EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 November 2016
EMA/466102/2007-Rev.28
Veterinary Medicines Division

Dossier requirements for submission of marketing authorisation and maximum residue limit (MRL) applications to the European Medicines Agency (EMA) and to members of the Committee for Medicinal Products for Veterinary use (CVMP)

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EMA, (Co-)Rapporteurs and CVMP Members/Alternates</th></tr>
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Electronic submission via the EMA e-Submission Gateway or Web Client is currently strongly encouraged (no hard-copy cover letter required) and will become mandatory as of 1 January 2017.
Until 31 Dec 2016 submission can be made alternatively via CD/DVD or Eudralink (Eudralink possible for post-authorisation procedures only). In case of submission via CD/DVD, a separate hard-copy cover letter should be provided.
Dossiers submitted electronically should follow the current version of the Guideline on the specifications for provision of an electronic submission (e-submission) for a veterinary medicinal product, published on the Vet e-Submission website: http://esubmission.ema.europa.eu/tiges/vetesub.htm

<u>CVMP:</u>
<u>(Co)-Rapporteur</u>: 1 dossier at the time of submission, updated dossier after validation (if changes have been made)

<u>Other members and alternates</u>: 1 dossier after validation (at start of procedure)</td></tr>
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Application / Submission Type	Dossier Requirements for: EMA, (Co-)Rapporteurs and CVMP Members/Alternates
Type IA	**EMA:** Electronic submission via the EMA e-Submission Gateway or Web Client is currently strongly encouraged (no hard-copy cover letter required) and will become mandatory as of 1 January 2017. Until 31 Dec 2016 submission can be made alternatively via CD/DVD or Eudralink (Eudralink possible for post-authorisation procedures only). In case of submission via CD/DVD, a separate hard-copy cover letter should be provided. Dossiers submitted electronically should follow the current version of the Guideline on the specifications for provision of an electronic submission (e-submission) for a veterinary medicinal product, published on the Vet e-Submission website: http://esubmission.ema.europa.eu/tiges/vetesub.htm **CVMP:** (Co)-Rapporteur: **1 dossier** at the time of submission for information Other members and alternates: no submission required
Transfers	
Active Substance Master Files (ASMFs) new submissions and updates	**EMA:** Electronic submission via the EMA e-Submission Gateway or Web Client is currently strongly encouraged (no hard-copy cover letter required) and will become mandatory as of 1 January 2017. Until 31 Dec 2016 submission can be made alternatively via CD/DVD or Eudralink (Eudralink possible for post-authorisation procedures only). In case of submission via CD/DVD, a separate hard-copy cover letter should be provided. Dossiers submitted electronically should follow the current version of the Guideline on the specifications for provision of an electronic submission (e-submission) for a veterinary medicinal product, published on the Vet e-Submission website: http://esubmission.ema.europa.eu/tiges/vetesub.htm **CVMP:** (Co)-Rapporteur: **1 dossier** at the time of submission, updated dossier after validation (if changes have been made) Other members and alternates: **1 dossier** after validation (at start of procedure)

The above requirements apply also to the submission of responses to list of questions (LoQ) and list of outstanding issues (LoOI).

Except when indicated in the column “Submission via Portal” below, any submission should be addressed to the name and details of the respective CVMP members and alternates whose details are available on the EMA website: List of CVMP members

For submission to CVMP, applicants are encouraged to submit applications via CESP as a first option. Where CESP is not accepted as a submission channel, Eudralink should be used or CD/DVD. Use of multiple submission channels to the same authority (eg. CESP **and** Eudralink or CESP **and** CD/DVD) are not allowed.

National Competent Authority	Submission via Portal
Austria (AT) representative or alternate	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts Eudralink cannot be used for Austria. Submission via CD/DVD should be accompanied with signed hard-copy cover letter.
Belgium (BE) representative or alternate	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts Alternatively, if sent via Eudralink, the address should be: Pre.authorisation.v@fagg-afmps.be for new applications Post.authorisation.v@fagg-afmps.be for renewals, variations
Bulgaria (BG) representative or alternate	NO (please refer to the CESP portal for updated status) https://cespportal.hma.eu/Public/Contacts
Croatia (HR) representative or alternate	NO (please refer to the CESP portal for updated status) https://cespportal.hma.eu/Public/Contacts
Cyprus (CY) representative or alternate	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts
Czech Republic (CZ) representative or alternate	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts
Denmark (DK) representative or alternate	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts
Estonia (EE) representative or alternate	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts
Finland (FI) representative or alternate	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts Alternatively e-submission should be used: applications to be sent on 2 identical CD/DVD media along with signed cover letter and application form on paper (read more at www.fimea.fi). Eudralink cannot be used for Finland.

National Competent Authority	Submission via Portal
France (FR) representative or alternate	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts Alternatively, if sent via Eudralink: **Immunologicals** applications: E-submission to be addressed to esubimmuno@anses.fr **Pharmaceuticals** and MRL applications: E-submissions to be addressed to esubpharma@anses.fr
Germany (DE) representative or alternate	*Paul-Ehrlich-Institut (PEI)* YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts Alternatively, submission can be via CD/DVD or Eudralink (Eudralink possible for post-authorisation procedures only) *Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)* NO (please refer to the CESP portal for updated status) https://cespportal.hma.eu/Public/Contacts
Greece (GR) representative or alternate	NO (please refer to the CESP portal for updated status) https://cespportal.hma.eu/Public/Contacts
Hungary (HU) representative or alternate	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts
Iceland (IS) representative or alternate	YES: submission via CESP is very much preferred https://cespportal.hma.eu/Public/Contacts Alternatively CD/DVD submission is accepted. Please note that Eudralink/email submission is not accepted.
Ireland (IE) representative, alternate or co-opted member	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts Submissions to the co-opted member Dr Rory Breathnach should be made directly to the Health Products Regulatory Authority (HPRA).
Italy (IT) representative or alternate	NO (please refer to the CESP portal for updated status) https://cespportal.hma.eu/Public/Contacts
Latvia (LV) representative or alternate	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts
Lithuania (LT) representative or alternate	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts

National Competent Authority	Submission via Portal
Luxemburg (LU) representative or alternate	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts
Malta (MT) representative or alternate	NO (please refer to the CESP portal for updated status) https://cespportal.hma.eu/Public/Contacts
Netherlands (NL) representative, alternate or co-opted member	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts **Pharmaceuticals response dossiers** sent via Eudralink to be addressed to case@cbg-meb.nl, mentioning the word 'case' followed by the procedure number in the email heading.[1] Submissions to the co-opted member Dr Gerrit Johan Schefferlie should be made directly to the Medicines Evaluation Board - Veterinary Medicinal Products Unit (CBG-MEB).
Norway (NO) representative or alternate	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts Alternatively, if sent via Eudralink: CVMP member: to post@legemiddelverket.no CVMP alternate: to Vet.Felles@legemiddelverket.no
Poland (PL) representative or alternate	NO (please refer to the CESP portal for updated status) https://cespportal.hma.eu/Public/Contacts
Portugal (PT) representative or alternate	NO (please refer to the CESP portal for updated status) https://cespportal.hma.eu/Public/Contacts
Romania (RO) representative or alternate	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts
Slovakia (SK) representative or alternate	NO (please refer to the CESP portal for updated status) https://cespportal.hma.eu/Public/Contacts
Slovenia (SI) representative or alternate	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts
Spain (ES) representative or alternate	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts

[1] The procedure number should be quoted for centralised procedure. Information on responses by e-submissions is available on their website: http://www.cbg-meb.nl/CBG/en/human-medicines/regulatory-affairs/e-submission/how-should-response-documents-be-submitted/default.htm

National Competent Authority	Submission via Portal
Sweden (SE) representative or alternate	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts Alternatively if sent via Eudralink, use the address ric@mpa.se For CD-Roms and dossiers, the address is: Medical Products Agency, Registration Office, P.O. Box 26, SE-75103 Uppsala, Sweden.
United Kingdom (UK) representative, alternate or co-opted member	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts Alternatively, if sent via Eudralink, to: s.response@vmd.defra.gsi.gov.uk Paper submissions to be sent to: Information Services Veterinary Medicines Directorate Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS, United Kingdom Submissions to the co-opted member Dr Jason Weeks should be made directly to the Veterinary Medicines Directorate (VMD).
Co-opted members:	Submissions should be directed to the contact details stated in the List of CVMP members available on the EMA website, unless specified otherwise for the respective Member State above.