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DRAFT

CORE SPC FOR PANDEMIC INFLUENZA VACCINES

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CORE SPC FOR PANDEMIC INFLUENZA VACCINES

Introduction

Two guidelines have been developed by the Vaccine Expert Group (VEG) on Pandemic Influenza vaccines:

- Guideline on dossier structure and content for marketing authorisations for pandemic influenza vaccines (EMEA/CPMP/VEG/4717/03);
- Guideline on submission of marketing authorisation applications for pandemic influenza vaccines through the centralised procedure (EMEA/CPMP/VEG/4986/03).

This harmonised SPC has been developed by the VEG in order to facilitate the submission of the core pandemic dossier and subsequent approval of the pandemic variation: the SPC, based upon this harmonised SPC proposal, labels and package leaflet approved in the core pandemic dossier authorisation will normally not have to change (except for some information on the pandemic strain) when the pandemic variation is submitted. It is intended solely for inactivated pandemic virus derived vaccines. Please note that the text proposal should be considered as a minimum requirement. Additional claims should be substantiated with data.

It should be read in conjunction with the following additional guidance documents:

- Guideline on Summary of Product Characteristics, published by the European Commission[1];
- Guideline on Pharmaceutical aspects of the product information for human vaccines (EMEA/CPMP/BWP/2758/02).
- QRD Product Information Template with explanatory notes[2]
- Convention to be followed for QRD Templates[3]

Wordings between <> should be chosen;
Wordings between {} mean that they have to appear when necessary.

[1] http://pharmacos.eudra.org/F2/eudralex/vol-2/C/SPCGuidRev0-Dec99.pdf
[2] http://www.emea.eu.int/htms/human/qrd/qrdplt/H01a%20EN%20NOTE%20SPC-II-lab-pl%20v6.1.pdf
[3] http://www.emea.eu.int/htms/human/qrd/qrdplt/qrdconventionv6.pdf

CORE SPC

FOR

PANDEMIC INFLUENZA VACCINES

1. NAME OF THE MEDICINAL PRODUCT

(INVENTED) NAME OF PRODUCT <pharmaceutical form>
Common name[1]

[[1] by the common name we mean: Pandemic influenza vaccine, <monovalent> <strain identifier>]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<Whole virion influenza vaccines of pandemic strain(s)> or
<Influenza virus surface antigens (haemagglutinin and neuraminidase)* of strain(s)> or
<split Influenza virus, inactivated containing antigens equivalent to>:

A/Official strain(s) (H_xN_y) like strain(s) used (add : specific, actual strains used).....X micrograms** per X ml dose

* propagated in {specific}

** expressed in µg haemagglutinin, unless justified

This vaccine complies with the WHO recommendation and EU decision for the pandemic.

[If an adjuvant is present in the vaccine, the qualitative and quantitative composition should be given in this section.]

[In case of multidose preparation, include the following statement:]
This is a multidose container. See section 6.5 for the number of doses per vial.

For excipients see section 6.1.

3. PHARMACEUTICAL FORM

<Solution for injection>
<Suspension for injection>
<Emulsion for injection>

[Product specific - Rules given by the Standard terms should be applied]

[Include here a description of the visual appearance of the product pharmaceutical form as marketed. Information on appearance of the reconstituted solution, if applicable, should appear under section 6.6.]

4. CLINICAL PARTICULARS

4.1. THERAPEUTIC INDICATIONS

Prophylaxis of influenza in an officially declared pandemic situation. Pandemic influenza vaccine should be used in accordance with official guidance.

4.2. POSOLOGY AND METHOD OF ADMINISTRATION

[The text below may need to be amended based upon the clinical trials performed with the mock-up vaccines.]

Adults and children: x ml.
<A second dose of vaccine should be given after an interval of at least x weeks.>

For further information, see section 5.1.

[The route of administration should be given, e.g.:]
Immunisation should be carried out by intramuscular or deep subcutaneous injection.

4.3 CONTRAINDICATIONS

Evidence of an anaphylactic reaction (i.e. life-threatening) to any of the constituents of this vaccine.
See section 4.4. for Special warnings and special precautions for use.

4.4. SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE

Caution is needed when administrating this vaccine to persons with a known hypersensitivity (other than anaphylactic reaction) to the active substances, to any of the excipients, <to thiomersal> and to {residues (product specific) e.g. eggs, chicken proteins, antibiotics, thiomersal, etc.}

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following the administration of the vaccine.

If time allows, immunisation shall be postponed in patients with febrile illness or acute infection.

The vaccine (Invented name) should under no circumstances be administered intravascularly.

Antibody response in patients with endogenous or iatrogenic immunosuppression may be insufficient.

4.5. INTERACTIONS WITH OTHER MEDICAMENTS AND OTHER FORMS OF INTERACTION

In general, the vaccine (Invented name) should not be given at the same time as other vaccines. However, if co-administration with a pneumococcal vaccine is indicated, immunisation
should be carried out on separate limbs. It should be noted that the adverse reactions may be intensified.

The immunological response may be diminished if the patient is undergoing immunosuppressant treatment.

Following influenza vaccination, false positive results in serology tests using the ELISA method to detect antibodies against HIV1, Hepatitis C and especially HTLV1 have been observed. The Western Blot technique disproves the results. The transient false positive reactions could be due to the IgM response by the vaccine.

4.6. PREGNANCY AND LACTATION

For pregnant women, administration of the pandemic influenza vaccine is recommended, irrespective of their stage of pregnancy.
The vaccine (Invented name) may be used during lactation.

4.7. EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The vaccine has no or negligible influence on the ability to drive and use machines.

4.8. UNDESIRABLE EFFECTS

Adverse reactions from clinical trials with the mock-up vaccine (see section 5.1 for more information on mock-up vaccines): (list)
Undesirable effects reported are listed according to the following frequency.
[follow SPC guidance, classification of Adverse Events via the Medra system]

Adverse reactions from clinical trials with interpandemic trivalent vaccines:
Undesirable effects reported are listed according to the following frequency.
[follow SPC guidance, classification of Adverse Events via the Medra system]

Common (>1/100, <1/10):
Local reactions: redness, swelling, pain, ecchymosis, induration
Systemic reactions: Fever, malaise, shivering, fatigue, headache, sweating, myalgia, arthralgia.
These reactions usually disappear within 1-2 days without treatment.

From Post-marketing surveillance additionally, the following adverse events have been reported:

Uncommon (>1/1,000, <1/100):
Generalised skin reactions including pruritus, urticaria or non-specific rash

Rare (>1/10,000, <1/1,000):
neuralgia, paraesthesia, convulsions, transient, thrombocytopenia.

Allergic reactions, in rare cases leading to shock, have been reported.

Very rare (<1/10,000):
Vasculitis with transient renal involvement
Neurological disorders, such as encephalomyelitis, neuritis and Guillain Barré syndrome.

[If the vaccine contains thiomersal as a preservative the following should be mentioned:]
<This medicinal product contains thiomersal (an organomercuric compound) as a preservative and therefore, it is possible that sensitisation reactions may occur (see section 4.4).>

<Adverse event from post-marketing surveillance with the pandemic vaccine: *[list, no frequencies]*>

4.9 OVERDOSE

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1. PHARMACODYNAMIC PROPERTIES

Pharmacotherapeutic group: {group *[lowest available level]*}, ATC Code {code}

[This section should describe the quality of response, including description of results of neutralising antibodies if available. This section should also describe the principle of mock-up and pandemic vaccines, including a statement that the clinical efficacy and safety data obtained with this mock-up vaccine are of relevance for the pandemic vaccine.]

This section describes the clinical experience with the mock-up vaccines <following a two-dose administration>. <After the second dose, an><A> HI antibody titre of more than 40 is generally obtained within xx to yy weeks.
The persistence of antibodies for the mock-up vaccines varies, but is usually xx-yy months.

5.2. PHARMACOKINETIC PROPERTIES

Not applicable

5.3. PRECLINICAL SAFETY DATA

<Not applicable>

[If preclinical data are generated with the mock-up vaccine according to the Guideline on dossier requirements for pandemic influenza vaccines, this should be reported here.]

6. PHARMACEUTICAL PARTICULARS

6.1. LIST OF EXCIPIENTS

[Product specific]

[According to the recommendation given by the Guideline on Summary of Product Characteristics, residues of production should not be stated in this section.]

6.2. INCOMPATIBILITIES

<In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.>
<This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.>

6.3. SHELF-LIFE

<X months> <1 year> <18 months> <2 years> <…>

6.4. SPECIAL PRECAUTIONS FOR STORAGE

[Product specific.]

<Do not store above <25°C> <30°C>> or
<Store below <25°C> <30°C>>
<Store in a refrigerator (2°C – 8°C)>
<Store and transport refrigerated (2°C – 8°C)>
<Store in a freezer {temperature range}>
<Store and transport frozen {temperature range}>
<Do not <refrigerate> <or> <freeze>>
<Store in the original <package>>
<This medicinal product does not require any special storage conditions>

<in order to protect from <light> <moisture>>

6.5. NATURE AND CONTENTS OF THE CONTAINER

X ml <pharmaceutical form*> in <container>, <nature>, {additional characteristics (nature)} {other components (nature)} - pack of Y

[only applicable when the SPC relates to more than one pharmaceutical form]*

[In case of multidose presentations, the number of doses per vial should be stated.]

<Not all pack sizes may be marketed.>

6.6. INSTRUCTIONS FOR USE AND HANDLING <AND DISPOSAL>

The vaccine should be allowed to reach room temperature before use.
Shake before use.

[Other SPC sections
See the Guideline on Summary of Product Characteristics]