



Decentralized Procedure (DCP) with Cyprus as the Reference Member State (RMS)

Applicants are advised, so that both applicants' requests for desired submission dates are fulfilled and for the efficient planning of our resources, to request time slots for their application(s), for which they wish Cyprus to act as the RMS in the decentralized procedure, within a reasonable time period prior to the proposed submission date.

Time slots may be requested at any time and there are currently no restrictions. However, it is recommended that the requests are limited to no longer than 18 months from the proposed date.

Time slots are allocated on a "first come first served" basis. If the requested time slot is not available, a suitable alternative will be offered.

Requests for a time slot are to be made using the CMDh request form (<https://www.hma.eu/219.html>). The completed form should be sent by e-mail to rmscyprus@phs.moh.gov.cy.

Following the submission of a fully completed slot request form, the applicants will be informed within 30 calendar days whether a time slot has been reserved for their submission or not. The timeslot is reserved for a specific medicinal product, a specific pharmaceutical form and all its concerned strengths.

Following the booking of a timeslot, any changes in the applications to be submitted (i.e. other product, other pharmaceutical form or other strengths from the ones initially planned etc) require the submission of a new slot request.

Changes to already agreed time slots should be notified, in writing, to the Pharmaceutical Services (PhS), as soon as possible so that a new submission date may be scheduled/agreed.

As soon as the applicant receives confirmation of a valid payment of fee, the applicant must submit the Marketing Authorization Application (MAA) eCTD dossier solely via the CESP (Common European Submission Portal). The applicant must also concurrently send an email with the subject: "CY/H/xxxx/xx INN + Applicant – Initial submission" to rmscyprus@phs.moh.gov.cy. This email shall contain details of the CESP number and the Dispatch list of the submission to the CMSs (Concerned Member States). The validation step will begin immediately once all 3 of these requirements are fulfilled.



REPUBLIC OF CYPRUS
MINISTRY OF HEALTH

PHARMACEUTICAL SERVICES
1475 ΛΕΥΚΩΣΙΑ

Mutual Recognition Procedure (MRP) and Repeat Use Procedure (RUP) with Cyprus as Reference Member State (RMS)

The information provided above for the DCP procedure also applies for MRP and RUP procedures. The form can also be accessed from the CMDh website (<https://www.hma.eu/481.html>). Please note that prior to the submission of a slot request for the Mutual Recognition Procedure (MRP) and Repeat Use Procedure (RUP) the dossier must be updated. The flow chart for the MRP and RUP procedures can be found on the CMDh website at the following link https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/Application_for_MA/MRP_RUP/CMDh_081_2007_MRP_RUP_Flow_chart.pdf

Change of the RMS role for UK procedures in relation to BREXIT

The Pharmaceutical Services (PhS) of the Ministry of Health of Cyprus are in the position to take over the RMS role for any procedures where the RMS is the UK as a result of BREXIT.

The PhS do not have any special national requirements and the procedure shall proceed in accordance with the CMDh document "CMDh procedural advice on changing the RMS"

https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/01_General_Info/CMDh_039_2002_Rev.8_2018_07_CMDh_procedural_advice_on_changing_the_RMS_CLEAN.pdf

03/01/2020