contains any article to which this Act or any regulations made thereunder apply;
(d) examine any books, documents, or other records found in any place mentioned in paragraph (a) of subsection (1) of this section that he believes contain any information relevant to the enforcement of this Act with respect to any article to which this Act or any regulations made hereunder apply and make copies thereof or take extracts therefrom;

(e) seize and detain for such time as may be necessary any article by means of or in relation to which he believes any provision of this Act or any regulations made thereunder has been contravened.

(2) An authorized officer acting under this section shall, if so required, produce his authority.

(3) Any owner, occupier or person in charge of any premises entered by an authorized officer pursuant to paragraph (a) of subsection (1) of this section, or any person found therein, who does not give to the authorized officer all reasonable assistance in his power and furnish him with such information as he may reasonably require, shall be guilty of an offence.

(4) Any person who obstructs or impedes any authorized officer in the course of his duties or by any gratuity, bribe, promise, or other inducement prevents, or attempts to prevent the due execution by the authorized officer of his duty under this Act or any regulations made hereunder shall be guilty of an offence.

(5) Any person who knowingly makes any false or misleading statement either verbally or in writing to any authorized officer engaged in carrying out his duties under this Act or any regulations made thereunder, shall be guilty of an offence.

(6) An authorized officer shall release any article seized by him under this Act when he is satisfied that all the provisions of this Act and any regulations made thereunder with respect thereto have been complied with.

(7) Where an authorized officer has seized an article under this Act and the owner thereof or the person in whose possession the article was at the time of seizure consents to the destruction thereof, the article may be destroyed or otherwise disposed of as the authorised officer may direct.

(8) Where a person has been convicted of an offence under this Act or any regulations made hereunder, the court may order that any article by means of or in relation to which the offence was committed or anything of a similar nature belonging to or in the possession of the convicted person or found with such article, be forfeited, and upon such order being made such articles and things may be disposed of as the court may direct.

(9) Where any article has been seized under the provisions of paragraph (e) of subsection (1) of this section and the owner thereof has been convicted of an offence under this Act, the article may be destroyed or otherwise disposed of as the authorized officer may direct.

(10) Any article seized under this Act may at the option of an authorized officer be kept or stored in the premises where it was seized or may at the direction of an authorized officer be removed to any other proper place; and any person who removes, alters or interferes in any way with articles seized under this Act without the authority of an authorized officer shall be guilty of an offence.
(11) An authorized officer may submit any article seized by him or any sample taken by him to a public analyst for analysis or examination; and a public analyst shall as soon as practicable analyse or examine any sample sent to him in pursuance of this Act and shall give the authorized officer a certificate specifying the result of the analysis or examination and such certificate shall be in such form as may be prescribed by the Minister on the advice of the Board.

(12) In this section, “premises” includes a street, open space, place of public resort, or bicycle or other vehicle utilised for the preparation, preservation, packaging, storage or conveyance of any article.

31. Power of Director or Medical Services or Director of Agriculture to have articles analysed

The Director of Medical Services in relation to any matter appearing to him to affect the general interests of the consumer, and the Director of Agriculture in relation to any matter appearing to him to affect the general interests of agriculture in Kenya, and any other person authorized in writing by the Minister so to do, may direct a public officer to procure for analysis samples of any food, drug, device, cosmetic or chemical substance, and thereupon that officer shall have all the powers of an authorized officer under this Act and this Act shall apply as if the officer were an authorized officer.

32. Duty of municipal council to enforce Act

(1) It shall be the duty of every municipal council to exercise such powers with which it is invested as may be, in its special circumstances, reasonably practicable so as to provide proper safeguards for the sale of food, drugs, cosmetics, devices and chemical substances in a pure and genuine condition, and in particular to direct its officers to procure samples for analysis.

(2) If the Minister is of the opinion that a municipal council has failed to execute or enforce any of the provisions of this Act in relation to any article and that its failure affects the general interests of the consumer, the Minister may by order empower an officer to execute and enforce those provisions or to procure the execution and enforcement thereof in relation to any article mentioned in the order.

(3) The expenses incurred under any such order shall be recoverable by the Minister from the municipal council and the amount so recovered shall be treated as expenses incurred by the municipal council under this Act.

[L.N. 41/1970.]

33. Power of Minister to obtain particulars of certain food ingredients

(1) The Minister may direct any person who at the date of the direction or at any subsequent time carries on a business which includes the production, importation or use of substances of any class to which this Act applies to furnish to him, within such time as may be specified in such direction, such particulars as may be so specified of the composition and use of any such substance sold or for sale in the course of that business or used in the preparation of food or drugs.
(2) Without prejudice to the generality of subsection (1), a direction made thereunder may require the following particulars to be furnished in respect of any substance, that is to say—

(a) particulars of the composition and chemical formula of the substance;
(b) particulars of the manner in which the substance is used or proposed to be used in the preparation of food;
(c) particulars of any investigations carried out by or to the knowledge of the person carrying on the business in question, for the purpose of determining whether and to what extent the substance, or any product formed when the substance is used as aforesaid, is injurious to, or in any other way affects health;
(d) particulars of any investigations or inquiries carried out by or to the knowledge of the person carrying on the business in question for the purpose of determining the cumulative effect on the health of a person consuming the substance in ordinary quantities.

(3) No particulars furnished in accordance with a direction under this section, and no information relating to any individual business obtained by means of such particulars shall, without the previous consent in writing of the person carrying on the business in question, be disclosed except—

(a) in accordance with regulations made by the Minister, so far as may be necessary for the purposes of section 26;
(b) for the purposes of any proceedings for an offence against the order or any report of those proceedings,

and any person who discloses any such particulars or information in contravention of this subsection shall be guilty of an offence.

34. Power of court to order licence to be cancelled

On the conviction of any person for any offence under this Act or any regulations made thereunder, the court may, in addition to any other penalty which it may lawfully impose, cancel any licence issued under this Act, or any regulations made thereunder, to such person.

35. Prosecution

(1) An authorized officer may take out proceedings for an offence under this Act or the regulations before any magistrate having jurisdiction in the place where any article sold was actually delivered to the purchaser or where the sample was taken.

(2) In any proceedings under this Act, the contents of any container appearing to be intact and in the original state of packing by the manufacturer thereof shall be deemed, unless the contrary is proved, to be an article of the description specified on the label.

[Act No. 20 of 1989, Sch.]
36. Penalties

(1) A person who is guilty of an offence under this Act for which no special penalty is provided shall be liable—

(a) in the case of a first offence, to a fine not exceeding five hundred thousand shillings or to imprisonment for a term not exceeding two years, or to both such fine and imprisonment;

(b) in the case of a subsequent offence, to a fine not exceeding seven hundred thousand shillings or to imprisonment for a term not exceeding five years, or to both such fine and imprisonment.

(2) In any prosecution under this Act the summons shall state the particulars of the offence or offences alleged and also the name of the prosecutor and shall not be made returnable in less than fourteen days from the date on which it is served.

[Act No. 2 of 2002, Sch.]

37. Certificates of analysis and presumptions

In any proceedings under this Act—

(a) a certificate of analysis purporting to be signed by a public analyst shall be accepted as prima facie evidence of the facts stated therein:

Provided that—

(i) the party against whom it is produced may require the attendance of the public analyst for the purposes of cross-examination; and

(ii) no such certificate of a public analyst shall be received in evidence unless the party intending to produce it has, before the trial given to the party against whom it is intended to be produced, reasonable notice of such intention together with a copy of the certificate;

(b) evidence that a package containing any article to which this Act or any regulations made thereunder apply bore a name, address or registered mark of the person by whom it was manufactured or packed shall be prima facie evidence that such article was manufactured or packed, as the case may be, by that person;

(c) any substance commonly used for human consumption shall, if sold or offered, exposed or kept for sale, be presumed, until the contrary is proved, to have been sold or, as the case may be, to have been or to be intended for sale for human consumption;

(d) any substance commonly used for human consumption which is found on premises used for the preparation, storage, or sale of that substance and any substance commonly used in the manufacture of products for human consumption which is found on premises used for the preparation, storage or sale of those products, shall be presumed, until the contrary is proved, to be intended for sale, or for manufacturing products for sale, for human consumption;
(e) any substance capable of being used in the composition or preparation of any substance commonly used for human consumption which is found on premises on which that substance is prepared shall, until the contrary is proved, be presumed to be intended for such use.

38. **Saving of Public Health Act and Dangerous Drugs Act**

The provisions of this Act shall be in addition to and not in derogation of the provisions of the Public Health Act (Cap. 242) and the Dangerous Drugs Act (Cap. 245).

39. **Minister’s power to amend Schedule**

The Minister may, by order, amend the Schedule to this Act.

**PART V – REPEAL**

40. **Amendment of Cap. 63**

Sections 187 to 190 (inclusive) of the Penal Code are hereby repealed.

41. **Amendment of Cap. 244**

Section 36 of the Pharmacy and Poisons Act is hereby repealed.

42. **Amendment of Cap. 127 (1948)**

The Food and Drugs (Adulteration) Act is hereby repealed.

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**SCHEDULE**

[Sections 2 and 10.]

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<td>The British Pharmacopoeia</td>
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<td>The Pharmacopoeia of the United States of America</td>
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