10 January 2013
EMA/PRAC/5086/2013

PRAC List of questions to be addressed by the Stakeholders

For tetrazepam containing medicinal products

Article 107i of Directive 2001/83/EC

Procedure number: EMEA/H/A-107i/1352

INN/active substance: Tetrazepam

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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On 20 December 2012, the French Competent Authority (ANSM – Agence Nationale de Securité du Medicament et des produits de santé) notified the European Medicines Agency, in accordance with article 107i of Directive 2001/83/EC, of its intention to suspend the marketing authorisation of all tetrazepam containing medicinal products in its territory due to serious cutaneous effects. These medicines are indicated in the treatment of painful muscle spasm in rheumatological diseases.

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 04 February 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 cutaneous adverse reactions with tetrazepam containing medicinal products.

Question 2

Taking into account the efficacy and in view of the cutaneous concerns, please provide your views on the use of tetrazepam containing medicinal products in the treatment of painful muscle spasm in rheumatological diseases.