DG PRE authorisation/Marketing Authorisation Division (human use)/MRP, DCP and NP Entity

Strategy paper for Reference Member State request - Decentralised procedure on medicinal products for human use

Version: 2022

If you would like the FAMHP to act as Reference Member State (RMS) for a new marketing authorisation application according to the decentralised procedure (DCP), please **reserve a timeslot at least three months prior to the planned submission date**.

Please note that an RMS timeslot is booked **for a specific medicinal product, meaning one pharmaceutical form, and all its strengths**. Modification of one of these parameters, results in a new timeslot reservation.

Postponing a reserved timeslot for a **maximum period of three months** will only be allowed **after clear justification** was given to and accepted by the FAMHP.

If a planned submission for which a timeslot was reserved, is **cancelled**, the FAMHP needs to be notified as soon as possible.

Within existing active substances, priority will be given to active substances for which the FAMHP has acted as RMS or (co-)rapporteur in the past.

Overview of the available FAMHP timeslots

Period	Available timeslots	
	Foreseen	Remaining
1 January 2022 – 31 December 2022	5	0

Period	Available timeslots	
	Foreseen	Remaining
1 January 2023 – 31 December 2023	5	4

Book a timeslot
Please complete the 'Common Request Form' published on the CMDh website and send it to prelicensing@fagg-afmps.be. The FAMHP will reply within ten calendar days.

Legal base
- Full application: Directive 2001/83, article 8.3, 10.a, 10.b
- Abridged application: Directive 2001/83, article 10.1, 10.3, 10c, 16