23 November 2026[1]
EMA/PRAC/237906/2026
Pharmacovigilance Risk Assessment Committee (PRAC)

PRAC recommendations on signals

Adopted at the 26-29 October 2026 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 26-29 October 2026 (including the signal European Pharmacovigilance Issues Tracking Tool [EPITT][2] 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 (9-12 November 2026) 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] Expected publication date. The actual publication date can be checked on the webpage dedicated to PRAC recommendations on safety signals.
[2] 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[3]

1.1. Cefpodoxime – Drug interaction between cefpodoxime and proton pump inhibitor resulting in a potentially reduced efficacy of cefpodoxime

Authorisation procedure	Non-centralised
EPITT No	20280
PRAC Rapporteur	Amelia Cupelli (IT)
Date of adoption	29 October 2026

Recommendation

Having considered the available evidence and the mechanistic plausibility of a potential interaction between cefpodoxime and proton pump inhibitors (PPIs), as well as the use of cefpodoxime for the treatment of bacterial infections, including those caused by resistant pathogens, and the widespread use of PPIs, the PRAC has agreed that it is important to raise awareness among prescribers of the potential for reduced cefpodoxime absorption and bioavailability in patients receiving concomitant treatment with PPIs.

The PRAC has agreed that the Marketing Authorisation Holders (MAHs) of cefpodoxime-containing medicinal products should submit a variation within 2 months from the publication of the PRAC recommendation, to amend the product information as described below, taking into account the already existing wording in nationally authorised products; the text should be adapted by MAHs to individual products (new text underlined).

Summary of product characteristics

4.5 – Interaction with other medicinal products and other forms of interaction

Paragraph to be included under the current text on antacids/H2 blockers

Proton pump inhibitors (PPIs) cause sustained suppression of gastric acid secretion and may therefore reduce the absorption and bioavailability of cefpodoxime. The magnitude and clinical relevance of this potential interaction have not been established.

Package leaflet

2 What you need to know before you use <product name>

Taking <product name> with other medicines

Tell your doctor or pharmacist if you are taking proton pump inhibitors (medicines used to reduce stomach acid), as these medicines may reduce the absorption of cefpodoxime.

[3] Translations in all official EU languages of the new product information adopted by PRAC are also available to MAHs on the EMA website.

2. Recommendations for submission of supplementary information

INN	Signal (EPITT No)	PRAC Rapporteur	Action for MAH	MAH
Human normal immunoglobulin	Batch-associated hypersensitivity reactions (20318)	Dirk Mentzer (DE)	Supplementary information requested (submission by 13 January 2027)	MAHs of all human normal immunoglobulin -containing-products (Instituto Grifols S.A.; CSL Behring GmbH; Takeda Manufacturing Austria AG; Baxalta Innovations GmbH; Octapharma S.A.; Prothya BioSolutions Netherlands B.V.; LFB Biomedicaments; Oxbridge Pharma Limited; Kedrion S.P.A.; Biotest Pharma GmbH; BB - NCIPD ltd.; Pharma Plasma s.r.o.)

3. Other recommendations

INN	Signal (EPITT No)	PRAC Rapporteur	Action for MAH	MAH
Lithium; dulaglutide; insulin degludec / liraglutide; insulin glargine / lixisenatide; insulin icodec / semaglutide; liraglutide; semaglutide; tirzepatide	Drug interaction between lithium and GLP-1 agonists leading to increased lithium levels (20275)	Dennis Lex (DE)	· No action yet on product information update proposed by PRAC	· MAHs of oral lithium-containing medicinal products
			· Provide comments on proposed product information wording (submission by 30 November 2026)	· Eli Lilly Nederland B.V., Novo Nordisk A/S, Sanofi Winthrop Industrie
			· Draft a joint Direct Healthcare Professional Communication (DHPC) and communication plan (submission by 30 November 2026)	· Eli Lilly Nederland B.V., Novo Nordisk A/S, Sanofi Winthrop Industrie, Teva, Laboratoires Delbert, Teofarma, Oba Pharma
Oseltamivir; intravenous zanamivir	New information on safety in patients critically ill with influenza (20299)	Terhi Lehtinen (FI)	Monitor in PSURs	Roche Registration GmbH, GlaxoSmithKline Trading Services Limited