HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Submitting a Request for a New National Application Procedure for a Human Medicinal Product

1 SCOPE

This guidance applies to the submission of requests for new national applications to IE.

2 INTRODUCTION

The Health Products Regulatory Authority (HPRA) is transitioning towards a system of allocating slots (expected submission dates) for new national product authorisation submissions, e.g. purely national applications which result in a licence in Ireland only.

Submitting applications in an agreed month will facilitate capacity planning for efficient assessment of these applications. This will also maintain access for applicants to a focused authorisation route for products particularly relevant to the Irish market.

3 APPLICATION FORM

Applicants are requested to submit their request for Ireland to act as RMS as early as possible and no later than two months prior to the preferred submission date 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 'National MA submission' in the email subject title. All sections of the form should be completed. A justification of the relevance of the product to the Irish market should also be provided.

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 6-month window) and a non-refundable booking fee of €1,000 will be required from the MAH to secure the national 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
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