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Administration and Corporate Management Division

Dossier requirements for centrally authorised products (CAPs)

Submission of applications to the European Medicines Agency, members of the Committee for Medicinal Products for Human use (CHMP), Pharmacovigilance Risk Assessment Committee (PRAC) and Committee for Advanced Therapies (CAT)*

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Application / Submission Type	Dossier Requirements for EMA, (Co-)Rapporteurs and Members/Alternates
Full application Extension Renewal Type IB variation (with PRAC involvement). Grouping or Worksharing containing NAPs Type II variation (with or without PRAC involvement) Grouping or Worksharing containing NAPs Periodic Safety Update Report (PSUR)[1] Post Authorisation Safety Studies (PASS) Post-Authorisation Measures (PAMs) Annual Re-Assessment Article 20 procedure	All **eCTD format** submission for **Centrally Authorised products** sent to EMA via eSubmission Gateway/Web Client **will be considered delivered to all National Competent Authorities'** representatives, alternates and scientific experts**. **Do not submit** any additional copies of eCTD format CAP submissions **directly to the NCAs** on CD/DVD or via CESP as this might lead to validation issues and cause delays. All Centralised Procedure submissions should be made via EMA eSubmission Gateway/Web Client only. **Committee for Advanced Therapies (CAT) members nominated by the European Commission <u>not</u> linked to EMA Common Repository:** 1 copy of eCTD format submission on hard media, e.g.CD/DVD, after EMA technical validation (or by start of the content/regulatory validation phase) and after Validation Supplementary Information. CAT* submissions are only required if the product is an advanced therapy (AT). The Names and Dossier delivery addresses for CAT members nominated by the European Commission can be found here.
Type IA or IB variation Transfer Art 61(3) Notification Art. 58 (WHO) submissions Active Substance Master File (ASMF) Plasma Master File (PMF)	As above Note: ***No CAT* or PRAC submissions required for these procedure types.***

Application / Submission Type	Dossier Requirements for EMA, (Co-)Rapporteurs and Members/Alternates

For any other procedure type, such as Referrals submissions, PASS 107, workshare, Signal Detection and Ancillary Medical device submissions please review the
Dossier requirements for Referrals, ASMFs and Nationally authorised products.

* for CAT, the dossier is only required by its members if the product is an advanced therapy (AT).

** From 1 January 2021 this will no longer include UK authorities. However, in view of the validity of Union authorisations in the territory of Northern Ireland, the marketing authorisation holders are advised to also submit the dossier to the UK authorities. With regards to the modalities of such submissions the marketing authorisation holders are advised to contact directly the UK authorities.