HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Submitting a Request for Ireland to Act as RMS in a Decentralised Procedure for a Human Medicinal Product

1 SCOPE

This guidance applies to the submission of requests for Ireland to act as Reference Member State (RMS) in a decentralised procedure (DCP) for a human medicine.

2 INTRODUCTION

The Health Products Regulatory Authority (HPRA) wishes to actively participate as RMS in the decentralised procedure and welcomes requests for Ireland to act as RMS in a DCP procedure.

3 APPLICATION FORM

Applicants are requested to submit their request for Ireland to act as RMS as early as possible and no later than three months prior to the planned submission of the application.

Requests should be made using the common request form for RMS published on the CMDh website and submitted to RMS@hpra.ie, including 'DCP submission' in the email subject title. All sections of the form should be completed.

4 ALLOCATION

All requests received will be reviewed by the HPRA. Successful applicants will be contacted by email to confirm availability for submission of dossier at a specified allotted time (next available slot in a 2-year window) and a non-refundable booking fee of €1,000 will be required from the MAH to secure the DCP slot. The booking fee will be offset against the full application fee once the submission is received.

Please note that slots are allocated for specific active substance(s), dosage form(s) and the submission time specified in the communication. If the applicant intends to change one of those parameters, a new request and booking deposit may be required. HPRA also operates a cancellation list for slots which become available at short notice.

5 FURTHER INFORMATION

Repeat use DCP requests

Requests to include additional concerned member states relative to the original procedure can be submitted at any time to the HPRA. Requests for repeat use must also be sent to RMS@hpra.ie and the HPRA will contact you by return.

Please consult the HPRA website regularly for any updates and further developments in this area.

Further procedural guidance on applications for decentralised procedures is available on the CMDh website.

HPRA
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