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Procedure Management & Business Support

Important changes to the Controlled Vocabulary lists: eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) Pharmaceutical Dose Forms and Routes of Administration

Please note that in the context of the improvement of the XEVMPD Controlled Vocabulary data quality, Proposed Pharmaceutical Dose Forms (PDFs) / Routes of Administration (RsoA) have been re-mapped to Standard PDFs/ RsoA in the XEVMPD production system.

Please refer to the published Controlled Vocabulary lists to determine how individual proposed terms have been re-mapped.

Medicinal products affected by the re-mapping have been automatically updated with the Standard PDFs and/or RsoA as applicable.

- Pharmaceutical Dose Forms (PDFs)

The list of Proposed PDFs re-mapped to Standard PDFs can be found in the published Controlled Vocabulary list "Extended EudraVigilance product report message (XEVMPD) pharmaceutical dose forms", spread sheet "**Re-mapped_PDFs**", available at the [Agency's website](#).

- Routes of Administration (RsoA)

The list of Proposed RsoA re-mapped to Standard RsoA can be found in the published Controlled Vocabulary list "Extended EudraVigilance product report message (XEVMPD) routes of administration", spread sheet "**Re-mapped_RoA**", available at the [Agency's website](#).

IMPORTANT NOTES

Please note that the proposed PDFs and RsoA, which were re-mapped to a Standard PDF/RsoA have been nullified in the XEVMPD production environment and cannot be used for medicinal products submission.

- Should you need to use the nullified proposed PDF or RsoA in your product submission, please check which standard term it was re-mapped to, and use this standard term in your product submission instead.
- Marketing Authorisation Holders, whose medicinal product entries were affected by the re-mapping will be contacted by the Agency.

Should you require further information or clarification please contact the Article 57 helpdesk (art57@ema.europa.eu).