8 February 2013
Patient Health Protection
EMA/PRAC/78185/2013

PRAC List of questions to be addressed by the Stakeholders

For cyproterone acetate / ethinylestradiol (2 mg/0.035 mg) containing medicinal products

Article 107i of Directive 2001/83/EC

Procedure number: EMEA/H/A-107i/1357

INN/active substance:
cyproterone acetate / ethinylestradiol (2 mg/0.035 mg)

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

On 5 February 2013, the French Competent Authority (ANSM – Agence Nationale de Sécurité du Médicament et des produits de santé) notified the European Medicines Agency, in accordance with Article 107i of Directive 2001/83/EC, of its plan to suspend the marketing authorisation of all cyproterone acetate / ethinylestradiol (2 mg /0.035 mg) containing medicinal products for acne treatment in France over the next three months. This was the result of an analysis of known data, including reports of venous and arterial thrombo-embolism (VTE and ATE).

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 11 March 2013:

Question 1

Please provide information or analysis on data (i.e. clinical data, epidemiological studies and published literature) that you may be aware of and which could be relevant to evaluate the risk of venous and arterial thrombo-embolic events with cyproterone acetate / ethinylestradiol (2 mg/0.035 mg) containing medicinal products.

Question 2

Taking into account the efficacy and in view of the thrombo-embolic concerns, please provide your views on the use of cyproterone acetate / ethinylestradiol (2 mg/0.035 mg) containing medicinal products for the indication approved in your country.

Question 3

Do you consider that you are sufficiently informed on the thrombo-embolic risks related to the use of cyproterone acetate / ethinylestradiol (2 mg/0.035 mg) containing medicinal products? Answer yes, no or more or less.

Question 4

Do you consider that you are sufficiently informed on a scientific basis on the contraceptive effect of cyproterone acetate / ethinylestradiol (2 mg/0.035 mg) combination containing medicinal products? Answer yes, no or more or less and provide all data (i.e. clinical data, epidemiological studies and published literature) that you may be aware of and which could be relevant.