13 June 2024
EMA/PRAC/264723/2024

PRAC List of questions to be addressed by the stakeholders

For metamizole-containing medicinal products

Procedure under Article 107i of Directive 2001/83/EC

Procedure number: EMEA/H/A-107i/1537

INN/active substance: metamizole

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1. Background

On 05 June 2024, the Finnish Competent Authority (Fimea) triggered an urgent referral procedure for all metamizole-containing products (monocomponent and fixed dose combinations) in accordance with article 107i of Directive 2001/83/EC.

The notification of Fimea triggering a procedure together with the scientific background is available on the webpage of the procedure.

In accordance with article 107j(1) of the Directive 2001/83/EC, all stakeholders (e.g. healthcare professionals, patients' organisations or the general public) are invited to submit data relevant to the procedure, addressing the below Pharmacovigilance and Risk Assessment Committee (PRAC) questions by 01 July 2024.

2. Questions to the Stakeholders

1. Please comment on the therapeutic role of metamizole and the medical need for it in the respective authorised indications.
2. Please provide your views on the risk of agranulocytosis with metamizole-containing medicinal product(s) and comment on the appropriate measures to minimise this risk.