



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

01 September 2022
EMAP/PRAC/709548/2022

PRAC List of questions to be addressed by the Stakeholders

For pholcodine-containing medicinal products

Article 107i of Directive 2001/83/EC

Procedure number: EMEA/H/A-107i/1521

INN/active substance: pholcodine

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Background

On 19 August 2022, the French Competent Authority (ANSM) notified the European Medicines Agency, in accordance with article 107i of Directive 2001/83/EC and triggered an urgent referral procedure for all pholcodine-containing products under the abovementioned Article.

The notification of the ANSM 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 26 September 2022.

Questions to the Stakeholders

Question 1

Please provide any relevant information you may have on the risk of neuromuscular-blocking agents (NMBA)-related anaphylaxis with pholcodine-containing medicinal product(s), including awareness of the risk and possible risk minimisation measures.

Question 2

Please provide your views on the benefits of pholcodine-containing medicinal products.