

**L.N. 315 of 2006**

**MEDICINES ACT  
(CAP. 458)**

**Medicines Authority (Fees) Regulations, 2006**

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

**1.** The title of these regulations is the Medicines Authority (Fees) Regulations, 2006. Citation.

**2.** For the purposes of these regulations – Interpretation.

“Active Pharmaceutical Ingredient” (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;

“API manufacturer” means a person, group of persons or company involved in the manufacture of active pharmaceutical ingredients;

“Certificate of a pharmaceutical product (CPP)” or “Export Certificate” means a certificate, complying with the format specified by World Health Organisation, providing details about a single named medicinal product, which may be licensed or unlicensed in Malta. It provides details about the product and its manufacture including, but not limited to, the marketing authorisation (MA) holder, where applicable, the active ingredients and excipients, the manufacturing and packaging sites and whether or not the product is placed on the market in Malta;

“Concerned Member State” means a Member State or States in which mutual recognition is sought in the Mutual Recognition and Decentralised procedures;

“Directive 2001/83/EC” means Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on

the Community code relating to medicinal products for human use, and its amendments as amended by Directive 2004/27/EC and Directive 2004/24/EC;

“Extension application” is an application for changes that cannot be considered as variations. These changes are listed in Annex II of Regulations 1084/2003/EC and 1085/2003/EC and must fulfil the conditions set out therein;

“Follow-up inspections” refers to inspections other than those referred to as major inspections;

“GMP Certificate” means a certificate issued by the Medicines Authority for the purpose of confirming to a manufacturer the overall conclusion of an inspection with respect to compliance with good manufacturing practice;

“Good clinical practice inspection” means an inspection performed to assess the standards for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of clinical trials so as to provide assurance that the data and reported results are credible and accurate, and that the rights, integrity and confidentiality of trial subjects are provided;

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

“Importer” means any person or group of persons or company involved in the importation of Medicinal products obtained from a source outside the European Union or the European Economic Area;

“Importing activity” is the action by which medicinal products sourced from outside the European Union or the European Economic Area are obtained, stored and distributed;

“Major inspection” refers to inspections carried out for the first time in a particular area or site, or inspections to already existing sites that had major variations or alterations;

“Marketing authorisation transfer” is when a marketing authorisation is transferred from the existing Marketing Authorisation Holder to another using a transfer procedure. A

transfer may occur either during or after issue of a marketing authorisation;

“Partial Manufacturing” has the same meaning as “assembly” in Medicines Act;

“Pharmacovigilance inspection” means an inspection carried out to assess the pharmacovigilance programme of a Market Authorization Holder during which the following are assessed:

- (a) monitoring of adverse drug reactions endorsed by company for its licensed products;
- (b) the assessment of risk and benefits of medicines used to determine what action should be taken to improve their safe use;
- (c) supply of information to optimise safe and effective use of medicines;
- (d) monitor impact of any action taken by the company;

“Reference Member State” means the Member State, which has produced the assessment report for a given medicinal product, which serves as the basis for the Mutual Recognition and Decentralised Procedures;

“Traditional Herbal Medicinal Product” is a herbal medicinal substance that fulfils the conditions laid down in the Herbal Medicinal Products Regulations, 2005;

L.N. 379 of 2005.

“Variation relating to a pharmaceutical activity” means any change pertaining to the related activity that may or may not require an inspection. Variations not requiring an inspection are those changes in the administrative details appearing on the licence, such as changes in name of company or change in names of key personnel. Variations that require an inspection are changes that can have an effect on the quality system of the company and, or on the quality of the product directly or indirectly which hence requires an inspection, such as in a change in a particular stage of the manufacturing process or installation of new equipment;

“Variation to the terms of a marketing authorisation” means an amendment to the contents of the documents referred to in regulations 5 to 9 of the Medicines (Marketing Authorisation) Regulations, 2006:

(1) “Type I variation” means a minor variation listed in Annex I of Regulation 1084/2003/EC and which fulfils the conditions set out therein;

(2) “Type II variation” means a variation that cannot be deemed to be a minor variation or an extension of the marketing authorisation;

(3) “Type II Complex variation” means a variation, when it falls within one or more of the following descriptions:

(a) the application relates to the results of clinical trials or other data (including pharmacological and toxicological tests as well as extensive evidence from post marketing experience or publications) that need to be newly assessed;

(b) the application is supported by substantial amounts of data, that have not previously been assessed;

(c) the application relates to changes in indications for use in a therapeutic area for which the product was not previously indicated for use;

(d) the application relates to changes in indications for use in respect of an organ, or any other part, of the human body for which the product was not previously indicated for use;

(e) the application is supported by data which comprises or includes the results of clinical trials or physico-chemical, microbiological or pharmacological and toxicological tests;

(f) the application relates to an increase in the maximum dose;

(g) the application relates to a new dosage regimen;

(h) the application relates to a change in the method of sale or supply of an active ingredient from prescription only to pharmacy sale;

(i) the application relates to a change in the conditions of prescribing;

(j) the application relates to the removal of a contra-indication;

(k) the application relates to an increased duration of treatment;

(l) the application relates to a change in the route of administration of the same dosage form;

(m) the application relates to a new route of synthesis that has not previously been assessed and a European Pharmacopoeia Certificate of Suitability is not available for the active ingredient;

(n) the application relates to a new method of sterilisation of the product;

(o) the application relates to a new container materials for a sterile product;

(p) the application relates to a new active ingredient manufacturer not previously approved to manufacture the active ingredient concerned and who does not hold a European Pharmacopoeia Certificate of Suitability for the substance concerned;

(q) the application relates to a major formulation change which affects more than one section in the Part II dossier and, or requires a re-evaluation of the safety or efficacy of the product, such as –

(i) a change in more than one excipient, except for a change in a key excipient (such as a preservative, release-controlling excipient, or stabiliser);

(ii) when a change in the key excipient alone will be regarded as a major formulation change;

(iii) the inclusion for the first time of a novel excipient not used before in any product;

(iv) a change which requires an *in-vivo* bioavailability study to be carried out;

(v) a change which results in a change to the therapeutic characteristics of the product;

(r) the application relates to change in the method of manufacture of the active ingredient which introduces new impurities or changes the level of impurities and which requires further qualification in safety studies;

(s) the application relates to any change in the source materials, method of manufacture or analytical procedures for a product of biological or biotechnological origin which might significantly affect the quality of the product;

(t) the application relates to a change in the qualitative composition of the immediate packaging of a sterile product, where the container material has not been previously approved for such use;

(u) the application relates to the introduction of a novel method of analysis;

(v) the application relates to a new manufacturer or process for a Flu Vaccine;

“Wholesale dealer” means any person or group of persons or company involved in the wholesale dealing activity;

“Wholesale dealing activity” has the same meaning as “wholesale distribution” in the Medicines Act.

Fees for marketing  
authorisation.

**3.** (1) There shall be paid to the Medicines Authority, in respect of a marketing authorisation and related activities, the fees specified in Schedules 1, 2, 3 and 4 of these regulations.

(2) Such fees shall not include any fees charged by other competent authorities in relation to any documentation, reports, or services required by the Medicines Authority for final issue of authorisations and licences.

(3) Any additional expenses incurred by the Medicines Authority shall be charged separately.

Products on  
derogation list.

**4.** For the purpose of these regulations, products which were on the derogation list and were granted a marketing authorisation through the transitional PMA/MA process prior to 31<sup>st</sup> December, 2006 and

their line extensions, will be charged fees as applicable to the mutual recognition procedure (Malta Concerned Member State), provided that the authorisation requested would have already been approved in at least one other Member State. Alternatively, national fees shall apply.

**5.** The Marketing (Authorisation) Fees Regulations, 2003 and the Medicines Authority (Fees) Regulations, 2006 are hereby repealed.

Repeals L.N. 372  
of 2003 and  
L.N. 26 of 2006.

**SCHEDULE 1**

(Regulation 3)

**PRODUCT AUTHORISATION FEES AND OTHER ACTIVITIES**

| <b>Type of Application</b>                                                                          | <b>Fee<br/>Lm</b> |
|-----------------------------------------------------------------------------------------------------|-------------------|
| <b>MUTUAL RECOGNITION PROCEDURE/<br/>DECENTRALISED PROCEDURE<br/>(Malta Concerned Member State)</b> |                   |
| <b>New Applications per product</b>                                                                 |                   |
| Article 8.3 of Directive 2001/83/EC: New active substance                                           | 50                |
| Article 8.3 of Directive 2001/83/EC: Known active substance                                         | 50                |
| Article 10 (a) of Directive 2001/83/EC                                                              | 50                |
| Article 10 (b) of Directive 2001/83/EC                                                              | 50                |
| Article 10 (c) of Directive 2001/83/EC                                                              | 50                |
| Article 10 (5) of Directive 2001/83/EC ( <i>new indication</i> )                                    | 50                |
| Line extension of a medicinal product authorised by the Mutual Recognition/Decentralised procedures | 50                |
| Additional strength/pharmaceutical form (applied for at the same time)                              | 50                |

| <b>Type of Application</b>                                  | <b>Fee<br/>Lm</b> |
|-------------------------------------------------------------|-------------------|
| <b>NATIONAL PROCEDURE</b>                                   |                   |
| Article 8.3 of Directive 2001/83/EC: New active substance   | 50,000            |
| Article 8.3 of Directive 2001/83/EC: Known active substance | 45,000            |
| Article 10 of Directive 2001/83/EC                          | 15,000            |
| Article 10 (a) of Directive 2001/83/EC                      | 15,000            |

|                                                                                           |        |
|-------------------------------------------------------------------------------------------|--------|
| Article 10 (b) of Directive 2001/83/EC                                                    | 15,000 |
| Article 10 (c) of Directive 2001/83/EC                                                    | 3,000  |
| Article 10 (5) of Directive 2001/83/EC ( <i>new indication</i> )                          | 10,000 |
| Additional strength/pharmaceutical form (applied for at the same time)                    | 2,500  |
| Line extension of a product authorised by the Mutual Recognition/Decentralised Procedures | 3,000  |

| Type of Application                                                                                 | Fee<br>Lm |
|-----------------------------------------------------------------------------------------------------|-----------|
| <b>MUTUAL RECOGNITION PROCEDURE/<br/>DECENTRALISED PROCEDURE<br/>(Malta Reference Member State)</b> |           |
| Outgoing supplement over the fee for National applications                                          | 20%       |

| Type of Application                                                              | Fee<br>Lm |
|----------------------------------------------------------------------------------|-----------|
| <b>OTHER ACTIVITIES</b>                                                          |           |
| <b>Renewal application per product (if applicable)</b>                           |           |
| National Procedure                                                               | 200       |
| Mutual Recognition Procedure/Decentralised Procedure                             | 50        |
| <b>Annual Fee (for each form and strength, for all marketing authorisations)</b> | 50        |
| <b>Market Authorisation Transfer</b>                                             | 50        |

| Type of Application                                                                                 | Fee<br>Lm |
|-----------------------------------------------------------------------------------------------------|-----------|
| <b>Traditional Herbal Medicinal Products</b>                                                        |           |
| National Simplified Registration for Traditional Herbal Medicinal Product (Quality assessment only) | 250       |
| <b>Variations:</b>                                                                                  |           |
| Administrative                                                                                      | 15        |
| Technical                                                                                           | 30        |

| Type of Application                                                                                                                                                              | Fee<br>Lm |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| <b>Authorisation in line with article 4(2) of the Medicines (Marketing Authorisations) Regulations in accordance with article 126(a) of Directive 2001/83/EC of the European</b> |           |

|                                                                                                                                                                                                                                            |    |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|
| <b>Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use, as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31<sup>st</sup> March 2004</b> |    |
| Issue of authorisation                                                                                                                                                                                                                     | 50 |
| Renewal of authorisation (every 5 years)                                                                                                                                                                                                   | 50 |
| Annual fee                                                                                                                                                                                                                                 | 50 |

|                                    |                   |
|------------------------------------|-------------------|
| <b>Homeopathic Product</b>         | <b>Fee<br/>Lm</b> |
| New Product (single stock)         | 100               |
| New Product (for 2 or more stocks) | 200               |
| <b>Variations:</b>                 |                   |
| Administrative                     | 15                |
| Technical                          | 30                |

|                                                                  |                   |
|------------------------------------------------------------------|-------------------|
| <b>Parallel Import Licence</b>                                   | <b>Fee<br/>Lm</b> |
| New Product (for each strength, pharmaceutical form per country) | 50                |
| Annual Fee                                                       | 50                |
| Renewal (every 5 years if applicable)                            | 50                |

|                                                   |                        |
|---------------------------------------------------|------------------------|
| <b>Clinical Trial Application/Trial</b>           | <b>Fee<br/>Lm</b>      |
| Phase 1,2 or 3 patient trial with a known product | 500 (150) <sup>1</sup> |
| Phase 1,2 or 3 patient trial with a new product   | 750 (300) <sup>1</sup> |
| Phase 4 patient trial                             | 600 (100) <sup>1</sup> |
| Amendment/s                                       | 40                     |

|                                             |                   |
|---------------------------------------------|-------------------|
|                                             | <b>Fee<br/>Lm</b> |
| <b>Classification Committee per product</b> | 20                |

|                                                                                                                        |                   |
|------------------------------------------------------------------------------------------------------------------------|-------------------|
|                                                                                                                        | <b>Fee<br/>Lm</b> |
| <b>Pre-Submission Meetings with Malta as Reference Member State in MRP/DCP /national procedure (Scientific advice)</b> | 1,000             |

<sup>1</sup> Fees in brackets are for applications for academic research without financial support from industry. Decision will be at the discretion of the Licensing Authority

**SCHEDULE 2**

(Regulation 3)

**VARIATION FEES PER PRODUCT**

| <b>Variation Type</b>                                                                                                                                | <b>Fee<br/>Lm</b>           |
|------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|
| <b>Type I</b>                                                                                                                                        | <b>National<sup>2</sup></b> |
| Change in the name and, or address of the marketing authorisation holder                                                                             | 50                          |
| Change in the name of the medicinal product                                                                                                          | 50                          |
| Change in name of the active substance                                                                                                               | 50                          |
| Change in the name and, or address of a manufacturer of the active substance where no European Pharmacopoeia certificate of suitability is available | 50                          |
| Change in the name and, or address of a manufacturer of the finished product                                                                         | 50                          |
| <b>Type I (Other)</b>                                                                                                                                | <b>National</b>             |
| All other Type IA <sup>3</sup>                                                                                                                       | 75                          |
| All other Type IB <sup>3</sup>                                                                                                                       | 150                         |
| <b>Type II<sup>4</sup></b>                                                                                                                           | <b>National</b>             |
| Type II Simple <sup>5</sup>                                                                                                                          | 350                         |
| Type II Complex <sup>5</sup>                                                                                                                         | 2600                        |

<sup>2</sup>For products authorised by the mutual recognition procedure/decentralised procedure (Malta Reference Member State) there is a 20% additional fee to the national fee. The variations for products that were authorised during the transitional arrangement and their line extensions are included in the annual fee, provided that the variation is already approved in another European Union/European Economic Area country.

<sup>3</sup>For type 1A and 1B variation applications a bulk 'discount' applies where a number of simultaneous applications are made for identical variations. The first of those applications is charged at the full rate shown above and second and subsequent applications are charged at 50%.

<sup>4</sup>Variations to change the strain in viral vaccines are charged at 35% of the fees shown for type 2 complex variations. The reduction in fee to change the strain in viral vaccines will not apply when Malta is the reference member state in a mutual recognition/decentralised procedure.

<sup>5</sup>For type 2 variation applications a bulk 'discount' applies where a number of simultaneous applications are made for identical variations. The first of those applications is charged at the full rate shown above and second and subsequent applications are charged at 50%.

**SCHEDULE 3**

(Regulation 3)

**INSPECTORATE FEES**

| Activity<br>(involving an inspection in Malta or within the European Union/European Economic Area) | Fee per type of Licence<br>Lm                                      |                                        |
|----------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|----------------------------------------|
|                                                                                                    | Issue of new licence and, or major initial Inspection <sup>6</sup> | Annual renewal of licence <sup>7</sup> |
| <b>GOOD MANUFACTURING PRACTICE<sup>8</sup></b>                                                     |                                                                    |                                        |
| <b>Issue of licence and annual renewal</b>                                                         |                                                                    |                                        |
| <b>Full manufacture</b>                                                                            |                                                                    |                                        |
| Small (less than 15 employees <sup>9</sup> )                                                       | 2000                                                               | 420                                    |
| Medium (15 to 75 employees <sup>9</sup> )                                                          | 3000                                                               | 630                                    |
| Large (76 to 200 employees <sup>9</sup> )                                                          | 4000                                                               | 840                                    |
| Super (more than 200 employees <sup>9</sup> )                                                      | 6000                                                               | 1250                                   |
|                                                                                                    |                                                                    |                                        |
| <b>Partial manufacturing</b>                                                                       | 600                                                                | 125                                    |

| Activity<br>(involving an inspection in Malta or within the European Union/European Economic Area) | Issue of new licence and, or major initial Inspection <sup>6</sup> | Annual renewal of licence <sup>7</sup>      |
|----------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|---------------------------------------------|
| <b>IMPORTATION, WHOLESALE DEALING</b>                                                              |                                                                    |                                             |
| <b>Issue of licence and annual renewal</b>                                                         |                                                                    |                                             |
| Import <sup>10</sup>                                                                               | 400                                                                | 200                                         |
| Wholesale                                                                                          | 200                                                                | 100                                         |
| <b>PHARMACY</b>                                                                                    |                                                                    |                                             |
| Issue of pharmacy licence and inspection every year (includes all follow up and other inspections) | 150                                                                | As per L.N 143 of 1998 and L.N. 486 of 2004 |
| Variation to pharmacy licence                                                                      |                                                                    | 20                                          |
| <b>OTHER ACTIVITIES</b>                                                                            |                                                                    |                                             |
| <b>(Frequency as required and involving an inspection in Malta or within the European Union)</b>   | <b>Initial Inspection</b>                                          | <b>Follow up and routine Inspections</b>    |
|                                                                                                    |                                                                    |                                             |
| Good Clinical Practice (clinical trials) / centre / trial                                          | 450                                                                | 100                                         |
| Pharmacovigilance inspections                                                                      | 250                                                                | 100                                         |

| Activity<br>(involving an inspection in a third country outside the European Union/European Economic Area <sup>11</sup> ) | Fee per type of Licence (Lm)                                             |                                                       |
|---------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|-------------------------------------------------------|
| <b>GOOD MANUFACTURING PRACTICE</b><br>Issue of licence and annual renewal                                                 | <b>Issue of new licence and, or major initial Inspection<sup>6</sup></b> | <b>Annual renewal of licence<sup>7</sup></b>          |
| <b>Full manufacture</b>                                                                                                   | Lm5000 plus Lm250 per day per inspector <sup>12</sup>                    | Lm1500 plus Lm250 per day per inspector <sup>12</sup> |
| <b>Partial manufacturing</b>                                                                                              | Lm4000 plus Lm250 per day per inspector <sup>12</sup>                    | Lm1000 plus Lm250 per day per inspector <sup>12</sup> |
| <b>OTHER ACTIVITIES</b><br>(Frequency as required and involving an inspection in a third country <sup>11</sup> )          | <b>Initial Inspection</b>                                                | <b>Follow up and routine Inspections</b>              |
| Good Clinical Practice (clinical trials) / centre / trial                                                                 | Lm600 plus Lm250 per day per inspector <sup>12</sup>                     | Lm400 plus Lm250 per day per inspector <sup>12</sup>  |
| Pharmacovigilance inspections                                                                                             | Lm600 plus Lm250 per day per inspector <sup>12</sup>                     | Lm400 plus Lm250 per day per inspector <sup>12</sup>  |

| <b>ADMINISTRATIVE ACTIVITIES</b>                        | <b>Fee Lm</b> |
|---------------------------------------------------------|---------------|
|                                                         |               |
| Variations (not requiring an inspection)                | 25            |
| Issue of CPP's                                          | 15            |
| Issue of CPP's (fast track) <sup>13</sup>               | 30            |
| Issue of GMP certificates (not requiring an inspection) | 25            |
| Supervision of destruction of pharmaceutical waste      | 20            |

<sup>6</sup> Includes issue of licence and inspection on a first time basis

<sup>7</sup> Includes inspections for renewal of licence, routine inspections and other necessary inspections e.g. to investigate a complaint, following a variation

<sup>8</sup> Includes manufacture of finished dosage forms, Active Pharmaceutical Ingredients and Investigational Medicinal Products. When a company additionally manufactures IMP's and a separate inspection is required the fee for this service shall be charged at 25% of that for initial inspections

<sup>9</sup> Include all the personnel employed within the company

<sup>10</sup> Applications for an import authorisation by a company already in possession of a manufacturing or wholesale dealer licence will be charged at 50% of the normal applicable rates for import activities

<sup>11</sup> For applications involving an inspection in a third country outside the European Union the applicant has to additionally cover for the flight and all accommodation expenses of the inspectors

<sup>12</sup> Includes days spent for actual inspection and for travel

<sup>13</sup> This fee applies for the issue of CPP's within 48 hours

## SCHEDULE 4

(Regulation 3)

### GENERAL

| Activity                                             | Fee<br>Lm |
|------------------------------------------------------|-----------|
| Consultation (per man hour)                          | 15        |
| Issue of original copies of<br>licences/certificates | 5         |
| Appeals                                              | 15        |
| Appeals to Medicines Review Board*                   | 5,000     |

(\*Fee for appeals will be fully refunded if appeal is successful)