Our Ref: 6/2012

CONSULTATION DOCUMENT ON THE AMENDMENT TO LEGAL NOTICE 315 OF 2006 – MEDICINES AUTHORITY (FEES) REGULATIONS, 2006, AS REGARDS FEES RELATED TO PRODUCT REGISTRATION ACTIVITIES WHERE MALTA IS REFERENCE MEMBER STATE IN THE EUROPEAN PROCEDURES (MUTUAL RECOGNITION AND DECENTRALISED PROCEDURE)

Objectives and Scope

The draft legal notice is proposed as an amendment to Legal Notice 315 of 2006 on fees to be paid to the Medicines Authority. The fees in relation to registration and post-authorisation activities for procedures were Malta acts as Reference Member State in the Decentralised and the Mutual Recognition Procedure are being revised following the experience gained with these procedures in the past 5 years. The aim is to make the fees more competitive with those of other Member States. Some gaps have also been addressed where some new processes which had not been taken into consideration in previous legal notices have now been included.

It is hoped that the change in fees will bring about a larger interest by applicants to submit applications to Malta as Reference Member State.

Main Changes

The main changes, **only for procedures where Malta acts as Reference Member State**, to the current Legal Notice are:

- Inclusion of new or amended definitions (mostly variations) to bring these in line with current European legislation (Directive 1234/2008/EC) or clarification of current definitions (e.g. transfer of Marketing Authorisation Holder).

- Changes to Schedule I –

    - decrease in the fees for applications submitted according to Article 10 (majority of applications)
        - Article 10(1), 10(3)
        - Article 10(a), 10(b)

    - increase in the fees for other applications submitted according to Article 10
        - Article 10(c)
        - Additional strength and form submitted at the same time
        - Line extension

    - Introduction of fees for new types of applications such as parallel applications submitted with the same procedure (DCP or MRP), repeat use MRP and duplicate applications. A fee for when Malta takes up a procedure as Reference Member State from a Concerned Member State was introduced.

- The introduction of the annual maintenance fee and a renewal fee which were not addressed for products where Malta is Reference Member State.

- Changes to Schedule II –

  – Changes to the fees for variations to take into account possibility of grouping variations. Fees for additional strengths and forms for grouped variations have been waived.
  – The 50% discount for additional strengths and forms for single variations has been maintained.
  – Introduction of fees for new post-authorisation activities, in line with the new Pharmacovigilance legislation – assessment of Post Authorisation Safety Studies, Post-Authorisation Efficacy Studies and Periodic Safety Update Reports if Malta is Reference Member State or Rapporteur.

Comments

Your comments on the proposed Legal Notices are invited.

Comments are to reach the Medicines Authority in writing or via email consultations.medicinesauthority@gov.mt by the **11th May 2012.**

Should any further information be required kindly contact the Medicines Authority using the following contact details:

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DRAFT LEGAL NOTICE - MEDICINES AUTHORITY (FEES)(AMENDMENT) REGULATIONS, 2012:

L.N. of 2012

MEDICINES ACT
(CAP. 458)

Medicines Authority (Fees) (Amendment) Regulations, 2012

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:-

Citation.

1. The title of these Regulations is the Medicines Authority (Fees) (Amendment) Regulations, 2012.

Interpretation.

2. For the purposes of these Regulations, the following amendments and additions to the definitions in Legal Notice 315, 2006 are being made –

"Extension of a marketing authorisation" or "extension" means a variation which is listed in Annex I of Regulation 1234/2008 and fulfils the conditions laid down therein;

"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 and entails a change in legal entity;

"Periodic Safety Update Report" refers to the periodical reports containing the records referred to in regulation 32 of the Pharmacovigilance Regulations;

"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;

"Urgent safety restriction" means an interim change in the terms of the marketing authorisation due to new information having a bearing on the safe use of the medicinal product;

"Variation to the terms of a marketing authorisation" means an amendment to the contents of the particulars and documents referred to in regulations 5 to 8 of the Medicines (Marketing Authorisation) Regulations, and its amendments, Article 6(2) of Regulation (EC) No 726/2004, point (a) of Article 7(1) and Article 34(1) of Regulation (EC) No 1901/2006 of the European Parliament and of the Council (2) and Articles 7 and 14(1) of Regulation (EC)

No 1394/2007 of the European Parliament and of the Council (3) in the case of medicinal products for human use:

(1) "Minor variation of type IA" means a variation which has only a minimal impact or no impact at all, on the quality, safety or efficacy of the medicinal product concerned;

(2) "Minor variation of type IB" means a variation which is neither a minor variation of type IA nor a major variation of type II nor an extension;

(3) "Major variation of type II" means a variation which is not an extension and which may have a significant impact on the quality, safety or efficacy of the medicinal product concerned. Major type II variations may be simple or complex;

(4) "Grouped variations" are variations that can be submitted in one application form; grouping must be in line with Annex III of Regulation 1234/2008 and official grouping guidelines;

Payment of fees

3. (1) There shall be paid to the Medicines Authority, in respect of marketing authorisation activities where Malta is Reference Member State, the fees specified in these Regulations. These replace the fees specified in L.N. 315 of 2006 specific to activities where Malta is Reference Member State.

(2) Validation of applications will not start unless the relevant fees are paid.

(3) 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, where these are required.

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

Amends **L.N. 315 of 2006**

4. The Medicines Authority (Fees) Regulations, 2006 are hereby amended.

SCHEDULE 1

PRODUCT AUTHORISATION FEES AND OTHER ACTIVITIES

Type of Application	Fee €
MUTUAL RECOGNITION PROCEDURE/ DECENTRALISED PROCEDURE (Malta Reference Member State)*	
New Applications per product	
Article 8.3 of Directive 2001/83/EC: New active substance	140,000
Article 8.3 of Directive 2001/83/EC: Known active substance	125,000
Article 10 (a) of Directive 2001/83/EC	28,000
Article 10 (b) of Directive 2001/83/EC	28,000
Article 10 (1)of Directive 2001/83/EC	25,000
Article 10 (3) of Directive 2001/83/EC	25,000
Article 10 (c) of Directive 2001/83/EC	18,000
Article 10(4) of Directive 2001/83/EC	28,000
Additional strength/pharmaceutical form (applied for at the same time)	8,000
Line extension applied for after grant of Marketing Authorisation	10,000
Parallel application (applied for at the same time)	10,000
Repeat use MRP	10,000
Application withdrawn during validation	90% of relevant fee is refunded
Duplicate application	10,000
Change from Malta CMS to RMS	4,000

Type of Application	Fee €
Renewals of product licences	
Renewal application per product	
Mutual Recognition Procedure/Decentralised Procedure	500

Annual maintenance fee (for each form and strength)	
First strength or form	300
Additional strengths and forms (each)	100
Additional parallel procedures	50

SCHEDULE 2

VARIATION FEES PER PRODUCT

	MRP MT RMS/MT WS rapporteur €*
Type I	
Type IA Annual Report	500
Type IA/IA $_{IN}$	200
Type IB	400
Type II	
Type II	900
Type II Complex	7,000
Article 61(3) notifications	Included in annual fees

* For single variations, the fee for each additional strength and form subject to same variation is 50% of the applicable fees.
Fees for grouped variations as per Annex III of Regulation 1234/2008 are to be paid for each variation included in the group but no fees for additional strengths and forms subject to same variation/s and acceptable groupings are required.

Other post-authorisation activities	Fee €
Assessment of PSURs	2,300
Assessment of Post Authorisation Safety Studies (PASS)	800 (400)
Assessment of Post Authorisation Efficacy Studies (PAES)	800 (400)

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