7 April 2026[1]
EMA/PRAC/44423/2026
Pharmacovigilance Risk Assessment Committee (PRAC)

PRAC recommendations on signals

Adopted at the 9-12 March 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 9-12 March 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 (23-26 March 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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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. Chikungunya vaccine (live) – New aspect of the known risk of aseptic meningitis

Authorisation procedure	Centralised
EPITT No	20250
PRAC Rapporteur	Dirk Mentzer (DE)
Date of adoption	12 March 2026

Recommendation *[see also section 3]*

Having considered the available evidence in EudraVigilance including the answers to the List of Questions submitted by the Marketing Authorisation Holder (MAH), the PRAC has agreed that […] the MAH of Ixchiq (VALNEVA AUSTRIA GMBH) should submit a variation within 1 month from the publication of the PRAC recommendation to amend the product information as described below (new text underlined):

Summary of product characteristics

4.4 Special warnings and precautions for use

Serious adverse reactions have been reported with the use of IXCHIQ, particularly in individuals aged 65 years and older and in individuals with multiple underlying chronic and/or uncontrolled medical conditions, but also in young adults with no relevant comorbidities (see section 4.8). Severe reactogenicity or chikungunya-like adverse reactions may lead to deterioration of general condition including malaise and decreased appetite, exacerbation of pre-existing diseases, confusional state, aseptic meningitis, encephalopathy, or encephalitis, leading to falls, hospitalisation and death. Vaccinees should be instructed to promptly seek medical attention if they experience, after vaccination, symptoms suggestive of severe reactogenicity or severe chikungunya-like adverse reactions.

4.8 Undesirable effects

Adults ≥ 18 years of age

In the post-marketing setting, serious adverse reactions have been reported, particularly in males aged 65 years and older with underlying chronic medical conditions such as cardiovascular disease, diabetes mellitus or chronic kidney disease, but also in young adults with no relevant comorbidities. These adverse reactions included neurological events such as fatal encephalitis, aseptic meningitis, deterioration of general condition, and exacerbation of chronic medical conditions (see section 4.4).

Package leaflet

2 What you need to know before you receive IXCHIQ

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

Warnings and precautions

Your doctor will carefully weigh the benefits and risks before recommending the vaccine, taking into consideration the risk of infection with the chikungunya virus in the regions where you are living or going to stay. Serious reactions to the vaccine have been reported mostly in persons 65 years and older and in persons with chronic medical conditions, such as high blood pressure, diabetes or heart disease, but also in healthy young adults. Tell your doctor or nurse immediately if you experience worsening of your general health or existing diseases (see section 4).

1.2. Galantamine – Nightmares

Authorisation procedure	Non-centralised
EPITT No	20196
PRAC Rapporteur	Karin Bolin (SE)
Date of adoption	12 March 2026

Recommendation

Having considered the available evidence in EudraVigilance, literature, national reviews, including the cumulative review submitted by the innovator Marketing Authorisation Holder (MAH), JANSSEN-CILAG, the PRAC has agreed that the MAHs of galantamine 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

4.8 Undesirable effects

Under SOC Psychiatric disorders with frequency "Uncommon"

Nightmare

Package leaflet

4 Possible side effects

Under frequency "Uncommon"

Nightmares

2. Recommendations for submission of supplementary information

INN	Signal (EPITT No)	PRAC Rapporteur	Action for MAH	MAH
Levonorgestrel intrauterine device 13.5 mg	Increased risk of ectopic pregnancy (20251)	Dennis Lex (DE)	Supplementary information requested (submission by 6 May 2026)	Bayer

3. Other recommendations

INN	Signal (EPITT No)	PRAC Rapporteur	Action for MAH	MAH
Chikungunya vaccine (live)	New aspect of the known risk of aseptic meningitis (20250)	Dirk Mentzer (DE)	· See section 1.1 · Update the risk management plan (RMP)	Valneva Austria GmbH
Gemcitabine	Drug reaction with eosinophilia and systemic symptoms (DRESS) (20256)	Mari Thörn (SE)	Provide comments to the proposed updates to the product information (submission by 8 May 2026)	Cheplapharm Arzneimittel GmbH, Sun Pharmaceutical Industries Europe B.V.