5 January 2023
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Pharmacovigilance Risk Assessment Committee (PRAC)

PRAC recommendations on signals

Adopted at the 28 November-1 December 2022 PRAC meeting

This document provides an overview of the recommendations adopted by the Pharmacovigilance Risk Assessment Committee (PRAC) on the signals discussed during the meeting of 28 November-1 December 2022 (including the signal European Pharmacovigilance Issues Tracking Tool [EPITT][1] reference numbers).

PRAC recommendations to provide supplementary information are directly actionable by the concerned marketing authorisation holders (MAHs). PRAC recommendations for regulatory action (e.g. amendment of the product information) are submitted to the Committee for Medicinal Products for Human Use (CHMP) for endorsement when the signal concerns Centrally Authorised Products (CAPs), and to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) for information in the case of Nationally Authorised Products (NAPs). Thereafter, MAHs are expected to take action according to the PRAC recommendations.

When appropriate, the PRAC may also recommend the conduct of additional analyses by the Agency or Member States.

MAHs are reminded that in line with Article 16(3) of Regulation No (EU) 726/2004 and Article 23(3) of Directive 2001/83/EC, they shall ensure that their product information is kept up to date with the current scientific knowledge including the conclusions of the assessment and recommendations published on the European Medicines Agency (EMA) website (currently acting as the EU medicines webportal).

For CAPs, at the time of publication, PRAC recommendations for update of product information have been agreed by the CHMP at their plenary meeting (12-15 December 2022) and corresponding variations will be assessed by the CHMP.

For nationally authorised medicinal products, it is the responsibility of the National Competent Authorities (NCAs) of the Member States to oversee that PRAC recommendations on signals are adhered to.

Variations for CAPs are handled according to established EMA procedures. MAHs are referred to the available guidance. Variations for NAPs (including via mutual recognition and decentralised procedures) are handled at national level in accordance with the provisions of the Member States.

[1] The relevant EPITT reference number should be used in any communication related to a signal.

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The timeline recommended by PRAC for submission of variations following signal assessment is applicable to both innovator and generic medicinal products, unless otherwise specified.

For procedural aspects related to the handling of PRAC recommendations on signals (e.g. submission requirements, contact points, etc.) please refer to the Questions and Answers on signal management.

1. Recommendations for update of the product information

Not applicable.

2. Recommendations for submission of supplementary information

INN	Signal (EPITT No)	PRAC Rapporteur	Action for MAH	MAH
COVID-19 vaccine (ChAdOx1-S [recombinant]) - Vaxzevria	Pemphigus and pemphigoid (19858)	Jean-Michel Dogné (BE)	Supplementary information requested (submission by 9 February 2023)	AstraZeneca AB
Elasomeran (COVID-19 mRNA vaccine) - Spikevax	Pemphigus and pemphigoid (19860)	Marie Louise Schougaard Christiansen (DK)	Supplementary information requested (submission by 9 February 2023)	Moderna Biotech Spain, S.L.
Evolocumab	Weight increase and abnormal weight gain (19867)	Kimmo Jaakkola (FI)	Supplementary information requested (submission by 9 February 2023)	Amgen Europe B.V.
Tozinameran (COVID-19 mRNA vaccine) - Comirnaty	Pemphigus and pemphigoid (19859)	Menno van der Elst (NL)	Supplementary information requested (submission by 9 February 2023)	BioNTech Manufacturing GmbH

3. Other recommendations

INN	Signal (EPITT No)	PRAC Rapporteur	Action for MAH	MAH
Cetuximab	Nephrotic syndrome (19819)	Ulla Wändel Liminga (SE)	Routine pharmacovigilance	Merck Europe B.V.
Diphtheria, tetanus, pertussis (acellular, component), poliomyelitis (inactivated) vaccine (adsorbed); diphtheria, tetanus, pertussis (acellular, component), poliomyelitis (inactivated) vaccine (adsorbed, reduced antigen(s) content)	Immune thrombocytopenia (19831)	Anette Kirstine Stark (DK)	Routine pharmacovigilance	GlaxoSmithKline, Sanofi, AJ Vaccines A/S