Q&A

What is the meaning of the terms "unresolved" and "outstanding" in Article 8(3), Article 22(2)(e)(vi) and Article 22(3)(d)(ii) of the Commission Implementing Regulation (EU) 2021/1281 (EUR-Lex - 32021R1281 - EN - EUR-Lex [europa.eu])?

An error in some national language versions of Articles 8(3), 22(3)(d)(ii) and 22(2)(e)(vi) of Commission Implementing Regulation (EU) 2021/1281 (EUR-Lex - 32021R1281 - EN - EUR-Lex [europa.eu]) has been identified, where the two different terms in the English version, "unresolved" and "outstanding" with reference to critical and/or major findings, are translated with either the same term/or having the same meaning in the national language versions. Until a translation-corrigendum of the language versions concerned is published and to ensure a consistent and harmonised implementation across all EU Member States of the aforementioned provisions of Commission Implementing Regulation (EU) 2021/1281, all relevant stakeholders are invited to consider the following.

Article 22(2)(e)(vi) of Commission Implementing Regulation (EU) 2021/1281 requires that "*The main part of the pharmacovigilance system master file shall contain the following Sections: (…) Section E containing a description of the quality management system for pharmacovigilance activities, including all of the following: (…) (vi) a list of audits associated with unresolved critical or major findings*".

The abovementioned reference to 'unresolved critical or major findings' should be interpreted as referring to audits during which critical or major findings were detected and for which the due date to implement the corrective and preventive action plan (CAPA) has already passed.

Pursuant to Article 22(3)(d)(ii) of Commission Implementing Regulation (EU) 2021/1281, Annex IV to the pharmacovigilance system master file shall contain "*a list of all scheduled and completed audits including outstanding critical and major findings*" (similar wording is included under Article 8(3) of Commission Implementing Regulation (EU) 2021/1281).

The abovementioned reference to 'outstanding critical and major findings' should be interpreted as referring to audits during which critical and major findings were detected and for which the due date to address the corrective and preventive action plan (CAPA) has not passed yet.

Considering the above, it can be concluded that:

- Section E of the main part of the pharmacovigilance system master file shall list those audits with critical and major findings where the due date to implement the CAPA for the critical or major findings has already passed.

- Annex IV, point (ii) of the pharmacovigilance system master file shall include:

- A list of all scheduled and completed audits, including critical and major findings where the due date to implement the CAPA for the critical and major findings has not passed yet (outstanding critical and major findings).

Corrective and preventive action plans shall include findings from audits and inspections, in accordance with Article 9 of Commission Implementing Regulation (EU) 2021/1281.

The timeframe to implement the CAPA for critical and major findings should be clearly stated, and long-term or extended timelines should be duly justified.