Presentation and format of the dossier for re-registration

Module 1: Administrative information

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.

1.2 Application Form
1.8 Information relating to Pharmacovigilance (electronic version in PDF format)
1.8.1 Pharmacovigilance System
1.8.2 Risk Management Plan (RMP)[2]
1.9 Information relating to Clinical Trials (if applicable)

Additional Data

1.12 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[3]).
1.13 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).
1.14 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.
1.21. Periodic Safety Update Report (electronic version in PDF format)
1.22. 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.

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[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 The updated RMP and where relevant, the new RMP. Where there are no new data justifying changes to the latest approved RMP, the MAH should provide declaration and confirm that the current approved RMP remain unchanged and applicable. Where there is no RMP for the medicinal product, this should be stated in the cover letter.

[3] 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.

1.23. History of pharmacovigilance system inspections (date, inspecting authority, site inspected, type of inspection and if the inspection is product specific, the list of products concerned) and an analysis of the impact of the findings overall on the benefit/risk balance of the medicinal product (if available).