CONTROL OF DRUGS AND COSMETICS REGULATIONS
1984

ARRANGEMENT OF REGULATIONS

PART V

MISCELLANEOUS

CONTROL OF DRUGS AND COSMETICS REGULATIONS
1984

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

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 commecement 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.

2. Interpretation.

In these Regulations, unless the context otherwise requires -

“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 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 used, or capable or purported or claimed to be capable of being used, on the various external external parts of the human body (including epidermis, hair system, nails, lips and external genital organs) or the teeth and the mucous membranes of the oral cavity for the exclusive or main purpose of cleaning, perfuming or protecting them, or of keeping them in good condition, or of changing or modifying their appearance, or correcting body odours;

“dental practitioner” means a person registered in the Register under the Dental Act 1971;

“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 under section 14 of the Medical Act 1971;

“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 disease are treated by the use of minute amounts of such substances which are capable of producing in healthy persons 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 occuring substances;

“licence” means any of the licences under regulations 12;

“licensed 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 of the foregoing activities;

“pharmacist” means a person registered under the Registration of Pharmacists Ordinance 1951;

“possess for sale” includes –
(a) keeping or storing for sale or supply; or

(b) having in possession knowing that the product is likely to be sold or exposed for sale;

“product” means a drug in a pharmaceutical dosage form, or a cosmetic, having a singular identity, composition, characteristics and origin;

“product variant” means a product which is whithin 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);

“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 medicines, in which the drug consist solely of one or more naturally occuring substances of a plant, animal or mineral, of parts thereof, in the unextracted or crude extract form, and a homeopathic medicine.

PART II

THE DRUG CONTROL AUTHORITY

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 Laboratory; and
(d) seven other members to be appointed by the Minister

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

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

(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 he 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 Regulations shall be published in the Gazette.

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.

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 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 he questioned on the ground

(a) of the existence of any vacancy in the membership, or any defect in the constitution, of theAuthority; or
(b) of any omission, defect or irregularity in procedure not affecting the merits of the case.

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

7. Control of manufacture,sale, supply and importation.

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

(a) the product is a registered product; and
(b) the person holds the appropriate licence required and issued under these Regulations.

(2) The requirement of subregulations (1) (b) does not apply to the sale or supply of any product by a retailer.

(3) The provisions of subregulations (1) relating to importation do not apply to any person arriving in the Federation from a place outside the 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.

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 RM100.00 for cosmetics and RM50.00 for each product variant; or
(c) a processing fee of RM1000.00 for products other than traditional medicines and cosmetics; 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 laboratory investigation prior to the registration of any product.

(4) The processing fees and such costs as may be incurred by the Authority under sub-regulation (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 17, the period of registration of a product shall be as specified in the registration certificate issued under subregulation (8) and where so specified the registration shall be valid till the end of the specified period.

(7) Subject to regulation 17, where the period of registration of a product is not specified the registration shall be valid until it is cancelled.

(8) Upon registration of a product the Authority shall issue to the applicant a registration certificate in Form I in the Schedule.

(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.

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 and cosmetics.

(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 certificate holder;

(e) the registration certificate 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 RM5.00, inspect the register or registers kept under subregulation (1).

10. Declaration relating to imported product.

The Authority may require any person applying for the registration of any imported product to furnish written declaration made by or on behalf of the manufacturer of the product that all the legal requirements governing the manufacture of such product imposed by the laws of the country of manufacture have been complied with.

11. Rejection of application for registration.

The Authority may, without assigning any reason, reject any application for the registration of any product.

12. Licences.

(1) The Authority may, subject to the provisions of these Regulations, issue any of the following licences subject to such conditions as it 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 drugs and cosmetics are not included together in one licence, 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 Authority 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.

13. Application for licence.

(1) An application for a licence under these Regulations shall be made in such manner or form as the Authority 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 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 Authority may require.

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

14. Refusal of application for licence.

The Authority may, if it thinks fit and without assigning any reason, refuse any application application for a licence.

15. Exemptions and savings.

(1) Any person who wishes to import any product 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 may on application be exempted by the Authority from the provisions or regulation 7(1).

(2) The requirement of regulation 7 (1) as regards a licence to supply or manufacture does not apply to the dispensing, or the doing of any act falling within the definition of "manufacture" which is necessary for the dispensing, of any drug for the purpose of its being used for medical treatment 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 the 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 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 for teaching and research purposes may on application be exempted by the Authority from the provisions of regulation 7 (1).

(5) any person who wishes to manufacture any product solely for the purpose of producing samples for clinical trials or for registration under these Regulations may on application be exempted by the Authority from the provisions of regulation 7 (1).

(6) any person who wishes to import or manufacture any product solely for the purposes of treatment of any person suffering from a life treatening illness may on application be exempted by the Authority from the provisions of regulation 7 (1) subject to such conditions or restrictions as it may impose in such exemption.

16. Certification.

(1) The Authority 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.

17. Suspension or cancellation of registration and revocation of licence.

(1) The Authority may, at any time and without assigning any reason, suspend or cancel the registration of any product or revoke any licence issued under these Regulations and may amend the conditions to which such licence or 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.

(2) 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 sub-regulation (1) shall not affect the position of other registered products listed in the licence.

18. Appeal.

Any person aggrieved by any decision of the Authority 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 IV

MANUFACTURE OF REGISTERED PRODUCTS

19. Personnel.

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

(a) possess suitable qualifications required for their jobs;

(b) have adequate experience and 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.

20. Premises.

(1) Registered products 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 or returned materials, or intermediate or finished registered products, 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.

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, and their containers during manufacture; and

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

(2) A licensed manufacturer shall -

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

22. Manufacturing operations.

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

23. Quality control department.

(1) A licensed manufacturer 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.

(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.

24. Inspections.

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

25. Distribution records.

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

PART V

MISCELLANEOUS

26. Entry, inspection and seizure.

(1) Any officer or inspector may, at all reasonable times, enter any premises used for or connected with the manufacture, sale, supply or import of any product for the purposes of inspecting

(a) the product with which the premises are concerned;

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

(c) any licence, registration certificate, record or document required under these Regulations.

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

(2) Any officer or inspector may seize any product 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, has been or being committed, and any plant, equipment, book, document or other article which he reasonably believes would furnish evidence of the commission of such offence or breach.

27. Records of transactions.

(1) Every licensed wholesaler and importer shall maintain proper records of each transaction involving a registered product, showing the particulars specified in this regulation, 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, the records shall show the date of importation, the name and address of the supplier, the name and quantity of the registered product imported, the number of the bill of lading, the date of any sale or supply made and the name and address of the purchaser.

28. Reporting adverse reactions.

A licensed manufacturer, a licensed wholesaler, a licensed importer or the holder of a registration certificate in respect of any product shall inform the Authority of any adverse reactions arising from the use of the registered product immediately after he receives notice of such adverse reactions.

29. Directions.

(1) The Authority may issue such directions to any person as it thinks necessary for the better carrying out the provisions of these Regulations and which may in particular relate to the recall of any registered product from the market and the disposal of any registered product.

(2) Any person who contravenes any directions issued by the Authority under subregulation (1) commits an offence.

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).

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 the Regulations subject to such conditions or restrictions as he may impose in such exemption.

SCHEDULE

FORM 1

CONTROL OF DRUGS AND C0SMETICS REGULATIONS
1984

[Regulation 8(8)]

DRUG CONTROL AUTHORITY
MINISTRY OF HEALTH MALAYSIA

REGISTRATION CERTIFICATE

CERTIFICATE NO .....……

Name and address of holder:
……..
……
…..……..

PARTICULARS OF PRODUCT:
Name .....…….
Name of manufacturer
.....……..
Address of manufacturer .....……
……..

Manufacturer's licence No. (if any) .....……

The above product is registered subject to the following conditions:
……..
……
……
……
……
(*Continued on another sheet attached to this ceztificate**.)

This period of registration is from ……20 …….
to ……20 ……*

Date …… ……
Chairman,
Drug Control Authority

*Delete where no applicable.

Previous Certificate No ……
Date of issue ……

FORM 2

C0NTROL OF DRUGS AND COSMETICS REGULATIONS 1984
[Regulation 12 (1)]

DRUG CONTROL AUTHORITY
MINISTRY OF HEALTH MALAYSIA

MANUFACTURER'S LICENCE

LICENCE NO ……..

This licence authorises
……..... of
……
to manufacture the products specified in the list attached to this licence at the manufacturing premises mentioned below and to sell by wholesale or supply the said products.

Name of manufacturing premises ……

……..

Address
.....……..
……

This licence is subject to the following conditions:
……
……
……
……
……
(*Continued on other sheet attached to this licence*.*)

This licence is valid from ……20 …….
to ……..20 ……*

Date …… ……..
Chairman,
Drug Control Authority

*Delete where no applicable.

Previous Certificate No ……
Date of issue ……..

(Reverse of Form 2)

LIST OF PRODUCTS

Name of Product	Registration Certificate No.

FORM 3

CONTROL OF DRUGS AND COSMETICS REGULATION 1984

[Regulation 12 (1)]

DRUG CONTROL AUTHORITY
MINISTRY OF HEALTH MALAYSIA

WHOLESALER'S LICENCE

LICENCE NO ……..

This licence authorises …… of ……to sell by wholesaler or supply -

*(a) registered products; or

*(b) registered products other than poisons as defined under the Poisons Act 1952[1],

as specified in the list attached to this licence.

Name of premises where the wholesaler business is done…….....
……
Address…….....
……

Address of stores (if different from above) ……...……
……..…

This licence is subject to the following conditions:
……
……
……
……
……
(*Continued on other sheet attached to this licence**.*)

This licence is valid from ……20 ……..
to ……20……*

Date …….. ……...
Chairman,
Drug Control Authority

*Delete where no applicable.

Previous Certificate No ……
Date of issue ……

(Reverse of Form 3)

LIST OF PRODUCTS

Name of Product	Registration Certificate No.

[1]Act 366.

FORM 4

CONTROL OF DRUGS AND COSMETICS REGULATIONS 1984

[Regulation 12 (1)]

DRUG CONTROL AUTHORITY
MINISTRY OF HEALTH MALAYSIA

CLINICAL TRIAL IMPORT LICENCE

LICENCE NO .....

This licence authorises ……...
of……...
to import for purposes of clinical trials the product whose particulars are mentioned below:

Name of products .....

Name of manufacturer .....

Manufacturer's licence No. (if any) .....

Address of manufacturer .....
.....

This licence is subject to the following conditions:
……
……
……
……
……
(*Continued on other sheet attached to this licence**.)

This licence is valid from ……20 ……
to ……20 ……*

Date …… ……
Chairman,
Drug Control Authority

*Delete where no applicable.

Previous Certificate No ……
Date of issue ……

FORM 5

CONTROL OF DRUGS AND COSMETICS REGULATIONS 1984

[Regulation 12 (1)]

DRUG CONTROL AUTHORITY
MINISTRY OF HEALTH MALAYSIA

IMPORT LICENCE

LICENCE NO .....

This licence authorises ……of…….
.....
to import, sell by retail or wholesale or supply the products listed an the reverse of this licence.

This licence is subject to the following conditions:

An authenticated copy of the invoice and an analytical certificate of each batch of the item imported shall be sent to the Authority on receipt of each consignment.
……
……
……
……
……
(*Continued on other sheet attached to this licence*.*)

This licence is valid from …… 20 …….
to ……20 ……*

Date …… ……..
Chairman,
Drug Control Authority

*Delete where no applicable.

Previous Certificate No …….
Date of issue ……

(Reverse of Form 5)

LIST OF PRODUCTS

Name of product	Registration Certificate No.	Name of Manufacturer	Address of Manufacturer	Manufacturer Licence Number (if any)