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Statement by the Medicines Authority regarding Implanon®:
Europe adopts the Dutch position – Implanon® still safe and effective

Following a discussion between European experts during a meeting of the MRFG (Mutual Recognition Facilitation Group), on Monday, 18 October, 2004, to which the Maltese MRFG representative from the Medicines Authority also contributed, all EU Member States, including Malta, are recommending that the contraceptive implant Implanon® is still considered to be effective and safe, provided it is inserted in the appropriate manner according to the product information. In doing so, the Member States are following the position of the Netherlands' authority for the registration of medicines.

The MRFG is a group of representatives from the European Member States that is responsible for the registration of medicines through a procedure of mutual recognition. The mutual recognition procedure is based upon the recognition of a national Marketing Authorization issued in one of the Member States of the EU (the Reference Member State or RMS), by one or more of the other Member States (the Concerned Member States or CMSs). The Netherlands is the RMS for Implanon®. Implanon® is registered in all European Member States, including Norway and Iceland.

During the MRFG meeting discussions were held on the results and consequences of recently performed inspections at clinical centres where registration research involving Implanon® was performed in the early nineties. In April 2004 the Member States decided to perform these inspections following the announcement of Organon, the Marketing Authorisation Holder for Implanon®, that incorrect data were included in the study reports of Indonesian studies with this product and that Organon therefore wished to withdraw these studies from the registration file. The 1998 registration of Implanon® in Europe was partly based on these studies.

Although several critical points related to the performance of the studies were observed, the fact that Implanon® has also been actively and closely followed through periodic safety reports in the past 6 years was taken into consideration in the final conclusions of the MRFG. Because of the under-reporting of the frequency of side effects in some trials, it was decided that Organon has to update the frequency of the incidence of most common side effects (e.g. irregular bleeding) in the product information. Moreover, an inspection will evaluate Organon’s quality control systems on trials as required by current legislation. Furthermore an inspection of its pharmacovigilance reporting system will take place.

Implanon® consists of a rod that is 4 cm long and 2 mm in diameter. It is placed under the skin on the inside of the upper arm. The period of contraceptive action is three years. It contains the hormone etonogestrel, a progestogen, which is released gradually into the blood in small concentrations.

Staff at the Medicines Authority are willing to answer questions relating to Implanon® and can be contacted on 23439153 during office hours or on postlicensing.mru@gov.mt .

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