07 March 2013
EMA/PRAC/144072/2013

PRAC List of questions to be addressed by the Stakeholders

For flupirtine containing medicinal products

Article 107i of Directive 2001/83/EC

Procedure number: EMEA/H/A-107i/1363

INN/active substance: flupirtine

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On 28 February 2013, the German Competent Authority (BfarM) notified the European Medicines Agency, in accordance with article 107i of Directive 2001/83/EC, of its plan to revise the product information of flupirtine containing medicinal products to restrict the therapeutic indications, include warnings and precautions for use.

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) list of questions by 8 April 2013:

Question 1

Please provide information or analysis on data (i.e. non clinical data, clinical data, epidemiological studies and published literature) that you may be aware of and which could be relevant to evaluate the risk of hepatotoxicity (liver enzyme elevations, hepatitis, liver failure) with flupirtine containing medicinal products.

Question 2

Taking into account the efficacy and in view of the concerns regarding hepatotoxicity, please provide your views on the use of flupirtine containing medicinal products in the treatment of acute and chronic pain.

Question 3

Do you consider that you are sufficiently informed on the risk of hepatotoxicity related to the use of flupirtine containing medicinal products? Answer yes, no or more or less, providing an explanation as applicable.