

**L.N. 372 of 2003**

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

**Marketing Authorisation (Fees) Regulations, 2003**

IN exercise of the powers conferred by article 106 of the Medicines Act, 2003, the Minister of Health, with the concurrence of the Minister of Finance and Economic Affairs, has made the following regulations:-

**1.** (1) The title of these regulations is the Marketing Authorisation (Fees) Regulations, 2003. Title and commencement.

(2) These regulations shall come into force on the 1st December, 2003.

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

“Complex Application” means an application for a marketing authorisation, other than a major application, when it falls within one or more of the following descriptions:

(a) the application relates to a medicinal product which is intended to be used in accordance with an indication for use in respect of a new category of patients or as a treatment for a new category of disease;

(b) the application relates to a medicinal product containing a new combination of active ingredients that have not previously been included in that combination in a medicinal product in respect of which a marketing authorisation has previously been granted;

(c) the application relates to a medicinal product containing a new excipient;

(d) the application relates to a medicinal product that is intended to be administered by a route of administration different from that used in the administration of any medicinal product which contains the same active ingredient as the product in question and in respect of which a marketing authorisation has previously been granted;

(e) the application relates to a medicinal product containing an active ingredient, the manufacture of which involves a route of synthesis or, in the case of a medicinal product not synthetically produced, a method of manufacture, different from that used in the manufacture of the active ingredient of any medicinal product which contains the same active ingredient as the product in question and in respect of which a marketing authorisation has previously been granted;

(f) the application related to a medicinal product which is controlled release preparation and is not a simple application;

(g) the application relates to a sterile medicinal product the manufacture of which involves a method of sterilisation different from that used in the manufacture of any medicinal product which contains the same active ingredient as the product in question and in respect of which a marketing authorisation has previously been granted;

(h) the application relates to a sterile medicinal product the container of which is directly in contact with the medicinal product and is made from different material from the container of any medicinal product which contains the same active ingredient as the product in question and in respect of which a marketing authorisation has previously been granted;

(i) the application names as manufacturer of the active ingredient of the medicinal product in question a different manufacturer from the manufacturer of that active ingredient included in a medicinal product in respect of which a marketing authorisation has previously been granted;

(j) the application relates to a medicinal product which is an influenza vaccine and in respect of which the manufacturer or the manufacturing process is different from that specified in any other marketing authorisation which the applicant holds in respect of that product;

(k) the application is for the grant of a marketing authorisation for a medicinal product which is an influenza vaccine, except where it relates only to an influenza vaccine containing a different strain or strains from that specified in any other marketing authorisation which the applicant holds;

(l) the application is for the grant of a marketing authorisation for a medicinal product which is to be delivered by way of a metered dose inhaler;

(m) the application is for the grant of a marketing authorisation for a medicinal product which is in a powdered form and is to be delivered by way of inhalation;

(n) the application relates to a medicinal product -

(i) which is administered to the site of action of absorption by a method which has not previously been authorised in relation to any authorised medicinal product which contains the same active ingredient as the product in question and,

(ii) in respect of that other product, a marketing authorisation had been previously granted;

“Major Application” means an application submitted for a product containing new chemical entities;

“Market Authorisation Transfer” is when a market authorisation is transferred from the existing Market Authorisation holder to another using a transfer procedure. A transfer may occur either before or after authorisation;

“Simple Application” means:

(a) an application for a marketing authorisation, or

(b) an application other than one for a marketing authorisation, for a medicinal product which is a new strength or a product in respect of which a marketing authorisation has been previously been granted: or

(c) an application made no later than three months after the expiry of a marketing authorisation, containing identical provisions to those contained in the expired authorisation and which is made by the same holder.

“Standard Application” means any application for the grant of a marketing authorisation other than a major application, a complex application, a simple application, a marketing authorisation transfer application or an application for a marketing authorisation in a parallel import;

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

“Type II major variation” means a variation which cannot be deemed to be a minor variation or an extension of the marketing authorisation;

“annual fee” means a yearly fee, covering all aspects of routine dossier management and maintenance from the date of the initial authorisation.

Fees.

**2.** There shall be paid to the Medicines Authority, in respect of an application for the issue, maintenance and variation of the marketing authorisation shown under Column 1 of the Schedule to these regulations, an annual fee shown under Column 2 of the same Schedule.

**SCHEDULE**

| <b>Column 1<br/>Type</b>                                                                                                                                  | <b>Column 2<br/>Fee (Lm)</b> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| <b>TRANSITION LIST</b>                                                                                                                                    |                              |
| Centrally Authorised Products .....                                                                                                                       | No Fee                       |
| Products on the list which have an MA in compliance with the Acquis communautaire authorised in a country listed in Schedule 2 of the Medicines Act ..... | 50                           |
| Products on list not licensed in the EU                                                                                                                   |                              |
| Major Application (New Chemical Entity) .....                                                                                                             | 48,000                       |
| Complex Abridged (New product) .....                                                                                                                      | 15,000                       |
| Standard Abridged (Generics – Bioequivalence and Bibliographic data required) .....                                                                       | 7,000                        |
| Simple Abridged (Innovator gives full access to data on its product) .....                                                                                | 2,500                        |
| Products NOT on the Transition List (New Applications)                                                                                                    |                              |
| Major Application (New Chemical Entity) .....                                                                                                             | 48,000                       |
| Complex Abridged (New product) .....                                                                                                                      | 15,000                       |
| Standard Abridged (Generics – Bioequivalence and Bibliographic data required) .....                                                                       | 7,000                        |
| Simple Abridged (Innovator gives full access to data on its product) .....                                                                                | 2,500                        |
| Incoming Mutual Recognition – Complex (After Accession i.e. 1st May, 2004) .....                                                                          | 1,000                        |
| Incoming Mutual Recognition – Standard (After Accession i.e. 1st May, 2004) .....                                                                         | 500                          |
| Minor Variation - National (Type IA) .....                                                                                                                | 75                           |

|   |                                                           |     |
|---|-----------------------------------------------------------|-----|
| B | 4994                                                      |     |
|   | Minor Variation – National (Type IB) .....                | 250 |
|   | Major Variation – National (Type II) .....                | 500 |
|   | Minor Variation – Mutual Recognition (Type IA) .....      | 75  |
|   | Minor Variation – Mutual Recognition (Type IB) .....      | 200 |
|   | Major Variation – Mutual Recognition (Type II) .....      | 300 |
|   | Parallel Import Marketing Authorisation .....             | 190 |
|   | Market Authorisation Transfer (Change of Ownership) ..... | 75  |
|   | Annual fee (Post Licensing) .....                         | 25  |