EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 February 2016
EMA/466102/2007-Rev.27
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)

| Application / Submission Type | Dossier Requirements for: EMA, (Co-)Rapporteurs and CVMP Members/Alternates |
|---|---|
| Full application | **EMA:**<br>Electronic submission via the EMA e-Submission Gateway or Web Client is encouraged (no hard-copy cover letter required).<br>Alternatively, submission can be 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.<br>Dossiers submitted electronically should follow the latest 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<br><br>**CVMP:**<br>(Co)-Rapporteur: **1 dossier** at the time of submission, updated dossier after validation (if changes have been made)<br><br>Other members and alternates: **1 dossier** after validation (at start of procedure) |
| Extension | |
| Type IB variation | |
| Type II variation | |
| Renewal | |
| MRL application | |
| Periodic Safety Update Report (PSUR) | |
| Post-Authorisation Measures (PAMs) | |
| Annual Re-Assessment | |
| Referrals | |

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| Application / Submission Type | Dossier Requirements for: EMA, (Co-)Rapporteurs and CVMP Members/Alternates |
|---|---|
| Type IA | **EMA:**<br>Electronic submission via the EMA e-Submission Gateway or Web Client is encouraged. Alternatively, submission can be via CD/DVD or Eudralink (**Eudralink possible for post-authorisation procedures only**).<br>Dossiers submitted electronically should follow the latest 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<br><br>**CVMP:**<br>(Co)-Rapporteur: **1 dossier** at the time of submission for information<br><br>Other members and alternates: no submission required |
| Transfers | |

**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 last column "Submission via Portal", 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

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. Multiple submissions (CESP **and** Eudralink or CESP **and** CD/DVD) are not allowed.

| National Competent Authority | Submission via Portal |
|---|---|
| AT representative or alternate | YES: submission via CESP accepted<br><br>http://cesp1.hma.eu/Contacts<br><br>Eudralink cannot be used for Austria. Submission via CD/DVD should be accompanied with signed hard-copy cover letter. |
| BE representative or alternate | YES: submission via CESP accepted<br><br>http://cesp1.hma.eu/Contacts<br><br>Alternatively, if sent via Eudralink, the address should be be-v.cvmp@be-v.eudra.org |
| BG representative or alternate | NO (please refer to the CESP portal for updated status)<br><br>http://cesp1.hma.eu/Contacts |
| HR representative or alternate | NO (please refer to the CESP portal for updated status)<br><br>http://cesp1.hma.eu/Contacts |

| National Competent Authority | Submission via Portal |
|---|---|
| CY representative or alternate | NO (please refer to the CESP portal for updated status)<br><br>http://cesp1.hma.eu/Contacts |
| CZ representative or alternate | YES: submission via CESP accepted<br><br>http://cesp1.hma.eu/Contacts |
| DK representative or alternate | YES: submission via CESP accepted<br><br>http://cesp1.hma.eu/Contacts |
| EE representative or alternate | YES: submission via CESP accepted<br><br>http://cesp1.hma.eu/Contacts |
| FI representative or alternate | YES: submission via CESP accepted<br><br>http://cesp1.hma.eu/Contacts<br><br>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).<br><br>Eudralink cannot be used for Finland. |
| FR representative or alternate | YES: submission via CESP accepted<br><br>http://cesp1.hma.eu/Contacts<br><br>Alternatively, if sent via Eudralink:<br>**Immunologicals** applications: E-submission to be addressed to esubimmuno@anses.fr<br>**Pharmaceuticals** and MRL applications: E-submissions to be addressed to esubchimie@anses.fr |
| DE representative or alternate | YES: submission via CESP accepted<br><br>http://cesp1.hma.eu/Contacts<br><br>Alternatively, submission can be via CD/DVD or Eudralink (Eudralink possible for post-authorisation procedures only) |
| GR representative or alternate | NO (please refer to the CESP portal for updated status)<br><br>http://cesp1.hma.eu/Contacts |
| HU representative or alternate | YES: submission via CESP accepted<br><br>http://cesp1.hma.eu/Contacts |
| IS representative or alternate | YES: submission via CESP accepted<br><br>http://cesp1.hma.eu/Contacts<br><br>Eudralink cannot be used for Iceland. |

| National Competent Authority | Submission via Portal |
|---|---|
| IR representative or alternate | YES: submission via CESP accepted<br>http://cesp1.hma.eu/Contacts |
| IT representative or alternate | NO (please refer to the CESP portal for updated status)<br>http://cesp1.hma.eu/Contacts |
| LV representative or alternate | NO (please refer to the CESP portal for updated status)<br>http://cesp1.hma.eu/Contacts |
| LI representative or alternate | NO (please refer to the CESP portal for updated status)<br>http://cesp1.hma.eu/Contacts |
| LT representative or alternate | NO (please refer to the CESP portal for updated status)<br>http://cesp1.hma.eu/Contacts |
| LU representative or alternate | YES: submission via CESP accepted<br>http://cesp1.hma.eu/Contacts |
| MT representative or alternate | NO (please refer to the CESP portal for updated status)<br>http://cesp1.hma.eu/Contacts |
| NL representative or alternate | YES: submission via CESP accepted<br>http://cesp1.hma.eu/Contacts<br>**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] |
| NO representative or alternate | YES: submission via CESP accepted<br>http://cesp1.hma.eu/Contacts<br>Alternatively, if sent via Eudralink:<br>CVMP member: to post@legemiddelverket.no<br>CVMP alternate: to Vet.Felles@legemiddelverket.no |
| PL representative or alternate | NO (please refer to the CESP portal for updated status)<br>http://cesp1.hma.eu/Contacts |
| PT representative or alternate | NO (please refer to the CESP portal for updated status)<br>http://cesp1.hma.eu/Contacts |
| RO representative or alternate | NO (please refer to the CESP portal for updated status)<br>http://cesp1.hma.eu/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 |
|---|---|
| SK representative or alternate | NO (please refer to the CESP portal for updated status)<br><br>http://cesp1.hma.eu/Contacts |
| SI representative or alternate | YES: submission via CESP accepted<br><br>http://cesp1.hma.eu/Contacts |
| ES representative or alternate | YES: submission via CESP accepted<br><br>http://cesp1.hma.eu/Contacts |
| SE representative or alternate | YES: submission via CESP accepted<br><br>http://cesp1.hma.eu/Contacts<br><br>Alternatively if sent via Eudralink, use the address ric@mpa.se<br><br>For CD-Roms and dossiers, the address is:<br>Medical Products Agency,<br>Registration Office,<br>P.O. Box 26,<br>SE-75103 Uppsala, Sweden. |
| UK representative or alternate | YES: submission via CESP accepted<br><br>http://cesp1.hma.eu/Contacts<br><br>Alternatively, if sent via Eudralink,<br>to: s.response@vmd.defra.gsi.gov.uk<br><br>Paper submissions to be sent to:<br>Information Services<br>Veterinary Medicines Directorate<br>Woodham Lane, New Haw, Addlestone,<br>Surrey KT15 3LS, United Kingdom |