



## IRISH MEDICINES BOARD 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 Irish Medicines Board (IMB) wishes to actively participate as RMS in the decentralised procedure. To date, the IMB receives many more requests than we are able to accommodate. In order ensure the IMB continues its commitment to act as RMS in as many procedures as possible and to continue to provide a high level of service to its stakeholders, the IMB is introducing a new system for managing requests to act as RMS for 2011 and beyond.

A 'window' for requests for the IMB to act as RMS for DCP applications will open at least once a year inviting applications for submission during a specified time period. All requests will be considered and successful requests will be allocated a dedicated slot for assessment of the application. Requests received outside of these windows will not be accepted. If an applicant is unsuccessful in receiving a slot, they will need to reapply when the window reopens at a later date.

### 3. APPLICATION FORM

Requests should be made using the form 'Request for RMS in a decentralised procedure, medicinal products for human use' agreed by the Heads of Medicines Agencies which is available on the [CMD\(h\) website](#). All sections should be filled in.

The finished product manufacturer(s) should be declared either as an addition to the application form or in the cover letter.

### 4. SUBMISSION OF REQUESTS

The IMB will inform applicants via our website when the 'window' for requests is open. The message will invite applicants to submit requests for Ireland to act as RMS for submission of application at a specified time period.

Requests should be submitted by email to [rmsrequests@imb.ie](mailto:rmsrequests@imb.ie) using the request form. Requests received without the request form or outside the window for requests will automatically be rejected.

It is intended that a 'window' for requests will open for submission of applications during specific quarters the following year (minimum 9 months in advance).

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A message will be posted on the website to advise when the window has closed. A further invitation may be posted resulting from the first round targeting specific types of products, active substances etc. These will be processed as outlined above.

**Proposed rounds:**

Round	Requests invited	Dossier submission dates
1.	September Year N	Quarter 2, 3 and 4, Year N+1
2.	March Year N	Year N+1

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**5. ALLOCATION**

All requests received during the window period will be reviewed by the IMB. Successful applicants will be contacted by the IMB to confirm availability for submission of dossier at a specified allotted time and a booking fee of €1,000 will be required to secure the 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 should be submitted.

Unsuccessful applicants will be notified by email once all slots are filled.

**6. FURTHER INFORMATION**

**Repeat use DCP requests**

The above procedure for managing requests does not apply to repeat use procedures. It is possible to make requests to include additional concerned member states relative to the original procedure at any time. Requests for repeat use should also be sent to [rmsrequests@imb.ie](mailto:rmsrequests@imb.ie) and the IMB will contact you by return.

Please consult the IMB 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](#).

IMB

~~March 2011~~

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