EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Information Management Division

Dossier requirements for referral, ASMF and NAP submissions (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)

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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]	**EMA**: 1 electronic submission in eCTD, NeeS or unstructured format via eSubmission Gateway or eSubmission Web Client. **CHMP**: (Co)-Rapporteurs and other members: 1 electronic submission in eCTD or NeeS format via Portal or on DVD/CD-ROM[2] ***Please note:*** ***eCTD format is strongly recommended for all referral submissions and is mandatory for referrals related to Centrally Authorised Products (CAPs)*** ***Nationally Authorised Products (NAPs), submitted in any format, are not available via the Common Repository and should be sent separately to each NCA. For further information about how to submit, please follow the link.*** ***For technical issues with the submissions visit the EMA Service Desk portal***
Article 107i procedure [1] Article 20 pharmacovigilance procedure [1] Article 31 pharmacovigilance referral (safety) [1]	**EMA**: 1 electronic submission in eCTD, NeeS or unstructured format via eSubmission Gateway or eSubmission Web Client. **PRAC**: (Co)-Rapporteurs and other members: 1 electronic submission in eCTD or NeeS format via Portal or on DVD/CD-ROM[2] ***Please note:*** ***eCTD format is strongly recommended for all referral submissions and is mandatory for referrals related to Centrally Authorised Products (CAPs)*** ***Nationally Authorised Products (NAPs), submitted in any format, are not available via the Common Repository and should be sent separately to each NCA. For further information about how to submit, please follow the link.*** ***For technical issues with the submissions visit the EMA Service Desk portal***

Referrals; Application / Submission type	Dossier requirements for EMA, (Co-)Rapporteurs and members/alternates
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
ASMF submissions provided in eCTD format, mandatory for submissions related to CAPs[1]	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 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.

ASMF; Application / Submission type	Dossier requirements for EMA, (Co-)Rapporteurs and members/alternates
The use of eCTD format for centralised procedure human ASMF submissions is mandatory from 1 July 2016. The Statement of Intent can be found here.	**EMA**: 1 electronic submission in NeeS format via eSubmission Gateway or eSubmission Web Client. **CHMP/PRAC**: (Co)- Rapporteurs and other members National Competent Authorities: 1 electronic submission via Portal or on DVD/CD-ROM[2] It is strongly recommended to provide all submissions in eCTD format. ***Nationally Authorised Products (NAPs), submitted in any format, are not available via the Common Repository and must be sent separately to each NCA.***

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	**EMA:** 1 electronic submission in eCTD or NeeS format via eSubmission Gateway or eSubmission Web Client **CHMP/PRAC**: (Co)- Rapporteurs and other members National Competent Authorities: 1 electronic submission via Portal or on DVD/CD-ROM[2] It is strongly recommended to provide all submissions in eCTD format. ***Nationally Authorised Products (NAPs), submitted in any format, are not available via the Common Repository and must be sent separately to each NCA.***

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)	**EMA**: 1 electronic submission in electronic Ancillary Medicinal Substance submission format via eSubmission Gateway or eSubmission Web Client. **CHMP**: (Co)- Rapporteurs and other members National Competent Authorities: 1 electronic submission in electronic Ancillary Medicinal Substance submission format via Portal or on DVD/CD-ROM[2]

[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 "Dossier delivery address for each National Competent Authority for CHMP and PRAC members" to check which National Competent Authorities accept submissions via CESP portal

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

Dossier delivery address for each national competent authority for CHMP and PRAC members

Please note that the address below may be different from the address mentioned on the list of CHMP and PRAC Committee members. For submission purposes, only the address listed in the 'Dossier Delivery Address' column below should be used, and only one submission is needed. Please mention the names of the relevant CHMP and PRAC members on the submission package and/or cover letter.

For names of CHMP or PRAC members, please refer to the official list of members (click on links below):

List of CHMP members

List of PRAC members

National competent authority	Dossier delivery address	Submission via portal
AT representative or alternate	AGES PharmMed Traisengasse 5, A-1200 Vienna AUSTRIA	YES: submission via CESP accepted
BE representative or alternate	Federal Agency for Medicines and Health Products FAMHP Victor HORTA Place 40 BP 40 1060 Brussels BELGIUM	NO: please refer to the CESP portal for updated status https://cespportal.hma.eu/Public/Contacts
BG representative or alternate	Bulgarian Drug Agency 8, Damyan Gruev str. 1303 Sofia BULGARIA	NO: please refer to the CESP portal for updated status https://cespportal.hma.eu/Public/Contacts
HR representative or alternate	Croatian Agency for Medicinal Products and Medical Devices Ksaverska cesta 4 10 000 Zagreb CROATIA	YES: submission via CESP accepted
CY representative or alternate	Ministry of Health Pharmaceutical Services 1475 Lefkosia Nicosia CYPRUS	NO: please refer to the CESP portal for updated status https://cespportal.hma.eu/Public/Contacts

National competent authority	Dossier delivery address	Submission via portal
CZ representative or alternate	State Institute for Drug Control Šrobárova 48 100 41 Praha 10 CZECH REPUBLIC	YES: submission via CESP accepted
DK representative or alternate	Danish Health and Medicines Authority Axel Heides Gade 1 DK-2300 København S DENMARK	YES: submission via CESP accepted
EE representative or alternate	State Agency of Medicines Nooruse 1 50411 Tartu ESTONIA	YES: submission via CESP accepted
FI representative or alternate	Finnish Medicines Agency P.O.Box 55 FI-00034 FIMEA FINLAND	YES: submission via CESP accepted
FR representative or alternate	ANSM 143-147 Bd. Anatole France 93285 Saint Denis Cedex FRANCE	YES: submission via CESP accepted
DE representative or alternate	Bundesinstitut für Arzneimittel und Medizinprodukte Kurt-Georg-Kiesinger-Allee 3 53175 Bonn GERMANY	YES: submission via CESP accepted
GR representative or alternate	National Organization for Medicines 284 Messogeion Avenue Holargos 155 62 Athens GREECE	NO: please refer to the CESP portal for updated status https://cespportal.hma.eu/Public/Contacts
HU representative or alternate	National Institute of Pharmacy Zrinyi u. 3 1051Budapest HUNGARY	NO: please refer to the CESP portal for updated status https://cespportal.hma.eu/Public/Contacts
IS representative or alternate	Lyfjastofnun, Licensing Unit Vínlandsleið 14 IS-113 Reykjavík ICELAND	YES: submission via CESP accepted

National competent authority	Dossier delivery address	Submission via portal
IR representative or alternate	Receipts and Validation Health Products Regulatory Authority Earlsfort Centre Earlsfort Terrace Dublin 2 IRELAND	YES: submission via CESP accepted
IT representative or alternate	AIFA- Agenzia Italiana del Farmaco Via del Tritone, 181 00187 Roma ITALY	YES: submission via CESP accepted
LV representative or alternate	State Agency of Medicines 15 Jersikas iela Riga, LV-1003 LATVIA	YES: submission via CESP accepted
LT representative or alternate	State Medicines Control Agency Savanorių, Pr. 220 LT-50196 Kaunas LITHUANIA	YES: submission via CESP accepted
LU representative or alternate	Division de la Pharmacie et des Médicaments Villa Louvigny Allée Marconi 2120 Luxembourg LUXEMBOURG	YES: submission via CESP accepted
MT representative or alternate	Medicines Authority 203, Level 3, rue D'Argens GZR 1368 Gzira MALTA	YES: submission via CESP accepted
NL representative or alternate	College ter Beoordeling van Geneesmiddelen Graadt van Roggenweg 500 3531 AH Utrecht THE NETHERLANDS	YES: submission via CESP accepted
NO representative or alternate	Statens legemiddelverk Sven Oftedals vei 6 N-0950 Oslo NORWAY	YES: submission via CESP accepted

National competent authority	Dossier delivery address	Submission via portal
PL representative or alternate	Office for Medicinal Products, Medical Devices and Biocides 41 Zabkowska Str. 03-736 Warsaw POLAND	NO: please refer to the CESP portal for updated status https://cespportal.hma.eu/Public/Contacts
PT representative or alternate	INFARMED Autoridade Nacional do Medicamento e Produtos de Saúde I.P., Parque de Saúde de Lisboa Avenida do Brasil, 53 1749-004 Lisboa PORTUGAL	YES: submission via CESP accepted
RO representative or alternate	National Medicines Agency Str. Aviator Sănătescu 48 Sector 1 71324 Bucharest ROMANIA	YES: submission via CESP accepted
SK representative or alternate	State Institute of Drug Control Kvetna 11 82508 Bratislava 26 SLOVAK REPUBLIC	YES: submission via CESP accepted
SI representative or alternate	Agency for Medicinal Products and Medical Devices Ptujska ulica 21 1000 Ljubljana SLOVENIA	YES: submission via CESP accepted
ES representative or alternate	Agencia Española del Medicamento y Productos Sanitarios Parque Empresarial Las Mercedes Edificio 8 C/Campezo 1 28022 Madrid SPAIN	YES: submission via CESP accepted
SE representative or alternate	Medical Products Agency Dag Hammarskjölds väg 42, P.O.Box 26 751 03 Uppsala SWEDEN	YES: submission via CESP accepted
UK representative or alternate	Medicines and Healthcare products Regulatory Agency 151 Buckingham Palace Road, Victoria London, SW1W 9SZ UNITED KINGDOM	YES: submission via CESP accepted

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
CHMP Co-Opted Members:		
Jan Mueller-Berghaus	N/A	YES: submission via CESP to the respective NCA (DE-PEI) accepted
Jean-Louis Robert	N/A	YES: submission via CESP to the respective NCA (LU) accepted
Sol Ruiz	N/A	YES: submission via CESP to the respective NCA (ES) accepted
Robert James Hemmings	N/A	YES: submission via CESP to the respective NCA (UK) accepted
Koenraad Norga	Universitair Ziekenhuis Antwerpen Wilrijkstraat 10 2650 Edegem BELGIUM	NO: please refer to the CESP portal for updated status https://cespportal.hma.eu/Public/Contacts
PRAC Independent Scientific experts:		
Brigitte Keller-Stanislawski	N/A	YES: submission via CESP to the respective NCA (DE-PEI) accepted

Name	Dossier delivery address	Submission via portal
Thierry Trenque	CHU Reims Avenue du General Koenig 51092 Reims FRANCE	NO: submission on CD-ROM or DVD is required
Marie Louise (Marieke) De Bruin	N/A	YES: submission via CESP to the respective NCA (NL)accepted
Herve Le Louet	N/A	YES: submission via CESP to the respective NCA (FR) accepted
Stephen J. W. Evans	N/A	YES: submission via CESP to the respective NCA (UK) accepted
Lennart Waldenlind	N/A	YES: submission via CESP to the respective NCA (SE) accepted
PRAC Representatives of Patient Organisation		
Member: Marco Greco	N/A	YES: submission via CESP to the respective NCA (IT) accepted