L.N. 381 of 2005

MEDICINES ACT, 2003
(ACT NO.III OF 2003)

Manufacture and Importation of Medicinal Products for Human Use Regulations, 2005

IN exercise of the powers conferred by article 106 of the Medicines Act, 2003, the Minister of Health, the Elderly and Community Care has made the following regulations:-

Title and commencement.

1. (1) The title of these regulations is the Manufacture and Importation of Medicinal Products for Human Use Regulations, 2005.

(2) These regulations shall come in force on the 30th October, 2005.

Interpretation.

2. (1) For the purposes of these regulations-

"the Act" means the Medicines Act;

"active substance (API)" means any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that when used in the production of a medicinal product, becomes an active ingredient of the said product. These substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body;

"the Agency" means the European Medicines Agency established by Regulation (EC) No. 726/2004;

"the Commission" means the Commission in accordance with Council Decision 1999/468/EC of 28th June, 1999;

"the Community" means the European Community and the European Economic Area;

"imported medicinal products" means medicinal products obtained from a source outside the European Union or the European Economic Area;

"Member State" means a State which is a member of the European Union and includes Iceland, Norway and Liechtenstein.

(2) The provisions of these regulations shall not apply to:

(a) any medicinal product prepared in a pharmacy in accordance with a medical prescription for an individual patient (commonly known as the magistral formula);

(b) 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 the pharmacy in question, (commonly known as the officinal formula);

(c) medicinal products intended for research and development trials but without prejudice to the provisions of the Clinical Trials Regulations, 2004 or Directive 2001/20/EEC of the European Parliament and of the Council of the 4th April, 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products on human use;

(d) intermediate products intended for further processing by an authorised manufacturer;

(e) any radionuclides in the form of sealed sources;

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

(g) 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.

Manufacturing licence.

3. (1) (a) No medicinal product, biological active substance, or active substance to be used directly as an investigational medicinal product, may be manufactured in Malta unless there is, in respect of such product or substance, a manufacturing licence, hereinafter referred to as "licence", to that effect. This manufacturing licence shall also be required for the processes of sterilisation of active substances.

(b) This manufacturing licence shall be required notwithstanding that the medicinal products manufactured are intended for export.

(2) (a) A licence, which shall remain in force for a period to be determined by the Licensing Authority, hereinafter referred to as "the Authority", shall be required for both total and partial manufacture, and for the various processes of dividing up, packaging or presentation.

(b) A licence shall not be required for preparation, dividing up, changes in packaging or presentation where such processes are carried out solely for retail supply, by pharmacists in pharmacies, or by persons legally authorised to carry out such processes.

(3) An importer's licence, hereinafter also referred to as "licence", shall be required for the importation of medicinal products.

(4) A licence shall include a licence to distribute by wholesale the medicinal products in respect of which the licence has been issued.

(5) The Authority shall forward to the Agency a copy of the licence referred to in sub-regulation (1) hereof.

Grant or renewal of a licence.

4. The Authority, shall only grant or renew a licence, if the applicant:

(a) specifies the medicinal products and pharmaceutical forms which are to be manufactured or imported and the place where they are to be manufactured and, or controlled;

(b) has at his disposal, for the manufacture or import of medicinal products, suitable and sufficient premises, technical equipment and control facilities complying with requirements set by the Authority;

(c) has at his disposal the services of at least one qualified person within the meaning of regulation 8; and

(d) provides all necessary documentation in support of his application.

Processing of licence.

5. (1) (a) The Authority shall issue the licence after verifying the contents of the application but in any case not later than ninety days from receipt of the application.

(b) This time period shall be suspended when the Authority requests additional information from the applicant.

(c) The Authority may grant a conditional licence subject to the carrying out of certain obligations imposed on the applicant.

(2) The licence shall apply only to the premises, medicinal products and pharmaceutical forms specified in the application.

Change in particulars.

6. When the holder of the licence requests a change in the particulars specified in regulation 4(a) and (b), the process of verification of such information shall not exceed thirty days. However, in exceptional cases, this period of time may be extended to ninety days.

Obligation of licence holder.

7. (1) The holder of a licence shall apart from his obligations under article 44 of the Act, comply with Community principles and guidelines of good manufacturing practice and any annexes thereof for medicinal products, and use as starting materials only active substances, which have been manufactured in accordance with the detailed Community guidelines on good manufacturing practice for starting materials.

(2) For the purposes of this regulation, manufacture of active substances used as starting materials shall include both total and partial manufacture or import of an active substance used as a starting material as defined in Part I, point 3.2.1.1 (b) Annex I of Directive 2001/83, and the various processes of dividing up, packaging or presentation prior to its incorporation into a medicinal product, including repackaging or re-labelling, such as are carried out by a distributor of starting materials.

Requirement for qualified person and holder as qualified person.

8. (1) The holder of the licence shall have permanently and continuously at his disposal the services of at least one qualified person, in accordance with the conditions laid down in regulation 9 hereof, responsible in particular for carrying out the duties specified in regulation 11.

(2) If the manufacturing licence holder personally has the qualifications laid down in regulation 9 hereof, then he may himself assume the responsibility of a qualified person.

Qualified person.

9. For a person to be designated as qualified person, he must possess the following qualifications:

(a) (i) be in possession of a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course of study, or a course recognised as equivalent, extending over a period of at least four years of theoretical and practical study in any of the following scientific disciplines;

pharmacy, medicine, veterinary medicine, chemistry, pharmaceutical chemistry and technology, biology ;

(ii) where the course is followed by a period of theoretical and practical training of a minimum duration of one year and including a training period of at least six months in a pharmacy open to the public, such period being corroborated by an examination at university level, then the minimum duration of the university course may be three and half years;

(iii) where two university courses or two courses recognised as equivalent co-exist in a Member State, and where one of these extends over four years and the other over three years, the three-year course leading to a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course or its recognised equivalent shall be considered to fulfil the condition of duration referred to above, in so far as the diplomas, certificates or other evidence of formal qualifications awarded on completion of both courses are recognised as equivalent;

(b) the course shall include theoretical and practical study on at least the following basic subjects:

(i) experimental physics;

(ii) general and inorganic chemistry;

(iii) organic chemistry;

(iv) analytical chemistry;

(v) pharmaceutical chemistry, including analysis of medicinal products;

(vi) general and applied biochemistry (medical);

(vii) physiology;

(viii) microbiology;

(ix) pharmacology;

(x) pharmaceutical technology;

(xi) toxicology;

(xii) pharmacognosy (study of the composition and effects of the natural active substances of plants and animal origin);

(c) studies in these subjects shall be so balanced as to enable the qualified person to fulfil the obligations specified in regulation 11 hereof;

(d) in those cases where diplomas, certificates or other evidence of formal qualifications do not fulfil the criteria above mentioned, the Authority shall ensure that the person concerned provides evidence of adequate knowledge of the subjects involved;

(e) (i) the qualified person shall have acquired practical experience over at least two years, in one or more undertakings which are authorised to manufacture medicinal products, in the activities of qualitative analysis of medicinal products, of quantitative analysis of active substances, and of the testing and checking necessary to ensure the quality of medicinal products;

(ii) the duration of practical experience may be reduced by one year where a university course lasts for at least five years, and by a year and a half where the course lasts for at least six years.

Exemptions for existing qualified person.

10. (1) The holder of a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course, or a course recognised as equivalent, in a scientific discipline allowing him to perform the duties of a qualified person, may, if he began his course prior to the 21st May, 1975, be considered as qualified to carry out the duties of a qualified person, provided that he was, for at least two years before the 21st May, 1985, engaged with one or more undertakings authorised to manufacture, and as having carried out the duties of production supervision and, or qualitative and quantitative analysis of active substances, and the necessary testing and checking under the direct authority of a qualified person in order to ensure the quality of the medicinal products.

(2) If the person concerned has acquired the practical experience referred to in sub-regulation (1) before the 21st May, 1965, a further one year's practical experience in accordance with the conditions referred to in sub-regulation (1) will be required to be completed immediately before he engages in such activities.

(3) A person engaging in the activities of a qualified person from the time of the application of Directive 75/319/EEC in a Member State without complying with the provisions of regulation 9 shall be eligible to continue to engage in those activities within the Community.

Responsibility of qualified person.

11. (1) The qualified person, without prejudice to his relationship with the holder of the licence, shall be responsible to ensure that:

(a) each batch of medicinal products manufactured in Malta has been manufactured and checked in terms of the laws in force and is in accordance with the requirements of the marketing authorisation;

(b) in the case of medicinal products coming from third countries, irrespective of whether the product has been manufactured in the Community, each production batch has undergone in a Member State a full qualitative analysis, a quantitative analysis of at least all the active substances and all the other tests or checks necessary to ensure the quality of the medicinal product in accordance with the requirements of the marketing authorisation:

Provided that when the batches of medicinal products have already undergone the controls above mentioned in a Member State, they shall be exempt from further controls if they are accompanied by the control reports signed by the qualified person, and are marketed within the Community.

(2) The qualified person need not carry out the controls above mentioned in the case of imported medicinal products, where arrangements have been made by the Community with the exporting country to ensure that the manufacturer of the medicinal products applies standards of good manufacturing practice at least equivalent to those laid down by the Community, and to ensure that the controls referred to above have been carried out in the exporting country.

Keeping of registers.

12. (1) It shall be the duty of the qualified person to keep a register to document and certify that each production batch satisfies the provisions of these regulations.

(2) The said register shall be kept up to date as operations are carried out and must be made available for inspection by the Authority for at least five years.

Repeals L.N. 143 of 2004.

13. The Manufacture of Medicinal Products for Human Use Regulations, 2004, are hereby repealed.

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