# ANNEX I

# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

OVIGEST 60 mg medicated sponge for ewes

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition per sponge:
**Active substance:**
Medroxyprogesterone acetate…….. 60 mg

**Excipients:**
Methylparahydroxybenzoate (E-218) …… 3.6 mg
Propylparahydroxybenzoate (E-216) …….. 2 mg

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Medicated sponge.
White or yellowish, cylindrical sponge with a knotted string.

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Ewes.

### 4.2 Indications for use, specifying the target species

Induction and synchronisation of oestrus during breeding and non-breeding season. During anoestrus periods OVIGEST should be used in conjunction with PMSG (Pregnant Mare Serum Gonadotrophin) to enhance ovulation.

### 4.3 Contraindications

Do not use in case of hypersensitivity to medroxyprogesterone.
Do not use in pregnant ewes.
Do not use in unfertile and/or sexually immature ewes.
Do not use in ewes displaying vaginal flow, which have recently aborted, or which are ill.

### 4.4 Special warnings for each target species

Medroxyprogesterone does neither constitute a therapy nor a curative approach to sterility.

### 4.5 Special precautions for use

Special precautions for use in animals

Animals must be sexually mature and in good healthy conditions. If primiparous animals are used, these should be 7 months old at least and weigh 70 % of the expected adult body weight.

The sponges must be placed into the vagina with the aid of an applicator, which has been previously disinfected (alcohol, cresols and phenols are not recommended as disinfectants).

When the application of the sponges is difficult (excessively resistant hymen, malformations…) it should not be attempted to introduce the applicator by force, but to make a massage or manual rupture of the hymen, if necessary.

The sponge should be removed before the end of the treatment in the following situations:

If blood is observed in the applicator after insertion.
If the string brakes.
In case abnormal secretion or acute metritis is observed.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

People with known hypersensitivity to medroxyprogesterone should avoid contact with the veterinary medicinal product.
Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product.
The veterinary medicinal product should not be administered by pregnant women.

## 4.6 Adverse reactions (frequency and seriousness)

Very rarely vaginitis, increase of vaginal flow and/or adherences between the mucosa and the sponge may appear.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

## 4.7 Use during pregnancy, lactation or lay

The veterinary medicinal product can be used in lactating ewes, although less efficacy is expected. A minimum interval of 60 days is recommended between labour and treatment with sponges during the breeding season and 75 days during the anoestrus period.

Do not use during pregnancy.

## 4.8 Interaction with other medicinal products and other forms of interaction

None known.

## 4.9 Amounts to be administered and administration route

Vaginal use.

Ewes: 1 sponge/animal.

Clean the vulva of each ewe. Carefully, insert one sponge per ewe into the vagina with the aid of an applicator, which has been previously disinfected.

Remove the applicator leaving the retrieval strings hanging out of the vaginal opening.

The applicator should be cleaned after each insertion.

The sponge must remain inside the vagina for 12-14 days.

After the administration period, the sponge should be removed by gently pulling on the retrieval strings.

At removal of the sponge, a 500 IU PMSG injection can be administered to enhance ovulation, especially during the anoestrus period. In case of PMSG injection, it must not be administered before removing the sponge or from 6 h on after it has been removed (it may cause a diminution of the ovulation).

Ewes can be mated between 24-72 h after sponge removal. In case of artificial insemination it should be conducted 56 h after sponge withdrawal. Those ewes that have not been successfully mated during first oestrus will come on heat again 15-17 days later. This second oestrus might also be used for mating.

### 4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

The administration route makes overdosing very unlikely.

The presence of sponges for a long period of time may produce vaginal irritation and endometric alterations.

### 4.11 Withdrawal period(s)

Meat and offal: 2 days.
Milk: 24 hours.

## 5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: sex hormones and modulators of the genital system, pregnen (4) derivatives.
ATCvet code: QG03DA02.

### 5.1 Pharmacodynamic properties

Medroxyprogesterone acetate is a synthetic analogue of the natural steroid hormone progesterone with the ability to regulate the occurrence of oestrus for extended periods to cycling females. As long as it is administered, the treatment impedes gonadotrophin secretion and, therefore, LH surge. Removal of the sponge removes the progestagen block and induces synchronous re-instatement of gonadotrophin release and subsequent ovulation in treated ewes if they are in oestral season. If not, it is necessary to inject PMSG that act on the ovarian and produce heat and ovulation.

### 5.2 Pharmacokinetic particulars

MAP is released from the sponge in a rather constant rate. A progressive increase of MAP release versus time is observed during the treatment with a mean *in vivo* release rate of approximately 1.8 mg

MAP/day/sponge. Plasma levels of MAP are relatively constant throughout the administration period achieving mean plasma levels around 0.26 ng/ml.

MAP is metabolized in the liver and it is excreted mainly as glucuronide conjugates in the urine and faeces. In sheep, a faecal excretion of 77% of the dose has been reported. The expected elimination half-life for OVIGEST is 24.5h.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Methylparahydroxybenzoate
Propylparahydroxybenzoate
Polyurethane sponge with knotted polyester string

### 6.2 Incompatibilities

None known.

### 6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 6 months.

### 6.4 Special precautions for storage

Do not store above 25 °C.
Keep the bag tightly closed in order to protect from light.

### 6.5 Nature and composition of immediate packaging

The sponges are packed in heat-sealed polyester-aluminum bags, with an inner LLDPE layer, containing 25 units.

### 6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

## 7. MARKETING AUTHORISATION HOLDER

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## 8. MARKETING AUTHORISATION NUMBER(S)

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26/11/2008.

## 10 DATE OF REVISION OF THE TEXT

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## PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.