

DIPARTIMENT TAS-SAHHA

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DIPARTMENT OF HEALTH

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To: Wholesale dealers in pharmaceuticals

RE: MARKETING AUTHORISATIONS FOR MEDICINAL PRODUCTS (HUMAN USE)

Background

The current system for the regulation of medicinal products to be placed on the Maltese market is based on the WHO certification scheme for pharmaceuticals moving in International Commerce. This necessitates the validation of a CPP by the Medicines Regulatory Unit within the Health Division and adherence to other criteria such as the appointment of a pharmacist responsible for all technical matters related to the medicinal, including the release of the medicinal from quarantine on the basis of a valid CPP and a certificate of analysis.

The introduction of the above system for regulation of medicinal products on the local market was a first step towards the setting up of a higher standard system in line with systems in operation in the more developed countries. Such a new system will be regulated by a new Medicines Act which is currently in the final stages of drafting. Apart from regulating the placing of medicinal products on the local market, the Medicines Act will also regulate the manufacture, preparation, importation and distribution of medicinal products. It will also establish the necessary infrastructure to regulate and enforce the set standards.

PROVISIONAL MARKET AUTHORISATION – LICENCE OF RIGHT (PMA)

As of 1 September 2002, all medicinal products currently registered with the Medicines Regulatory Unit (MRU) will require a PMA to be retained on the local market. These products will be granted a PMA as follows:

A Products licenced in countries listed in Annex 3 of attached questionnaire

A PMA for these products will be granted upon submission of a valid CPP (already available at MRU), a summary of products characteristics (SPC), a copy of the official package insert and the packaging of the product. Products not currently on the market will also be granted a PMA upon submission of the aforementioned documents.

B Products licenced in other countries

A PMA for these products will be granted upon submission of an EU-type dossier(Annex 1). Alternatively, a new CPP from one of the countries listed in Annex 3 of the questionnaire together with the other documents listed in A above may be submitted.

APPLICATION FOR PMA

Applications for a PMA will be done in two stages. The first stage consists of the filling of the attached questionnaire. The questionnaire has to be filled and signed by the prospective Market Authorisation Holder (MAH) i.e. the applicant. The applicant will thence shoulder all the responsibilities of an MAH (vide Annex4). You are strongly advised to liaise with your principals abroad and to discuss the questionnaire with them. Since each medicinal product has its own particular characteristics, the questionnaire must be filled in for **EACH PRODUCT** for which a PMA is being requested.

Sealed envelopes containing the completed questionnaire are to be clearly marked "MARKET AUTHORISATION PROJECT" and must reach the MRU by not later than 31st January 2002.

Once the completed questionnaires have been validated by the MRU, applicants will be requested to submit the relevant documentation as described in A and B above. It is envisaged that this will take place in March/April 2002 by which time the definite schedule of fees will be established. At this stage a PMA will be issued upon payment of the relevant fee. The PMA will be issued within two weeks of the date of payment.

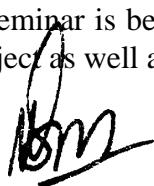
After this date:

- It will not be possible to process any requests for a PMA for any product currently on the local market to be issued within the above time frames.
- Applications for putting a new medicinal product licenced in a country listed in Annex 3 will require the same documents listed in A above together with the payment of the relevant fee. The above time frames for issuing a PMA will not apply.
- Applications for putting a new medicinal product licenced in any other country will require the submission of the appropriate dossier for which a risk-benefit assessment will be carried out upon payment of the relevant fee. Following a positive assessment, a Market Authorisation (not provisional) will be issued.

REVIEW OF MEDICINAL PRODUCTS FOR WHICH A PMA HAS BEEN GRANTED

All medicinal products on the local market will eventually be issued with a Market Authorisation(MA). In the first instance, MAs will be issued for products for which a PMA was issued under B above. Following this, MAHs for products for which a PMA was issued under A will be asked to submit an EU type dossier for assessment prior to a MA being issued.

A seminar is being held on the 29 and 30 November in order to supply further information on the subject as well as to answer any queries you may have. You are strongly encouraged to attend.



Dr R. Busuttill
Director General