ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRAPOX lyophilisate and solvent for suspension for injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose (0.01 ml) contains:

Active substance:
Live attenuated Fowl Pox Virus, strain FPV-92 …….….. $10^{4.0}$ -$10^{4.4}$ EID_{50}*
*Embryo Infective Doses 50%

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

Lyophilisate: brownish tablet.
Solvent: transparent and colourless solution.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens and turkeys.

4.2 Indications for use, specifying the target species

For active immunization of chickens and turkeys to reduce clinical signs after infection with Fowl Pox Virus.
Onset of immunity: 21 days after vaccination.
The duration of immunity is not established.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Do not vaccinate diseased chickens and turkeys, only vaccinate healthy birds.

4.5 Special precautions for use

Special precautions for use in animals
Apply carefully the vaccine by wing-web-stab use in a manner that does not provoke lesions in the blood vessels.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Very common adverse reactions:
By days 7 to 10 post-vaccination one or two nodules should appear at the inoculation site of all vaccinated animals, which will become scabs; they are a sign that vaccination has taken. Those scabs will disappear by 2 to 3 weeks post-vaccination.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Do not use in birds in lay and within 4 weeks before the onset of the laying period.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

4.9 Amounts to be administered and administration route

The solvent used to dissolve the lyophilisate should not be at high temperature.

The posology is 1 dose (0.01 ml)/bird.

For the preparation of the vaccine, peel the aluminium capsule off the vial containing the solvent, insert a syringe with hypodermic needle and aspirate in order to remove a certain volume of the content. Then inject this volume of solvent into the vial with the lyophilized vaccine. Shake until the tablet is completely dissolved. Once reconstituted, withdraw all the suspension obtained and inject in the vial containing the remaining solvent. Shake well to obtain a homogeneous suspension. Finally, completely immerse the scarifier in the vaccine preparation. The final administration depends on whether the vaccine is administered to chickens or to turkeys.

Routes of administration: Wing-web-stab use (chickens) and skin scarification (turkeys).

Chickens: Once the scarifier has been immersed into the vaccine preparation, extend the wing membrane and apply carefully the vaccine by wing-web-stab in a manner that does not provoke lesions in the blood vessels. The scarifier must be freshly impregnated with the vaccine suspension to perform each administration.

Turkeys: Once the scarifier has been immersed into the vaccine preparation one drop of vaccine suspension will be applied by skin scarification on the thigh. The scarifier must be freshly impregnated with the vaccine suspension to perform each administration.

Vaccination schedule:
- Broilers: vaccinated from one day of age.
- Future layers and breeders: vaccinate between 8 and 12 weeks of age. In areas at high risk for the disease, birds can be vaccinated from one day of age and revaccinated before lay.
- Turkeys: vaccinated from one day of age.

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

Administering a ten-fold dose of that recommended does not produce adverse effects other than those mentioned in section 4.6.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Avian pox virus.
ATCvet code: QI01AD12.

To stimulate active immunity against infection with Fowl Pox Virus.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:
Disodium hydrogen phosphate dodecahydrate
Potassium dihydrogen phosphate
Sodium chloride
Potassium chloride
Povidone
Sucrose
Sodium glutamate

Solvent:
Disodium hydrogen phosphate dodecahydrate
Potassium dihydrogen phosphate
Sodium chloride
Potassium chloride
Water for injections

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after dilution or reconstitution according to directions: use immediately.

6.4. Special precautions for storage

Lyophilisate: store and transport refrigerated (2 °C – 8 °C). Protect from light. Do not freeze.
Solvent: do not store above 25 ºC. Protect from light. Do not freeze.

6.5 Nature and composition of immediate packaging

Containers for the lyophilisate and for the solvent: 10 ml Type I, neutral glass vials; Type I bromobutyl rubber closures and aluminium cap.

Cardboard box with 5 vials of 1,000 doses of lyophilisate and 5 vials of 10 ml of solvent for reconstitution of 1,000 doses.
A double-bladed nickel-plated steel scarifier with plastic handle is also included.

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

Laboratorios Hipra S.A.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN
Tel. +34 972 430660
Fax +34 972 430661
E-mail: hipra@hipra.com

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation (ES): 27/09/1955
Date of last renewal: 05/05/2011

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

Dispensation conditions: Medicament by veterinary prescription.
Administration conditions: Administration under veterinary control or supervision.