9 February 2026[1]
EMA/PRAC/1387/2026
Pharmacovigilance Risk Assessment Committee (PRAC)

PRAC recommendations on signals

Adopted at the 12-15 January 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 12-15 January 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 (26-29 January 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. Cefazolin; cefazolin, lidocaine hydrochloride – Kounis syndrome

Authorisation procedure	Non-centralised
EPITT No	20204
PRAC Rapporteur	Sonja Radowan (AT)
Date of adoption	15 January 2026

Recommendation

Having considered the available evidence in EudraVigilance and the literature, including the cumulative review submitted by the Marketing Authorisation Holder (MAH) for the innovator product (ASTRO-PHARMA GMBH), the PRAC has agreed that the MAHs of products containing cefazolin 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 some nationally authorised products the text needs to be adapted by MAHs to individual products) (new text underlined):

Summary of product characteristics

4.4. Special warnings and precautions for use

Hypersensitivity

Cases of Kounis syndrome have been reported in patients treated with cefazolin. Kounis syndrome has been defined as cardiovascular symptoms secondary to an allergic or hypersensitive reaction associated with constriction of coronary arteries and potentially leading to myocardial infarction.

4.8 Undesirable effects

SOC Cardiac disorders with frequency "Not known"

Kounis syndrome

Package leaflet

2 - What you need to know before you take <product name>

Warnings and precautions

Signs of an allergic reaction to this medicine, including breathing problems and chest pain, have been reported with cefazolin. Stop immediately cefazolin and contact immediately your doctor or medical emergencies if you notice any of these signs.

4 - Possible side effects

Other possible side effects

Not known (frequency cannot be estimated from the available data)

Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

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

1.2. Erdafitinib – Growth accelerated

Authorisation procedure	Centralised
EPITT No	20194
PRAC Rapporteur	Bianca Mulder (NL)
Date of adoption	15 January 2026

Recommendation *[see also section 3]*

Having considered the available evidence in EudraVigilance and literature, including the cumulative review submitted by the Marketing Authorisation Holder (MAH), the PRAC has agreed that the MAH of Balversa, Janssen-Cilag International N.V., should submit a variation within 2 months from the publication of the PRAC recommendation, to amend the product information as described below (new text underlined, text to be deleted ~~strikethrough~~):

Summary of product characteristics

4.2 Posology and method of administration

Paediatric population

There is no relevant use of erdafitinib in the paediatric population for the treatment of urothelial carcinoma. The safety and efficacy of erdafitinib in paediatric patients (<18 years of age) have not been established. Currently available safety data are described in section 4.8.

4.8 Undesirable effects

(under 'Description of selected adverse reactions' and after the paragraph on 'Abnormal laboratory findings')

Paediatric population

Growth acceleration and epiphysiolysis of the femoral head have been reported in paediatric patients (<18 years of age) receiving erdafitinib in clinical trials outside of the authorised indication and off label in the post-marketing setting.

5.1 Pharmacodynamic properties

Paediatric population

The European Medicines Agency has waived the obligation to submit the results of studies with erdafitinib in all subsets of the paediatric population in urothelial carcinoma (see sections 4.2 and 4.8 for information on paediatric use).

Package leaflet

2 What you need to know before you take Balversa

Children and adolescents

This medicine is not for use in children and adolescents. This is because there is ~~no~~ limited experience with using Balversa in this age group. See section 4 for more information.

4 Possible side effects

Additional side effects in children and adolescents

Balversa may cause accelerated growth or irregular hip joint growth or damage in paediatric patients (<18 years of age). If you or your child experience pain in the hip or knee or have an unexplained limp, talk to your doctor.

1.3. Pegylated liposomal doxorubicin – Renal-limited thrombotic microangiopathy

Authorisation procedure	Centralised and non-centralised
EPITT No	20193
PRAC Rapporteur	Eva Jirsová (CZ)
Date of adoption	15 January 2026

Recommendation

Having considered the available evidence from case reports in EudraVigilance and the literature, including the cumulative review submitted by the Marketing Authorisation Holder/s (MAH/s), the PRAC has agreed that the MAH/s of pegylated liposomal doxorubicin should submit a variation within 2 months from the publication of the PRAC recommendation to amend the product information as described below (new text underlined):

Summary of product characteristics

4.8 Undesirable effects

SOC Renal and urinary disorders:

Renal-limited thrombotic microangiopathy: frequency – not known

Package leaflet

4 Possible side effects

Not known (frequency cannot be estimated from the available data)

- clogging of very small blood vessels in the kidneys (renal-limited thrombotic microangiopathy)

2. Recommendations for submission of supplementary information

INN	Signal (EPITT No)	PRAC Rapporteur	Action for MAH	MAH
Atropine (eyedrops indicated for slowing the progression of myopia in paediatric patients)	Strabismus (20244)	Martin Huber (DE)	Assess in the ongoing PSUR (submission of data by 12 March 2026 with the MAH's comments to the PSUR preliminary assessment report)	Santen Oy
Darolutamide	Angioedema (20237)	Jan Neuhauser (AT)	Supplementary information requested (submission by 8 April 2026)	Bayer AG
Oxacillin	Drug reaction with eosinophilia and systemic symptoms (DRESS) (20223)	Eva Jirsová (CZ)	Supplementary information requested (submission by 8 April 2026)	Laboratoires Delbert
Vortioxetine	Acute pancreatitis (20234)	Jo Robays (BE)	Supplementary information requested (submission by 8 April 2026)	H. Lundbeck A/S
X-ray contrast agents: iobitridol; iodixanol; iohexol; iomeprol; iopamidol; iopromide; ioversol; ioxitalamic acid	Fixed drug eruption (20229)	Pernille Harg (NO)	Supplementary information requested (submission by 8 April 2026)	Bracco Imaging, GE Healthcare, Bayer, Guerbet
Zolbetuximab	Protein-losing gastroenteropathy (20236)	Bianca Mulder (NL)	Supplementary information requested (submission by 8 April 2026)	Astellas Pharma Europe B.V.
Zuranolone	Suicidal ideation (20232)	Guðrún Stefánsdóttir (IS)	Assess in the next PSUR (submission by 14 April 2026)	Biogen Netherlands B.V.

3. Other recommendations

INN	Signal (EPITT No)	PRAC Rapporteur	Action for MAH	MAH
Erdafitinib	Growth accelerated (20194)	Bianca Mulder (NL)	· See section 1.2 · Assess musculoskeletal disorders in adult patients in the next PSUR (submission by 20 June 2026)	Janssen-Cilag International N.V.
Pemetrexed	Lupus erythematosus (20185)	Tiphaine Vaillant (FR)	Monitor in PSUR	MAHs of pemetrexed containing products with an obligation to submit PSURs