

# Frequently asked questions (FAQs) about influenza vaccines during the 2009/2010 influenza season

## Pandemic and Seasonal influenza vaccines

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**The Health Service Executive has a 24 Hour Flu Information Line  
- Freephone 1800 94 11 00**

### ***What is the best way to prevent influenza?***

Vaccination is the best way to protect against influenza and its associated complications. Vaccination is particularly important for those at increased risk of influenza-related complications and those likely to transmit influenza to a person at high risk of influenza complications.

Click [here](#) for general information on influenza

### ***Since when have influenza vaccines been used?***

Following the identification of influenza virus (1933) and recognition that this virus was the cause of previous epidemics and pandemics, influenza vaccines were developed and tested. They were first used in the 1930s and 1940s in the United States. The first commercial vaccines were approved for use there in 1945. Now, millions of doses of influenza vaccines are used each year world-wide.

### ***What are the benefits of influenza vaccination?***

Vaccination is particularly effective in preventing severe disease, hospitalisation and death from influenza or associated complications- this is particularly important for those individuals most at risk of influenza related complications.

Vaccination of health care workers protects both the individual as well as the patients they care for.

### ***For which groups is seasonal influenza vaccine routinely recommended?***

There are [guidelines](#) set out by the Royal College of Physicians Immunisation Advisory Committee in Ireland. Two groups are targeted:

1. Any individual over the age of six months of age who is at risk of influenza related complications
2. Those at increased risk of transmitting influenza to a person who is at high risk of influenza related complications.

These two groups include:

- All persons aged 50 years and over
- Persons with chronic illness such as chronic heart disease, chronic lung disease, diabetes mellitus
- Persons who are Immunosuppressed due to disease or treatment, including asplenia or splenic dysfunction
- Children and teenagers on long-term aspirin therapy (because of the risk of Reye's Syndrome)
- Children with any condition (e.g. spinal cord injury, seizure disorder or other neuromuscular disorder) that can compromise respiratory function
- Residents of nursing homes, old people's homes and other long stay facilities where rapid spread is likely to follow introduction of infection
- Healthcare workers both for their own protection (as these are a group likely to come in contact with influenza during outbreaks) and for the protection of their patients
- Poultry workers, veterinary inspectors, agricultural workers, park rangers and those with likely contact with water fowl (as this puts them at risk of co-infection with avian influenza)
- Those likely to transmit influenza to a person at high risk of influenza complications (including household contacts and out-of-home caregivers)

### ***What influenza vaccines are available during the 2009/2010 season?***

In 2009 the HSE is providing two different vaccines; a seasonal flu vaccine to protect against the seasonal flu strains (developed before the pandemic) as well as a pandemic flu vaccine to protect specifically against the pandemic flu strain.

### ***What is the difference between the seasonal flu vaccine and the pandemic vaccine?***

**The seasonal influenza** tri-valent vaccine contains three different influenza virus strains; two A subtypes H3N2 and H1N1 (different from the pandemic strain) and one type B virus.

The **pandemic influenza monovalent vaccine** is derived from the strain that is causing the current pandemic, the Influenza A/California/7/2009 strain (subtype), which was identified in California earlier this year (2009).

### ***How effective is seasonal influenza vaccine?***

Currently available inactivated influenza vaccines provide 70%-90% protection against influenza in individuals less than 65 years of age. Protection in the elderly and those with weakened immune systems may be less, but even in these groups disease severity and deaths are markedly reduced in immunised individuals compared to non-immunised.

### ***How effective is the pandemic influenza vaccine?***

Data on vaccine efficacy for this particular vaccine is not available yet. However, based on previous experience with influenza vaccines and experience with mock-up vaccines (see below on mock-up vaccines), it is expected that the pandemic vaccine will provide similar levels of protection (70-90% in healthy adults under 65 years of age).

### ***Are there any safety concerns with regard to the pandemic influenza vaccine?***

Influenza vaccines have been used for more than 60 years and have an established record of safety in all age groups. The pandemic vaccines have passed safety tests in clinical trials.

Nonetheless, special safety issues will inevitably arise during a pandemic when vaccine is administered on a massive scale. For example, adverse events too rare to show up even in a large clinical trial may become apparent when very large numbers of people receive a pandemic vaccine.

Some adverse events will be coincidental – that is, associated in time with vaccine administration, yet not directly caused by the vaccine. Genuine adverse events directly caused by the vaccine may also occur, but cannot be predicted in advance. Given the safety record of seasonal vaccines, such events are expected to be rare.

All countries, including Ireland, administering pandemic vaccines will be conducting intensive monitoring for safety and efficacy.

Click [here](#) for further information from WHO.

Click [here](#) for link to Irish Medicines Board (IMB) the Irish agency responsible for monitoring vaccine safety in Ireland.

### ***How many injections of seasonal influenza vaccine are needed each season?***

One dose of inactivated influenza vaccine is recommended for anyone 9 years of age or older. Children less than 9 years are recommended two doses if receiving influenza vaccine for the first time.

### ***How many injections of pandemic influenza vaccine are needed this year?***

Two doses of the pandemic influenza vaccine, separated by at least three weeks, have been recommended by the manufacturers. However, preliminary data results from a few studies suggest that one dose may be sufficient to stimulate sufficient immunity in adults. Two doses are probably needed for children. Further studies are being conducted which will inform national decisions on the number of doses required in both adults and children.

### ***What strains are contained in the 2009/2010 trivalent seasonal influenza vaccine?***

The virus strains recommended by WHO for inclusion in the 2009/2010 seasonal flu vaccine in the northern hemisphere contain the following strains:

- an A/Brisbane/59/2007 (H1N1)-like virus;
- an A/Brisbane/10/2007 (H3N2)-like virus;
- a B/Brisbane/60/2008-like virus.

### ***What is meant by the term 'inactivated influenza vaccines'?***

Inactivated vaccines are vaccines in which the virus is killed. As a result, inactivated vaccines can never cause the viral illness.

There are three types of inactivated influenza vaccine; whole virus vaccines, split virus vaccines and subunit vaccines.

- In inactivated whole cell virus vaccines the whole virus is used in the vaccine (but the virus is killed)
- In split virus vaccines (also called subvirion), during the manufacturing process the virus membrane is dissolved or disrupted and purified surface antigens (haemagglutinin (HA) mainly) are extracted for use in the vaccines.
- In subunit vaccines, surface antigens have been further purified by removal of other viral components (influenza matrix protein and nucleoprotein).

Click [here](#) for general information from WHO on seasonal influenza vaccines.

***Both the pandemic influenza vaccine and the seasonal flu vaccine have H1N1 strains – are these strains different?***

**Yes-** there are substantial differences between the pandemic influenza A (H1N1) 2009 strain and the influenza A H1N1 strain in this year's seasonal influenza vaccine. Because of this, seasonal vaccine is unlikely to offer substantial protection against the pandemic strain. That is why individuals most at risk are recommended both vaccines. However, preliminary evidence from recently published Mexican research suggests some protection from the 2008/2009 trivalent inactivated vaccine against pandemic influenza A/H1N1 2009, particularly severe forms of the disease. Click [here](#) for more information on that research.

***Can the seasonal and pandemic flu vaccines be administered at the same time?***

**Yes-** they can be administered at the same time, but at separate sites.

***If someone is getting both seasonal and pandemic flu vaccines, but at different times, do they need to be separated by a specific time interval?***

**No-** the different vaccines may be given at any time before or after each other. But when two separate doses of the same vaccine are recommended it is necessary to have a minimum interval between administration. For the pandemic flu vaccine, when two doses are recommended, an interval of at least three weeks is required between doses.

***Are many companies producing pandemic flu vaccines?***

Around the world many vaccine companies are producing pandemic vaccines. Baxter Vaccines and Glaxo Smith Kline (GSK) are the vaccine companies that will be supplying Ireland with the pandemic vaccine. The vaccines differ from each other in manufacturing technique and vaccine components, but both have been developed to do the same thing - protect against the pandemic influenza A (H1N1) 2009 strain.

***Is there any difference between the two pandemic flu vaccines that will be used in Ireland?***

Both vaccines that will be used in Ireland have been developed to protect those who get the vaccine from the pandemic flu. The vaccines differ in their manufacturing process and some vaccine components but this is not expected to make any difference in the amount of protection they give. Both vaccines have been assessed and found to be safe and to stimulate immunity in people vaccinated with these vaccines.

**The Baxter vaccine is called Celvapan.** The vaccine is an inactivated whole virion (whole virus) influenza vaccine. The virus used in the vaccine was propagated in Vero cells (continuous cell line of mammalian origin). The vaccine does not contain egg protein. This vaccine does not contain an adjuvant. The vaccine complies with the WHO and EU decision for the pandemic vaccine

Click [here](#) for more information on Celvapan

**The GSK vaccine is called Pandemrix.** The vaccine is split virion (meaning that it contains the proteins from the surface of the virus but the other parts of the virus are removed). Even though the vaccine virus is inactivated it still contains the proteins that stimulate the immune system to protect an individual against infection. This vaccine contains an adjuvant called ASO3. ASO3 is composed of squalene, DL- $\alpha$ -tocopherol (more commonly known as vitamin E) and polysorbate 80. The vaccine complies with the WHO and EU decision for the pandemic vaccine

The vaccine contains a small amount of thiomersal as a preservative.

The virus is propagated in hens' eggs and the final product may contain residual hens' egg protein.

Click [here](#) for more information on Pandemrix.

***Are both pandemic vaccines (Celvapan and Pandemrix vaccines) authorised for use in Ireland?***

**Yes**, both vaccines have been authorised by the European Commission for the purpose of protecting against the Pandemic (H1N1) 2009 strain. National advisory bodies in each European country will recommend what groups should be prioritised for the vaccine.

***I have heard that the pandemic flu vaccines were developed based on 'mock-up vaccines'- what does this mean?***

A mock-up vaccine is a vaccine that was developed in advance of a pandemic occurring. The vaccine was developed to mimic the future pandemic influenza vaccine in terms of its composition, manufacturing and control. However, instead of the pandemic influenza virus strain (which was unknown before the outbreak), the mock-up vaccines contained a strain of the influenza virus that was specifically chosen because the population was immunologically naïve to it (i.e. has never been exposed to it).

Prior to the current pandemic the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) assessed the safety profile and vaccine efficacy of the two vaccines that will be used in Ireland (the GSK and the Baxter mock-up vaccines). Both vaccines were authorised under 'Exceptional Circumstances'.

Now that we are in an influenza pandemic situation, the pandemic influenza A(H1N1) 2009 strain is being used to manufacture the pandemic influenza vaccine. These vaccines (no longer called mock-up) are currently being tested in humans for safety and the ability to stimulate immunity against the pandemic influenza. Both these vaccines have now been authorised by the EMA.

Click [here](#) for links to the EMA website and information on pandemic vaccines.

### ***What influenza strain is contained in the pandemic vaccines?***

Both vaccines contain antigen to stimulate protection against the pandemic strain. The strain that has been used is called A/California/7/2009 (H1N1)v-like strain

### ***How do the pandemic vaccines work?***

Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Both vaccines contain a virus called A(H1N1)v that is causing the current pandemic. The virus has been inactivated (killed) so that it does not cause any disease.

When a person is given the vaccine, the immune system recognises the inactivated virus as 'foreign' and makes antibodies against it. The immune system will then be able to produce antibodies more quickly when it is exposed to the virus again. This helps to protect against the disease.

### ***How do the pandemic vaccines differ?***

#### **Celvapan**

- Celvapan is called a whole cell virion vaccine. It contains the influenza virus similar to the strain Pandemic (H1N1) 2009 that is causing the pandemic. It is inactivated (killed), meaning it cannot cause disease.
- The viruses used in Celvapan are grown in mammal cells ('vero cells'), unlike those in some other flu vaccines, which are grown in hen's eggs.
- Celvapan does not contain thiomersal or any adjuvant.

#### **Pandemrix**

- Pandemrix is called a split virus vaccine. It contains small amounts of haemagglutinins (proteins from the surface) of the virus called Pandemic (H1N1) 2009 that is causing the current pandemic. The virus has first been inactivated (killed) so that it does not cause any disease.
- The viruses used in Pandemrix are grown in hen's eggs.
- Pandemrix contains thiomersal (a preservative).
- To stimulate immunity in the person receiving the vaccine, an adjuvant is included in the vaccine (AS03). This adjuvant is a compound containing oil which has been shown to boost immunity provided by the vaccine.

### ***Are there any side effects with Celvapan?***

- The most common side effect with Celvapan (seen in more than 1 in 10 people vaccinated) is pain at the site of the injection. For the full list of all side effects reported with Celvapan, see the Package Leaflet on the EMEA website.

- **Contraindications:** Celvapan should not be given to people who have had an anaphylactic reaction (severe allergic reaction) to any of the components of the vaccine, or to any of the substances found at trace (very low) levels in the vaccine, such as formaldehyde, benzonase or sucrose.
- **Special warnings:** Caution is needed when administering the vaccine to a person with a known hypersensitivity (other than anaphylaxis) to any of the ingredients or trace residues (outlined above).

### ***Are there any side effects with Pandemrix?***

- The most common side effects with Pandemrix (seen with more than 1 in 10 people vaccinated) are headache, joint pain, muscle pain, reactions at the site of the injection (hardening, swelling, pain and redness), fever and tiredness. For the full list of all side effects reported with Pandemrix, see the Package Leaflet on the EMEA website.
- **Contraindications:** Pandemrix should not be given to people who have had an anaphylactic reaction (severe allergic reaction) to any of the components of the vaccine, or to any of the substances found at very low levels in the vaccine, such as egg or chicken protein, ovalbumin (a protein in egg white), formaldehyde, gentamicin sulphate (an antibiotic) and sodium deoxycholate.
- **Special warnings:** Caution is needed when administering the vaccine to a person with a known hypersensitivity (other than anaphylaxis) to the active substance or to any of the vaccine components (outlined above).

### ***I have a risk condition – should I get the pandemic flu vaccine as well as the seasonal flu vaccine when it becomes available?***

All individuals with medical risk conditions should get the seasonal flu vaccine and the pandemic flu vaccine when it becomes available for their group. The pandemic flu vaccine will be made available to the population in order of priority. The first priority group are the young (< 65 years of age) medical at risk group.

Every year seasonal influenza vaccine is recommended for individuals at increased risk of getting influenza complications, and for those people caring for people who may be at risk (health care workers and carers of people at risk). For more details on seasonal flu and who is recommended seasonal flu vaccine please click [here](#) .

Click [here](#) for more information on the 2009/2010 seasonal influenza vaccination campaign.

### ***Who will be offered the pandemic flu vaccine in Ireland?***

The National Immunisation Advisory Committee and National Pandemic Expert group have recommended that the vaccine should be administered to priority groups initially - those most

at risk of influenza complications and health care workers. This decision has been made based on both national and international evidence demonstrating that people < 65 years of age with chronic medical conditions are most at risk of severe disease. Health care workers will be offered the vaccine to protect themselves and their patients.

### ***What is thiomersal?***

Thiomersal is a preservative. It is also known as thimerosal, mercuriothiolate and sodium 2-ethylmercuriothio-benzoate. It is a mercury-containing compound used to prevent bacterial and fungal growth in some vaccines during storage, and especially during use of opened multi-dose vials. It has also been used during vaccine production both to inactivate certain organisms and toxins and to maintain a sterile production line. Thiomersal has been used since the 1930s in the manufacture of some vaccines and other medical products. Click [here](#) for more information on thiomersal and thiomersal safety.

### ***What are adjuvants?***

Adjuvants are agents included in some vaccines to boost the immune response to a vaccine. The word adjuvant comes from the Latin word *adjuvare*, meaning 'to help or aid'. Adjuvants have been used since the 1920s to improve the immune response to various vaccines.

Adjuvants can be natural or synthetic substances. Mineral salts such as alum adjuvants are the most commonly used world-wide. Other adjuvants widely used include those derived from bacterial substances, oil- emulsion, or synthetic substances.

One of the pandemic influenza vaccines (Pandemrix produced by GSK) contains an adjuvant called ASO3.

Click [here](#) for additional information from the World Health Organization (WHO) on adjuvants.

### ***What is the ASO3 adjuvant?***

**ASO3** is a novel oil-in-water adjuvant, has been used by GSK in recently developed vaccines. ASO3 is composed of squalene, DL- $\alpha$ -tocopherol (more commonly known as vitamin E) and polysorbate 80.

### ***What is squalene?***

Squalene is a naturally occurring substance found in plants, animals, and humans. It is manufactured in the liver of every human body and circulates in our bloodstream. It is also found in a variety of foods, cosmetics, over-the-counter medications, and health supplements. Squalene is commercially extracted from fish oil, and in particular shark liver oil. Squalene used in pharmaceutical products and vaccines is purified from this source.

Click [here](#) for further information on squalene from WHO

### ***Is there any link between Guillain-Barré Syndrome (GBS) and influenza vaccination?***

In 1976, in the United States, vaccination with the swine flu vaccine was associated with getting Guillain-Barré syndrome (GBS) - the vaccination programme was discontinued when it was identified. GBS is an illness characterized by fever, nerve damage, and muscle weakness and when it occurs it is often preceded by viral infections or a bacterial infection (campylobacter). Each year between 1-2 people per 100,000 people develop (GBS) in Ireland. Although several studies have been done to evaluate if other influenza vaccines used since 1976 were associated with GBS there is no clear association between GBS and influenza vaccines since then. If any risk does exist it is estimated at approximately one person out of 1 million vaccinated.

### ***Should individuals who have had GBS get the pandemic flu vaccines?***

The National Immunisation Advisory Committee (NIAC) has recommended the following

- Any individual who developed Guillain–Barré Syndrome (GBS) within 6 weeks of an influenza vaccine is not routinely recommended the vaccine.
- Any individual who has had GBS within the past year is advised to consider deferral of vaccination, only as a precaution.

The individual decision needs a risk benefit analysis with the patients' risks also taken into account.

Please visit the EMEA website for details on the pandemic flu vaccines

<http://www.emea.europa.eu/influenza/vaccines/home.htm>

Other resource sites

[www.immunisation.ie](http://www.immunisation.ie)

[www.swineflu.ie](http://www.swineflu.ie)