CHAPTER 458

MEDICINES ACT

To make provision for matters connected with the manufacture, preparation and assembly, wholesale distribution, storage, destruction, disposal, advertising and authorisation of medicinal products and any activity connected therewith and the regulation of the sale of medicinal products, pharmacies and related pharmaceutical activities and for any other matters ancillary thereto or connected therewith.

21st November, 2003;
1st December, 2003

ACT III of 2003, as amended by Acts III of 2004 and XI of 2007; Legal Notice 427 of 2007; and Acts XXIX of 2007 , V of 2013 and VII and XXXV of 2020.

ARRANGEMENT OF ACT

Short title.

1. The short title of this Act is the Medicines Act.

PART I

PRELIMINARY

Interpretation.
Amended by:
III. 2004.44;
XI. 2007.2;
V. 2013.2.

2. In this Act, unless the context otherwise requires -

"adverse reaction" means a response to a medicinal product which is noxious and unintended;

"advertising" in relation to medicinal products includes any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products and without prejudice to the generality of the foregoing in particular includes:

(*a*) the advertising of medicinal products to the general public;

(*b*) the advertising of medicinal products to persons qualified to prescribe or supply them;

(*c*) visits by medical or sales representatives to persons qualified to prescribe medicinal products;

(*d*) the supply of samples;

(*e*) the provision of inducements to prescribe or supply medicinal products, by way of a gift, offer or promise of any benefit or bonus, whether in money or in kind, except when the intrinsic value of such an inducement is minimal;

(*f*) sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products;

(*g*) sponsorship of any scientific congress attended by persons qualified to prescribe or supply medicinal products and in particular where payment of their travelling and accommodation expenses is offered in connection therewith;

but shall exclude:

(i) the labelling and the accompanying package leaflets, as may be specified in accordance with the provisions of Part III, Title I of this Act;

(ii) correspondence, even if accompanied by material of a non-promotional nature, which is in reply to a specific question about a particular medicinal product;

(iii) factual, informative, announcement or reference material relating to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues, price lists and other material of a similar nature provided that such material does not include any product claim;

(iv) any statement relating to human health or

disease, provided there is no reference, whether direct or indirect, to a medicinal product;

"active substance" means any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis;

"analysis" includes testing of a medicinal product or any of its constituents, both active or inactive, in respect of their chemical, physical, pharmaceutical, biological, toxicological or pharmacological properties;

"assemble", in relation to a medicinal product, means to enclose the product in a container which is labelled before the product is sold or supplied, or, where the product is already enclosed in the container in which it is to be sold or supplied, labelling the container before the product is sold or supplied in it, and shall also include the act of introducing approved information in or on the container and "assembly" shall be construed accordingly;

"authorised officer" in relation to the Medicines Authority means any officer or employee of the Authority or any other person authorised by the Authority to act on its behalf and in relation to the Licensing Authority means any officer or employee of the Department as referred to in article 5 of the Department of Health (Constitution) Ordinance authorised by the Licensing Authority to act on its behalf; Cap. 94.

"brokering of medicinal products" means all activities in relation to the sale or purchase of medicinal products, except for wholesale distribution, that do not include physical handling and that consist of negotiating independently and on behalf of another legal or natural person;

"business" means any economic activity whether carried out by the individual or by a body of persons, whether corporate or unincorporate and includes the exercise of a profession;

"clinical trial" means any investigation in human subjects intended to discover or verify, the clinical, pharmacological and, or other pharmacodynamic effects of one or more investigational medicinal products, and, or to identify any adverse reactions to one or more investigational medicinal products, and, or to study the absorption, distribution, metabolism and excretion of one or more investigational products with the object of ascertaining their safety and, or efficacy. This includes clinical trials carried out in either one site or multiple sties, whether in one or more than one Member State;

"common name" means the international non-proprietary name recommended by the World Health Organization, or, if one does not exist, the usual common name;

"composition" in relation to a medicinal product, means the ingredients constituting it and the proportions, and the degrees of strength, quality and purity, in which those ingredients are

respectively contained in it and as may be established in a recognised pharmacopoeia;

"container" in relation to a medicinal product, means the immediate packaging or outer packaging;

"cosmetic product" shall have the same definition as found under the Product Safety Act; Cap. 427.

"dental practitioner" means a person who is authorised to exercise such profession under the Medical and Kindred Professions Ordinance or any other law replacing the same; Cap. 31.

"designated Minister" means the Minister who is designated by the Prime Minister as being responsible for the Medicines Authority;

"disease" includes any injury, ailment or adverse condition, whether of body or mind;

"dispensing" means the sale or supply of medicinal products from a pharmacy;

"excipient" means any constituent of a medicinal product other than the active substance and the packaging material;

"falsified medicinal product" means any medicinal product with a false representation of:

(*a*) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;

(*b*) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or

(*c*) its history, including the records and documents relating to the distribution channels used,

but excludes unintentional quality defects and is without prejudice to infringements of intellectual property rights;

"foodstuff" shall have the same meaning as that under the Food Safety Act; Cap. 449.

"good practice" in relation to manufacturing practice, laboratory practice, distribution practice, clinical practice and dispensing practice means the standards for the proper execution of the relative activity as established by or under this Act;

"herbal medicinal product" means any medicinal product, exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations;

"herbal preparations" means preparations obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation. These include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates;

"herbal substances" means all mainly whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed, usually dried, form, but sometimes fresh. Certain exudates that have not been subjected to a specific treatment are also considered to be herbal substances. Herbal substances are precisely defined by the plant part used and the botanical name according to the binomial system (genus, species, variety and author);

"homeopathic medicinal product" means any medicinal product prepared form substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in the Member States. A homeopathic medicinal product may contian a number of principles;

"immediate packaging" means the container or other form of packaging immediately in contact with the medicinal product;

"immunological medicinal product" means any medicinal product consisting of vaccines, toxins, serums or allergen products, where -

(*a*) vaccines, toxins and serums shall cover in particular:

(i) agents used to produce active immunity, such as cholera vaccine, BCG, polio vaccines, smallpox vaccine;

(ii) agents used to diagnose the state of immunity, including in particular tuberculin and tuberculin PPD, toxins for the Schick and Dick Tests, brucellin;

(iii) agents used to produce passive immunity, such as diphtheria antitoxin, anti-smallpox globulin, antilymphocytic globulin;

(*b*) "allergen product" shall mean any medicinal product which is intended to identify or induce a specific acquired alteration in the immunological response to an allergizing agent;

"importation" means any one or more of the following activities: procuring, holding, selling and release of imported medicinal products in any part of Malta notwithstanding any provisions in any other Act, but does not include imported medicinal products that are in transit where the whole consignment of the said products remains fully intact and its status is not changed for free circulation;

"ingredient" in relation to the manufacture or the preparation of a substance, includes anything which is the sole active ingredient of the substance as manufactured or prepared;

"investigational medicinal product" means a pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products already with a marketing authorization but used or assembled (formulated or packaged) in a way different from the authorised form, or when used for an unauthorised indication, or when used to gain further

information about the authorised form;

"kit" means any preparation to be reconstituted or combined with radionuclides in the final radiopharmaceutical, usually prior to its administration;

"labelling" means any information on the immediate or outer packaging;

"licence" means a licence issued under the provisions of this Act;

"licensee" means any person who is the holder of a licence for a particular activity granted under this Act;

"magistral formula" means any medicinal product prepared in a pharmacy in accordance with a medical prescription for an individual patient;

"manufacture", in relation to a medicinal product, includes any process carried out in the course of manufacturing the product, but does not include dissolving or dispersing the product in, or diluting or mixing it with, some other substance used as a vehicle for the purpose of administering it;

"medical practitioner" means a person who is authorised to exercise such profession under the Medical and Kindred Professions Ordinance or any other law replacing same;

Cap. 31.

"medicinal prescription" means any medicinal prescription issued by a professional person qualified to prescribe medicinal products by or under this Act;

"medicinal product" means any substance or combination of substances -

(*a*) presented as having properties for treating or preventing disease in human beings; or

(*b*) which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis;

"medicinal products derived from human blood or human plasma" means medicinal products based on blood constituents which are prepared industrially by public or private establishments, such medicinal products including, in particular, albumin, coagulating factors and immunoglobulins of human origin;

"medicinal purpose" includes any one or more of the following purposes:

(*a*) the treating or preventing disease;

(*b*) the diagnosing of disease or ascertaining the existence, degree or extent of a physiological condition;

(*c*) contraception;

(*d*) inducing anaesthesia;

(*e*) the prevention or interference with the normal operation of a physiological function, whether

permanently or temporarily, and whether by way of terminating, reducing or postponing or increasing or accelerating the operation of that function or in any other way.

"Medicines Authority" means the Authority established under article 4;

"Medicines Review Board" means the Board established under article 14;

"Minister" means the Minister responsible for public health;

"name of the medicinal product" means the name, which may be either an invented name not liable to confusion with the common name, or a common or scientific name accompanied by a trade mark or the name of the marketing authorisation holder;

"officinal formula" means any medicinal product which is prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and is intended to be supplied directly to the patients served by such pharmacy;

"outer packaging" means the packaging into which the immediate packaging is placed;

"package", in relation to any medicinal product, means any box, packet or other article in which one or more container of the product are, or are intended to be, enclosed, and, where any such box, packet or other article is, or is to be itself enclosed in one or more other boxes, packets or articles, includes any of the said boxes, packets or articles;

"package leaflet" means a leaflet containing information for the user which accompanies the medicinal product;

"pharmacist" means a person who is authorised to exercise such profession under the Medical and Kindred Professions Ordinance, or any other law replacing the same;

"pharmacy technician" means a person authorised to act as such under the Medical Kindred and Profession Ordinance or any other law replacing the same; Cap. 31.

"post-authorisation safety study" means any study relating to an authorised medicinal product conducted with the aim of identifying, characterising or quantifying a safety hazard, confirming the safety profile of the medicinal product, or of measuring the effectiveness of risk management measures;

"prescribed" means prescribed by regulations made by the Minister under this Act;

"qualified person" means any person who is a qualified person in relation to a manufacturer's licence as provided in article 38 (1)(*e*);

"radionuclide generator" means any system incorporating a fixed parent radionuclide from which is produced a daughter radionuclide which is to be obtained by elution or by any other method and used in a radiopharmaceutical;

"radionuclide precursor" means any radionuclide not being a

radiopharmaceutical, radionuclide generator or kit which is produced for the radio-labelling of another substance prior to administration;

"radiopharmaceutical" means any medicinal product which, when ready for use, contains one or more radionuclides (radioactive isotopes) included for a medicinal purpose;

"recognised laboratory" means any laboratory recognised as such by the Licensing Authority for the purposes of this Act;

"recognised pharmacopeia" means a pharmacopeia recognised by rules for the purpose of this Act;

"responsible person" means any person who is a responsible person in relation to a wholesale dealer's licence as provided in article 55(1)(*d*);

"risk-benefit balance" means an evaluation of the positive therapeutic effects of the medicinal product in relation to the risks as defined in paragraph (*a*) of the definition "risks related to use of the medicinal product";

"risks related to use of the medicinal product" means -

(*a*) any risk relating to the quality, safety or efficacy of the medicinal product as regards patients' health or public health;

(*b*) any risk of undesirable effects on the environment

"rules" means rules made by the Licensing Authority under the provisions of this Act;

"serious adverse reaction" means an adverse reaction which results in death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect

"strength of the medicinal product" means the content of the active substances expressed quantitatively per dosage unit, per unit of volume or weight according to the dosage form;

"substance" means any matter irrespective of origin be it human (including human blood and human blood products), animal (including micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products), vegetable (including micro-organisms, plants, parts of plants, vegetable secretions, extracts), or chemical (including elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis);

"Superintendent of Public Health" has the same meaning as is assigned to it by article 4 of the Department of Health (Constitution) Ordinance; Cap. 94.

"unexpected adverse reaction" means an adverse reaction, the nature, severity or outcome of which is not consistent with the summary of product characteristics;

"veterinary surgeon" means a person who is authorised to exercise such profession under the Veterinary Services Act, or any other law replacing the same; Cap. 437.

"wholesale distribution", in relation to a medicinal product and active substances, includes any one or all activities consisting of procuring, holding, supplying or exporting medicinal products and active substances, apart from supplying medicinal products to the public.

PART II

ADMINISTRATION

Title I - The Licensing Authority

Functions of the Licensing Authority. *Amended by: XI. 2007.3.*

3. (1) The Superintendent of Public Health shall be the Licensing Authority for the purposes of this Act.

(2) The Licensing Authority shall have the following functions:

(*a*) to establish standards to ensure the quality, safety and efficacy of medicinal products;

(*b*) to establish standards for the operation of pharmacies;

(*c*) to establish standards for the manufacture, preparation, assembly, packing, packaging or re-packing and labelling of medicinal products or any substance which is used or is intended to be used in such products;

(*d*) to establish standards for the operation of wholesale distribution;

(*e*) to establish standards for the testing or analysis of medicinal products or any substance which is used or is intended to be used therein;

(*f*) to establish standards for the carrying out of clinical trials;

(*g*) to establish standards for the reporting of adverse reactions, serious adverse reactions or suspected unexpected adverse reactions and make provision for the collection or submission of related information from any person or activity regulated by or under this Act;

(*h*) to establish standards in relation to the advertising of medicinal products;

(*i*) to advise the Minister in the making of regulations in respect of the classification of medicinal products;

(*j*) to issue, renew, amend, vary, suspend or revoke marketing authorisations for medicinal products;

(*k*) to withdraw or recall medicinal products from the market in the interest of public health; and

(*l*) to ensure compliance with international obligations entered into by the Government of Malta in relation to any matter regulated by or under this Act;

(*m*) to issue, renew, amend, vary, suspend or revoke any

authorisation or licence that may be required by or under this Act;

(*n*) to carry out inspections of any activity, service or procedures in relation to medicinal products and to do all such things as may be necessary for the purpose of ensuring compliance with any provisions of this Act, or made thereunder v;

(*o*) to authorise the advertising and promotion of medicinal products;

(*p*) to carry out any other activity as may be prescribed;

(*q*) to advise the Minister on any matter connected with its functions or any other provision of this Act.

(3) The Licensing Authority may by rules delegate any of its functions referred to in subarticle (2)(*l*), (*m*), (*n*) and (*o*) to the Medicines Authority.

(4) The Licensing Authority shall levy such fees as may be prescribed for the purpose of this Act:

Provided that such regulations may provide for the waiving of such fees in such circumstances as may be prescribed.

(5) For the proper exercise of its functions, the Licensing Authority may establish advisory committees as it may deem necessary.

Title II - The Medicines Authority

Establishment of the Medicines Authority. *Substituted by: XXIX. 2007.19. Amended by: V. 2013.3.*

4. There shall be established a Medicines Authority, or such other authority as the Prime Minister may, after consultation with the Minister and the designated Minister, designate in terms of article 109A.

Legal personality of the Medicines Authority.

5. (1) The Medicines Authority shall be a body corporate having a separate and distinct legal personality and shall be capable, subject only to the provisions of this Act, of entering into any contract, of acquiring, holding and disposing of any kind of property both movable and immovable, of employing personnel for the purposes of its operations; and of suing and being sued, and to which any function or operation of government are or may be assigned under this or any other law.

(2) The legal and judicial representation of the Medicines Authority shall vest in the Chief Executive Officer:

Provided that the Medicines Authority may appoint one or more of its officers or employees to appear in its name and on its behalf in any judicial proceedings or in any act, contract, instrument or other document whatsoever.

Functions of the Medicines Authority. *Amended by: III. 2004.45; V. 2013.4.*

6. (1) The Medicines Authority shall have the following functions:

(*a*) to carry out those such functions as may be delegated to it by the Licensing Authority in terms of article

3(3);

(*b*) to assist and advise the Licensing Authority on any matter relating to the regulation of medicinal products and related activities;

(*c*) to undertake such activities and projects as may be necessary or expedient for the proper exercise of its functions;

(*d*) to establish such procedures as may be necessary for obtaining and assessing information as regards the safety, quality and efficacy of medicinal products to be placed on the market in Malta;

(*e*) to establish such procedures as may be necessary to make such assessments of medicinal product safety, quality and efficacy as it may deem necessary for those products to be placed on the market in Malta;

(*f*) to establish such procedures as may be necessary for monitoring and obtaining reports on the quality, safety or efficacy of medicinal products;

(*g*) to make recommendations to the Licensing Authority in relation to standards and licensing;

(*h*) to advise the Licensing Authority on the precautions or restrictions to which medicinal products may be subjected for their marketing or continued use in Malta;

(*i*) to furnish, whenever it so thinks fit or is so requested by the Licensing Authority, advice or make recommendations to the Licensing Authority in relation to any matter connected with its functions; and

(*j*) to notify the EU Commission of non-prescription medicinal products which in its judgement are at risk of falsification and may inform the EU Commission of medicinal products which may be deemed not to be at risk according to the criteria set out in Article 54a(2b) of Directive 2001/83/EC as amended.

(2) For the proper exercise of its functions, the Medicines Authority may require the production of such information or documents as may be necessary for any of its functions and may seek expert advice from any person, who is not a member of the Medicines Review Board, possessing the necessary qualifications and experience, and may also establish such advisory committees as it may deem necessary, either for general or specific purposes.

(3) The Medicines Authority shall levy such fees as may be prescribed for the purposes of this Act:

Provided that such regulations may provide for the waiving of such fees in such exceptional circumstances as may be prescribed.

Organisation of the Medicines Authority.

7. The Authority shall establish such Directorates as may be necessary, and shall assign to each such Directorate those functions

which it may deem expedient for the proper exercise of its functions.

The Chief Executive Officer of the Medicines Authority. *Amended by: V. 2013.5.*

8. (1) The Chief Executive Officer shall be appointed by the Minister from amongst persons who are suitably qualified and experienced in the medical, pharmaceutical or medical science sector.

(2) The Chief Executive Officer shall be responsible for the overall management and performance of the Authority including the management of the day-to-day operations of the Authority.

(3) A person shall not be eligible to be appointed or to hold office as Director or Chief Executive Officer of the Authority if he:

(i) is a member of the House of Representatives; or

(ii) is a Judge or a Magistrate; or

(iii) is legally incapacitated; or

(iv) has been declared bankrupt or has made a composition or arrangement with his creditors; or

(v) has been convicted of fraud or any other offence against public trust, or has otherwise been sentenced to a term of imprisonment for a term not less than three months; or

(vi) has a financial or other interest whether direct or indirect, in any enterprise or activity which is likely to affect the discharge of his functions as a member of the Authority.

(4) (*a*) The Chief Executive Officer of the Authority shall hold office for a period not exceeding five years and shall be eligible for re-appointment for further periods each not exceeding five years.

(*b*) The Chief Executive Officer of the Authority may be relieved from office by the designated Minister prior to the expiry of his term of office where, in the opinion of the designated Minister, he has been guilty of misconduct or on the ground of inability to continue to perform the functions of his office, whether due to infirmity of mind or of body, or to any other cause, or of misbehaviour.

Employees of the Medicines Authority. *Amended by: V. 2013.6.*

9. (1) Subject to the provisions of the Constitution and of any other enactment applicable thereto, and without prejudice to the other provisions of this Act, the appointment of officers or employees of the Authority shall be made by the Authority. The terms and conditions of employment shall be established by the Authority with the concurrence of the designated Minister, given after consultation with the Minister responsible for finance.

(2) The Prime Minister may, at the request of the Authority after it consults with the designated Minister, from time to time and by direction detail a public officer for duty with the Authority in such a capacity and for such term and under such conditions as may be established in relation to the officer so detailed.

(3) The Prime Minister may at any time revoke any such direction given under subarticle (2).

(4) Where an officer is detailed for duty with the Authority such officer shall, during the time in which such a direction is in force, be under the administrative direction and control of the Chief Executive Officer and shall otherwise remain and retain all rights and duties as a public officer and for the purposes of any law relating to government service pension, service with the Authority shall be deemed to be service with the Government:

Provided that no account shall be taken in assessing the pensionable emoluments of such officer for the purposes of any law relating to government service pensions of any allowances, bonuses or gratuities paid to such officer by the Authority in excess to what he is entitled as a public officer:

Provided further that during the time in respect of which he is so detailed to perform duties with the Authority the terms and conditions of his service shall not be less favourable than those which are attached to his appointment under the Government during the period aforesaid. Such terms and conditions shall not be deemed to be less favourable merely because they are not in all respects identical with or superior to those enjoyed by the officer concerned at the date of such offer, if such terms and conditions, taken as a whole, in the opinion of the Prime Minister offer substantially equivalent or greater benefits.

Accounts of the Medicines Authority. *Amended by: XI. 2007.4; V. 2013.7.*

10. (1) The Authority shall keep proper books of account in such manner as the Minister of Finance may from time to time direct. Such accounts shall be audited by an auditor appointed for the purpose by the Authority and shall moreover be subject to audit by the Auditor General.

(2) The Authority shall, not later than six weeks after the end of each financial year, present to the designated Minister and the permanent secretary the audited accounts together with a report on the workings of the Authority which report shall state the manner in which the Authority has operated to fulfil its functions and its plans in the future.

(3) The reports referred to in subarticle (2) shall be laid on the Table of the House of Representatives by the designated Minister not later than six weeks after its receipt, or where the House is during the period not in session not later than the second week after the House resumes its sittings.

Procurement by the Medicines Authority. *Amended by: L.N. 427 of 2007; V. 2013.8.*

11. Except with the approval of the designated Minister, the Authority shall not enter into any contract for the supply of goods or materials or for the execution of work or for the rendering of services, to or for the benefit of the Authority, which is estimated by the Authority to involve an expenditure exceeding two hundred and thirty-two thousand and nine hundred and thirty-seven euro and thirty-four cents (232,937.34) or such other amount as the designated Minister may from time to time direct in writing, except after notice of the intention of the Authority to enter into such contract has been published and competitive tenders have been

issued.

Applicability of the Code of Ethics.

12. The Chief Executive Officer and all other executive officers and employees of the Authority shall conform with and abide by any public service values and Code of Ethics that may be in force from time to time in relation to public officers.

Exemption from tax, etc.

13. The Authority shall be exempt from any liability for the payment of any tax on income or duty on documents for the time being in force in Malta.

Title III - Medicines Review Board

Establishment of Medicines Review Board.

14. (1) There shall be a Medicines Review Board which shall be composed of three members and three substitute members appointed by the Minister, as follows:

(*a*) a person who shall be a legal practitioner having at least seven years' legal experience who shall act as the chairperson; and

(*b*) two other persons who possess the technical and scientific qualifications and experience in the field of regulation of medicinals.

(2) The Minister shall designate a public officer to act as secretary for the Medicines Review Board.

(3) The members of the Medicines Review Board shall be appointed by the Minister for a term of three years under such terms and conditions as may be specified in their appointment. Members so appointed may be re-appointed on the expiration of their term of office.

(4) Where any member of the Medicines Review Board is unable to act, the substitute member having the same qualifications shall act in his stead.

(5) A person shall not be qualified to hold office as a member or substitute member of the Medicines Review Board if he:

(i) is a member of the House of Representatives, or

(ii) is a Judge or a Magistrate; or

(iii) is legally incapacitated; or

(iv) has been declared bankrupt or has made a composition or arrangement with his creditors; or

(v) has been convicted of fraud or any other offence against public trust, or has otherwise been sentenced to a term of imprisonment for a term not less than three months; or

(vi) has a financial or other interest, whether direct or indirect, in any enterprise or activity which is likely to affect the discharge of his functions as a member of the Board.

Cap. 12.

(6) The provisions of Sub-title II of Title II of Book Third of the Code of Organization and Civil Procedure shall, *mutatis mutandis*, apply to members of the Medicines Review Board who

may be challenged or may abstain from sitting on that Board during the hearing of an appeal.

(7) A person shall cease to be a member of the Medicines Review Board at the expiration of his term of office, or if any circumstances arise that, if he were not a member of the Medicines Review Board, he would cease to be qualified for such appointment.

(8) A member of the Medicines Review Board may be removed from office by the Minister if, in his opinion, such member is no longer fit to continue in office or has become incapable of properly performing his duties as a member.

Medicines Review Board may appoint advisors.

15. (1) In the execution of its functions, the Medicines Review Board may seek the advice of any knowledgeable person on any matter which is the subject of an appeal being heard.

(2) The Board may also require any government department and, or authority to provide it with such information or advice it may deem necessary for the proper exercise of its functions.

Functions of the Medicines Review Board.
Amended by: XI. 2007.5; V. 2013.9.

16. (1) It shall be the function of the Medicines Review Board to hear an appeal submitted by the applicant of a marketing authorisation on any recommendation of the Medicines Authority in relation to the safety, quality and efficacy of a medicinal product and to provide advice and make its recommendations to the Licensing Authority in this regard.

(2) Concurrently with the submission of its recommendations to the Licensing Authority, the Board shall also submit a copy of such recommendations to the appellant and to the Medicines Authority.

(3) Any administrative and financial support required by the Medicines Review Board for the performance of its functions shall be provided by the Licensing Authority.

(4) Subject to the foregoing provisions the business of the Medicines Review Board shall be conducted in accordance with the rules contained in the Second Schedule and otherwise the Board may regulate its own procedure.

Procedure of appeal.

17. (1) Where an applicant for a marketing authorisation feels aggrieved by the findings and recommendations made by the Medicines Authority to the Licensing Authority, he may, within fourteen days of the receipt of a copy of such findings and recommendations, file an appeal with the Medicines Review Board.

(2) The Licensing Authority may, if it deems it necessary, within fourteen days of the receipt of the findings and recommendations of the Medicines Authority on the safety, quality and efficacy of a medicinal product, request the Medicines Review Board to provide it with a second opinion on the case.

(3) Any appeal or request for review shall be made in writing and shall be accompanied by the prescribed fee.

(4) The application for an appeal or request for review shall

clearly and comprehensively state the grounds for the appeal or review and shall provide all evidence and documentation to sustain any claim made and which may be necessary to enable the Board to decide on the case:

Provided that the Medicines Review Board may require the submission of such further information or documentation as it may deem necessary:

Provided further that the Medicines Review Board shall after obtaining all the relevant information, process the application within a time limit specified in regulations made under this Act.

Public hearing.

18. (1) The Medicines Review Board shall appoint the matter for public hearing within thirty days of the day of filing of the appeal or request for review and shall decide the matter as expeditiously as possible.

(2) The Medicines Review Board will inform the appellant, the Licensing Authority and the Medicines Authority of its opinion in writing as soon as is practicable.

PART III

GENERAL PROVISIONS

Applicability of certain provisions. *Amended by: III. 2004.46. Substituted by: XI. 2007.6.*

19. (1) The provisions of Titles I, II and III shall apply:

(*a*) to medicinal products for human use intended to be placed on the market in Member States and either prepared industrially or manufactured by a method involving an industrial process;

(*b*) in cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a medicinal product and within the definition of a product covered by other Community legislation.

(2) Titles I, II and III of this Act shall not apply to -

(*a*) any medicinal product prepared in accordance with a magistral formula;

(*b*) any medicinal product prepared in accordance with an officinal formula;

(*c*) medicinal products intended for research and development trials, but without prejudice to the provisions of the Clinical Trials Regulations;

S.L. 458.43

(*d*) radionuclides in the form of sealed sources;

(*e*) whole blood, plasma or blood cells of human origin, except for plasma prepared by a method involving an industrial process;

(*f*) intermediate products intended for further processing by an authorised manufacturer.

(3) (*a*) The Authority may, in accordance with legislation in force and to fulfil special needs, exclude from the provisions of this Act medicinal products supplied in response to a *bona fide* unsolicited order, formulated

in accordance with the specifications of an authorised health-care professional and for use by an individual patient under his direct personal responsibility.

(*b*) The Authority may temporarily authorise the distribution of an unauthorised medicinal product in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm:

Provided that marketing authorisation holders, manufacturers and health professionals are not subject to civil or administrative liability for any consequences resulting from the use of a medicinal product otherwise than for the authorised indications or from the use of an unauthorised medicinal product, when such use is recommended or required by the Authority in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm. This shall apply irrespective of whether or not national or Community authorisation has been granted:

Provided further that liability for defective products, as provided for by Council Directive 85/374/EEC of 25 July, 1985 on the approximation of the laws, regulations and administrative provisions of the Member States, concerning liability for defective products shall not be affected by the preceding proviso.

Title I - Marketing Authorisation Relating to Medicinal Products

Amended by: XI. 2007.7.

Authorisation to place medicinal products on the market.

20. (1) No person shall place a medicinal product on the market in Malta unless he is in possession of a marketing authorisation from the Licensing Authority, in accordance with the provisions of this Act or any regulations or rules made thereunder:

Provided that the Licensing Authority may, in exceptional cases, allow the use of a medicinal product without a marketing authorisation subject to such conditions as it may attach to it:

Provided further that a medicinal product that is essentially identical to a medicinal product for which a marketing authorisation has already been granted shall only be subject to conditions as may be determined by the Licensing Authority.

(2) Any application for the grant of a marketing authorisation shall be made to the Licensing Authority and shall be accompanied by the prescribed fee.

(3) The application shall contain all the information and documents necessary for the assessment of the safety, quality and efficacy of the medicinal product and shall be submitted in such form and manner as the Licensing Authority may by rules require.

(4) The Licensing Authority shall forward the application submitted to it to the Medicines Authority as soon as possible.

(5) Where an application for the issue of a marketing authorisation is received by the Medicines Authority, the Authority may -

(*a*) refuse to process the application if such application is not submitted in accordance with the provisions of this Act;

(*b*) request the applicant to furnish it with such further information relating to the application as it may consider necessary; and where any such request has been made, the Medicines Authority shall not be required to determine the application until the information as requested has been submitted to it;

(*c*) assess the application in respect of medicinal product safety, quality and efficacy in such a manner and within such period as may be prescribed by or under this Act; and

(*d*) carry out any other activity as may be prescribed by the Minister from time to time.

(6) The Medicines Authority shall report its findings and make its recommendations to the Licensing Authority, and shall submit a copy thereof to the applicant, in such a manner and within such period as may be prescribed.

Review or appeal.

21. Where the Licensing Authority or the applicant disagree with the findings or recommendations of the Medicines Authority, either party may lodge an appeal to the Medicines Review Board in the manner established under this Act.

Granting of marketing authorisation.

22. (1) On receipt of the findings and recommendations of the Medicines Authority, or following an appeal or a request for a review by the Medicines Review Board, the Licensing Authority may refuse or otherwise issue a marketing authorisation either as recommended by the Medicines Authority or subject to any such condition or obligation as it may deem necessary.

(2) The decision of the Licensing Authority shall be final and together with the detailed reasons for such decision shall be communicated to the Medicines Review Board, the Medicines Authority and the applicant as necessary.

Notification of marketing authorisation.

23. (1) In granting or refusing a marketing authorisation, the Licensing Authority shall also inform the Medicines Authority of such a decision.

(2) A marketing authorisation shall specify:

(*a*) the summary of product characteristics as approved;

(*b*) the approved labelling and packaging;

(*c*) any conditions that may be attached to the granting of the marketing authorisation;

(*d*) the classification of the medicinal product;

(*e*) the term of validity of the marketing authorisation;

(*f*) any other specification that the Licensing Authority may deem necessary.

Validity of market authorisation.

24. (1) Every marketing authorisation granted under this Act, shall unless previously revoked, expire at the end of its validity.

(2) Every marketing authorisation so granted under this Act shall unless previously revoked, be renewable upon an application by the holder made at least three months before the expiry of the period of validity.

Application of renewal.

25. (1) Where an application for the renewal of a marketing authorisation under this Act has been duly made, the validity of the marketing authorisation shall be deemed to continue to have effect until such time as the Licensing Authority has determined the application.

(2) Notwithstanding the provisions of any other law, no court may issue a warrant of prohibitory injunction restraining the Licensing Authority from determining any such application.

Notification of refusal.

26. The Licensing Authority shall refer an application for renewal of a marketing authorisation to the Medicines Authority, and in such case the provisions of article 20(4), (5) and (6) and of article 21 shall, *mutatis mutandis* apply.

Refusal to renew marketing authorisation.

27. (1) The Licensing Authority may refuse to grant or renew the marketing authorisation on the basis of poor quality, safety and efficacy of the medicinal product or in the interest of public health or any other reason that would normally be a valid reason for the suspension, revocation or refusal of a marketing authorisation:

Provided that the Licensing Authority shall notify the Medicines Authority and the applicant of the decision giving detailed reasons for such decision.

(2) A renewal of a marketing authorisation shall specify -

(*a*) the summary of product characteristics as approved;

(*b*) the approved labelling and packaging;

(*c*) any conditions that may be attached to the granting of the marketing authorisation;

(*d*) the classification of the medicinal product;

(*e*) the term of validity of the marketing authorisation;

(*f*) any other specification that the Licensing Authority may deem necessary.

Suspension or revocation of marketing authorisation. *Amended by: XI. 2007.8; V. 2013.10.*

28. (1) The Licensing Authority shall suspend, revoke, withdraw or vary the marketing authorization for a medicinal product, ensure that the supply of the medicinal product is prohibited and order its withdrawal from the market if:

(*a*) the medicinal product is harmful; or

(*b*) it lacks therapeutic efficacy, where such lack of therapeutic efficacy shall be deemed as occurring when it is concluded that therapeutic results cannot be

obtained from the medicinal product; or

(*c*) the risk benefit balance is not favourable; or

(*d*) its qualitative and quantitative composition is not as declared; or

(*e*) the controls on the medicinal product and, or on the ingredients and the controls at an intermediate stage of the manufacturing process have not been carried out, or if the requirement or obligation relating to the grant of the manufacturing authorisation has not been fulfilled:

Provided that the Licensing Authority may limit the prohibition to supply the medicinal product, or its withdrawal from the market, to those batches which are the subject of dispute.

(2) An authorisation shall also be suspended, revoked, withdrawn or varied where the particulars supporting the application as provided for in this Act are found to be incorrect or have been amended without authorisation or when the requisite controls required by or under this Act have not been carried out. This provision also applies in cases where the manufacture of the medicinal product is not carried out in compliance with the particulars provided pursuant to the description of the manufacturing method submitted in the application for a marketing authorisation, or where controls employed by the manufacturer are not carried out in compliance with the control methods described in the application for a marketing authorisation.

(3) When the packaging, labelling or the package leaflet of the medicinal product in question do not comply with the requirements as specified by or under this Act, the Licensing Authority may suspend the marketing authorisation by notice served on the holder of the marketing authorisation concerned and the suspension shall continue to have effect until the Licensing Authority is satisfied that the requirements have been fulfilled.

(4) If the Licensing Authority suspends or revokes a marketing authorisation, it shall notify the holder of the marketing authorisation and the Medicines Authority of such decision stating in detail the reasons on which such a decision is based.

(5) The holder of the marketing authorisation may, within fourteen days of such notification, request the Medicines Review Board to examine the circumstances leading to the suspension or the revocation of the marketing authorisation, and the Medicines Review Board shall make its recommendations on the matter to the Licensing Authority:

Provided that the request shall not suspend the effects of the decision of the Licensing Authority and that the Licensing Authority shall not be bound by the recommendations made by the Medical Review Board.

(6) The Licensing Authority shall suspend or revoke the marketing authorization for a category of preparations or all preparations where the provisions of Title II are not complied with.

(7) The provisions of this article and of articles 99 to 104, shall apply to homeopathic medicinal products.

Classification of medicinal products.

29. (1) When a marketing authorisation is granted or renewed, the Licensing Authority shall specify the classification of the medicinal product in accordance with the provisions of this Act, but in general into:

(*a*) a medicinal product subject to a medicinal prescription; or

(*b*) a medicinal product not subject to a medicinal prescription, where such medicinal product is considered that with reasonable safety it can be sold or supplied by or under the supervision of a pharmacist unless otherwise provided for by this Act that a medicinal product under subarticle (1)(*b*) is classified under subarticle (1)(*a*).

(2) The Licensing Authority may by rules determine the type, content and presentation or otherwise of a prescription and who is authorised to issue the said prescription that may be needed for a medicinal product or class of medicinal products.

List of medicinal products having a marketing authorisation.

30. (1) The Licensing Authority shall, at least annually, publish in the Gazette a list specifying -

(*a*) the medicinal products that have a valid marketing authorisation;

(*b*) the medicinal products which may only be sold by prescription; and

(*c*) where applicable, the type of prescription required and the person or persons authorised to issue the said prescription.

(2) Whenever a marketing authorisation has been issued in relation to a medicinal product the Licensing Authority shall publish in the Gazette the information specified in subarticle (1)(*a*), (*b*) and (*c*) and such publication shall be deemed to amend the list of medicinal products issued under subarticle (1).

(3) The Licensing Authority shall publish in the Gazette, as soon as is practical, the list of medicinal products for which the marketing authorisation has been suspended or revoked and such publication shall be deemed to amend the list of medicinal products issued under subarticle (1).

Advertising of medicinal products.

31. A medicinal product may only be advertised in accordance with such conditions as may be established by or under this Act.

Marketing authorisation holders to abide by standards.
Added by: V. 2013.11.

31A. Marketing authorisation holders shall abide by the standards on pharmacovigilance, marketing authorisations as well as labelling and packaging as may be established by or under this Act.

Homeopathic medicinal products. *Amended by: III. 2004.47; XI. 2007.9.*

32. (1) Without prejudice to article 28, homeopathic medicinal products which satisfy the conditions in paragraphs (*a*) to (*c*) shall be subject to special simplified procedures as provided in subarticle (2) to (4). The products to which this subarticle applies are products which -

(*a*) are administered orally and externally, subject to such regulations as may be made by the Minister in respect thereof;

(*b*) have no specific therapeutic indication appearing on the labelling of the medicinal product or in any information relating thereto; and

(*c*) have a sufficient degree of dilution to guarantee the safety of the medicinal product, in particular, the medicinal product may not contain either more than one part per 10,000 of the mother tincture or more than $1/100^{th}$ of the smallest dose used in allopathy with regard to active principles whose presence in an allopathic medicinal product results in the obligation to submit a medicinal prescription.

(2) The criteria and rules applicable to the granting of a marketing authorization shall also apply to the special simplified procedure with the exception of the proof of therapeutic efficacy.

(3) Any application for the registration of a homeopathic medicinal product shall contain such documents and information as may be prescribed by regulations made under this Act and such application may cover a series of medicinal products derived from the same homeopathic stock or stocks.

(4) Homeopathic medicinal products which do not satisfy the conditions prescribed in subarticle (1) shall be authorized and labelled in accordance with the provisions of this Act applicable to medicinal products, and shall also be subject to the requirements of pharmacovigilance as established by regulations under this Act.

(5) The Minister may by regulations under this Act prescribe rules for the toxicological and pharmacological tests and clinical trials of homeophathic medicinal products.

Products derived from human blood or human plasma.

33. The provisions of this Part shall apply to medicinal products based on blood constituents which are prepared industrially by a private or a public establishment but shall not apply to blood, plasma or blood cells of human origin.

Radio-pharmaceutical medicinal product.

34. The marketing authorisation referred to in article 20 shall be required for generators, kits, precursor radiopharmaceuticals and industrially prepared radiopharmaceuticals other than radiopharmaceuticals prepared at the time of use by a person or by an establishment authorised, under this Act, to use such medicinal products in an approved health care establishment exclusively from authorised generators, kits or precursor radiopharmaceuticals in accordance with the manufacturer's instructions.

Immunological medicinal products.

35. (1) The provisions of this Part shall apply to immunological medicinal products.

(2) The Licensing Authority may prescribe rules regulating the issue or otherwise of a marketing authorisation for immunological medicinal products.

Herbal medicinal products. *Amended by: III. 2004.48.*

36. The Licensing Authority may prescribe rules regulating the issue or otherwise of a marketing authorisation for herbal medicinal products.

Title II - Manufacture of Medicinal Products for Human Use

Manufacturer's licence. *Amended by: V. 2013.12.*

37. Without prejudice to any exemption that may be granted under this Act, no person shall import from countries which are outside the European Union or European Economic Area, manufacture, assemble or in any way modify any medicinal product except in accordance with a manufacturer's licence issued in accordance with the provisions of this Act or any regulations or rules made thereunder:

Provided that such a licence shall not be required for the preparation, division, changes in packaging or presentation where these processes are carried out for the purpose of dispensing or administering as provided under this Act.

Application for manufacturer's licence.

38. (1) Any application for the grant of a licence to manufacture, assemble or modify a medicinal product shall be made to the Licensing Authority and shall contain such information, documents, samples and other material as provided by or under this Act:

Provided that such application shall indicate the following:

(*a*) the name of the medicinal product and pharmaceutical form or forms, which is to be manufactured, assembled or in any way modified;

(*b*) the place where such activity is to take place, and such information and documentation as may be required in order to show that such place is suitable and sufficient for that purpose;

(*c*) the equipment and control facilities as may be required by or under this Act;

(*d*) the name and address of the applicant;

(*e*) the name of at least one qualified person who shall be professionally responsible for the activity, such person having such qualifications as may be prescribed:

Provided that when more than one qualified person is nominated, the application will clearly delineate the specific responsibilities of each person;

(*f*) any other information, documentation or evidence as may be requested by the Licensing Authority in accordance with or under this Act.

(2) The Licensing Authority shall determine the application in the period of time as may be established under this Act:

Provided that such time may be suspended until the relevant information is provided.

Granting of manufacturer's licence.

39. (1) The Licensing Authority shall, before determining an application, inspect the premises indicated in the application and shall not issue a licence until it is satisfied that such premises conform with the requirements established by or under this Act:

Provided that a licence may be made conditional to the carrying out of such obligations as may be imposed therein.

(2) The manufacturer's licence shall specify the premises and the medicinal products and pharmaceutical form or forms to which it applies.

(3) The licence holder shall ensure that the activity is carried out in accordance to the provisions of this Act and any regulations made thereunder.

Notice for further information.

40. Where the Licensing Authority considers that circumstances may exist which would render necessary the consideration of whether the licence should be varied, suspended or revoked, the Licensing Authority may serve on the holder of a manufacturer's licence a notice requiring him, within such time as may be specified in the notice, to furnish it with any information specified in the notice.

Suspension or revocation of manufacturer's licence.
Amended by: XI. 2007.10.

41. (1) The Licensing Authority may suspend a manufacturer's licence for such period as it may determine, or may revoke, or vary the provisions of, any such licence.

(2) The powers vested in subarticle (1) shall only be exercisable in any of the following circumstances, where:

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

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

(*c*) any of the conditions of the licence has been contravened;

(*d*) the requirements in relation to the licences as established by or under this Act have not been complied with;

(*e*) the processes of manufacture or assembly of a medicinal product are carried out in a manner that is not in compliance with the provisions of the marketing authorisation of that medicinal product;

(*f*) the conditions for good manufacturing practice are not being complied with; and

(*g*) in any other circumstance as is established by or under this Act.

Inspection in relation to manufacturers, etc.

42. (1) The Licensing Authority shall carry out regular inspections to ensure that the requirements established by or under

this Act in relation to the manufacture, assembly or modification of a medicinal product are complied with.

(2) The Licensing Authority or any person carrying out an inspection shall:

(*a*) inspect the manufacturing establishment and any other location he may deem necessary;

(*b*) examine any relevant documents;

(*c*) take any samples he may deem necessary;

(*d*) draw up a report of the findings and communicate the contents of such report to the licensee or the applicant for a licence in relation to such inspection and to the qualified person;

(*e*) carry out any other activity he may deem appropriate for the proper execution of his duties and responsibilities as provided for by or under this Act.

(3) Except in urgent cases an inspection shall be carried out in the presence of a qualified person or his representative, if any.

Duration and renewal of manufacturer's licence. *Substituted by: V. 2013.13.*

43. (1) Subject to the provisions of this Act, every licence granted under this Part shall, unless previously renewed or revoked, continue to be valid until such time as it is renewed by the Licensing Authority following an inspection.

(2) The Licensing Authority shall establish the period of validity of any licence issued under this Part.

(3) Following the inspection mentioned in sub-article (1), the Licensing Authority:

(*a*) may renew the licence, with or without modifications, for such a further period as specified; or

(*b*) if, having regard to the provisions of this Act, it considers it necessary or expedient to do so, may refuse to renew the licence.

Responsibilities of manufacturer's licence holder.

44. It shall be the duty of the holder of a manufacturer's licence -

(*a*) to immediately inform the Licensing Authority of any change of the qualified person;

(*b*) to provide authorised officers access to his premises at any reasonable time;

(*c*) to enable the qualified person to carry out his duties established by or under this Act;

(*d*) to maintain such records for any transaction in medicinal products as may be established by or under this Act and have such records available for inspection by any authorised officer for such period of time as may be required by or under this Act;

(*e*) to have at his disposal the services of staff to satisfy the requirements specified by or under this Act in

relation to the manufacture, assembly or modification of medicinal products;

(*f*) to apply in writing to the Licensing Authority of any change proposed or modification required in relation to the licence;

(*g*) to comply with the regulations or Orders relating to good practice in manufacture as may be established by or under this Act or under any other Act;

(*h*) to dispose of medicinal products as established by or under this Act or under any other Act;

(*i*) other responsibilities as may be established from time to time by or under this Act.

Responsibilities of the qualified person. *Amended by: III. 2004.49.*

45. (1) The responsibilities of a qualified person shall be:

(*a*) to ensure that standards of good practice in manufacturing are complied with at all times;

(*b*) to ensure that each batch of medicinal products has been manufactured, tested and complies in all respects with any requirement established by or under this Act; and

(*c*) to ensure that each batch of medicinal products has been manufactured in accordance with the requirements of the marketing authorisation.

(2) The qualified person shall be permanently and continuously at the disposal of the holder of the manufacturer's licence:

Provided that the qualified persons may nominate another person similarly qualified to act as his representative.

(3) When the qualified person has nominated a representative as aforesaid he shall immediately inform the Licensing Authority of such nomination.

Suspension of activity of a qualified person.

46. The Licensing Authority, may if it has reasonable suspicion to believe that any qualified person is acting in contravention of any of the provisions of this Act, suspend the activity of such qualified person by notice in writing specifying the reasons for such suspension until such person has complied with any requirement of the Licensing Authority to remedy the non-compliance.

Change in conditions of manufacturer's licence.

47. The Licensing Authority may upon an application made by the holder of licence in request thereof, vary the conditions of the licence if it is satisfied that such variation will not adversely affect standards of good practice in manufacture as may be prescribed.

Obligations of Licensing Authority.

48. The Licensing Authority may vary, suspend, revoke or refuse to renew a manufacturer's licence, or it may refer the matter to the Medicines Authority, and in such case the provisions of article 20(4), (5) and (6) and of article 21 shall, *mutatis mutandis* apply.

49. The provisions of articles 37 to 48 shall apply to the manufacture and assembly of homeopathic medicinal products.

Manufacture of homeopathic medicinal products. *Substituted by: XI. 2007.11.*

50. Without prejudice to article 33, the provisions of articles 37 to 48 and any regulations made thereunder shall apply to the manufacture and assembly of medicinal products derived from human blood and human plasma.

Manufacture of medicinal products derived from human blood and human plasma, etc. *Amended by: XI. 2007.12.*

51. Without prejudice to article 34, the provisions of articles 37 to 48 and any regulations made thereunder shall apply to the manufacture and assembly of radiopharmaceutical medicinal products.

Manufacture of radio-pharmaceuticals. *Amended by: XI. 2007.12.*

52. Without prejudice to article 35, the provisions of articles 37 to 48 and any regulations made thereunder shall apply to the manufacture and assembly of immunological medicinal products.

Immunological medicinal product. *Amended by: XI. 2007.12.*

53. Without prejudice to article 36, the provisions of articles 37 to 48 and any regulations made thereunder shall apply to the manufacture and assembly of herbal medicinal products.

Herbal medicinal products. *Amended by: XI. 2007.12.*

Title III - Wholesale Distribution and Brokering of Medicinal Products for Human Use

Substituted by: V. 2013.14.

54. (1) Without prejudice to any exemptions that may be granted by or under this Act, no person shall engage in the wholesale distribution of any medicinal product unless he is the holder of a wholesale dealer's licence issued in accordance with the provisions of this Act. and unless the medicinal product has been granted a marketing authorisation by the Licensing Authority.

Wholesale dealing.

(2) The wholesale distribution of a medicinal product by way of wholesale dealing shall only be carried out from the place specified in, and in accordance with the conditions of, the licence.

54A. (1) Persons may only broker medicinal products if they are established in Malta with a permanent address and are registered with the Licensing Authority. Those persons shall submit, at least, their name, corporate name and permanent address in order to register. They shall notify the Licensing Authority of any changes thereof without unnecessary delay. Persons brokering medicinal products who have commenced their activity on the date of coming into force of this Act* shall register with the Licensing Authority by the 2 March, 2013.

Brokering. *Added by: V. 2013.15.*

(2) The Licensing Authority shall enter the information referred to in sub-article (1) in a register that shall be publicly accessible.

55. (1) Any application for the grant of a wholesaler's licence shall be made to the Licensing Authority and shall contain such information, documents, and other material as provided by or under

Application for a wholesale dealer's licence.

*the reference is to Act V of 2013 which came into force on 1st October, 2013 - see Legal Notice 289 of 2013.

this Act:

Provided that such application shall indicate the following:

(*a*) the name and address of the applicant;

(*b*) the address of the premises that are to be used for the purpose of wholesale distribution;

(*c*) the equipment and control facilities as may be required by or under this Act;

(*d*) information, documentation or evidence to prove that the premises is suitable and adequate, and that there are suitable facilities, installations and equipment so as to ensure proper conservation and distribution of medicinal products;

(*e*) the name of at least one responsible or qualified person who shall be professionally responsible for the activity, such person having such qualifications as may be prescribed:

Provided that when more than one qualified or responsible person is nominated, the application will clearly delineate the specific responsibilities of each person;

(*f*) any other information, documentation or evidence as may be requested by the Licensing Authority in accordance with or under this Act.

(2) The Licensing Authority shall determine the application in the period of time as may be established under this Act:

Provided that such time may be suspended until the relevant information is provided.

Granting of a wholesale dealer's licence.

56. (1) The Licensing Authority shall, before determining an application, inspect the premises indicated in the application and shall not issue a licence until it is satisfied that such premises conform with the requirements established by or under this Act:

Provided that a licence may be made conditional to the carrying out of such obligations as may be imposed therein.

(2) The wholesale dealer's licence shall specify the premises and the activities to which it applies.

(3) The licence holder shall ensure that the activity is carried out in accordance to the provisions of this Act and any regulations made thereunder.

Notice for further information.

57. Where the Licensing Authority considers that circumstances may exist which would render necessary the consideration of whether the licence should be varied, suspended or revoked, the Licensing Authority may serve on the holder of a wholesale dealer's licence a notice requiring him, within such time as may be specified in the notice, to furnish it with any information specified in the notice.

Duration and renewal of wholesale dealer's licence. *Substituted by: V. 2013.15.*

58. (1) Subject to the provisions of this Act, every licence granted under this Part shall, unless previously renewed or revoked, continue to be valid until such time as it is renewed by the Licensing Authority following an inspection.

(2) The Licensing Authority shall establish the period of validity of any licence issued under this Part.

(3) Following the inspection mentioned in sub-article (1), the Licensing Authority:

(*a*) may renew the licence, with or without modifications, for such a further period as specified; or

(*b*) if, having regard to the provisions of this Act, it considers it necessary or expedient to do so, may refuse to renew the licence.

Obligations of holder of wholesale dealer's licence.

59. It shall be the duty of the holder of a wholesale dealer's licence -

(*a*) to immediately inform the Licensing Authority of any change of the qualified or responsible person;

(*b*) to provide authorised officers access to his premises at any reasonable time;

(*c*) to enable the Licensing Authority to carry out its duties established by or under this Act;

(*d*) to maintain such records for any transaction in medicinal products as may be established by or under this Act and have such records available for inspection by any authorised officer for such period of time as may be required by or under this Act.

Responsibilities of the responsible person. *Amended by: III. 2004.50.*

60. (1) The responsible person shall ensure that standards of good practice in wholesale distribution as may be prescribed are complied with at all times.

(2) The qualified person or responsible person shall be permanently and continuously at the disposal of the holder of the wholesale dealer's licence:

Provided that the qualified or responsible person may nominate another person to act as his representative.

(3) When the qualified or responsible person has nominated a representative as aforesaid he shall immediately inform the Licensing Authority of such nomination.

Suspension of responsible person. *Added by: V. 2013.17.*

60A. The Licensing Authority may, if it has reasonable suspicion to believe that any responsible person is acting in contravention of any of the provisions of this Act, suspend the activity of such responsible person by notice in writing specifying the reasons for such suspension until such person has complied with any requirement of the Licensing Authority to remedy the non-compliance.

Suspension or revocation of wholesale dealer's licence.

61. The Licensing Authority may suspend a wholesale dealers' licence granted under this Act for such period as it may determine, or may revoke, or vary the provisions of, any such licence in any of the following cases:

(*a*) where the matters stated in the application on which the licence was issued were false or incomplete in a material particular;

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

(*c*) where any of the conditions of the licence has been contravened;

(*d*) where the requirements in relation to the licence as established by or under this Act have not been complied with;

(*e*) where conditions of good practice in wholesale distribution are not being complied with; and

(*f*) in any other circumstance as may be established by or under this Act.

Change in conditions of a wholesale dealer's licence.

62. The Licensing Authority may, upon an application made by the holder of a licence in respect thereof, vary the conditions of the licence, if it is satisfied that such variation will not adversely affect the standards of good practice in wholesale distribution.

Obligations of Licensing Authority.

63. The Licensing Authority may vary, suspend, revoke or refuse to renew a wholesale dealer's licence, or it may refer the matter to the Medicines Authority, and in such case the provisions of article 20(4), (5) and (6) and of article 21 shall, *mutatis mutandis* apply.

Inspecting in relation to wholesale.

64. (1) The Licensing Authority shall ensure that the requirements established by or under this Act in relation to the wholesale dealing of a medicinal product are complied with.

(2) The Licensing Authority shall:

(*a*) inspect the wholesale dealing establishment and any other location it may deem necessary;

(*b*) examine any documents relating to the inspection;

(*c*) take any samples it may deem necessary;

(*d*) draw up a report of the findings, which shall be communicated to the licensee or the applicant for a licence in relation to such inspection and to the responsible person;

(*e*) carry out any other activity it may deem appropriate for the proper execution of its duties and responsibilities as provided for by or under this Act.

Special provisions.

65. Without prejudice to the provisions of this Part, the Licensing Authority may by rules establish additional requirements for the wholesale distribution of:

(*a*) narcotic or psychotropic substances;

(*b*) medicinal products derived from blood;

(*c*) immunological medicinal products;

(*d*) radiopharmaceuticals;

(*e*) such other medicinal products or class or classes of medicinal products as the Minister may prescribe.

Title IV - Pharmacies and Related Pharmaceutical Activity

Licence to open a pharmacy.

66. (1) It shall not be lawful for any person to open or keep a pharmacy unless he is in possession of a pharmacy licence issued in accordance with the provisions of this Act or any regulations made thereunder.

(2) Licences are to be issued in accordance with geo-demographic criteria as may be established by regulations made under this Act.

(3) Regulations under this article shall not be made unless the Minister shall have first published a draft thereof in the Government Gazette allowing any person a period of at least four weeks to make representations to the Minister.

(4) The Minister shall request the Licensing Authority to report on any representation made to him after hearing such person or taking such expert advice as it considers expedient, together with any views it may have and the Minister may, upon receipt of the report by the Licensing Authority proceed to revise the draft regulations and to promulgate such regulations in accordance with such revision.

(5) Without prejudice to any exemption that may be granted by or under this Act, no person shall sell by retail any medicinal product expect in accordance with a pharmacy licence issued in accordance with the provisions of this Act or any regulations or rules made thereunder.

(6) The licensee shall be responsible for complying with the conditions of the licence as may be established by or under this Act.

Application for a pharmacy licence. *Amended by: V. 2013.19.*

67. (1) Any application for the grant of a pharmacy licence shall be made to the Licensing Authority and shall contain such information, documents, samples and other material as provided by or under this Act:

Provided that such application shall indicate the following:

(*a*) the name and address of the applicant;

(*b*) the address of the premises that are to be used for the purpose of the retail sale of the medicinal products;

(*c*) the equipment and control facilities as may be required by or under this Act;

(*d*) the name of a managing pharmacist who shall be professionally responsible for all activities;

(*e*) any other information, documentation or evidence as may be requested by the Licensing Authority in

accordance with or under this Act.

(2) The Licensing Authority shall determine the application in the period of time as may be established under this Act:

Provided that such time may be suspended until the relevant information is provided.

Grant of a pharmacy licence. *Amended by: V. 2013.20.*

68. (1) The Licensing Authority shall, before determining an application, inspect the premises indicated in the application and shall not issue a licence until it is satisfied that such premises are suitable and adequate, and that there are suitable facilities, installations, and equipment so as to ensure proper conservation and dispensing of medicinal products:

Provided that a licence may be made conditional to the carrying out of such obligations as may be imposed therein.

(2) The pharmacy licence shall specify the premises and the activities to which it applies:

Provided that the Licensing Authority may, upon application, grant an additional licence for the use of identified premises to be used as a store for the purpose of the pharmacy after it is satisfied that such premises comply with any requirements established by or under this Act.

Notice for further information.

69. Where the Licensing Authority considers that circumstances may exist which would render necessary the consideration of whether the licence should be varied, suspended or revoked, the Licensing Authority may serve on the holder of a pharmacy licence a notice requiring him, within such time as may be specified in the notice, to furnish it with any information specified in the notice.

Duration and renewal of pharmacy licence. *Substituted by: V. 2013.21.*

70. (1) Subject to the provisions of this Act, every licence granted under this Part shall, unless previously renewed or revoked, continue to be valid until such time as it is renewed by the Licensing Authority following an inspection.

(2) The Licensing Authority shall establish the period of validity of any licence issued under this Part.

(3) Following the inspection mentioned in sub-article (1), the Licensing Authority:

(*a*) may renew the licence, with or without modifications, for such a further period as specified; or

(*b*) if, having regard to the provisions of this Act, it considers it necessary or expedient to do so, may refuse to renew the licence.

Transfer of a pharmacy licence.

71. No person may transfer a licence unless authorised by the Licensing Authority which authorisation shall not be issued unless the Licensing Authority is satisfied that the new licensee complies with any requirement established by or under this Act, and on payment of the prescribed fee.

Suspension or revocation of pharmacy licence.

72. The Licensing Authority may suspend a pharmacy licence granted under this Act for such period as it may determine or may revoke, or vary the provisions of any such licence in any of the following circumstances:

(*a*) where any matter stated in the application on which the licence was issued is false or incomplete

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

(*c*) where the provisions of the licence have been contravened by the licensee; or

(*d*) in any other circumstance as may be established by or under this Act:

Provided that the Licensing Authority shall notify the licensee of the decision giving detailed reasons for such decision.

Temporary closure of pharmacy.

73. (1) The licensee of a pharmacy shall not close a pharmacy, temporarily or otherwise, unless he has given at least twenty-four hours notice to, and such closure has been authorised by, the Licensing Authority:

Provided that the temporary closure shall not be construed to include the closure of a pharmacy resulting from the unforeseen or unexpected absence of a pharmacist, *force majeure* resulting in the inability to open the premises, or closure outside the business hours established for pharmacies by rules made the Licensing Authority.

(2) Subject to the provisions of subarticle (1), the licence in relation to a pharmacy which has remained closed for a period of five consecutive working days without the authorisation of the Licensing Authority shall be deemed to have been automatically revoked.

(3) The Licensing Authority may, on receipt of a notice as is referred to in subarticle (1), or where it has come to its knowledge that a pharmacy has been closed, seal all the medicinal products, wherever kept by the licensee in terms of the provisions of this Act, and take charge of any register required to be kept by the licensee under this or any other law.

Obligations of the holder of a pharmacy licence. *Amended by: V. 2013.22.*

74. It shall be the duty of the holder of a pharmacy licence -

(*a*) to inform the Licensing Authority of any change of the managing pharmacist, prior to such change;

(*b*) to provide authorised officers access to his premises at any reasonable time;

(*c*) to enable the Licensing Authority to carry out its duties established by or under this Act;

(*d*) to maintain such records for any transaction in medicinal products as may be established by or under this Act and have such records available for inspection by any authorised officer for such period of time as may be required by or under this Act;

(*e*) to comply with regulations or Orders relating to good practice in retail sale of medicinal products as may be established by or under this Act;

(*f*) to dispose of medicinal products as established by or under this Act or any other law;

(*g*) ensure that a pharmacist is present at all times during the time when the pharmacy is open;

(*h*) other responsibilities as may be established from time to time by or under this Act.

Managing pharmacist. *Amended by: V. 2013.23.*

75. (1) Every pharmacy shall be managed by a pharmacist hereinafter referred to as the "managing pharmacist".

(2) The managing pharmacist shall:

(*a*) act as the managing pharmacist of a licensed pharmacy including any other premises used as a store by the said pharmacy in terms of article 68(2);

(*b*) ensure that he or another pharmacist is present in the pharmacy at all times in order to sell or supervise the sale of medicinal products and to keep records of the pharmacist who was present while the pharmacy was open;

(*c*) keep any documents, information or evidence in the manner as may be required to be kept by or under this Act;

(*d*) carry out such obligations pertaining to a managing pharmacist as may be established by or under this Act;

(*e*) nominate a substitute managing pharmacist when he cannot carry out his duties for a period of five or more consecutive days and shall notify the Licensing Authority of this substitution:

Provided that in exceptional cases the licensee may nominate a replacement and notify the Licensing Authority;

(*f*) comply with regulations or rules relating to good practice in the dispensing of medicinal products as may be established by or under this Act;

(*g*) dispose of medicinal products as established by or under this Act or any other law.

(3) No pharmacist may, without the authority in writing of the Licensing Authority, act as a managing pharmacist of two or more pharmacies:

Provided that the Licensing Authority shall not give such authority unless it is satisfied that such pharmacist can reasonably carry out the duties of a managing pharmacist for more than one pharmacy.

(4) No pharmacist shall take up or abandon his duties as a managing pharmacist of any pharmacy without giving prior notice in writing to that effect to the Licensing Authority.

Suspension of managing pharmacist. *Added by: V. 2013.24.*

75A. The Licensing Authority may, if it has reasonable suspicion to believe that any managing pharmacist is acting in contravention of any of the provisions of this Act, suspend the activity of such managing pharmacist by notice in writing specifying the reasons for such suspension until such person has complied with any requirement of the Licensing Authority to remedy the non-compliance.

Duties of pharmacist.

76. (1) Unless otherwise provided by or under this Act, a medicinal product shall only be prepared or dispensed from a pharmacy and by a pharmasist:

Provided that a pharmacist may permit medicinal products to be prepared or dispensed by a pharmacy technician under his personal supervision as regulated by or under this Act.

(2) In carrying out his functions in the preparation and dispensing of medicinal products from a pharmacy, a pharmacist shall act in accordance with such standards as may be established by or under this Act or any other Act.

Interest in a pharmacy. *Substituted by: XI. 2007.13.*

77. The conditions and criteria where any person can have or not have a direct or indirect interest in a pharmacy shall be prescribed under this Act.

Licensee may employ one or more pharmacists.

78. The licensee shall employ a pharmacist to carry out the responsibilities of a managing pharmacist and shall provide all the support and in no way interfere with the managing pharmacist's or a pharmacist's professional responsibilities in the performance of his duties as defined in by or under this Act or under any other law.

Medicinal products to be sold from a pharmacy.

79. (1) A pharmacy shall only dispense in medicinal products and trade in products or groups or classes of products that may from time to time be established by rules made by the Licensing Authority.

(2) Unless otherwise provided by or under this Act, a medicinal product shall only be sold from a pharmacy:

Provided that the Licensing Authority may, in special circumstances relating to the provision of services to the public, by rules prescribe that a medicinal product or class or classes of medicinal products therein specified may be sold from a premises other than a pharmacy such premises not being a general retail outlet:

Provided further that the Licensing Authority may with same circumstances by rules prescribe that a medicinal product of class or classes of medicinal products therein specified may be sold, prepared or provided to a patient by a person, other than a pharmacist, who is suitably qualified for such purpose:

Provided also that such rules shall provide for the circumstances under which such a sale, preparation or provision may occur and impose such restrictions as may be provided.

(3) The Licensing Authority may by rules establish a list of medicinal products that as a minimum must be available at a pharmacy at all times:

Provided that this requirement may be temporarily waived in relation to a particular medicinal product or class of medicinal product in exceptional circumstances, if the Licensing Authority is satisfied that the unavailability of such a medicinal product or class of medicinal product from a pharmacy is beyond the control of the managing pharmacist.

Dispensing of a medicinal product. *Amended by: XI. 2007.14.*

80. (1) A pharmacist shall prepare or dispense any medicinal product required by any person presenting a prescription unless he has a justified reason of concern that the prescription is false, that the person is misusing the prescribed medicinal product, or that the medicinal product is not available or if he has professional reasons for not preparing or dispensing the prescription.

(2) Upon presentation of a prescription for a medicinal product, unless the prescriber specifically requests a particular branded product by writing "branded" or "®" on the prescription, a pharmacist can dispense the medicinal product prescribed or an equivalent medicinal product having the same chemical entity, dose, dosage form and dosage frequency as the medicinal product indicated on the prescription.

(3) When, in dispensing any medicinal product, a pharmacist discovers that there are reasons why the medicinal product should not be dispensed to the patient or that the dosage regimen indicated on the prescription goes beyond what can be considered a safe therapeutic dose, the pharmacist is bound to draw the attention thereto of the person prescribing the same and may require such person to write out in ink or in other indelible manner on the prescription a statement assuming responsibility for the prescription.

(4) The pharmacist shall assume full responsibility for the dispensing of medicinal products which do not need a prescription for dispensing to patients.

Dispensing against prescription. *Amended by: V. 2013.25.*

81. (1) It shall not be lawful for any pharmacist to dispense any medicinal product except on the prescription of a medical or dental practitioner, veterinary surgeon or other person authorized to prescribe under this or any other Act, unless the medicinal product is deemed not to require a medicinal prescription by the Licensing Authority.

(2) The provisions of subarticle (1) shall also apply to products or substances not classified as medicinal products but which have been deemed to require a medicinal prescription for their use by the relevant competent authority.

(3) It shall be lawful for a pharmacist to dispense any medicinal product on the prescription of a medical practitioner, dentist or veterinary surgeon from an EU member state provided that the pharmacist can ascertain that such medical practitioner, dentist or veterinary surgeon is licensed to practice his profession in the member state of origin.

Presentation of a prescription.

82. The Licensing Authority may by rules prescribe the format, content and presentation of a prescription required by or under this

Act.

Labelling of dispensed products. *Amended by: XI. 2007.15.*

83. The pharmacist shall label each medicinal product or magistral formula or officinal formula dispensed in accordance with such regulations or rules made under this Act.

Disposal of expired, deteriorated or imperfect products.

84. It shall not be lawful for any managing pharmacist to sell, allow the sale, dispensing or supply in any other way of -

(*a*) any imperfect, deteriorated or harmful substance;

(*b*) any medicinal product bearing an expiry date which has expired;

(*c*) food not in accordance with the provisions of the Food Safety Act, or any regulations made thereunder: Cap. 449.

Provided that such imperfect, deteriorated or expired substances or medicinal products shall only be kept in such place and in such a manner as the Licensing Authority may from time to time by rules establish.

Storage of medicinal products in pharmacy.

85. (1) It shall not be lawful for any managing pharmacist to keep anywhere within the pharmacy any medicinal product in any container or under such conditions which are not suitable to the nature thereof and which are not such as to protect it from alteration, deterioration or contamination.

(2) It shall not be lawful for any managing pharmacist to permit any medicinal product under his charge to be kept or stored outside the pharmacy under his management, and it shall be his duty to ensure that the pharmacy has the facilities to ensure that medicinal products are stored in accordance with storage recommendations:

Provided that in the case where the Licensing Authority has granted a licence for the keeping or storage of medicinal products in any premises other than the pharmacy, the responsibilities of the managing pharmacist shall also apply to such premises.

Premises, etc., in accordance with requirements and standards.

86. Premises, facilities, records and equipment used for the storage, preparation and dispensing of medicinal products are to be kept in accordance with the requirements and standards established by or under this Act.

Pharmacist to be guided by set standards. *Amended by: XI. 2007.16.*

87. The preparation of magistral and officinal formulas, and the division of authorised packs into smaller units, reconstitution, dispensing and administration of medicinal products and any other activity related to medicinal products and their use shall be in accordance with such standards as may be established under this Act.

Inspections of pharmacies.

88. (1) The Licensing Authority shall have the right to inspect pharmacies and any premises licensed for use as stores under article 68(2) whenever it deems necessary.

(2) Any inspection as aforesaid shall be carried out in the presence of the managing pharmacist or of the pharmacist for the time being in charge of the pharmacy.

(3) At the time of the inspection, the inspecting officer shall

draw up a list of deficiencies that may have been identified at the time of the inspection and shall sign this list, and such list shall be countersigned by the managing pharmacist or by the pharmacist for the time being in charge of the pharmacy:

Provided that the inspecting officer shall draw up a report of the inspection within seven working days of the inspection and shall forward a copy of such report to the Licensing Authority, the licensee and the managing pharmacist:

Provided also that the managing pharmacist or pharmacist for the time being in charge of the pharmacy may make comments or otherwise make reservations in respect of the contents of the said list.

(4) (*a*) If in the course of the inspection, any article is found to be in breach of the provisions of this Act or any regulation made thereunder, the inspecting officer shall forthwith seize the said article.

(*b*) The wrapper or receptacle containing the article so seized shall be sealed and the signature of the inspecting officer and the managing pharmacist shall be appended to the seal:

Provided that if the managing pharmacist so requests, the article in question shall be divided, by the inspecting officer, in two equal parts, sealed and signed in the manner as aforesaid, and one part be given to the managing pharmacist:

Provided further that the inspecting officer shall send the seized article, sealed and signed in the manner aforesaid to the Licensing Authority together with the inspection report as described in subarticle (3).

(5) If the managing pharmacist or the pharmacist for the time being in charge of the pharmacy refuses to countersign the list referred to in subarticle (3), the inspecting officer shall record such fact on the said list together with the reason given, if any, for such refusal.

Opening of pharmacies.

89. The Licensing Authority may by notice in the Gazette establish the business hours of pharmacies and may also require pharmacies in specified localities or districts to open for the serving of customers on such days and for such times as may be specified in such notice.

PART IV

POISONOUS SUBSTANCES

Definition of poisons.

90. For the purposes of the provisions contained in this Part, "poison" means -

(*a*) all those substances which, taken even in a very small dose, may cause the death or serious injury to any person,

(*b*) all those substances which the Minister may, on the

advice of the Licensing Authority, prescribe,

but does not include any similar substance which is used, or is intended to be used, for day to day domestic purposes, which latter substance, however shall be deemed to be a poison for the purpose of article 94.

Keeping, etc., of poisons.

91. It shall not be lawful for any person to keep for sale, manufacture, sell or otherwise distribute or deal in any poison without a licence from the Licensing Authority.

Licence for sale of poisons.

92. (1) The licence mentioned in article 91 shall only be granted to manufacturers of, and dealers in chemical products, colorists and such other persons as require to make use of poisons in the exercise of their trade or profession.

(2) Such licence shall show the name and surname of the licensee, his trade or profession, and the place in which he intends to carry on such trade or profession and any other information as may be established from time to time by rules made by the Licensing Authority.

Keeping of poisonous substances in a safe place.

93. Every person granted a licence under article 91 shall keep all poisonous substances in a separate and safe place the key whereof shall be always kept by the licence holder.

Sale of poisonous substances.

94. (1) No person granted a licence under article 91 shall sell or deliver any poisonous substance, either by wholesale or retail, to any person not being a pharmacist, except on production of a prescription or for purposes of disinfection or industry or for any other purpose as may be authorised by the Licensing Authority.

(2) Every person granted a licence under article 91 shall keep, maintain, update, store and make available to the Licensing Authority or any authorised person any information as may from time to time be required by the Licensing Authority and in any such manner as may be form time to time be required by the Licensing Authority.

(3) Poisonous substances shall be labelled in such a manner the Licensing Authority may from time to time by rules establish.

Power of inspection.

95. The Licensing Authority or any authorised officer, may in the interest of public health, pay surprise visits to the business premises of manufacturers of and dealers in chemical products and of the other persons referred to in article 91.

Poisoned grain, seed etc., Cap. 430.

96. Without prejudice to the provisions of the Pesticides Control Act, it is prohibited to sow, cast, put or place, or cause to be sown, cast, put or placed in or upon any land or other exposed place any grain, seed, meal, or flesh which has been so dipped or steeped in poison, or has been so mixed with poison or other ingredient or preparation as to be rendered poisonous and calculated to destroy life.

PART V

OTHER DEALINGS WITH MEDICINAL PRODUCTS

Special restrictions on persons to be supplied with medicinal products.

97. The Licensing Authority may by rules provide, either in respect of medicinal products generally or in respect of medicinal products of a description or falling within a class specified in the rules that, subject to such exceptions as may be so specified, no person -

(*a*) being the holder of a marketing authorisation, or

(*b*) in the course of business carried by him and consisting, in whole or in part, of manufacturing medicinal products or of selling medicinal products by way of wholesale dealing,

shall sell or supply any medicinal product to which the rules apply to any person who does not fall within a class specified in those rules.

Adulteration of medicinal products. *Amended by: V. 2013.26.*

98. No person shall -

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

(*b*) knowingly or unknowingly sell or supply, or offer or expose for sale or supply, or have in his possession for the purpose of sale or supply:

(i) any medicinal product whose composition has been injuriously affected by the addition or abstraction of any substance;

(ii) any medicinal product which is deliberately and fraudulently mislabeled with respect to identity and, or source including products with the correct ingredients, with the wrong ingredients, without active ingredients, in an insufficient quantity or excessive quantity of active ingredients or with fake packaging.

PART VI

OFFENCES AND PENALTIES

Offences and penalties. *Amended by: XI. 2007.17; L.N. 427 of 2007. Substituted by: V. 2013.27.*

99. (1) Without prejudice to any other liability under any other law, any person who fails to comply with any of the provisions of this Act or any regulations or rules made thereunder shall be guilty of an offence and shall, on conviction, be liable, in the case of an offence against:

(*a*) the provisions of articles 20(1), 37, 54, 54A, 98 and 104A, to a fine (*multa*) of not less than eleven thousand and six hundred and forty-six euro and eighty seven cents (11,646.87) and not exceeding one hundred and sixteen thousand and four hundred and sixty-eight euro and sixty-seven cents (116,468.67) or to imprisonment for a term not exceeding two years, or both such fine and imprisonment;

(*b*) the provisions of articles 31A, 44 and 56(3), to a fine (*multa*) of not less than five thousand eight hundred and twenty-three euro and seventy-five cents (5,823.75) and not exceeding sixty-nine thousand and eight hundred and eighty-one euro and twenty cents (69,881.20) or to imprisonment for a term not exceeding six months, or both such fine and imprisonment;

(*c*) the provisions of articles 32(4), 45, 66(1), 66(5), 66(6), 66A, 71, 75(3), 75(4), 76(1), 81(1) and 91, to a fine (*multa*) of not less than two thousand and three hundred and twenty-nine euro and thirty-eight cents (2,329.38) and not exceeding forty-six thousand and five hundred and eighty-seven euro and forty-seven cents (46,587.47) or to imprisonment for a term not exceeding three months, or to both such fine and imprisonment;

(*d*) the provisions of articles 59, 60, 74, 75(1), 75(2), 84, 93, 94(1) and 96, to a fine (*multa*) of not less than one thousand and one hundred and sixty-four euro and sixty-nine cents (1,164.69) and not exceeding twenty-three thousand and two hundred and ninety-three euro and seventy-three cents (23,293.73);

(*e*) the provisions of articles 78, 83, 85(1), 85(2), 86, 87 and 94(2), to a fine (*multa*) of not less than four hundred and sixty-five euro and eighty-seven cents (465.87) and not exceeding eleven thousand and six hundred and forty-six euro and eighty-seven cents (11,646.87);

(*f*) the provisions of articles 31, 73(1), 79(1), 79(2), 80(1), 80(2) and 94(3), to a fine (*multa*) of not less than two hundred and thirty-two euro and ninety-four cents (232.94) and not exceeding two thousand and three hundred and twenty-nine euro and thirty-seven cents (2,329.37).

(2) Without prejudice to the powers of the Licensing Authority under this Act, where any person who has committed an offence is the holder of a licence or an authorisation under this Act, the Court shall, at the request of the prosecution, order the revocation or suspension of the aforesaid licence or authorisation.

Special procedure.
Amended by: L.N. 427 of 2007; V. 2013.28.

100. (1) Notwithstanding any other law providing for the trial of offences, where the Licensing Authority believes that a person has committed an offence against this Act or any regulations or rules made thereunder, the Authority shall give notice in writing to such person describing the offence of which the person is accused, indicating the steps to be taken to remedy the offence and the penalty which he is required to pay in respect of that offence.

(2) The provisions of sub-article (1) shall not apply in offences where there is a breach of articles 20(1), 37, 44, 54, 56(3), 98 and 104A.

(3) The Minister shall prescribe the penalties that may be demanded by the Licensing Authority in relation to any specified offence:

Provided that such penalty shall not exceed an amount of twenty-three thousand and two hundred and ninety-three euro and seventy-three cents (23,293.73).

(4) Where a notice under this article has been given, the person named in the notice may, within twenty-one days of the service of the notice, accept responsibility for the offence specified in the notice and within the same period pay the penalty indicated in the notice, and comply with the relative provision of this Act, or of the regulations or rules made thereunder and no further proceedings may be taken under this Act in respect of such offence.

(5) Where the person to whom notice is given under subarticle (1) has not paid the penalty within the twenty-one day period referred to in subarticle (3) and has not, within the time specified, complied with the requirements of this Act, criminal proceedings may be taken against him in accordance with the provisions of the Criminal Code, of this Act and of any other law applicable of the offence.

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PART VII

ENFORCEMENT

Right of entry. *Amended by: XI. 2007.18.*

101. (1) Subject to the provisions of this article, and without prejudice to the other provisions of this Act, any person duly authorised in writing by the Licensing Authority shall, on production of his authorisation or credentials, have a right at any reasonable time to enter and carry out repeated and unannounced inspections at any premises:

(*a*) for the purpose of ascertaining whether there is or has been, or there is likely to be any contravention of any provisions of this Act or of any regulations or rules made thereunder;

(*b*) generally for the purposes of the exercise by the Licensing Authority of its function under this Act or under any regulations or rules made thereunder.

For the purposes of this Part, premises shall include any building, structure, any other place whatsoever or any means of transport.

(2) Any authorised officer shall, on the production of his authorisation, have a right at any reasonable time to board any ship or aircraft for the purpose of ascertaining whether there is in the ship or aircraft any substance or article imported in contravention of any provisions of this Act or of any regulations or rules made thereunder or whether the said craft is carrying out any activity in contravention to any of the said provisions.

Requirements for testing and inspections of manufacturers, importers, brokers and distributors of medicinal products, including APIs, excipients and other starting materials. *Added by: V. 2013.29.*

101A. (1) The Licensing Authority shall, in cooperation with the European Medicines Agency, ensure that the legal requirements governing medicinal products are complied with, by means of inspections, if necessary unannounced, and, where appropriate, by asking an Official Medicines Control Laboratory or a laboratory designated for that purpose to carry out tests on samples. This cooperation shall consist in sharing information with the European Medicines Agency on both inspections that are planned and that have been conducted as well as in the coordination of inspections in third countries.

(2) The inspections shall include but not be limited to the ones mentioned in paragraphs (*a*) and (*b*) as follows:

(*a*) manufacturers, located in the European Union or in third countries, and wholesale distributors of medicinal products shall be subject to repeated inspections;

(*b*) the Licensing Authority shall have a system of supervision including by inspections at an appropriate frequency based on risk, at the premises of the manufacturers, importers, or distributors of active substances, located in Maltese territory, and effective follow-up thereof.

(3) Whenever it considers that there are grounds for suspecting non-compliance with the legal requirements laid down in this Act and subsidiary legislation made thereunder, including the European Union principles and guidelines of good manufacturing practice and good distribution practices, the Licensing Authority may carry out inspections at the premises of:

(*a*) manufacturers or distributors of active substances located in third countries;

(*b*) manufacturers or importers of excipients.

(4) Inspections referred to in sub-articles (2) and (3) may also be carried out in the European Union and in third countries at the request of a European Union Member State, the European Union Commission or the European Medicines Agency.

(5) Inspections may also take place at the premises of marketing authorisation holders and of brokers of medicinal products.

(6) Inspections shall be carried out by officials representing the Licensing Authority who shall be empowered to inspect the premises, records, documents and pharmacovigilance system master file of the marketing authorisation holder or any firms employed by the marketing authorisation holder to perform any pharmacovigilance activities.

(7) Inspections shall be carried out in accordance with the guidelines and provisions referred to in articles 101 to 104.

(8) After every inspection, the Licensing Authority shall report on whether the inspected entity complies with the European Union principles and guidelines of good manufacturing practice and good

distribution as applicable, or on whether the marketing authorisation holder complies with the pharmacovigilance requirements laid down in this Act and subsidiary legislation made thereunder.

(9) The Licensing Authority shall communicate the content of those reports to the inspected entity. Before adopting the report, the Licensing Authority shall give the inspected entity concerned the opportunity to submit comments.

(10) Without prejudice to any arrangements which may have been concluded between the European Union and third countries, a Member State, the European Union Commission or the European Medicines Agency may require a manufacturer established in a third country to submit to an inspection as referred to in this article.

(11) Within ninety days of an inspection as referred to in sub-article (1), a certificate of good manufacturing practice or good distribution practices shall, when applicable, be issued to the inspected entity if the outcome of the inspection shows that it complies with the principles and guidelines of good manufacturing practice or good distribution practices as provided for by European Union legislation.

(12) If inspections are performed as part of the certification procedure for the monographs of the European Pharmacopoeia, a certificate shall be drawn up.

(13) Certificates of good manufacturing practice and good distribution practices issued shall be entered in the European Union database managed by the European Medicines Agency on behalf of the European Union. Information shall also be entered in that database regarding the registration of importers, manufacturers and distributors of active substances.

Power to inspect, take samples and seize goods and documents. *Amended by: XI. 2007.19; V. 2013.30.*

102. (1) For the purpose of ascertaining whether there is or has been or there is likely to be a contravention of this Act or of any regulations or rules made thereunder, an authorised officer shall have a right to inspect:

(*a*) any substance or article appearing to him to be a medicinal product;

(*b*) any article used or intended to be used to contain any medicinal product or to be a label or leaflet used or intended to be used in connection with a medicinal product;

(*c*) any plant or equipment appearing to him to be used or intended to be used in connection with the manufacture or assembly of medicinal products, and any process of manufacture or assembly of any medicinal products and the means employed, at any stage in the process of manufacture or assembly, for testing the materials after they have been subjected to those processes; or

(*d*) any premises, records, documents and pharmacovigilance system master file of the marketing authorisation holder

or any firms employed by the marketing authorisation holder to perform pharmacovigilance activities as established under article 31A:

Provided that an authorized officer may also carry out inspections of starting material manufacturers after a specific request for the purpose is made by such manufacturer himself:

Provided further that the samples that may be collected may be analysed at a designated laboratory identified by the Authority.

(2) An authorised officer may, for the purpose specified in the preceding subarticle, take a sample, including with a view to independent tests being carried out by an Official Medicines Control Laboratory or a laboratory designated for that purpose by an European Union Member State, of any:

(*a*) substance or medicinal product sold or supplied or intended to be sold or supplied; or

(*b*) substance or article used or intended to be used in the manufacture of a medicinal product.

(3) For the purposes of subarticle (1), an authorised person shall have the right:

(*a*) to inspect any records, in whatever form they are held, related to the manufacture, assembly, sale or supply of a medicinal product and, where such records are kept in electronic form:

(i) may have access to, and inspect and check the operation of any computer, any associated apparatus or material which is or has been in use in connection with the records; and

(ii) may require any person having charge of, or otherwise connected with the operation of, the computer, apparatus or material to afford him such assistance as he may reasonably require;

(*b*) to take copies of any entry in any book or document produced in pursuance of the preceding paragraph and where the records are kept electronically, by means of a computer or otherwise, require the records to be produced in an intelligible form which may be taken away;

(*c*) to take photographs of any equipment, premises, records and documents.

(4) Any authorised officer shall have a right to seize, remove and detain any substance or article which he has reasonable cause to believe to be a substance or article in relation to which, or by means of which, an offence under this Act is being or has been committed, and any document which he has reasonable cause to believe to be a document which may be required as evidence in proceedings under this Act.

(5) For the purpose of subarticle (4), any authorised person may, so far as is reasonably necessary in order to secure

compliance with the provisions of this Act and any regulations or rules made thereunder, require any person to break open any container, package or machine, or to permit him to do so:

Provided that where a person seizes any substance or article, including any document, for the purposes specified in subarticle (4), he shall inform the person from whom it is seized and give him a receipt thereof.

(6) Without prejudice to the preceding provisions of this article, any authorised person shall have the same rights conferred by those provisions in relation to things belonging to, or any business carried on by, an applicant for an authorisation or certificate under Part III of this Act, and may exercise such rights for the purpose of verifying any statements or information contained in the application for the authorisation or certificate; and, where by virtue of the provisions of this subarticle a person exercises any such right as is specified in subarticle (4), he shall be subject to the duty imposed by subarticle (5).

(7) Notwithstanding anything in the preceding provisions of this article, where a person claiming to exercise a right by virtue of the provisions of this article is required to produce his authorisation or credentials, the right shall only be exercisable by him on the production of the authorisation or credentials.

(8) After every inspection the authorized officer shall report on whether the manufacturer complies with the principles and guidelines of good manufacturing practice or, where appropriate, with the requirements relating to pharmacovigilance. The content of such reports shall be communicated to the manufacturer or marketing authorisation holder who has undergone the inspection.

(9) Within ninety days of an inspection a certificate of good manufacturing practice shall be issued to a manufacturer if the outcome of the inspection shows that the manufacturer complies with the principles and guidelines of good manufacturing practice as provided for by legislation in force at the time.

Application of sampling procedure to substance or article seized.
Amended by: XI. 2007.20; XXIX. 2007.20.

103. (1) The provisions of this article shall apply where an authorised officer seizes a substance or article, other than a document, in the exercise of such a right as is specified in article 102(4) and (6).

(2) If any person who in accordance with article 102(5) is entitled to be informed of the seizure so requests, either at the time of the seizure or at any subsequent time, not being later than twenty-one days after he is informed of the seizure, then subject to the following provisions of this article, the authorised officer shall either:

(*a*) set aside a sample of the substance or article seized; or

(*b*) treat that substance or article as a sample,

whichever he considers more appropriate having regard to the nature of that substance or article.

(3) An authorised officer shall not be required by virtue of

subarticle (2) to set aside a sample, or to treat a substance or article as a sample, if the nature of the substance or article is such that it is not reasonably practicable to do either of those things.

(4) Where in accordance with subarticle (2) an authorised officer sets aside a sample, or treat a substance or article as a sample, he shall divide it into three parts, each part to be marked and sealed or fastened up in such manner as its nature will permit, and shall supply one excerpt of it to the person who made the request under subarticle (2).

(5) (*a*) Where any medicinal product has been seized under the provisions of this Act, and the owner thereof consents in writing to the destruction of such medicinal product, the Licensing Authority may, after taking such samples as may be required to prove the offence, direct that the said medicinal product be destroyed without prejudice to the taking of any proceedings against the person responsible for the offence, and the said Licensing Authority shall recoup all the expenses involved in the destruction of the medicinal product.

(*b*) In those cases where the owner fails to consent to the destruction of the medicinal product, the Licensing Authority may, after filing an application requesting the Court to order the destruction at the expense of the owner, proceed with such destruction.

Supplementary provisions as to right of entry.

104. (1) Any person entering any property or any other premises, ship, aircraft, stall or place in accordance with the provisions of article 101, may be accompanied by such other person or take such equipment as may appear to him to be necessary; and on leaving any such property shall, if the property is unoccupied or the occupier or any other person who is in charge of a ship, aircraft, vehicle, stall or place, is temporarily absent, leave it as effectively secured.

(2) The authorised officer shall also have such other powers as may be prescribed by regulations made by the Minister for the proper execution of his functions.

Hindering, etc., the Licensing Authority. *Added by: V. 2013.32.*

104A. Any person who, by any means whatsoever, hinders or obstructs the Licensing Authority or an authorised officer from exercising any of his powers and functions under this Act shall be guilty of an offence against this Act.

Proof of controls carried out. *Added by: XI. 2007.21. Re-numbered by: V. 2013.31.*

104B. (1) The holder of the marketing authorization for a medicinal product and, where appropriate, the holder of the manufacturing authorization, shall furnish proof of the controls carried out on the medicinal product and, or the ingredients and of the controls carried out at an intermediate stage of the manufacturing process, in accordance with the methods laid down in Article 8(3)(h) of Directive 2001/83/EC and any amendments thereto.

(2) Manufacturers of immunological products shall submit to

the Authority copies of all the control reports signed by the qualified person.

(3) Where the Authority considers it necessary in the interests of public health, it may require the holder of an authorization for marketing -

(*a*) live vaccines,

(*b*) immunological medicinal products used in the primary immunization of infants or of other groups at risk,

(*c*) immunological medicinal products used in public health immunization programmes,

(*d*) new immunological medicinal products or immunological medicinal products manufactured using new or altered kinds of technology or new for a particular manufacturer, during a transitional period normally specified in the marketing authorization,

to submit samples from each batch of the bulk and, or the medicinal product for examination by a laboratory designated for that purpose before release on to the market unless, in the case of a batch manufactured in another Member State, the competent authority of that Member State has previously examined the batch in question and declared it to be in conformity with the approved specifications. The Authority shall ensure that any such examination is completed within sixty days of the receipt of the samples.

(4) In the interests of public health, the Authority may require the marketing authorization holder for medicinal products derived from human blood or human plasma to submit samples from each batch of the bulk and, or the medicinal product for testing by a laboratory designated for that purpose before being released into free circulation, unless the competent authorities of another Member State have previously examined the batch in question and declared it to be in conformity with the approved specifications. The Authority shall ensure that any such examination is completed within sixty days of the receipt of the samples.

Recalls and rapid alerts.
Added by: V. 2013.33.

104C. (1) The Licensing Authority shall ensure that there is a system in place which aims at preventing medicinal products that are suspected to present a danger to health from reaching the patient.

(2) The system referred to in sub-article (1) shall cover the receipt and handling of notifications of suspected falsified medicinal products as well as of suspected quality defects of medicinal products. The system shall also cover recalls of medicinal products by marketing authorisation holders or withdrawals of medicinal products from the market ordered by national competent authorities from all relevant actors in the supply chain both during and outside normal working hours. The system shall also make it possible to recall, where necessary with the assistance of health professionals, medicinal products from patients who received such products.

(3) If the medicinal product in question is suspected of presenting a serious risk to public health, the Licensing Authority shall, without any delay, transmit a rapid alert notification to all European Union Member States and all actors in the supply chain in Malta. In the event of such medicinal products being deemed to have reached patients, urgent public announcements shall be issued within twenty-four hours in order to recall those medicinal products from the patients. Those announcements shall contain sufficient information on the suspected quality defect or falsification and the risks involved.

PART VIII

MISCELLANEOUS PROVISIONS

Recognition of equivalent standards.

105. For the purposes of this Act, the Minister may, on the advice of the Licensing Authority, by regulations prescribe that a provision or provisions in relation to the marketing authorisation of a medicinal product shall be deemed to be satisfied, if the standards of manufacture, medicinal product quality, safety or efficacy, or the provisions in relation to the granting of a marketing authorisation of a country designated in such regulations, are satisfied.

Power of Minister to make regulations. *Amended by: XI. 2007.22; VII.2020.2.*

106. The Minister may, after consultation with the Licensing Authority, amend the schedules to this Act, prescribe by regulations anything that may be prescribed under this Act and make provision on any matter relating to medicinal products, poisons and pharmacies in order to give fuller effect to the provisions of this Act, and, in particular, but without prejudice to the generality of the aforesaid, shall by such regulations regulate or otherwise provide for:

(*a*) the grant of marketing authorisations;

(*b*) the manufacture of medicinal products and raw materials used in such manufacture;

(*c*) the wholesale distribution of medicinal products;

(*d*) the sale and supply of medicinal products;

(*e*) the licensing of pharmacies;

(*f*) the reporting of adverse drug reactions;

(*g*) advertising in respect of medicinal products, and the presentation and information contained in the advert:

Provided that the advertising of certain medicinal products or classes of medicinal products may, by such regulations, be prohibited;

(*h*) the conduct of clinical trials;

(*i*) the classification of medicinal products;

(*j*) the testing of medicinal products;

(*k*) the regulation of homeopathic medicinal products; radiopharmaceuticals and medicinal products derived from human blood and human plasma; immunological products, and herbal products;

(*l*) the roles and responsibilities of a licence or

authorisation holder;

(*m*) the roles and responsibilities of the managing pharmacist, responsible person and qualified person;

(*n*) standards of good practice in the manufacture, wholesale, distribution and dispensing of medicinal products:

Provided that in the case of dispensing the Minister may take the opinion of the Pharmacy Board;

(*o*) the recognition of equivalent standards for medicinal product quality and efficacy in relation to such countries as may be prescribed;

(*p*) the recognition of equivalent standards for good practice in manufacture in relation to such countries as may be prescribed;

(*q*) the fees that may be levied and the funds wherein such fees may be deposited by the Licensing Authority, the Medicines Authority and any other Committee established by or under this Act or regulations made thereunder;

(*r*) the regulation of the use of medical devices for medical and, or research purposes, but without prejudice to the generality of this paragraph, the Minister may make regulations for all or any of the following purposes:

(i) for prescribing the conditions under which the authorisations may be granted, renewed, suspended, transferred or cancelled;

(ii) for providing the manner in which applications for the grant, renewal, suspension, transfer or cancellation of the authorisations or of any one or more categories or classes thereof are to be made;

(iii) for providing the manner in which applications for such authorisations and approvals as may be prescribed are to be publicised and for providing the manner in which any person who may be prejudiced by such the authorisations and approvals may make an objection or representation thereon;

(iv) for establishing the duration of the validity of the authorisations or of any one or more categories or classes thereof;

(v) for establishing the qualifications that certain key personnel involved in or with the premises may be required to possess;

(vi) for regulating inspections to be carried out at the premises;

(vii) for prescribing the inventory controls, registers, records and databases that have to be kept by the

licence holder at the premises and any financial guarantees which the licence holder shall have to give;

(viii) for the establishment of quality controls and quality assurances, other than those already established under this Act, and any matter in relation to any activity carried on any premises or by any person licensed under this legislation;

(ix) for establishing the fees leviable in respect of the authorisations, approvals and for any other service provided by the Medicines Authority such as scientific advice or other work as may be deemed necessary for the Medicines Authority to carry out its function:

Provided that regulations made under this sub-paragraph may establish the minimum and the maximum of any fees leviable in respect of the authorisations, approvals and for any other service provided by the Medicines Authority such as scientific advice or other work as may be deemed necessary for the Medicines Authority to carry out its function; and

(x) for establishing the penalties or administrative sanctions to which any offender against the provisions of this Act or any regulations made thereunder shall be liable;

(*s*) the establishing of offences and the relative penalty in relation to the contravention of any provisions of this Act or regulations issued under this Act which penalty shall not be less than a fine (*multa*) of twelve thousand euro (€12,000) and not exceeding one hundred and twenty thousand euro (€120,000) or to imprisonment for a term not exceeding two years, or to both such fine and imprisonment;

(*t*) exceptions to any provision in the interest of public health.

Transitory provision.

107. Any medicinal products on the market on the date of the coming into force of article 20 shall only be subject to the provisions of that article at such time and subject to such conditions as may by rules be established by the Licensing Authority.

Amendment of Medical and Kindred Professions Ordinance. Cap. 31.

108. *Omitted under the Statute Law Revision Act, 1980.*

Saving. Cap. 31.

109. (1) Any regulations made under the provisions of the articles, of the Medical and Kindred Professions Ordinance, which have been repealed by article 108, shall, until provision is made under or by virtue of this Act, continue in force and have effect as if made under this Act.

(2) Any licence, permission or other authorisation granted under any provision of the repealed articles as aforesaid, shall continue in force thereafter as if it were a licence, permission or authorisation granted under a corresponding provision or authority granted under this Act and shall be treated and dealt with accordingly.

(3) Any action taken or proceedings commenced against or in relation to any person under the repealed articles as aforesaid shall continue to have effect as if it were action or proceedings taken or commenced under a corresponding provision of this Act.

Designation of competent authority. *Added by: XXIX. 2007.21.*

109A.* (1) The Prime Minister may, following consultation with the Minister responsible for health, by Order in the Gazette designate any authority to carry out the functions carried out by the Medicines Authority under this Act.

(2) Any such Order may delete any of the provisions of articles 5 and 7 to 13.

(3) Any such Order may also amend or delete subarticle (3) of article 3 and articles 4 and 6.

Saving provisions. *Added by: XI. 2007.23.*

110. (1) Nothing in this Act shall in any way derogate from any Acts or regulations for the radiation protection of persons undergoing medical examination or treatment, or from the Community rules laying down the basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation.

(2) This Act shall be without prejudice to Council Decision 86/346/EEC of 25 June 1986 accepting on behalf of the Community the European Agreement on the Exchange of Therapeutic Substances of Human Origin.

(3) The provisions of this Act shall not affect the powers of the Authority either as regards the setting of prices for medicinal products or their inclusion in the scope of national health insurance schemes, on the basis of health, economic and social conditions.

(4) This Act shall not affect the application of any law prohibiting or restricting the sale, supply or use of medicinal products as contraceptives or abortifacients.

Medical devices and in vitro diagnostic medical devices. *Added by: XXXV.2020.2.* Cap. 427.

111. Any regulations issued under the Product Safety Act dealing with medical devices and in vitro diagnostic medical devices shall be deemed to have been issued under this Act.

Language. *Added by: XXXV.2020.2.*

112. Regulations made under any provision of this Act may be made in the English language only.

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*this article was originally added as article 110 by Act XXIX. 2007.21.

FIRST SCHEDULE

(*Deleted by Act III.2004.45*)

SECOND SCHEDULE

Proceedings of the Medicines Review Board

1. All members of the Medicines Review Board shall be present for a hearing of an appeal or the development of a second opinion.

2. All members of the Board shall have a vote and the opinion of the Board shall reflect the opinion of the majority of members:

Provided that a dissenting member may also request that his opinion be attached to the Board's opinion report as a minority report.

3. The appellant shall appear before the Board either in person or through an agent on the day and at the time fixed for the hearing, make his submissions and produce such evidence as the Board may allow:

Provided that the Board may postpone the hearing of the appeal if it is satisfied that the appellant was prevented from appearing before it owing to illness or absence from Malta or other similar reasonable cause.

4. The Board shall give the Medicines Authority an opportunity to make its submissions in justification of its opinion/s, and bring such evidence as the Board may consider necessary.

5. The Board shall have the power to summon witnesses and to administer the oath to any person appearing before it.

6. The Board shall have power to confirm or issue a different opinion to that appealed against, as it may deem appropriate.

7. The opinion of the Board shall be final albeit not binding to the decision of the Licensing Authority and no appeal shall lie therefrom except on a question of law only.

8. Subject to the foregoing provisions and to the provisions of this Act, the Board shall regulate its own procedure.

THIRD SCHEDULE

(*Deleted by Act XI.2007.24*)
