

## ECDC HEALTH INFORMATION

# Q&A for the general public on vaccines and vaccination in relation to the 2009 influenza A(H1N1) pandemic

18 December 2009

### Q1. What is 2009 pandemic influenza A(H1N1) ?

The present pandemic influenza A(H1N1) virus is a new influenza virus affecting humans. New influenza viruses are often the result of a mixing of genes from two viruses. The 2009 pandemic influenza A(H1N1) virus is the result of a combination of two influenza viruses that contain flu genes of avian, swine and human origin. When such mixing occurs, most people have little or no immunity against the resulting new influenza virus.

### Q2. Why should I get vaccinated if I am offered the pandemic vaccine?

Vaccines are among the most important ways to reduce illness and deaths during the current influenza A(H1N1) pandemic.

While many people who are infected with the influenza A(H1N1)v virus will experience a moderate illness that will not require medical attention, there are the unfortunate few who will develop severe disease. These will not only be persons belonging to risk groups, but also some young and previously healthy people.

In order to help prevent the spread of this new influenza virus in Europe, we should all be practising good personal hygiene. However, vaccination provides the most effective protection.

Pandemic vaccines are becoming available across the EU and national vaccination programmes are starting. Given the significant risks to health from the pandemic, ECDC would strongly advise all those Europeans who are offered the vaccine to be vaccinated.

The risk of becoming seriously ill from the new influenza virus is far greater than the risk from possible side effects (for more information on side effects, please see Q12.).

By being vaccinated you protect not just your own health, but that of the people around you.

### Q3. Who will be vaccinated first?

This is for each country in the EU to decide, but the EU authorities have made recommendations in a [policy statement](#) on target and priority groups for vaccination:

- all adults and children older than six months with underlying chronic conditions (see Q3 for definition of underlying conditions in 'risk groups');
- pregnant women; and
- healthcare workers.

## Q4. How do I know if I belong to a risk group?

The 'risk groups' identified for influenza A(H1N1) pandemic are:

- people of all ages with chronic underlying conditions – diabetes, cardiovascular disease, chronic respiratory disease, including moderate and severe asthma, and other conditions that impair breathing and cause other chronic health problems, such as extreme obesity and some physical handicaps;
- pregnant women; and
- young children (especially those under two years of age).

In children, the risk groups are somewhat different, with more emphasis on neurodevelopmental handicaps and less on chronic medical conditions such as diabetes and cardiovascular disease.

## Q5. Why are pregnant women a 'risk group'?

A pregnant woman who becomes ill from pandemic influenza is four to five times more likely to become sufficiently ill to be hospitalised compared with other adults and up to 10 times more likely to end up in intensive care.

This is why ECDC and other authorities like the World Health Organization and the US Centers for Disease Control and Prevention put pregnant women in the 'risk groups'.

However, it is important not to overstate the risk for the individual. Most pregnant women who are infected are still much more likely to have a moderate illness which will not require medical attention.

## Q6. Who should not be vaccinated?

There are a very few individuals – those who have a severe allergy (life-threatening) to chicken, egg or any other substance in the vaccine – that should not be vaccinated.

If you are uncertain, please consult your doctor.

## Q7. Which pandemic vaccines have been approved in Europe?

In the European Union, the European Commission has granted authorisation for three specific pandemic influenza A(H1N1) vaccines following a positive scientific opinion issued by the European Medicines Agency.

The products authorised are [Focetria](#) (Novartis), [Pandemrix](#) (GlaxoSmithKline) and [Celvapan](#) (Baxter). The vaccines are authorised for use in all EU Member States, as well as in Iceland, Liechtenstein and Norway. For further information, including indications and doses in different age groups, see [www.emea.europa.eu](http://www.emea.europa.eu).

In addition, the Hungarian authorities have provided a national licence for a pandemic vaccine, [Fluval P](#) (Omninvest). The French authorities have provided a national licence for a pandemic vaccine, [Panenza](#), (Sanofi Pasteur). The German authorities have provided a national licence for a pandemic vaccine [PanVaxH1N1](#) (CSL). The Romanian authorities have provided a national licence for a pandemic vaccine [CANTGRIP](#) (Cantacuzino). Finally, the Swiss and German authorities have provided national licences for a pandemic vaccine, [Celtura](#) (Novartis).

Further pandemic vaccines from European manufacturers that regularly produce seasonal influenza vaccine may be developed within the coming months.

## Q8. What is in the pandemic vaccines?

All 2009 pandemic influenza vaccines are based on an initial isolate of the new pandemic virus A(H1N1). As there are several different pandemic vaccines available in the EU, their composition vary somewhat, however, they are all inactivated (containing killed virus) and either egg- or cell-derived and should be injected into the muscle.

In addition, some of the pandemic vaccines licensed for the EU contain adjuvants (see Q9.) and/or thiomersal (see Q.10).

## Q9. What are adjuvants and why are they used in some pandemic vaccines?

Some pandemic vaccines contain substances that enhance the immune response, so called 'adjuvants', which are substances that help boost the vaccine's potency.

Two types of adjuvants are included in the pandemic vaccines which have been licensed for Europe: alum-based and squalene-based. Alum-based adjuvants, used by Omniinvest, have been used in many different vaccines for the past 60 years and, therefore, the clinical experience is vast. Squalene-based adjuvants, used by Novartis and GlaxoSmithKline, have been introduced more recently, but they have been used in seasonal influenza vaccines provided to older people since 1997. It is estimated that more than 45 million doses of squalene-containing seasonal influenza vaccine have been distributed in Europe.

Squalene is a substance found in plants, animals, and humans. It is a component of human cell membranes and is manufactured in the liver of humans and circulates in human blood. It is commercially extracted from fish oil, and used in a variety of foods, cosmetics, over-the-counter medications, and health supplements. The squalene used in vaccines is purified from shark liver oil.

## Q10. What is thiomersal and why is it used in pandemic influenza vaccines?

Thiomersal is an antimicrobial organic mercury compound that is used either in the early stages of manufacturing or as a preservative in the final product. It prevents influenza vaccines from becoming contaminated by microorganisms.

Mercury is commonly found in foods, notably in fish and seafood, principally in the form of methylmercury. While exposure to methylmercury varies by country, intake estimates for European consumers are close to the internationally established safe intake limits.

In view of the recommendations for food products, as established by the [Joint FAO/WHO Expert Committee on Food Additives \(JEFSA\)](#), the total dose of thiomersal provided in one or two doses of pandemic vaccine is considered to be of little significance and harmless to those vaccinated, which is also the experience from many years of its use in other vaccines.

## Q11. How efficient are the vaccines?

Both adjuvanted and unadjuvanted pandemic vaccines have been shown to provide a good immune response. Adjuvanted vaccines commonly provide a stronger immune response compared with unadjuvanted vaccines and also provide a broader immune response allowing for some mutations the influenza virus.

Effectiveness of the current vaccines in Europe is being assessed in large studies. Infections that may occur in spite of vaccination, indicating a poor match between the given vaccine and circulating strains, will be reported and will be one of the tools to assess effectiveness.

## Q12. What are the expected side effects of the pandemic vaccines?

The side effects reported so far have mainly been mild, similar to those experienced following seasonal influenza vaccination.

Side effects commonly reported include swelling, redness or pain at the injection site, which usually goes away a short time after vaccination. Fever, headache, fatigue, and muscle aches, occurring shortly after vaccination, have also been reported. These symptoms also go away on their own, usually within 1–2 days.

Safety data are now publicly available on several National Regulatory Agencies of EU Member States. The [website of the Swedish National Regulatory Agency](#) after vaccinating almost 5 million individuals with the adjuvanted vaccine from Glaxo Smith Kline and the UK [Medicines and Healthcare products Regulatory Agency](#) using vaccines from Baxter and GSK. Their webpages will be updated on a weekly basis. To date there have been no safety concerns of clinical significance reported.

[The European Medicines Agency](#) is also regularly publishing reports on monitored side effects for the vaccines that have been authorised by the EU.

## Q13. How can I be sure that the pandemic vaccines are safe?

Vaccination is always an emotive issue and EU citizens rightly require assurance that vaccines are both safe and effective. Influenza vaccines have been used for more than 60 years and have one of the best safety records across all age groups. ECDC expects the pandemic vaccines to have a similar safety profile as seasonal influenza vaccines. We will continuously monitor their application across the EU to ensure the most up-to-date information is available to everyone.

All the manufacturers of pandemic vaccines are using the same process and testing that they use for making the seasonal and/or the avian flu vaccines.

The avian flu vaccines (mock-up vaccines) have been tested in clinical trials including children as young as six months (Novartis) and three years of age (GlaxoSmithKline), but there is no clinical experience with them in larger populations.

The avian flu vaccine contents are identical to the current pandemic vaccines, except for the virus strain included, and had a good safety and effectiveness profile in the trials.

Routine monitoring across the EU will continue and reports of serious side effects will be sent as usual to the European Medicines Agency. Manufacturers are also requested to send safety update reports on a monthly basis to the European Medicines Agency. Vaccine manufacturers have been requested to carry out a study in 9 000 persons for each vaccine.

ECDC is also developing a complementary vaccine safety monitoring system by linking large computerised clinical databases and immunisation registries.

## Q14. Will one or two doses of vaccine be required?

The European Medicines Agency has reviewed further data on the centrally authorised pandemic vaccines, Celvapan, Focetria and Pandemrix. Data on Focetria and Pandemrix indicate that a single dose may be used in adults aged between 18 and 60 years and in children from the age of 9 years for Focetria, and from 10 years for Pandemrix. Pandemrix may also be used as a single dose in the elderly.

For certain groups, such as younger children and people suffering from immune deficiency, the recommendation remains that two doses should be given, to ensure that their immune system responds adequately to the vaccination. However, for updated recommendations please consult national websites as authorities are constantly receiving new data.

Data on Celvapan are still being assessed.

For further information, see the European Medicine Agency [press release of 20 November](#).

## Q15. I am pregnant – are the pandemic influenza vaccines safe for me and my unborn baby?

More than 25 million Europeans, including pregnant women and children in different age groups, are estimated to have been vaccinated so far.

Most people have received one of the three vaccines (Pandemrix, Focetria and Celvapan) that have been authorised for use in all EU Member States and the EEA (Iceland, Liechtenstein and Norway). Side effects reported so far have mainly been symptoms such as fever, nausea, headache, allergic reactions and injection site reactions.

There is now significant experience of using influenza vaccines for pregnant women (> 200 000 vaccinated) and children and to date there are no reports of problems beyond what is experienced in other individuals.

Also worth noting is that immunisation will not only protect the mother-to-be but it will also give direct and indirect protection to the newborn child.

## Q16. Can I take the pandemic influenza vaccine if I am a breastfeeding mother?

Both seasonal influenza and pandemic vaccines can be given to breastfeeding mothers. Breastfeeding is fully compatible with flu vaccination, and preventing the flu in mothers will reduce the chance that the infant will get influenza. This is especially important as children under six months currently cannot be immunised against influenza.

Also, by breastfeeding, a mother who has been vaccinated passes on to her baby the antibodies that her body makes in response to the pandemic influenza vaccination. This in turn can reduce the baby's risk of getting sick with influenza.

## Q17. How quickly can I expect to be protected after vaccination?

A healthy individual is expected to develop an immune response within 10 to 14 days after vaccination.

## Q18. Will I need to be vaccinated every year for pandemic influenza?

The current vaccination strategy is mainly aimed at rapidly immunising the population. However, it is known from clinical trials with avian flu vaccines (H5N1) and seasonal influenza vaccines that immunity can wane over time and booster doses may therefore be needed.

Data from on-going trials will guide the decisions. Moreover, virus mutations are likely to occur over time and may call for updated vaccines.

## Q19. If I am vaccinated against pandemic influenza, should I still get the seasonal influenza vaccination?

People who usually receive the seasonal influenza vaccine, according to national recommendations, should still take the vaccine this year.

The experience from the winter season in the southern hemisphere suggests that seasonal influenza will also circulate with the new influenza A(H1N1) virus in varying degrees. Without immunising, older people and individuals with chronic conditions, in particular, would be left vulnerable if seasonal influenza strains continue to circulate even in small amounts.

## Q20. If I have recently experienced flu-like symptoms, should I still get vaccinated against pandemic influenza (H1N1) 2009?

Yes, as the symptoms of influenza are similar to those caused by many other viruses. Since most people with influenza-like illnesses have not been tested for the 2009 pandemic influenza A(H1N1) virus, the majority will not know whether they have been infected with the new influenza virus or something else.

Therefore, if you were ill but do not know if you had influenza A(H1N1), you should get vaccinated. Vaccinating a person with some existing immunity to the pandemic virus will not be harmful.

*More information about 2009 pandemic influenza A(H1N1), as well as a set of more technical Q&A on vaccines and vaccination, can be found at the ECDC website: [www.ecdc.europa.eu](http://www.ecdc.europa.eu).*