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Information 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)

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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***

[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:		
Thierry Trenque	CHU Reims Avenue du General Koenig 51092 Reims FRANCE	NO: submission on CD-ROM or DVD is required
PRAC Representatives of Patient Organisation		
Alternate: Albert van der Zeijden	International Allicance of Patients' Organisations (IAPO) 49-51 East Road London N1 6AH UK	NO: submission on CD-ROM or DVD is required