European Medicines Agency

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Questions and answers on the referral for Implanon subdermal implant etonogestrel 68 mg

The European Medicines Agency (EMEA) has completed an arbitration procedure following a disagreement among Member States of the European Union regarding the authorisation of the medicine Implanon. The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the benefits of Implanon outweigh its risks, and that the marketing authorisation granted in the Netherlands can be recognised in other Member States of the European Union.

The review was carried out under an 'Article 29' referral[1].

What is Implanon?
Implanon is a female contraceptive. It is presented as a small rod that is implanted by a doctor or a nurse using a special applicator just under the skin of the upper arm.
The active substance in Implanon, etonogestrel, is a synthetic female hormone resembling progesterone. Once implanted, the rod releases a small amount of etonogestrel continuously into the bloodstream. This changes the body's hormonal balance and help to prevent ovulation. Implanon can protect for up to three years; at the end of this period the implant must be removed.

Why was Implanon reviewed?
N.V. Organon submitted Implanon for a second renewal of the marketing authorisation through mutual recognition on the basis of the initial authorisation granted by the Netherlands on 25 August 1998. The company wanted the renewal of authorisation to be recognised in all the EU Member States, as well as Norway and Iceland where the product is already authorised. These member states were not able to reach an agreement. On 6 October 2008, the Dutch regulatory agency referred the matter to the CHMP.

The grounds for the referral were concerns regarding the side effects related to insertion and removal of the implant, the risk of breast cancer, the incidence of irregular bleedings leading to premature removal of the implant. Additionally, the data on effectiveness in obese women in particular in the third year of use was considered insufficient.

What are the conclusions of the CHMP?
Based on the evaluation of the currently available data and the scientific discussion within the Committee, the CHMP concluded that the benefits of Implanon outweigh its risks, and therefore the renewal of the marketing authorisation for Implanon should be granted in all concerned member states.

The CHMP also endorsed the changes to the product information for the medicine as agreed by the Coordination Group for the Mutual and Decentralised Procedures.

The European Commission issued a decision on 6 February 2009.

[1] Article 29 of Directive 2001/83/EC as amended, referral on the grounds of potential serious risk to public health

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