L.N. 143 of 2004

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

Manufacture of Medicinal Products for Human Use Regulations, 2004

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 commancement.

1. (1) The title of these regulations is the Manufacture of Medicinal Products for Human Use Regulations, 2004.

(2) These regulations shall come in force on the 1st May, 2004.

Interpretation.

2. For the purposes of these regulations-

"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 shall also include Iceland, Norway and Liechtenstein.

Manufacturing Licence.

3. (1) (a) No medicinal product may be manufactured in Malta unless there is in respect of such product a manufacturing licence, hereinafter referred to as "licence".

(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 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 authorised to carry out such processes.

(3) In addition to the licence referred to under subregulation (1) of this regulation an importer's licence shall also 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.

Grant or renewal of a licence.

4. The Licensing Authority, hereinafter referred to as the "Authority", shall only grant or renew an 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; 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 of 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 manufacturing licence requests a change in any of the particulars in the application, the process of verification of such information shall not exceed 30 days. However, in exceptional cases this period of time may be extended to 90 days.

Obligation of holder.

7. The holder of a manufacturing licence shall apart from his obligations under article 44 of the Act, comply with the principles and guidelines of good manufacturing practice and good distribution practice for medicinal products published by the Commission.

Holder as qualified person.

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

Qualified person.

9. For a person to be designated as qualified person such person he must at least possess the following qualifications as follows:

(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 awards 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) applied 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 fulfil the following obligations:

(i) ensure that medicinal products have been manufactured and checked in accordance with the marketing licence;

(ii) ensure, in the case of medicinal products from non Member States, that each production batch has undergone a full qualitative analysis and a quantitative analysis of at least three constituents and all other tests as may be necessary to ensure that the quality of the medicinal product is in accordance with the marketing licence:

Provided that the qualified person shall be exempt from complying with the afore mentioned duty in those cases where the

Community has an agreement with the exporting non Member State that the manufactured medicinal product be manufactured in accordance with standards of good manufacturing practice equivalent to those laid down by the Community and that the controls be carried out in the exporting country:

Provided further that medicinal products which are accompanied by control reports drawn up and signed by a qualified person shall be exempt from such controls if they are marketed in another Member State;

(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, or quantitative analysis of any active substance 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.

Saving about existing qualified person.

10. (1) A person who on the date of coming into force of these regulations and for a year thereafter, was carrying out the duties as a qualified person for a period of at least six months, shall be eligible to continue in those activities even though he does not fulfil the conditions set out under regulation 9, as long as such activities have been carried out to the satisfaction of the Authority.

(2) The holder of a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course, or a course in a scientific discipline recognised as equivalent in a scientific discipline, thereby allowing him to perform the duties of a qualified person, may, if he began his course prior to 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 21st May 1985, engaged with one or more undertakings authorised to manufacture and carried out his duties, under the direct authority of

a qualified person, in connection with production, supervision and, or qualitative and quantitative analysis of active substances, and the necessary testing and checking in order to ensure the quality of the medicinal products.

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

11. The qualified person shall be responsible to ensure that: Responsibility of qualified person.

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

(b) that each production batch of medicinal products coming from non Member States, has undergone, on importation, a full qualitative analysis and a quantitative analysis of at least all the active constituents and all the other tests or checks necessary to ensure the quality of medicinal products in accordance with the conditions of the marketing authorisation:

Provided that when the batches of medicinal products have already undergone the controls above mentioned, 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.

(c) 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 obliging the manufacturer of the medicinal products to apply 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.

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