

**PROCEDURE PROCEDURAL ADVICE**  
**FOR AUTOMATIC VALIDATION**  
**OF MR/REPEAT-USE/DC PROCEDURES FOR NEW APPLICATIONS**

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All days mentioned in this document should be regarded as calendar days.

This procedure has been agreed by the CMD(h) to ensure that validation times are within those agreed in the Best Practice Guide for Mutual Recognition Procedure, [Procedural Advice on Repeat-Use and Decentralised Procedure Member States' Standard Operating Procedure](#). Completion of CTS records by all involved is essential for the operation of this procedure.

The RMS should update the CTS record with the date the assessment report (AR) was sent [for MR and Repeat-Use procedures](#).

The applicant should inform the RMS about the date of receipt of the application by the CMS. The RMS will update the CTS record accordingly.

The validation period is 14 days and starts when all CMS have received [the application \(for DC procedures\) or](#) both the application and the AR [\(for MR and Repeat-Use procedures\)](#).

On receipt of [the application \(for DC procedures\) or](#) the application and the AR [\(for MR and Repeat-Use procedures\)](#), the CMS will update the CTS record. If, at day 7 of the validation period the CTS record is not complete with respect of valid or invalid application for each CMS, the RMS will notify (initially by Eudranet email) the CMS who have not completed the CTS record that the validation period will close at the end of the next 7 day period unless notification of an invalid application is received.

CMS should promptly inform both the applicant and the RMS about any validation issues. The CMS should indicate in CTS that the application is invalid when there are justified reasons to do so ~~(e.g. fee or part of the documentation missing)~~. An application will not automatically be set invalid if a CMS has not yet received the dossier and the validation period has not started. [Applicants are advised to check the CMD\(h\) Best Practice Guide on the compilation of the dossier for new applications submitted in Mutual Recognition and Decentralised Procedures as well as Common Grounds for Invalidation/Delaying Validation before submission of the application.](#)

The RMS will close the validation period 7 days ~~after~~ after sending this the notification to involved CMS and may start the procedure unless informed by a CMS that the application is not valid.

If a CMS has previously informed the RMS that the application is not valid, the procedure will not be started until that CMS confirms with the RMS that the issue has been resolved and the application is valid. The CMS has a duty to update the CTS record accordingly.

The CMS must inform the RMS that the application has become valid within 7 days of the missing information being supplied.

If it is not expected that the application will become valid within an acceptable time, the applicant will be advised to withdraw the application in the CMS.