



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Veterinary Medicine and Product Data Management

Committee for Medicinal Products for Veterinary Use

Summary of opinion*

COXEVAC

Inactivated *Coxiella burnetii* vaccine

On 14th July 2010 the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending the granting of a marketing authorisation under exceptional circumstances for the veterinary medicinal product COXEVAC, suspension for injection, intended for the active immunisation of cattle and goats to reduce infection with *Coxiella burnetii*. The applicant for this veterinary medicinal product is Ceva Sante Animale.

The active substance of COXEVAC is inactivated *Coxiella burnetii*, strain Nine Mile, an inactivated bacterial vaccine for cattle and goats. The vaccine contains phase I *Coxiella burnetii* as active ingredient inducing active immunity against Q-fever in cattle and goats.

The benefits of COXEVAC are the active immunisation of cattle to lower the risk for non-infected animals vaccinated when non-pregnant to become a shedder (five-times lower probability in comparison with animals receiving a placebo), and to reduce shedding of *Coxiella burnetii* in these animals via milk and vaginal mucus, and the active immunisation of goats to reduce abortion caused by *Coxiella burnetii* and to reduce shedding of the organism via milk, vaginal mucus, faeces and placenta.

The most common side effects are: in cattle it is very common to see a palpable reaction of maximum diameter of 9 to 10 cm at the injection site, which may last for 17 days. The reaction gradually reduces and disappears without need for treatment. In goats it is very common to see a palpable reaction of 3 to 4 cm diameter at the injection site which may last for 6 days. The reaction reduces and disappears without need for treatment. In goats it is also very common to observe a slight increase of rectal temperature for 4 days post-vaccination without other general signs.

The CVMP considered that due to the current epidemiological situation of Q-Fever and the consequent threat to animal and public health there are objective and verifiable reasons for recommending the granting of a Marketing Authorisation under exceptional circumstances for this product, namely that

- the epidemiological risk for animal health in the EU and the associated zoonotic risk constitute an objective need to have authorised products available for use in the coming months
- vaccination may form an important element of disease control policies at national, regional or Community level

* 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.



- the quality and safety of the product have been satisfactorily demonstrated as well as key elements of efficacy in cattle and goats
- the applicant has agreed to the necessary post-authorisation specific obligation to further investigate and elaborate the efficacy of the product in goats.

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 COXEVAC and therefore recommends the granting of the marketing authorisation under exceptional circumstances.***

*** Marketing Authorisation under exceptional circumstances refers to the fact that in exceptional circumstances an authorisation may be granted subject to certain specific obligations, to be reviewed annually.
