10 April 2014
EMA/PRAC/222825/2014

PRAC List of questions to be addressed by the Stakeholders

For methadone medicinal products for oral use containing povidone

Article 107i of Directive 2001/83/EC

Procedure number: EMEA/H/A-107i/1395

INN/active substances: methadone

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On 2 April 2014, the Norway Competent Authority (NOMA) notified the European Medicines Agency, in accordance with article 107i of Directive 2001/83/EC, of its consideration to suspend the marketing authorisations of Methadon Martindale Pharma 2mg/ml oral solution and triggered an article 107i referral procedure for all methadone products for oral use containing povidone.

The notification of the NOMA 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 2 May 2014:

Question 1

Please provide your views on the benefit-risk balance of methadone medicinal products for oral use containing povidone in the treatment of opioid-dependent patients.

Question 2

Please provide any relevant information you may have on the misuse by injection of methadone medicinal products for oral use containing povidone.

Question 3

Are you aware of alternative risk minimisation measures (instead of or in addition to povidone) that might result in a more favourable benefit/risk profile of methadone for oral administration?