European Medicines Agency
Veterinary Medicines and Inspections

London, 13 March 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE
SUMMARY OF OPINION*
IMPROVAC

GONADOTROPIN RELEASING FACTOR (GNRF) ANALOGUE-PROTEIN CONJUGATE

On 11 March 2009, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the veterinary medicinal product Improvac a solution for injection with min.300 µg per 2 ml dose, intended as an alternative to physical castration for the reduction of boar taint caused by the key boar taint compound androstenone, in entire male pigs following the onset of puberty. Another key contributor to boar taint, skatole, may also be reduced as an indirect effect.

The Applicant for this veterinary medicinal product is Pfizer Limited.

The active substance of Improvac is a Gonadotropin releasing factor (GnRF) analogue-protein conjugate, a synthetic peptide analogue of GnRF conjugated to Diphteria Toxoid which is an immunological medicinal product inducing antibodies against GnRF.

The benefit of Improvac is the induction of antibodies against GnRF to produce a temporary immunological suppression of testicular function for the use as an alternative to physical castration for the reduction of boar taint caused by the key boar taint compound androstenone, in entire male pigs following the onset of puberty. The most common side effects are injection site swellings of up to 4x8 cm, when administered to pigs at the youngest recommended age (8 weeks) and from 2 to 5 cm in diameter, when administered in older pigs (14-23 weeks). Accidental self- injection may produce similar effects in people to those seen in pigs. The risk of these effects is greater after a second or subsequent accidental injection than after a first injection. Therefore the product must only be used with a safety vaccinator which has a dual safety system providing both a needle guard and a mechanism to prevent accidental operation of the trigger.

The approved indication is: "Induction of antibodies against GnRF to produce a temporary immunological suppression of testicular function. For use as an alternative to physical castration for the reduction of boar taint caused by the key boar taint compound androstenone, in entire male pigs following the onset of puberty.
Another key contributor to boar taint, skatole, may also be reduced as an indirect effect.

The onset of immunity (induction of anti-GnRF antibodies) can be expected within 1 week post second vaccination. Reduction of androstenone and skatole levels has been demonstrated from 4 to 6 weeks post second vaccination. This reflects the time needed for clearance of boar taint compounds already present at the time of vaccination as well as the variability of response between individual animals."

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* Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the Opinion.

** Applicants may appeal any CVMP opinion, provided they notify the EMEA in writing of their intention to appeal within 15 days of receipt of the opinion.

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Detailed conditions for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for IMPROVAC and therefore recommends the granting of the marketing authorisation.