

DIPARTIMENT TAS-SAHHA

"PALAZZO CASTELLANIA"
15, TRIQ IL-MERCANTI
IL-BELT



DIPARTMENT OF HEALTH

"PALAZZO CASTELLANIA"
15, MERCHANTS STREET
VALLETTA

GPS 2863/00
DH Circular No. 144/2000

TELEPHONE: (0356) 224071
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15 June, 2000

To: Licensees and Qualified Persons
Wholesale dealers in pharmaceuticals

RE: MARKETING AUTHORISATIONS FOR MEDICINAL PRODUCTS (HUMAN USE)

As part of the project that will eventually lead to the granting of marketing authorisations for all medicinal products imported into the country you are being requested to submit photocopies of the receipts issued to you by the MRAU for valid and acceptable Certificates of a Pharmaceutical Product (CPP) in order to permit the Health Division to process data on each medicinal product. The marketing authorisations would facilitate importation of medicinal products under criteria established from time to time by the Health Division.

All Licensees and Qualified Persons are requested to abide by the following guidelines to ensure that the process runs smoothly.

- It is essential for you to inform the Health Division of those medicinal products for which you would eventually require an authorisation by submitting a photocopy of the receipts issued by the MRAU that refer to the products in question.
- In those cases where more than one product is listed on a receipt, you are required to strike out the name(s) of any product(s) for which you would not require a marketing authorisation, where applicable.
- The attached form 'Update of Records on Pharmaceutical Wholesale Dealers' and the attached letter are to be duly completed. The letter must be signed by both the Licensee and the Qualified Person.
- **Sealed envelopes containing the attached letter, photocopies of receipts and the Update form are to be clearly marked "MRAU DATA ENTRY PROJECT" and must reach the MRAU by not later than 7 July 2000.**
- It is recommended that envelopes be delivered to the Government Pharmaceutical Services by hand. A receipt for sealed envelopes will be issued at the reception desk. An acknowledgement for the photocopies of receipts and the Update form

will be issued after confirmation of the contents of the envelope. The acknowledgement will be sent by post or e-mailed to you as indicated by your choice in the attached letter.

It should be noted that the Government Pharmaceutical Services is only responsible to check certificates for medicines for human use. Any other products currently classified in the exporting country as foods, dietary supplements, cosmetics and medical devices do not fall within the remit of the Department. Standards for such products are laid down by the Malta Standardisation Authority. Consequently, such products would not be subject to the requirement for a marketing authorisation. Photocopies of receipts issued in the past for non-medicines that you submit will be returned to you in due course.

Due to the large number of medicinal products that must be entered into the Division's computer system and the administrative procedure that is involved it is envisaged that the process will take several months. In the meantime, the MRAU will still be issuing receipts for valid and acceptable CPPs. The receipts are to be presented to the Port Health Services at the time of importation according to current procedure. CPPs submitted to the MRAU after 7 July 2000 and those submitted prior to this date but which are still being checked will automatically be included in the process.

Further information may be obtained from the Medicines Regulatory Affairs Unit, Government Pharmaceutical Services, St Luke's Square, Guardamangia MSD 07 on telephone number 24 20 66 (12:00 - 13:00 hours), fax number 25 11 32, or e-mail address gps.mrau@magnet.mt.



R. BUSTJTLL
DIRECTOR GENERAL (HEALTH)