European Medicines Agency
Veterinary Medicines and Inspections

London, 12 December 2008
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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE
SUMMARY OF OPINION*
STARTVAC

International Non-proprietary Name (INN):
Inactivated vaccine for cattle

On 10 December 2008, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the veterinary medicinal product Startvac, emulsion for injection, intended for herd immunisation of healthy cows and heifers, in dairy cattle herds with recurring mastitis problems, to reduce the incidence of sub-clinical mastitis and the incidence and the severity of the clinical signs of clinical mastitis caused by *Staphylococcus aureus*, coliforms and coagulase-negative staphylococci.

The Applicant for this veterinary medicinal product is Laboratorios Hipra S.A..

The active substance of Startvac is:

Escherichia coli J5 inactivated..... > 50 RED_{60} *
Staphylococcus aureus (CP8) strain SP 140 inactivated, expressing Slime Associated Antigenic Complex (SAAC) .....…… > 50 RED_{80} **

* RED_{60}: Rabbit effective dose in 60 % of the animals (serology).
** RED_{80}: Rabbit effective dose in 80 % of the animals (serology).

Adjuvant:
Liquid paraffin..... 18.2 mg
Excipient:
Benzyl alcohol……..... 20 mg

The benefits of Startvac are its usefulness as an element of a control program intended to increase the cows' natural resistance to disease, by limiting the spread of the bacteria in the udder, and to diminish the infection pressure on healthy animals. Startvac also allows for a non-antibiotic approach for controlling mastitis, and the avoidance of potential problems associated with antibiotic residues. Less milk must be discarded if there is no withdrawal period for milk after immunisation in contrast to antibiotic treatment. Furthermore, antibiotic mastitis therapy is effective for the treatment of mastitis caused by non-invasive bacteria but often not successful if mastitis is caused by *S. aureus*, coliforms and coagulase-negative staphylococci.

The most common side effects are slight to moderate transient local reactions after the administration of one dose of vaccine. They would mainly be: swelling (up to 5 cm^2 on average), which disappears within 1 or 2 weeks at most. In some cases, there may also be pain at the inoculation site that spontaneously subsides in a maximum of 4 days.

* 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.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 47
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

The approved indication is:

For herd immunisation of healthy cows and heifers, in dairy cattle herds with recurring mastitis problems, to reduce the incidence of sub-clinical mastitis and the incidence and the severity of the clinical signs of clinical mastitis caused by *Staphylococcus aureus*, coliforms and coagulase-negative staphylococci.
The full immunisation scheme induces immunity from approximately day 13 after the first injection until approximately day 78 after the third injection (equivalent to 130 days post-parturition).

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 Startvac and therefore recommends the granting of the marketing authorisation.