Public Health Regulation Division
Diviżjoni Regolazzjoni Saħħa Pubblika
Ministry for Health, the Elderly and Community Care

Our Ref: L003/2010
Your Ref:

To: Marketing Authorisation Holders
Local contact persons

12 May 2010

Requirement for renewal of Marketing Authorisations granted through the PMA-MA process

Directive 2004/27/EC, amends Directive 2001/83/EC with respect to the validity of marketing authorizations (MAs). Marketing authorizations are valid for five years after which they have to be renewed on the basis of a re-evaluation of the risk-benefit balance. Once renewed, the marketing authorisation will be valid for an unlimited period unless there are justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. In addition, the five-yearly cycle of Periodic Safety Update Reports (PSURs) with renewal has been replaced by a three-year cycle.

National marketing authorisations

For all marketing authorisations granted through the PMA-MA project, which currently expire after 5 years from date of issue, the Medicines Authority will not require submission of further renewal applications. Since all the products previously on the market and authorised following accession have been re-evaluated upon the first granting of the marketing authorisation at the PMA/MA stage, there is no necessity for a further re-evaluation.

The products authorised by the PMA/MA process will therefore be given indefinite validity. If the benefit/risk ratio so dictates, the Medicines Authority may also, however, decide to renew the marketing authorisation for a new period of 5 years and not grant indefinite validity. All Marketing Authorisations will be re-issued with indefinite validity or with 5-year validity, where applicable.

Marketing authorisations for line extensions of products authorised through the PMA-MA have to be renewed at least once before indefinite validity can be granted. This is because these products approved through a line extension application had not been previously on the market in Malta.

Marketing authorisation holders (MAHs) will still have the option to renew their marketing authorisations if there is the need for major changes to the dossier which would not be submitted as separate variations or if the MAH would like to update his dossier with information in accordance with the new renewal guideline.

Marketing Authorisations which have already expired will be issued in due course. Where no re-evaluation is required, until renewed, they will be considered as valid until a new marketing authorisation is granted.

Marketing Authorisation granted through European procedures

All products authorised in Malta through the Mutual Recognition and the Decentralised Procedures have to undergo one renewal after which, as agreed with the Reference Member State, the marketing authorisation may be considered as having indefinite validity.

Withdrawal of marketing authorisations

Should marketing authorisation holders not wish to renew their marketing authorisations, they should submit a withdrawal of authorisation form to the Licensing Directorate at the Medicines Authority. The form can be downloaded from http://www.medicinesauthority.gov.mt/marketingauth.htm. Annual fees are to be paid for valid marketing authorisations, irrespective of whether the product is being marketed or not.

More information can be obtained from the Medicines Authority website http://www.medicinesauthority.gov.mt/, in the respective sections. Should you have any queries please submit them to prelicensing.mru@gov.mt.

Dr R Busuttil
Licensing Authority