25 January 2021
EMA/13015/2014 Rev.10
Administration and Corporate Management Division

Dossier requirements for NAPs (referral, PASS107, workshare, signal detection procedures) and ancillary medicinal substances in a medical device

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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

Referrals; Application / Submission type	Dossier requirements for EMA, (Co-)Rapporteurs and members/alternates
Article 31 referral (non-safety) [1] Article 20 procedure (non-safety)[1] Article 29(4) referral Article 30 referral Article 13 referral Article 29PAE procedure[3] Article 5(3) procedure[1] Article 107i procedure [1] Article 20 pharmacovigilance procedure [1] Article 31 pharmacovigilance referral (safety) [1]	All **Referral** submissions sent to EMA via eSubmission Gateway/Web Client **will be considered delivered to all National Competent Authorities'* representatives, alternates and experts of the scientific committees**. **Do not submit** any additional copies of referral submissions **directly to the NCAs** on CD/DVD or via CESP as this might lead to validation issues and cause delays. All EMA referral submissions should be sent via EMA eSubmission Gateway/Web Client only. ***Please note:*** ***eCTD format is strongly recommended for all referral submissions and is mandatory for referrals related to Centrally Authorised Products (CAPs)*** ***For technical issues with the submissions visit the EMA Service Desk portal***

Note for Centrally Authorised Products (CAPs) involved in the referral procedure:

CAP referral submissions should always be submitted as the next sequence in the product lifecycle for each CAP. Standalone eCTD submissions for the active substance are not allowed for CAPs included in Referral Procedures.

For Referral submissions for CAPs, follow the CAP Dossier Requirements document.

ASMF; **Application / Submission type**	**Dossier requirements for EMA, (Co-)Rapporteurs and members/alternates**
All ASMF submissions must be provided in eCTD format	eCTD submission via eSubmission Gateway/Web Client only; the submission **will be considered delivered to all National Competent Authorities*' representatives and alternates**. **Do not submit** any ASMF submissions **directly to the NCAs** on CD/DVD or via CESP as this might lead to validation issues and cause delays.

NAP submissions (PASS107, workshare, signal detection procedures)	**Dossier requirements for EMA, (Co-)Rapporteurs and members/alternates**
NAP submissions related to EMA coordinated procedures (PASS107, workshare and Signal Detection)	All **NAP** submissions (PASS107, workshare, signal detection procedures) sent to EMA via eSubmission Gateway/Web Client **will be considered delivered to all National Competent Authorities*' representatives, alternates and experts of the scientific committees**. **Do not submit** any additional copies of submissions **directly to the NCAs** on CD/DVD or via CESP as this might lead to validation issues and cause delays. All EMA submissions should be sent via EMA eSubmission Gateway/Web Client only. ***Please note:*** ***eCTD format is strongly recommended for all submissions and is mandatory for related to Centrally Authorised Products (CAPs)*** ***For technical issues with the submissions visit the EMA Service Desk portal***

Ancillary medicinal substances in medical device; Application / Submission type	Dossier requirements for EMA, (Co-)Rapporteurs and members/alternates
Initial consultation procedure Post-consultation procedures (equivalent to Type IA, IB, II)	All **Ancillary medicinal substances in medical device submissions** sent to EMA via eSubmission Gateway/Web Client **will be considered delivered to all National Competent Authorities*' representatives, alternates and experts of the scientific committees**. **Do not submit** any additional copies of submissions **directly to the NCAs** on CD/DVD or via CESP as this might lead to validation issues and cause delays. All EMA submissions should be sent via EMA eSubmission Gateway/Web Client only. ***For technical issues with the submissions visit the EMA Service Desk portal***

*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.

[1] Centrally authorised products concerned by this procedure should follow the dossier requirements as detailed here. For information on eCTD submissions please refer to Harmonised Guidance for eCTD Submissions in the EU

[2] Please refer to the table below to check which CHMP Co-Opted members and PRAC members, nominated by the European Commission, will need to be contacted directly.

[3] Article 29PAE includes validation, therefore submission to all other members is only required after EMA content/regulatory validation

Names and dossier delivery address for CHMP Co-Opted members and for PRAC members, nominated by the European Commission, which require dossier submission

Name	Dossier delivery address	Submission via portal
PRAC Independent Scientific experts:		
Milou Daniel Drici	Laboratoire de Pharmacologie-Bât. J4 Hôpital Pasteur 1, 30 Avenue de la Voie Romaine CS 51069 06001 Nice cedex 1 FRANCE	NO: submission on CD-ROM or DVD is required