

SALE OF DRUGS ACT 1952

P.U.(A) 223/84 CONTROL OF DRUGS AND COSMETICS REGULATIONS 1984

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Preamble

IN exercise of the powers conferred by section 28 (1) of the Sale of Food and Drugs Ordinance 1952, the Minister makes the following regulations :

PART I – PRELIMINARY

Regulation 1. Citation and commencement.

(1) These Regulations may be cited as the **Control of Drugs and Cosmetics Regulations 1984**.

(2) These Regulations shall come into force on such date as the Minister may appoint by notification in the *Gazette*, and the Minister may -

(a) appoint one commencement date for drugs and a different commencement date for cosmetics; or

(b) appoint different commencement dates for different groups of products; or

(c) appoint different commencement dates for different provisions of these Regulations; or

(d) appoint different commencement dates for different parts of the Federation; or

(e) adopt any combination of the foregoing alternatives.

Regulation 2. Interpretation.

In these Regulations, unless the context otherwise requires -

"administer", in relation to any product, means—

(a) give or apply to a human being or an animal, whether orally, by injection or by introduction into the body in any other way or by external application; and

(b) give or apply it either in existing state or it has been dissolved or dispersed in, or diluted or mixed with, some other substance used as a vehicle;'

"Authority" means the Drug Control Authority established under regulation 3;

"clinical trial" means an investigation or series of investigations on persons conducted by or under the direction and supervision of persons with scientific training or experience for the purpose of finding out about, or determining, the safety , effectiveness and other effects of any product;

"colour" means a substance used as an ingredient of a cosmetic product solely to give tonality to the product;

"contract manufacturer" means any person who manufactures any product on the order of another person to whom a manufacturer's licence has been issued under these Regulations;

"cosmetic" means any substance or preparation intended to be placed in contact with the various external parts of the human body (including epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucuos membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance or correcting body odours,

protecting them or keeping them in good condition;

"dental practitioner" means a person registered and having a valid annual or temporary practising certificate under the Dental Act 1971 [Act 51];

"drug " has the meaning assigned to it in the Ordinance but does not include a herbal remedy;

"flavour" means a substance used as an ingredient of a cosmetic product solely to impart taste to the product;

"fragrance" means a substance used as an ingredient of a cosmetic product solely to impart odour to the product;

"fully registered medical practitioner" means a person registered and having a valid annual or temporary practising certificate under the the Medical Act 1971[Act 50];

"herbal remedy" means any drug consisting of a substance or a mixture of substances produced by drying, crushing or comminuting, but without subjecting to any other process, a natural substance or substances of plant, animal or mineral origin, or any part of such substance or substances;

"homeopathic medicine" means any pharmaceutical dosage form used in the homeopathic therapeutic system in which diseases are treated by the use of minute amount of such substances which are capable of producing in healthy person symptoms similar to those of the disease being treated;

"indigenous medicine" means a system of treatment and prevention of disease established through traditional use of naturally occurring substances;

"label" means a display of information, safety marks or features —

- (a) accompanying a product; or
- (b) on or attached to a container and package in relation to a product;

"licence" means any of the licences issued under regulation 12;

"licenced importer" means a person to whom an import licence has been issued under these Regulations;

"licensed manufacturer" means a person to whom a manufacturer's licence has been issued under these Regulations, and includes a contract manufacturer;

"licensed wholesaler" means a person to whom a wholesaler's licence has been issued under these Regulations;

"life threatening illness" means a disease where the likelihood of death is high unless the course of the disease is interrupted;

"manufacture", in relation to any product includes -

(a) the making or assembling of the product;

(b) the enclosing or packing of the product in any container in a form suitable for administration or application, and the labelling of the container; and

(c) the carrying out of any process in the course of any or the foregoing activities;

"pharmacist" means a person registered under the Registration of Pharmacists Ordinance 1951[62/51];

" possess", in relation to any product, includes keeping, storing, possessing for sale, possessing or supply, possessing for self administration or administering to any person or animal or causing any person to administer to him;

"product" means—

(a) a drug in a dosage unit or otherwise, for use wholly or mainly by being administered to one or more human beings or animals for a medicinal purpose; or

(b) a drug to be used as an ingredient of a preparation for a medicinal purpose.

(c) [*Deleted P.U.(A) 477/2009*];

"product variant" means a product which is within a range of cosmetics produced by the same manufacturer that are similar in composition and are intended for the same use but are available in different colours, fragrance or flavours;

~~"registration certificate" means a registration certificate issued under regulation 8 (8);~~*[Deleted P.U.(A) 257/2014]*

"registered product" means a product currently registered in accordance with the provisions of these Regulations;

"Secretary" means the Secretary to the Authority appointed under regulation 3 (6).

" traditional medicine " means any product used in the practice of indigenous medicine, in which the drug consist solely of one or more naturally occurring substance of a plant, animal or mineral, of parts thereof, in the unextracted or crude extract form, and a homeopathic medicine.

"veterinary practitioner" means a veterinary surgeon registered and having a valid annual practising certificate or temporary permit to practise under the Veterinary Surgeons Act 1974 [Act 147].

PART II - THE DRUG CONTROL AUTHORITY

Regulation 3. Establishment and membership of the Authority.

(1) An authority to be called the Drug Control Authority is established for the purposes of these

Regulations.

(2) The Authority shall consist of the following members :

- (a) the Director-General of Health;
- (b) the Director of Pharmaceutical Services;
- (c) the Director of the National Pharmaceutical Control Bureau; and
- (d) eight other members to be appointed by the Minister.

(3) Members appointed under subregulations (2) (d) shall be the following persons :

- (a) a consultant physician in the public service;
- (b) a pharmacist in the public service; and
- (c) three persons from any local universities with expertise in pharmaceutical sciences.
- (d) two fully registered medical practitioners; and
- (e) a veterinary practitioner in the public service

(4) Subject to subregulation (5), a member appointed under subregulation (2) (d) shall, unless he sooner resigns, hold office for a period of three years but shall be eligible for reappointment.

(5) The Minister may, at any time and without assigning any reason, suspend or terminate the appointment of any member appointed under subregulation (2) (d).

(6) The Minister shall, after consultation with the Authority, appoint a pharmacist in the public service to be Secretary to the Authority.

(7) The Secretary shall not be a member of the Authority.

(8) Any appointment to, or suspension or termination of, membership under these Regulation shall be published in the *Gazette*.

Regulation 4. Alternate member.

(1) The Minister may appoint in respect of each member appointed under regulation 3 (2) (d) an alternate member who shall be similarly qualified as the substantive member, as provided in regulation 3 (3).

(2) An alternate member may attend meetings of the Authority or otherwise act for the substantive member when the substantive member is temporarily unable to act.

(3) An alternate member attending any meeting of the Authority or acting for the substantive member under subregulation (2) shall be deemed for all purposes to be a member of the Authority.

Regulation 5. Meetings.

(1) Subject to subregulation (2), the Director-General of Health shall be the Chairman of the Authority and shall preside at all meetings of the Authority.

(2) The Director of Pharmaceutical Services shall be the alternate Chairman and shall preside at meetings of the Authority in the absence of the Chairman.

(3) The chairman of a meeting shall have an original vote and, in the event of an equality of votes, a second or casting vote.

(4) Four members of the Authority including the chairman shall form a quorum.

(5) The Authority shall meet at such times and places as the Chairman may determine.

(6) The Authority may invite any person appointed under regulation 6 or any other person to attend any meeting of the Authority but such persons shall not have the right to vote at the meeting.

(7) They may be paid to members of the Authority, to the Secretary, to persons invited under subregulation (6), to attend any meeting of the Authority and to persons appointed under regulation 6 such allowances and other expenses as may be approved by the Government from time to time and such allowances and expenses shall be payable out of the general revenues of the Government.

(8) Subject to this regulations, the Authority shall regulate its own procedure.

(9) No action or proceeding of the Authority shall be questioned on the ground -

(a) of the existence of any vacancy in the membership, or any defect in the constitution of the Authority; or

(b) of any omission, defect or irregularity in procedure not affecting the merits of the case.

Regulation 6. Advisors.

The Authority may appoint a person or persons as it may think necessary as advisors for the purpose of giving it advice when discharging any of its functions.

PART III - REGISTRATION AND LICENSING

Regulation 7. Prohibition against manufacture, sale, supply , importation, possession and administration.

(1) Except as otherwise provided in these Regulations, no person shall manufacture, sell, supply, import or possess or administrator any product unless -

(a) the product is a registered product; and

(b) the person holds the appropriate licence required and issued under these Regulations.

(1A) Notwithstanding subregulation (1), no person shall manufacture, sell, supply, import, possess or administer any product—

(a) which is a mixture of a registered product with another substance that is not intended for reconstitution;

(b) which is a mixture of a registered product with another registered product;

(c) which is labelled with an additional name other than the name registered by the Authority;

- (d) which is labelled with a registration number or listing number which belongs to a particular registered product;
- (e) which is labelled with any words, symbols or letters purporting to be true but which is otherwise;
- (f) whose label is not complying to the directives or guidelines issued under regulation 29; or
- (g) the registration of which has been suspended or cancelled by the Authority.
- (h) which contains any metal contaminant unless naturally occurs, which contained in any traditional medicine as specified in column (1) of Table 1 to the Schedule in a proportion not greater than the maximum permitted proportion specified opposite the substance in column (2) of the Table.

[(h) Ins. P.U.(A) 105/2013]

(1B) No person shall possess any written information, statement or document which describes the indication or use of a product other than the indication or use as approved in its registration by the Authority.

(2) Notwithstanding any other provisions of these Regulations —

(a) the Director of Pharmaceutical Services may, on application with a fee of RM100.00, issue a written approval to any person who is not the product registration holder to import any product—

(i) where he is satisfied that the particular product is in all respects the same as a registered product; and

(ii) subject to the terms and conditions as he may impose.

(b) No person shall import any product to be assembled, enclosed, packed or labelled for the sole purpose of re-exporting the product unless the person is issued with a written approval by the Director of Pharmaceutical Services, subject to the terms and conditions as he may impose.

(3) The provisions of subregulations (1) relating to importation do not apply to any person arriving in the Federation from a place outside of Federation who imports, as part of his personal luggage, any product meant solely for his use or for the use of his family in a quantity not exceeding that which may be reasonably required for one month's use by one person, or to any officer of the Government importing any product in the course of his duty, or to any person who, in accordance with the written consent of the Authority, brings any product into the Federation in transit.

(4) In subregulations (3), "in transit " means taken or sent from any country and brought into the Federation by land, air, or water, whether or not landed or transhipped in the Federation, for the sole purpose of being carried to another country either by the same or another conveyance.

Regulation 7A. Prohibition regarding traditional medicine.

No person shall manufacture, sell, supply, import, possess or administer any traditional medicine which contain any substance as set out in Table II to the Schedule.

[(Ins. P.U.(A) 105/2013]

Regulation 7B. Presumption relating to registered product.

When a product refers to an existing registered product, the product shall not be deemed to be a

registered product if the product—

(a) contains any ingredient other than the ingredient of the existing registered product; or

(b) is labelled with a label other than a label of the existing registered product,

as approved by the Authority.

[Ins. P.U.(A) 257/2014]

Regulation 8. Registration of product.

(1) The Authority may, on application made in such manner or form as it may require, register any product subject to such conditions as it may impose.

(2) Every application for the registration of a product shall be accompanied by—

(a) a processing fee of RM500.00 for traditional medicines;

(b) a processing fee of RM50.00 for each product variant; or

(c) a processing fee of RM1000.00 for products other than traditional medicines; and

(d) such documents, items, samples, particulars or information as the Authority may require.

(3) The Authority may charge any applicant such costs as it may incur for the purpose of carrying out any evaluation or investigation prior to the registration of any product.

(4) The processing fee and such costs as may be incurred by the Authority under subregulation (3) shall not be refundable in the event of the application being rejected under regulation 11.

(5) Any change in any document, item, sample, particulars or information mentioned in subregulation (2) shall be notified in writing by the applicant to the Authority within fourteen days from the date of such change.

(6) Subject to regulation 11, the period of registration of a product shall be as notified by the Authority and where so notified, the registration shall be valid until the end of the notified period.

[(6) Subs.P.U.(A) 257/2014]

(7) Subject to regulation 11, where the period of registration of a product is not notified the registration shall be valid until it is cancelled.

[(7) Am.P.U.(A) 257/2014]

(8) Upon registration of a product, the Authority shall notify the product registration holder and assign a product registration number or a product listing number to each registered product.

(9) Any person who knowingly supplies any false or misleading information to the Authority in connection with his application for the registration of a product commits an offence.

Regulation 9. Register of products.

(1) The Secretary shall keep and maintain a register of the products registered; and separate registers may be kept and maintained for drugs.

(2) The register shall contain -

- (a) the name under which the product is registered;
- (b) the content and quantity of the active ingredients;
- (c) the name and address of the manufacturer;
- (d) the name and address of the product registration holder;
- (e) product registration number or product listing number ; and
- (f) the date of issue and expiry of the registration certificate, if any.

(3) Any person may, upon written application to the Secretary and upon payment of a fee of \$5.00, inspect the register or registers kept under subregulation (1).

(4) A certificate issued by the Secretary or the officer who is responsible for the registration of any product shall be *prima facie* evidence of the facts stated.

Regulation 10. Declaration relating to imported product or cosmetic.

(1) The Authority may, in the case of an imported product, require any person applying for the registration of the imported product to furnish a written declaration made by or on behalf of the manufacturer of the imported product that all requirement governing the manufacture of the product imposed by the law of the country of manufacture have been complied with.

(2) The Director of Pharmaceutical Services may, in the case of an imported cosmetic, require any person applying for the issuance of a notification note for the imported cosmetic to furnish a written declaration made by or on behalf of the manufacturer of the imported cosmetic that all requirement governing the manufacture of the cosmetic imposed by the law of the country of manufacture have been complied with.

[Subs.P.U.(A) 257/2014]

Regulation 11.Rejection, suspension or cancellation.

(1) The Authority may, at any time and without assigning any reason, reject, suspend or cancel the registration of any product and may amend the conditions to which such registration is subject.

(2) Subject to subregulation (3), any suspension or cancellation of the registration of any product under subregulation (1) shall similarly and at the same time affect any licence issued under these Regulations relating to that product.

(3) Notwithstanding subregulation (2), where a licence issued under these Regulations relates to several registered products, the suspension or cancellation of the registration of any product under subregulation (1) shall not affect the position of other registered products listed in the

licence.

Regulation 12. Licences.

(1) The Director of Pharmaceutical Services may, subject to the provisions of these Regulations, issue any of the following licences subject to such conditions as he may impose:

(a) a manufacturer's licence in Form 2 in the Schedule, authorising the licensee to manufacture the registered products in the premises specified in the licence and to sell by wholesale or supply the products;

(b) a wholesaler's licence in Form 3 in the Schedule, authorising the licensee to sell by wholesale or supply the registered products from the address of the business premises specified in the licence;

(c) a clinical trial import licence in Form 4 in the Schedule, authorising the licensee to import any product for purposes of clinical trials, notwithstanding that the product is not a registered product;

(d) an import licence in Form 5 in the Schedule, authorising the licensee to import and sell by wholesale or supply the registered products from the address of the premises specified in the licence.

(2) Provided that, any number of registered products may be included in any licence other than a clinical trial import licence, which shall include only one product.

(3) Subject to subregulation (2), the Director of Pharmaceutical Services may, on application by the licensee, add to the registered products included in any licence other than a clinical trial import licence, and make such addition or amendment to the conditions of the licence as are rendered necessary by the addition of the other registered products.

(4) Subject to regulation 17, a licence issued under these Regulations, other than a clinical trial import licence, shall be valid for one year.

(5) Subject to regulation 17, a clinical trial import licence shall be valid for such period, not exceeding three years from the date of issue of the licence, as may be specified in the licence.

(6) Every licence shall be personal to the licensee named in the licence and shall not be transferable to another person.

Regulation 13. Application for licence.

(1) An application for licence under these Regulations shall be made in such manner or form as the Director of Pharmaceutical Services may require and shall be accompanied with a processing fee of RM1000.00 in the case of an application for a manufacturer's licence and RM500.00 in the case of an application for any other licence.

(2) The processing fee shall not be refundable.

(3) The applicant for a licence shall furnish such documents, particulars or information as the Director of Pharmaceutical Services may require.

(4) Any person who knowingly supplies any false or misleading information to the Director of

Pharmaceutical Services in connection with his application for a licence commits an offence.

Regulation 14. Refusal of application for licence.

The Director of Pharmaceutical Services may, if he thinks fit and without assigning any reason, refuse any application for a licence.

Regulation 15. Exemptions and savings.

1) Any person who wishes to import any product or cosmetic for the purpose of research in a school of pharmacy or a research or training institution or in order to obtain samples for purposes of registration or issuance of a notification note may on application be exempted by the Director of Pharmaceutical Services from the provisions of regulation 7 (1) or regulation 18A.

(2) The requirement of regulation 7 (1) as regards a licence to supply or manufacture does not apply to the dispensing, of any drug for the purpose of it being used for medical treatment of a particular patient or animal, by the following persons and in the following circumstances:

(a) a pharmacist or a person working under the immediate personal supervision of a pharmacist in a retail pharmacy;

(b) a person acting in the course of his duties who is employed in a hospital or dispensary maintained by the Federal or any State Government or out of public funds or by a charity approved for the purposes of section 9 (1) (b) of the Poisons Ordinance 1952 or in an estate hospital and who is authorised in writing as provided in that section; and

(c) a fully registered medical practitioner or a dental practitioner or a veterinary practitioner or a person working under the immediate personal supervision of such a practitioner if the drug in question is for the use of such practitioner or of his patients.

(3) Regulation 7 (1) (a) shall not apply to any drug manufactured by persons and in the circumstances described in subregulation (2) if the drug is manufactured for the purpose of dispensing.

(4) A school of pharmacy or any research or training institution which wishes to manufacture any product or cosmetic for teaching and research purposes may on application be exempted by the Director of Pharmaceutical Services from the provisions of regulation 7 (1) or regulation 18A.

(5) Any person who wishes to manufacture any product solely for the purpose of producing samples for clinical trials, for registration or issuance of notification note under these Regulations may on application be exempted by the Director of Pharmaceutical Services from the provisions of regulation 7 (1) or regulation 18A.

(6) Any person who wishes to import or manufacture any product solely for the purpose of treatment of any person suffering from a life-threatening illness may on application be exempted by the Director of Pharmaceutical Services from the provision of regulation 7(1) subject to such condition or restrictions as he may impose in such exemption.

Regulation 16. Certification.

(1) The Director of Pharmaceutical Services may issue such certification on any matter relating to

any product where such certification is required by any country importing such a product.

(2) A fee of RM50.00 is payable on the issue of such certification.

Regulation 17. Revocation of licence.

The Director of Pharmaceutical Services may, at any time and without assigning any reason, revoke any licence issued under these Regulations and may amend the conditions of the licence.
[Subs.P.U.(A) 257/2014]

Regulation 18. Appeal.

Any person aggrieved by any decision of the Authority or the Director of Pharmaceutical Services under these Regulations may make a written appeal to the Minister within fourteen days from the date the decision is made known to him and any decision of the Minister made on an appeal shall be final.

PART III A - NOTIFICATION OF COSMETICS

Regulation 18A. Prohibition to manufacture, sell, supply, import, possess or administer cosmetic.

(1) No person shall manufacture, sell, supply, import, possess or administer any cosmetic—

(a) unless the cosmetic is a notified cosmetic;

(b) unless he is the person responsible for placing the notified cosmetic in the market or a person authorized in accordance with the notification note which is issued by the Director of Pharmaceutical Services;

(c) which is a mixture of a notified cosmetic and any poison within the meaning of the Poisons Act 1952;

(d) which is a mixture of a notified cosmetic with a registered product;

(e) which is labelled with any additional name other than the name notified by the Director of Pharmaceutical Services;

(f) which label does not comply with the directives or guidelines issued by the Director of Pharmaceutical Services;

(g) which notification as a notified cosmetic has been cancelled by the Director of Pharmaceutical Services; or

(h) which is labelled with any word, symbol, letter, figure, mark or safety feature purporting to be true but which is otherwise;

[(1) Subs.P.U.(A) 257/2014]

(2) For the purpose of subregulation (1), “notified cosmetic” means a cosmetic as specified in the notification note issued by the Director of Pharmaceutical Services, in the manner as he deems fit;

[(2) Subs.P.U.(A) 257/2014]

(3) The provisions of subregulation (1) do not apply to any person—

(a) arriving in the Federation from a place outside Federation who imports, as part of his personal luggage, any cosmetic solely for his personal use or for the use of his family in a quantity not exceeding that which may be reasonably required for one month's use by one person; or

(b) who manufactures any cosmetic for the purpose of export only or for assessing the market acceptance if a written approval with or without conditions is issued by the Director of Pharmaceutical Services; or

[(3)(b) Am.P.U.(A) 257/2014]

(c) who imports any cosmetic—

[(3)(c) Am.P.U.(A) 257/2014]

(i) for assessing the market acceptance;

(ii) to be assembled, enclosed, packed or labelled for the sole purpose of re-exporting;

(iii) in transit; or

(iv) to be sold or supplied in the free-trade zone or international carriage by ships, aircrafts or other forms of international public transport entering or leaving Malaysia,

if a written approval with or without conditions is issued by the Director of Pharmaceutical Services.

(3A) In addition to subregulation (3), paragraph (1)(b) does not apply to the administration, possession, and sale or supply of any notified cosmetic;

[(3A) Ins.P.U.(A) 257/2014]

(4) In subregulation (3), "in transit" means taken or sent from any country and brought into the Federation by land, air, or water, whether or not landed or transhipped in the Federation, for the sole purpose of being carried to another country either by the same or another conveyance.

(5) Any person responsible for placing the notified cosmetic in the market may apply for the issuance of notification note in such manner as determined by the Director of Pharmaceutical Services and shall be accompanied with a processing fee as it may require.

(6) The processing fee shall not be refundable.

(7) The Director of Pharmaceutical Services may issue a notification note to the person responsible for placing the notified cosmetic in the market, subject to such conditions as he may impose.

(7A) The Director of Pharmaceutical Services may, at any time and without assigning any reason, reject any application for the issuance of notification note;

[(7A) Ins.P.U.(A) 257/2014]

(8) The Director of Pharmaceutical Services may, at any time and without assigning any reason, cancel the notification note of any cosmetic and may amend any conditions to which the

notification note is subject.

(9) The person responsible for placing the notified cosmetic in the market or the authorized person shall report to the Director of Pharmaceutical Services any serious or high incidences of adverse events that occurred regardless of the source and the report shall be in the manner as determined by him.

[(9) Am.P.U.(A) 257/2014]

(10) The person responsible for placing the notified cosmetic in the market or the authorized person shall comply to any directives or guidelines issued and any conditions imposed by the Director of Pharmaceutical Services.

[(10) Am.P.U.(A) 257/2014]

(11) The person responsible for placing the notified cosmetic in the market or the authorized person shall maintain proper records in the manner as determined by the Director of Pharmaceutical Services.

[(11) Am.P.U.(A) 257/2014]

(12) Where any notified cosmetic is found to have contravened or reasonably suspected to have contravened any provision of these Regulations, the Director of Pharmaceutical Services may, by directive in writing, order the person responsible for placing the notified cosmetic in the market, or the authorized person to recall, remove, or withdraw the notified cosmetic from any premises within such time as may be specified in the directive.

[(12) Am.P.U.(A) 257/2014]

(13) Notwithstanding subregulation (12), it shall be the duty of the person responsible for placing the notified cosmetic in the market, or the authorized person if he knows or has reason to believe or it has come to his knowledge that the notified cosmetic has contravened any of the directives or guidelines of the Director of Pharmaceutical Services, to recall, remove or withdraw such notified cosmetic with immediate effect.

[(13) Am.P.U.(A) 257/2014]

(14) No person shall possess or publish any label, information, pictorial, statement or document which describes the claim of the cosmetics otherwise than in the manner as determined in the directives or guidelines issued by the Director of Pharmaceutical Services.

(15) Any person who contravenes subregulations (1), (3), (9), (10), (11), (13) and (14) commits an offence.

[Ins. P.U.(A) 477/2009].

PART IV - MANUFACTURE OF REGISTERED PRODUCTS OR NOTIFIED COSMETICS

Regulation 19. Personnel.

A licensed manufacturer shall ensure that all personnel employed at all levels of manufacture -

(a) possess suitable qualifications required for their job;

(b) have adequate experience and are technically competent;

(c) are regularly trained during their employment for the purposes of keeping up to date with any advances or changes; and

(d) are medically examined regularly.

Regulation 20. Premises.

(1) Registered products or notified cosmetic shall be manufactured, processed, packed, labelled and tested in premises which are in accordance with the standards set by the Authority.

(2) Adequate storage areas shall be provided so that all starting, rejected and returned materials, or intermediate or finished registered products or notified cosmetic, are adequately separated.

(3) Manufacturing premises shall be maintained in good and sanitary conditions; there shall be a sanitation programme for the maintenance of the premises in these conditions and records of the performance of the programme shall be kept.

Regulation 20. Premises.

(1) A registered product or notified cosmetic shall be manufactured, processed, packed, labelled and tested in the premises which are in accordance with the standards set by—

(a) in the case of a registered product, the Authority; or

(b) in the case of a notified cosmetic, the Director of Pharmaceutical Services.

[(1) Subs.P.U.(A) 257/2014]

(2) Adequate storage areas shall be provided so that all starting, rejected and returned materials, or intermediate or finished registered products or notified cosmetic, are adequately separated.

[(1) &(2) Am.P.U.(A) 477/2009].

(3) Manufacturing premises shall be maintained in good and sanitary conditions; there shall be a sanitation programme for the maintenance of the premises in these conditions and records of the performance of the programme shall be kept.

Regulation 21. Equipments.

(1) Manufacturing and testing equipments shall be designed, placed and maintained in such a way so as to -

(a) be suitable for their intended use;

(b) facilitate thorough cleaning whenever necessary;

(c) minimise any contamination of registered products or notified cosmetic and their containers during manufacture; and

(d) minimise the risks of confusion or omission of any manufacturing steps.

(2) A licensed manufacturer or manufacturer of the notified cosmetic shall –

(a) ensure all weighing, measuring and recording equipments are maintained in good

working conditions and are regularly calibrated;

(b) where suitable, have manufacturing steps monitored by recording devices;

(c) ensure all manufacturing equipments are thoroughly and regularly cleaned in accordance with such written specifications as the Authority may determine; and

(d) ensure records of the matters in paragraphs (a), (b) and (c) are kept and maintained.

Regulation 22. Manufacturing operations.

Manufacturing operations shall be carried out in accordance with such requirements as may be determined by the Authority.

Regulation 23. Quality control department.

(1) A licensed manufacturer or manufacturer of the notified cosmetic shall establish a quality control department under the supervision of a suitably qualified person.

(2) A quality control department shall -

(a) control all materials used in the manufacturing process;

(b) monitor the quality aspects of all manufacturing steps; and

(c) control the quality and stability of the finished registered products or notified cosmetics.

(3) For the purposes of this regulation, a licensed manufacturer shall provide such facilities as may be necessary for a quality control department to discharge its duties.

Regulation 24. Inspections.

For the purposes of this Part, a licensed manufacturer or manufacturer of the notified cosmetic shall conduct regular inspections of his manufacturing and quality control activities.

Regulation 25. Distribution records.

A licensed manufacturer or manufacturer of the notified cosmetic shall maintain proper records of every batch of finished registered products or notified cosmetics distributed to enable the complete and rapid recall of the registered product or notified cosmetic if necessary.

PART V – MISCELLANEOUS

Regulation 26. Entry, inspection and seizure.

(1) For purposes of investigating the commission of any offence under these Regulations, any officer or inspector may, at all reasonable times, enter any premises used for or connected with the manufacture, sale, supply, possess, administer or import of any product or notified cosmetic for the purposes of inspecting -

(a) the product or notified cosmetic with which the premises are concerned;

(b) the premises and the operations carried out in the premises; and

(c) any licence, registration certificate, the notification note, record or document required

under these Regulations.

and every licensed person and every agent and servant of the licensed person, and the person responsible for placing the notified cosmetic in the market shall afford every assistance required by the officer or inspector and shall, on demand by the officer or inspector, produce any product or notified cosmetic or any licence, registration certificate, record or document required under these Regulations.

(2) Any officer or inspector may seize any product or cosmetic or notified cosmetic in respect of which he reasonably believes that an offence under these Regulations, or any breach of the conditions subject to or upon which any licence or registration has been granted or effected, or any notification note has been issued, has been or being committed and any plant, equipment, book, document or other article which he reasonable believes would furnish evidence of the commission of such offence or breach.

Regulation 27. Records of transactions.

1) Every licensed wholesaler and importer or person responsible for placing the notified cosmetic in the market shall maintain proper records of each transaction involving the registered product, or notified cosmetic showing the particulars specified in this regulation, or any directive or guideline issued by the Director of Pharmaceutical Services for a period of not less than five years from the date of the transaction.

(2) In the case of a licensed wholesaler, the records shall show the date of sale or supply, the name and address of the purchaser, the name and quantity of the registered product sold, the registration reference of the product and the number of the invoice or delivery order.

(3) In the case of a licensed importer, or an importer of any cosmetic the records shall show the date of importation, the name and address of the supplier, the name and quantity of the registered product or notified cosmetic imported, the number of the bill of lading, the date of any sale or supply made and the name and address of the purchaser.

Regulation 28. Reporting adverse reactions.

The product registration holder or any person who possesses any registered product shall inform immediately the Director of Pharmaceutical Services of any adverse reactions arising from the use of the registered product.

Regulation 29. Directions.

(1) The Director of Pharmaceutical Services may issue written directives or guidelines to any person or a group of persons as he thinks necessary for the better carrying out of the provisions of these Regulations and which in particular relate to—

- (a) product quality, safety and efficacy;
- (b) labelling;
- (c) change of particulars of a product;
- (d) transfer of licences;
- (e) manufacturing;
- (f) storage includes requirements as to containers;
- (g) retailing;

- (h) promotion of sale including product information;
- (i) product recall;
- (j) product disposal;
- (k) the cost of product recall or product disposal;
- (l) clinical trials; or
- (m) records and statistics pertaining to manufacture, sale, supply, import or export of any products.

(2) Any person who contravenes any directives or guidelines issued by the Director of Pharmaceutical Services under subregulation (1) commits an offence.

Regulation 30. General penalty.

(1) Any person who contravenes any of the provisions of these Regulations or any condition of any licence issued under these Regulations or any condition subject to which a product is registered under these Regulations commits an offence.

(2) [*Deleted by P.U.(A) 186/2001*]

Regulation 31. Power to grant exemption.

The Minister may, after consultation with the Authority, exempt any person or class of persons by notification in the *Gazette* from any of the provisions of these Regulations subject to such conditions or restrictions as he may impose in such exemption.

SCHEDULE - TABLE I AND TABLE II

TABLE I

(Regulation 7)

MAXIMUM PERMITTED PROPORTION OF NATURALLY OCCURRING METAL CONTAMINANT
IN TRADITIONAL MEDICINE

(1) Substance (Metal Contaminant)	(2) Maximum permitted proportion
Arsenic	5.0 mg/kg or 5.0 mg/litre or 5.0 ppm
Cadmium	0.3 mg/kg or 0.3 mg/litre or 0.3 ppm
Lead	10.0 mg/kg or 10.0 mg/litre or 10.0 ppm
Mercury	0.5 mg/kg or 0.5 mg/litre or 0.5 ppm

TABLE II

(Regulation 7A)

PROHIBITED SUBSTANCES IN TRADITIONAL MEDICINE

The following substances are prohibited in traditional medicine:

1. Caffeine
2. Nicotinamide
3. Paracetamol
4. Poison within the meaning of the Poisons Act 1952 [Act 366].

[Table I and Table II Ins. P.U.(A) 105/2013]