REG-85

Slot allocation for decentralised marketing authorization procedure with Czech Republic as the RMS

This guideline is effective as of February 18 2009

The guideline provides a detailed specification of the process of slot allocation for applicants for marketing authorisation via decentralised procedure with the Czech Republic as the Reference Member State (RMS).

I.

A "slot" shall mean a position/place for the applicant which shall be determined by the State Institute for Drug Control (SÚKL) on the basis of its available capacity and information submitted by the applicant in compliance with section II hereof.

At present, SÚKL in the position of the RMS is able to run marketing authorisation procedures only for generic medicinal products.

The application for slot allocation shall be sent only electronically (by e-mail) to the following address: mrp@sukl.cz. In the course of 2009, it is possible to submit applications for slot allocation for DCPs for generic medicinal products whose commencement is planned only in 2013. The applicant shall be informed about slot allocation by e-mail.

Towards the end of 2009, this guideline shall be updated in terms of specification of expected slot dates for further years.

Within the scope of slot allocation, SÚKL assesses only applications containing complete information required by section II. Where an application is incomplete, it shall not be assessed and the slot date not allocated to the applicant.

If a slot is not allocated
An applicant who has submitted complete information and satisfied all of the requirements, but to whom the slot is not necessarily allocated for capacity reasons, shall be informed to this effect. SÚKL shall not provide any waiting list for products to which the slot has not been allocated.