

REG-85 version 2

This Guideline supersedes guideline REG-85version 1 with the effect from 27 October 2014.

With the aim to harmonize procedures with other EU Member States and based on the CMD recommendation „BEST PRACTICE GUIDE FOR THE DECENTRALISED AND MUTUAL RECOGNITION PROCEDURES“ (Doc. Ref.CMDh/068/1996/Rev10, adopted in April 2013) the State Institute for Drug Control (hereinafter referred to as „the Institute“) shall allocate DCP timeslots.

In order to ensure transparency of allocating DCP timeslots, the Institute adopted and hereby publishes Information on rules pursuant to which DCP timeslots shall be allocated as **from October 27, 2014**. DCP timeslots which were allocated prior to October 27, 2014, remain valid.

In accordance with the above mentioned CMD recommendation, should a subject intending to ask the Czech Republic to act as the Reference Member State (hereinafter as “RMS”) in a decentralized procedure for granting marketing authorization for a medicinal product, he/she should notify the Institute on this intention. Based on this information, the Institute shall allocate a DCP timeslot while taking all effort to ensure smooth running of the procedure and applying the principle of the most effective use of its capacity, and keeping in mind the aim of harmonization of procedures with other Member States.

DCP timeslot

A DCP timeslot is a time interval during which a subject is entitled to submit a request to the Institute and other competent authorities from the concerned Member States for granting marketing authorization for a medicinal product in the course of a DCP procedure.

A DCP timeslot shall be allocated by the Institute only in cases when the Czech Republic acts as the RMS in the DCP procedure.

The notification on an intention to submit a request in order to ask a MS to be the RMS (hereinafter referred to as “request for a DCP timeslot”) should be addressed to the following e-mail address: dcp.slot@sukl.cz.

When allocating a DCP timeslot the Institute shall take into account the following

1. free capacity of the Institute (of the assessors)
2. chronological order of requests received (according to the day of receipt and should the day of receipt be the same then according to the exact time of receipt)

Process of allocating DCP timeslots:

1. Date of submission of a request

DCP timeslots are allocated by the Institute for a two-year-period. This period starts as from the submission deadline.

The submission deadlines shall be March 31, June 30, September 30 and December 31 of a calendar year (hereinafter referred to as the “submission deadline”).

After the submission deadline the Institute shall allocate DCP timeslots with respect to the criteria stipulated above.

2. Notice on allocating a DCP timeslot

The Institute shall notify the applicant on the DCP timeslot allocated to him/her within 15 days from the submission deadline, *i.e.* not later than April 15, July 15, October 15 or January 15 of the given calendar year, and the notification shall take form of an e-mail.

The applicant shall inform the Institute on his acceptance of the DCP timeslot allocated to him/her within 15 days from notification on allocating a DCP timeslot, and should he/she fail to do so the DCP timeslot shall be deemed to be unaccepted by the applicant and as a consequence of this the Institute shall dispose of such an unaccepted DCP timeslot in accordance with point 3 of this Information.

In case the Institute receives acceptance notice of the allocated DCP timeslot from the applicant within 15 days from notification on allocating a DCP timeslot, it shall then inform the applicant on the reference number under which the DCP procedure will be run.

3. Unaccepted DCP timeslots

In case the applicant decides not to accept the allocated DCP timeslot, the two following situation may occur:

- a) the applicant either fails to inform the Institute in accordance with point 2 on his/her acceptance or informs the Institute on his/her non-acceptance.

In such case the Institute shall consider the DCP timeslot as unaccepted, and should it be possible due to time delay the Institute shall decide on its allocation to another applicant in the course of the timeslots allocation which will follow after the next submission deadline.

- b) the applicant accepts the allocated DCP timeslot, nevertheless some later circumstances prevent him from using the timeslot.

In such case the applicant shall immediately inform the Institute on these circumstances, and the Institute shall then proceed as if the timeslot was unaccepted under par. a), *i.e.* should it be possible due to time delay the Institute shall decide on its allocation to another applicant in the course of timeslots allocation which will follow after the next submission deadline.

In exceptional cases, a DCP timeslot may be postponed upon an agreement initiated by a request from the applicant. This agreement is possible only under the following conditions:

- a) the expert capacity of the Institute enables the postponement (capacity of assessors)
- b) new time interval to which the DCP timeslot shall be postponed is free.