

## **ΦΑΡΜΑΚΕΥΤΙΚΕΣ ΥΠΗΡΕΣΙΕΣ** 1475 ΛΕΥΚΩΣΙΑ

#### PHARMACEUTICAL SERVICES 1475 LEFKOSIA

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# TO ALL MARKETING AUTHORISATION HOLDERS (MAH)/APPLICANTS

# New dedicated electronic mailboxes for MRP/DCP procedures

The Pharmaceutical Services would like to inform all Marketing Authorisation Holders/Applicants that in an effort to reduce the excessive amounts of paper circulating during and after registration procedures for pharmaceutical products, will now be able to receive via email responses and national texts relevant to MRP/DCP procedures.

Specifically, as of 1/2/2012 the following dedicated email accounts will be used to receive documents:

- 1) <a href="mailto:mrp-dcp@phs.moh.gov.cy">mrp-dcp@phs.moh.gov.cy</a> : For submission of responses and supplementary information during MRP/DCP procedures for new applications, variations and renewals (including consolidated update after validation)
- 2) <a href="mailto:mrp-dcpnew@phs.moh.gov.cy">mrp-dcpnew@phs.moh.gov.cy</a>: For submission of initial national translations for **new**<a href="mailto:MRP/DCP">MRP/DCP</a> application procedures
- 3) <a href="mailto:mrp-dcpvar@phs.moh.gov.cy">mrp-dcpvar@phs.moh.gov.cy</a>: For submissions of initial national translations for MRP/DCP renewal and variation procedures

## Please note the following:

- All emails must clearly state in the subject line the following:
   Name of the product, Procedure number and the Type of documentation
   e.g. XXXXX tablets, RMS/H/XXXX/DC, Day 106 Responses.
- The acceptable formats for submission of responses are the formats according to NeeS and eCTD requirements which are the only acceptable electronic formats.
   For national translations SPCs, PILs and labeling must be in Word format and for the mock ups, the following formats are acceptable: jpeg, pdf, gif, bmp.
- MAH/applicants who wish to have a proof of submission please note that when the email
  is sent, the "request read receipt" function should be used to which the Pharmaceutical
  Services will respond upon reading emails. Pharmaceutical Services do not intent to
  regularly send individual official email responses other than the automated read receipt
  response.

Documents can be send in one of the following ways:

- As an attachment, zip or rar file with a limit of 5MB per email
- A eudralink link with package expiry of 3 months
- As multiple emails (only for National Translations but not the preferable way)

Responses sent via email **should not** be sent to Pharmaceutical Services through any other way. For submissions of excessive size which cannot be sent with one of the above mentioned ways, a CD-ROM should be sent to Pharmaceutical Services.

The Pharmaceutical Services would like to urge the applicants/MAHs to submit via email the above mentioned documents wherever possible. This will result in less process delays and earlier assessment. However, the Pharmaceutical Services would also like to clarify that submissions to email accounts other than the ones indicated above will not be considered valid unless an applicant has been specifically requested to respond in another mailbox.

For any further information or clarifications you may contact Ms Emilia Mavrokordatou (emavrokordatou@phs.moh.gopv.cy Tel +357 22 407 118). For future reference, please note that this circular can also be found on the Pharmaceutical Services website (www.moh.gov.cy/phs).

George L. Antoniou Registrar Drugs Council