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

Strategy paper for RMS request in view of the Decentralized Procedure (DCP) concerning medicinal products for human use

March 2017

If you want the FAMHP to act as RMS for a new marketing authorisation application following the DCP procedure, please **reserve a timeslot at least three months before the planned submission date**.

Note that an RMS timeslot is booked **for a specific medicinal product, meaning one pharmaceutical form, and all its concerned strengths**. Changing 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.

If you submit RMS requests within the FAMHP's domains of excellence (such as **oncology and vaccines**), note that medicinal products containing new active substances in those domains will follow almost exclusively the centralized procedure except for preventive vaccines, which do not fall in the mandatory scope of the Annex to Regulation (EC) 726/2004 unless they belong to other categories within the mandatory scope of the Annex to the Regulation. Consequently, RMS requests for medicinal products within these domains containing existing active substances, will be the main goal. Within these existing active substances, priority will be given to active substance for which the FAMHP acted as RMS or (Co-) Rapporteur in the past.

Overview of the available FAMHP timeslots: timeslots for 2017 are fully booked

Period	**Full** applications		**Abridged** applications	
	Foreseen	Remaining	Foreseen	Remaining
01.01.2017 – 31.12.2017	1	0	1	0

Booking starts three months before the first day of the period marked in the first column!

Complete the 'Common Request Form' published on the CMDh website and send it to presubmission-HUM@fagg.be. The FAMHP will reply within ten calendar days.

Legal base

- Full application: Directive 2001/83 Art 8.3 or Art.10.a, Art 10.b,
- Abridged application: Directive 2001/83 Art 10.1, Art 10.3, Art 10c, Art 16