

Notice to applicants regarding the Belgian Federal Agency for Medicines and Health Products acting as RMS – Human medicinal products

The Belgian Agency wishes to participate actively in the Mutual Recognition Procedure and the DeCentralised procedure as Reference Member State (RMS).

Nevertheless, the capacity of the Belgian Agency to act as RMS is limited.

The Belgian Agency gives priority to the applications for medicinal product in the following domains

- Oncology (with special focus on treatment of cancerpain and paediatrics)
- vaccines.

For existing substances, the Belgian Agency also gives priority to those where we have been RMS or rapporteur in previous procedures.

To allow an efficient handling of your request to act as RMS in the DCP, please complete the enclosed template and send it to the contact person:

katherine.sterck@fagg.be

The common request form from the CMDh could be used too. See for further details on <http://www.hma.eu/219.html>

The request should be sent at least 3 months before the expected date of submission of the application.

You will receive a response within 3 weeks.

Please note that applications with BE as RMS are booked for a specific active substance, dosage form and submission date. If the applicant intends to change one of those parameters, a new request should be introduced.

The applicant is advised to inform the Belgian Agency as early as possible if the booked application will not be submitted.