EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

RMP publication and Specific adverse reaction Follow-up questionnaires guideline

Industry Stakeholder Platform – Operation of EU Pharmacovigilance

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RMP publication

An update on process and current status

All RMPs from all procedures are currently published (EPARs)

- ✓ All RMPs in all procedures with outcome on or after 20 October 2023 (iMAA Opinions, variations CHMP Opinions, IB notifications, PRAC recommendations, etc.)
- ✓ Redacted RMP is published; MAH send to EMA for review redacted RMP + RMP showing redactions + declaration
- ✓ EMA guidance updated: https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/pharmacovigilance/risk-management/risk-management-plans , including pre- and post-authorisation procedural Q&As
- ✓ All EMA templates updated (on EMA website and internal repository)

Preliminary checks and monitoring show: very good response times, complete documents, almost prefect compliance for PD redaction, good compliance on CCI redaction (e.g. over-redaction of exposure data on regions), still some "confidential" labels in the documents.

Next steps: continue monitoring, re-evaluate early next year MAH and EMA if the process could be improved (i.e. simpler steps, fewer requirements for MAHs).

RMP publication will stay in place for all RMPs, all products, all procedures.

Specific adverse reaction Follow-up questionnaires (Specific AR FUQ) guideline

An update on status and the public consultation phase

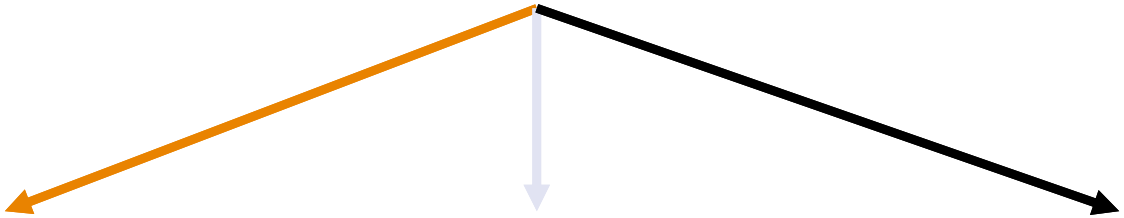
Specific AR FUQ guideline

This paper provides guidance on the use of Specific AR FUQs and focuses on Specific AR FUQs developed by the MAHs at the request of NCAs and does not intend to modify the MAHs internal policies for FUQs.

It emphasizes the importance of obtaining structured and detailed information on reported adverse reactions that may impact the benefit-risk balance of a product or have implications for public health.

Specific AR FUQ guideline

The document identifies **three** main directions:



- Providing general guidance on when and how to use Specific AR FUQs
- Guidance for MAHs on developing Specific AR FUQs
- When to consider discontinuation and removal of Specific AR FUQs

Table of content of the Specific AR FUQ guideline

Guideline will be out for **public consultation** from

06 December 2023

for **nine (9)** weeks

Thank you for your attention

Further information

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