

**AD-HOC WORKING-GROUP CMDh PROCEDURAL ADVICE ON
VALIDATION ISSUES/NATIONAL REQUIREMENTS
COMMON GROUNDS FOR INVALIDATION/DELAYING VALIDATION***

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~~CMD(h) has set up a~~ CMDh created in November 2006 the Ad Hoc Working Group on Validation issues/National requirements in MR/DC procedures in order to achieve transparency about raised invalidation/delayed validation issues and national requirements and consequently avoid procedural delays. The working group ~~has~~ defined in July 2007 the most common grounds for invalidation/delayed validation and applicants ~~are~~ were encouraged to be more thorough when compiling the documentation before submission of the application. The CMDh has continued the work on validation to streamline the MRP/DCP and an Agreement has been reached between all MS to divide issues raised as Validation Issues respectively Non-Validation Issues allowing the RMS to start the procedure when all stated Validations Issues have been solved cf. CMDh Template for Validation of Application for marketing authorization(current version).

Although many initiatives have been made we still experience the following Common grounds for invalidation/delayed validation ~~are~~:

- Application not received/modules are missing
- Proposed MAH not established in the EEA
- Missing/incorrect fee
- Application form/cover letter not signed/not signed with original signature
- The application form is incorrect (eg. information missing, incorrect type of procedure, legal basis incorrect, incorrect reference medicinal product, reference to an European reference medicinal product although there is a nationally authorised medicinal product)
- Documents in accordance with NtA, vol. 2B are missing or absence not justified (eg. Braille, Consultation with Target Patient Groups, Pharmacovigilance System, Environmental Risk Assessment, Specific Requirements for Different Application Types, Paediatric Regulation(where applicable))
- Annexes to the application form are missing or absence not justified (eg Declaration from the QP, TSE certificates for excipients of animal origin)
- Manufacturing licenses, GMP certificates and/or import licenses have not been updated or ~~are~~ missing. Proposed batch releaser is situated outside the EEA
- ASMF and/or letter of access to ASMF missing or incorrect version of the ASMF has been submitted
- Confirmation that identical dossiers are submitted in both RMS and the CMS is missing.
- The comparator for the bioequivalence study does not originate from the EEA
- Proposed SPCSmPC, PL and labelling not in the QRD format or are missing.
- The submitted documentation cannot be identified (name of applicant, name of the product etc. are missing)
- Complete Module 3 for extension applications (where applicable) is not submitted
- Insufficient number of copies submitted

** Technical Validation of Electronically submitted Applications is outside the scope of this Procedural Advice and is /will be dealt with in other CMDh papers.*

- For electronically submitted applications: Format, media or number of copies are not acceptable/missing cf. the requirements for electronic submission published by the NCA
- Specific published national requirements are not met cf. Table “Data requested for New Applications in the MRP/DCP...”(current version)

The following issues are not likely to be solved during a validation period, leading to invalidation of the application:

- The reference product has not been licensed in accordance with the Community *acquis*
- Data exclusivity period not expired
- The suitability of bibliographic data to demonstrate eligibility of "well-established use" according to the rules and criteria of Annex 1 of the Medicines Directive and Chapter 1 of the Notice to Applicants

More information on dossier requirements can be found on:

- http://ec.europa.eu/enterprise/health/documents/eudralex/homev2vol-2/index_en.htm
- ~~additional data for new applications (MRP/DCP):~~
- ~~Data requested for New Applications in the MRP/DCP: <http://www.hma.eu/91.html>~~
- ~~Requirements on electronic submission for New Applications: <http://www.hma.eu/277.html>~~