European Medicines Agency
Evaluation of Medicines for Human Use

London, 23 July 2009
EMEA/CHMP/VWP/193031/2004 Rev- 1

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

CORE SPC FOR PANDEMIC INFLUENZA VACCINES

DISCUSSION IN THE VACCINE EXPERT GROUP	May 2004 July 2004 November 2004
DISCUSSION IN THE QUALITY REVIEW OF DOCUMENTS GROUP	November 2004
TRANSMISSION TO CHMP	December 2004
RELEASE FOR CONSULTATION	January 2005
DEADLINE FOR COMMENTS	April 2005
DISCUSSION IN THE VACCINE WORKING PARTY	May 2005
TRANSMISSION TO CHMP	May 2005
ADOPTION BY CHMP	June 2005
DATE FOR COMING INTO OPERATION	July 2005
DRAFT REV 1 AGREED BY THE VACCINE WORKING PARTY	July 2009
ADOPTION BY CHMP	July 2009
DATE FOR COMING INTO OPERATION	August 2009

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CORE SPC FOR PANDEMIC INFLUENZA VACCINES

Introduction

Two guidelines have been developed by the Vaccine Working Party (VWP) on Pandemic Influenza vaccines:

- Guideline on dossier structure and content for marketing authorisations for pandemic influenza vaccines (EMEA/CPMP/VEG/4717/03 Rev-1);
- 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 VWP 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)[2].
- QRD Product Information Template with explanatory notes[3]
- Convention to be followed for QRD Templates[4]

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/pdfs/human/bwp/275802en.pdf
[3] http://www.emea.eu.int/htms/human/qrd/qrdplt/H01a%20EN%20NOTE%20SPC-II-lab-pl%20v6.1.pdf
[4] 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) (HxNy) like strain(s) used (add: specific, actual strains used)..….X micrograms** per X ml dose.

* propagated in {specific}.

** expressed in microgram 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 (see sections 4.2 and 5.1).

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.]
[Describe age populations and relevant posology. Describe populations for which there is no or limited experience to give a dose recommendation e.g.
<There is no experience in children under X years of age>;
<There is limited experience in children between X and Y years of age>;
<There no experience in adults above the age of X>;
<There limited experience in adults above the age of X>]

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

History of an anaphylactic (i.e. life-threatening) reaction to any of the constituents or trace residues {(list of product specific residues)} of this vaccine. However, in a pandemic situation, it may be appropriate to give the vaccine, provided that facilities for resuscitation are immediately available in case of need.

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 substance(s), 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 the pandemic situation allows, immunisation shall be postponed in patients with severe 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 medicinal products and other forms of interaction

There are no data on co-administration of the vaccine{(Invented name)} with other vaccines. However, if co-administration with another 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 may disprove the false positive results and confirm the true results. The transient false positive reactions could be due to the IgM response by the vaccine.

4.6. Pregnancy and lactation

[For non-adjuvanted vaccines]
Data from vaccinations with unadjuvanted interpandemic trivalent vaccines in pregnant women do not indicate that adverse foetal and maternal outcomes were attributable to the vaccine.
Healthcare providers need to assess the benefit and potential risks of administering the vaccine to pregnant women.

[For adjuvanted vaccines]
No data have been generated in pregnant women with the vaccine {(Invented name)} or with any other vaccine containing Adjuvant X (see section 5.3 for description of pre-clinical studies).
Healthcare providers need to assess the benefit and potential risks of administering the vaccine to pregnant women.

The vaccine {(Invented name)} may be used during lactation.

4.7. Effects on ability to drive and use machines

The vaccine is unlikely to produce an effect 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]

From Post-marketing surveillance with interpandemic trivalent vaccines, 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(s) 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 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.

Mock-up vaccines contain influenza antigens that are different from those in the currently circulating influenza viruses. These antigens can be considered as ‘novel’ antigens and simulate a situation where the target population for vaccination is immunologically naïve. Data obtained with a mock-up vaccine will support a vaccination strategy that is likely to be used for the pandemic vaccine: clinical efficacy and safety data obtained with mock-up vaccines are relevant for the pandemic vaccines.

[Describe here relevant information obtained in the clinical trials with the mock-up vaccine, including the quality of response, including description of results of neutralising antibodies if available.]

The persistence of antibodies for the mock-up vaccines varies, but is usually xx-yy months.

[Text to be added on approval of the pandemic vaccine:]

The pandemic vaccine has been approved on the basis of quality data that is new and relevant for the pandemic strain. <No> <Limited> pre-approval <preclinical> <and> <clinical> data with the pandemic strain have been generated. Clinical effectiveness and safety data of the pandemic vaccine <will be> <have been> gathered as the influenza pandemic progresses.

[Describe here relevant clinical information obtained with the pandemic vaccine (during clinical trials or post-authorisation).]

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. If preclinical data with the pandemic vaccine have been generated, this should also 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]