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EMA Update: Publication of RMPs and their Summaries

The EMA has lately announced an update regarding publication of RMPs and their Summaries for increasing transparency of the safety review process for all centrally authorized products.

Per this update, from 20th October 2023, EMA will be publishing the Risk Management Plan (Main Body, Annex 4 [Specific Adverse Drug Reaction Forms] and Annex 6 [Details of Proposed Additional Risk Minimization Activities]) for all centrally authorized products during initial evaluations as well as for RMP updates. Furthermore, from the same day (20th October 2023), RMP summaries will not be published. A list of all historical summaries would, however, be available for reference on EMA website.

With this shift, protection of personal and commercial confidential data becomes of foremost importance. Therefore, EMA will now require the MAH to provide a duly signed declaration confirming that the RMP (Main Body + Annex 4 + Annex 6) sent to EMA for publication via Eudralink does not contain any personal protected data nor commercial confidential information. The template for this declaration has been recently updated by EMA can be found **here:** template-declaration-risk-management-plan-rmp-publication_en.docx (live.com).

The guidance published by EMA on anonymization of personal data and assessment of commercially identical information during the preparation of RMPs (Main Body and Annexes 4 and 6) can be found on Process RMP - Guidance - preparation for publication - Covid products (europa.eu)