ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PHARMAVAC PHA emulsion for injection for pigeons

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One vaccine dose (0.3 ml) contains

Active substance<s>:

Inactivated Pigeon Paramyxovirus type 1 (PPMV1), strain 988M	≥ 6.9 log2 HIU*
Inactivated Pigeon Herpesvirus 1 (PHV1), strain V298/70	≥ 38.1 EU**
Inactivated Fowl Adenovirus type 8 (FAdV-8), strain M2/E	≥ 24.7 EU**

* Haemagglutination inhibition units in chicken
** ELISA units in chicken

Adjuvant<s>:

Paraffin oil	156.9 mg
Sorbitan oleate	15.8 mg
Polysorbate 80	5.7 mg

Excipient<s>:

Formaldehyde	max. 0.060 mg
Thiomersal	max. 0.036 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection.
White emulsion with easily shakeable sediment.

4. CLINICAL PARTICULARS

4.1 Target species

Pigeon.

4.2 Indications for use, specifying the target species

For active immunization of pigeons from the age of 4 weeks onwards:

- to reduce mortality and frequency and severity of clinical signs caused by paramyxovirus type 1 (PMV1).
- to reduce the severity of clinical signs, gross lesions and virus shedding caused by pigeon herpesvirus (PHV1)
- to reduce the severity of clinical signs and gross lesions caused by adenovirus (AdV) namely type 7/E, 2/D, 3/D and 4/C belonging to subgroup I

Onset of immunity: 3 weeks after vaccination
Duration of immunity: 12 months after vaccination for PMV1 component
5 months after vaccination for PHV1 and AdV component

The duration of immunity against PHV1 and AdV was demonstrated by cell-mediated immunity and serological data.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.
The timing of vaccination/revaccination should be based on risk-benefit assessment of the responsible veterinarian considering the prevalence of particular diseases in breeding and the most risky periods related to transmission of diseases (i.e. beginning of flying season, exhibition season and/or breeding season).

4.5 Special precautions for use

Special precautions for use in animals

Avoid administration of the vaccine to the site of previous subcutaneous vaccinations.
Careful palpation of the chosen vaccination site is recommended before administration.

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.

To the user:
This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

4.6 Adverse reactions (frequency and seriousness)

Creation of a slight swelling up to 1.0 cm in diameter at the site of injection, which disappears within 9 days, is common.

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 safety of the veterinary medicinal product has not been established during lay.
Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

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

One dose: 0.3 ml
Administer one dose subcutaneously in the dorsal region of the neck towards the tail (not to the head) from 4 weeks of age onwards.

Shake well before and occasionally during administration.
Before administration allow warming of vaccine to room temperature.
Administer under usual aseptic conditions using sterile syringes and needles only.
Use appropriately graduated syringes allowing administration of the exact vaccination dose 0,3 ml.

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

Following the administration of an overdose, no adverse reactions other than those mentioned in section 4.6 occur.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated viral vaccine
ATC vet code: QI01EA

The vaccine is intended to stimulate active immunity against Pigeon Paramyxovirus type 1 (PPMV1), Pigeon Herpesvirus type 1 (PHV1), and Fowl Adenovirus type 8 (FAdV-8). The antigens are inactivated with formaldehyde or beta-propiolactone and are adjuvanted with light paraffin oil, sorbitan oleate and polysorbate 80.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Paraffin oil
Sorbitan oleate
Polysorbate 80
Formaldehyde
Thiomersal

6.2 Major 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 first opening the immediate packaging: 8 hours

6.4. Special precautions for storage

Store in a refrigerator (2°C – 8°C).
Protect from frost. Protect from light.

6.5 Nature and composition of immediate packaging

Paper carton containing one glass vial, type I closed with chlorobutyl rubber stopper sealed with aluminium cap.
Package size: 1 vial of 50 doses (17.5 ml)

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

Name: PHARMAGAL-BIO spol. s r.o.
Address: Murgašova 5, 94901 Nitra
Country: Slovak Republic
Tel.: +421 (0)37 6533 171
E-mail: bio@pharmagalbio.sk

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: DD/MM/YYYY

10 DATE OF REVISION OF THE TEXT

MM/YYYY

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

cardboard box 1 x 50 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PHARMAVAC PHA emulsion for injection for pigeons

2. STATEMENT OF ACTIVE SUBSTANCES

One vaccine dose (0.3 ml) contains

Active substance<s>:

Inactivated Pigeon Paramyxovirus 1 (PPMV1), strain 988M	≥ 6.9 log2 HIU*
Inactivated Pigeon Herpesvirus 1 (PHV1), strain V298/70	≥ 38.1 EU**
Inactivated Fowl Adenovirus type 8 (FAdV-8), strain M2/E	≥ 24.7 EU**

* Haemagglutination inhibition units in chicken
** ELISA units in chicken

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

1 x 50 doses

5. TARGET SPECIES

Pigeon

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneously in the dorsal region of the neck.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): zero days

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous. Read the package leaflet before use.

10. EXPIRY DATE

EXP {day/month/year}
Once broached use within 8 hours.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2°C – 8°C).
Protect from frost. Protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

PHARMAGAL-BIO spol. s r.o.
Murgašova 5, 94901 Nitra
Slovak Republic

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

vials 50 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PHARMAVAC PHA emulsion for injection for pigeons

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

One vaccine dose (0.3 ml) contains
Inactivated strains of PPMV1 ≥ 6.9 log2 HIU, PHV1 ≥ 38.1 EU and FAdV-8 ≥ 24.7 EU

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 doses

4. ROUTE(S) OF ADMINISTRATION

SC injection.

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s): zero days

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {day/month/year}
Once broached use within 8 hours

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
PHARMAVAC PHA
Emulsion for injection for pigeons

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:
PHARMAGAL-BIO spol. s r.o., Murgašova 5, 94901 Nitra, Slovak Republic

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

PHARMAVAC PHA emulsion for injection for pigeons

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

One vaccine dose (0.3 ml) contains

Active substance<s>:

Inactivated Pigeon Paramyxovirus type 1 (PPMV1), strain 988M	≥ 6.9 log2 HIU*
Inactivated Pigeon Herpesvirus 1 (PHV1), strain V298/70	≥ 38.1 EU**
Inactivated Fowl Adenovirus type 8 (FAdV-8), strain M2/E	≥ 24.7 EU**

* Haemagglutination inhibition units in chicken
** ELISA units in chicken

Adjuvant<s>:

Paraffin oil	156.9 mg
Sorbitan oleate	15.8 mg
Polysorbate 80	5.7 mg

Excipient<s>:

Formaldehyde	max. 0.060 mg
Thiomersal	max. 0.036 mg

White emulsion with easily shakeable sediment.

4. INDICATION(S)

For active immunization of pigeons from the age of 4 weeks onwards:
- to reduce mortality and frequency and severity of clinical signs caused by paramyxovirus type 1 (PMV1).
- to reduce the severity of clinical signs, gross lesions and virus shedding caused by pigeon herpesvirus (PHV1)
- to reduce the severity of clinical signs and gross lesions caused by adenovirus namely type 7/E, 2/D, 3/D and 4/C belonging to subgroup I

Onset of immunity: 3 weeks after vaccination
Duration of immunity: 12 months after vaccination for PMV1 component
5 months after vaccination for PHV1 and AdV component
The duration of immunity against PHV1 and AdV was demonstrated by cell-mediated immunity and serological data.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Creation of a slight swelling up to 1.0 cm in diameter at the site of injection which disappears within 9 days is common.

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)

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigeon

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

One dose: 0.3 ml

Administer one dose subcutaneously in the dorsal region of the neck towards the tail (not to the head) from 4 weeks of age onwards.

9. ADVICE ON CORRECT ADMINISTRATION

Administer in the dorsal region of the neck towards the tail, not to the head.
Shake well before and occasionally during administration.
Before administration allow warming of vaccine to room temperature.
Administer under usual aseptic conditions using sterile syringes and needles only.
Use appropriately graduated syringes allowing administration of the exact vaccination dose 0,3 ml.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in a refrigerator (2°C – 8°C).
Protect from frost. Protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
Shelf life after first opening the container: 8 hours

12. SPECIAL WARNING(S)

Special warnings for each target species:

Vaccinate healthy animals only.
The timing of vaccination/ revaccination should be based on risk-benefit assessment of the responsible veterinarian considering the prevalence of particular diseases in breeding and the most risky periods related to transmission of diseases (i.e. beginning of flying season, exhibition season and/or breeding season).

Special precautions for use in animals:
Avoid administration of the vaccine to the site of previous subcutaneous vaccinations.
Careful palpation of the chosen vaccination site is recommended before administration.

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.

To the user:
This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Lay:
The safety of the veterinary medicinal product has not been established during lay.
Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

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.

Overdose (symptoms, emergency procedures, antidotes):
Following the administration of an overdose, no adverse reactions other than those mentioned in section 6 occur.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Package size:
Box with 1 vial of 50 doses.