

**Strategy paper for RMS request in view of the Decentralized Procedure (DCP)  
concerning medicinal products for human use  
07/2015**

If you want the FAMHP to act as RMS for a new marketing authorization 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** of a reserved timeslot for a **maximum period of three months** will only be allowed **after clear justification** was given and accepted by the FAMHP.

If a planned submission for which a timeslot was reserved, is cancelled, the FAMHP would be pleased being notified as soon as possible!

If you submit RMS requests within the FAMHP's domains of excellence, oncology and vaccines, note that medicinal products containing new active substances in those domains will follow almost exclusively the centralised 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.

**Way to proceed:**

Overview of the available FAMHP timeslots

2015

Period	Foreseen timeslots for <b>full</b> applications	Remaining timeslots	Foreseen timeslots for <b>abridged</b> applications	Remaining timeslots
01-2015/ 06-2015	1	0	4	0
07-2015/ 12-2015	1	0	4	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 (<http://www.hma.eu/219.html>) and send it to [presubmission-HUM@fagg.be](mailto:presubmission-HUM@fagg.be)

Within 10 calendar days the FAMHP will reply on your request.

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 16a