Veterinary medicinal products
Presentation and format of the dossier for re-registration

1.0 Cover Letter

Confirm with the cover letter that all post-registration changes/variations are approved by the Ministry of Health of the Republic of Armenia[1]. Inform with the cover letter about all strengths, pharmaceutical forms, presentation forms, other manufacturing sites of medicinal product for which current re-registration dossier is applicable.

1.1 Table of content
1.2 Application Form
1.3 Worldwide registration status (if available): Copies of Marketing Authorisations or tabular listing of authorizations by specifying marketing authorization number, date of authorization, country, trade name and etc.
1.4 Chronological list of all post-registration/variation submissions since registration: a list of all approved or pending variations, PSURs, giving the procedure number (where applicable), date of submission, date of approval (if approved) and brief description of the change.
1.5 GMP certificates or other proof of GMP compliance or EudraGMP documents or inspection reports for all manufacturing sites involved in the manufacturing process of the medicinal product and the active substance issued by the competent authority of country of origin (duly certified copy[2]).
1.6 Marketing Authorisation (Registration certificate) or Certificate of Pharmaceutical Product (CPP – WHO format) issued by the competent authority of the country of Applicant (Marketing authorization holder) (original or duly certified copy).
1.7 Periodic Safety Update Report or Summary Bridging Report, if applicable *(electronic version in PDF format, searchable)*
1.8 Declaration of current TSE status (e.g. EDQM certificate of suitability, if appropriate)

[1] Note: The re-registration assessment will be suspended if not approved variations are detected, and the assessment will be continued after their approval.

[2] Duly certified copy - a notarized copy of the document and, in the case of the Member States of the Hague Convention, also approved by the Apostille.