14 February 2019
EMA/PRAC/100386/2019

PRAC List of questions to be addressed by the Stakeholders

For fenspiride-containing medicinal products

Article 107i of Directive 2001/83/EC

Procedure number: EMEA/H/A-107i/1480

INN/active substance: fenspiride

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On 8 February 2019, the French Competent Authority (ANSM) notified the European Medicines Agency, in accordance with article 107i of Directive 2001/83/EC, that it had suspended the marketing authorisations of Pneumorel 0.2 %, syrup and 80 mg, coated tablets and triggered an urgent referral procedure for all fenspiride-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 11 March 2019:

Question 1. Please provide any relevant information you may have on the risk of QT prolongation and cardiac arrhythmia with fenspiride-containing medicinal products.

Question 2. Please provide your views on the benefits of fenspiride-containing medicinal products, including with regards to any specific patient population.