26 October 2026[1]
EMA/PRAC/206892/2026
Pharmacovigilance Risk Assessment Committee (PRAC)

PRAC recommendations on signals

Adopted at the 28 September-1 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 28 September-1 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 (12-15 October 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.

[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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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.

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. Binimetinib; encorafenib – Neutropenia, febrile neutropenia

Authorisation procedure	Centralised
EPITT No	20255
PRAC Rapporteur	Carla Torre (PT)
Date of adoption	1 October 2026

Recommendation

Having considered the available evidence in EudraVigilance, clinical studies, and the literature, as well as the discussion of a possible class effect, the PRAC has agreed that the Marketing Authorisation Holder (MAH) for MEKTOVI and BRAFTOVI (Pierre Fabre Medicament) 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):

ENCORAFENIB

Summary of product characteristics

4.8 – Undesirable effects

Table 5 - "Encorafenib 450 mg in combination with binimetinib" column

Under the SOC Blood and lymphatic system disorders with a frequency "Common":

Neutropenia

Package leaflet

4. Possible side effects

Side effects when Braftovi and binimetinib are taken together for treatment of melanoma or NSCLC

Common (may affect up to 1 in 10 people)

- some types of skin tumours such as skin papilloma

- decrease in the number of white blood cells, cells that fight infection (neutrophils)

BINIMETINIB

Summary of product characteristics

4.8 – Undesirable effects

Under the SOC Blood and lymphatic system disorders with a frequency "Common":

Neutropenia

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

Package leaflet

4. Possible side effects

Other side effects when Mektovi and encorafenib are taken together

Common (may affect up to 1 in 10 people)

- some types of skin tumours such as skin papilloma

- decrease in the number of white blood cells, cells that fight infection (neutrophils)

2. Recommendations for submission of supplementary information

INN	Signal (EPITT No)	PRAC Rapporteur	Action for MAH	MAH
Cisplatin	Acute pancreatitis (20319)	Marie Louise Schougaard Christiansen (DK)	Supplementary information requested (submission by 1 December 2026)	Ebewe Pharma
Elranatamab	Tumour lysis syndrome (20314)	Barbara Kovacic Bytyqi (HR)	Assess in the next PSUR (submission by 22 October 2026)	Pfizer Europe MA EEIG
Liraglutide; liraglutide / insulin degludec	Alopecia (20311)	Bianca Mulder (NL)	Assess in the next PSUR (submission by 31 March 2027)	Novo Nordisk A/S
Semaglutide; insulin icodec / semaglutide	Gastrointestinal volvulus (20260)	Karin Bolin (SE)	Reassess in the next PSUR (submission by 29 August 2027)	Novo Nordisk A/S
Semaglutide	Ischaemic colitis (20309)	Karin Bolin (SE)	Supplementary information requested (submission by 1 December 2026)	Novo Nordisk A/S
Tarlatamab	Tumour lysis syndrome (20313)	Jan Neuhauser (AT)	Supplementary information requested (submission by 1 December 2026)	Amgen Europe B.V.

3. Other recommendations

INN	Signal (EPITT No)	PRAC Rapporteur	Action for MAH	MAH
Dapagliflozin; dapagliflozin / metformin; dapagliflozin / saxagliptin; dapagliflozin / sitagliptin	Lichen sclerosus (20259)	Karin Bolin (SE)	Routine pharmacovigilance	AstraZeneca AB
Ixekizumab	Behçet's syndrome (20269)	Dirk Mentzer (DE)	Monitor in PSUR	Eli Lilly and Company (Ireland) Limited