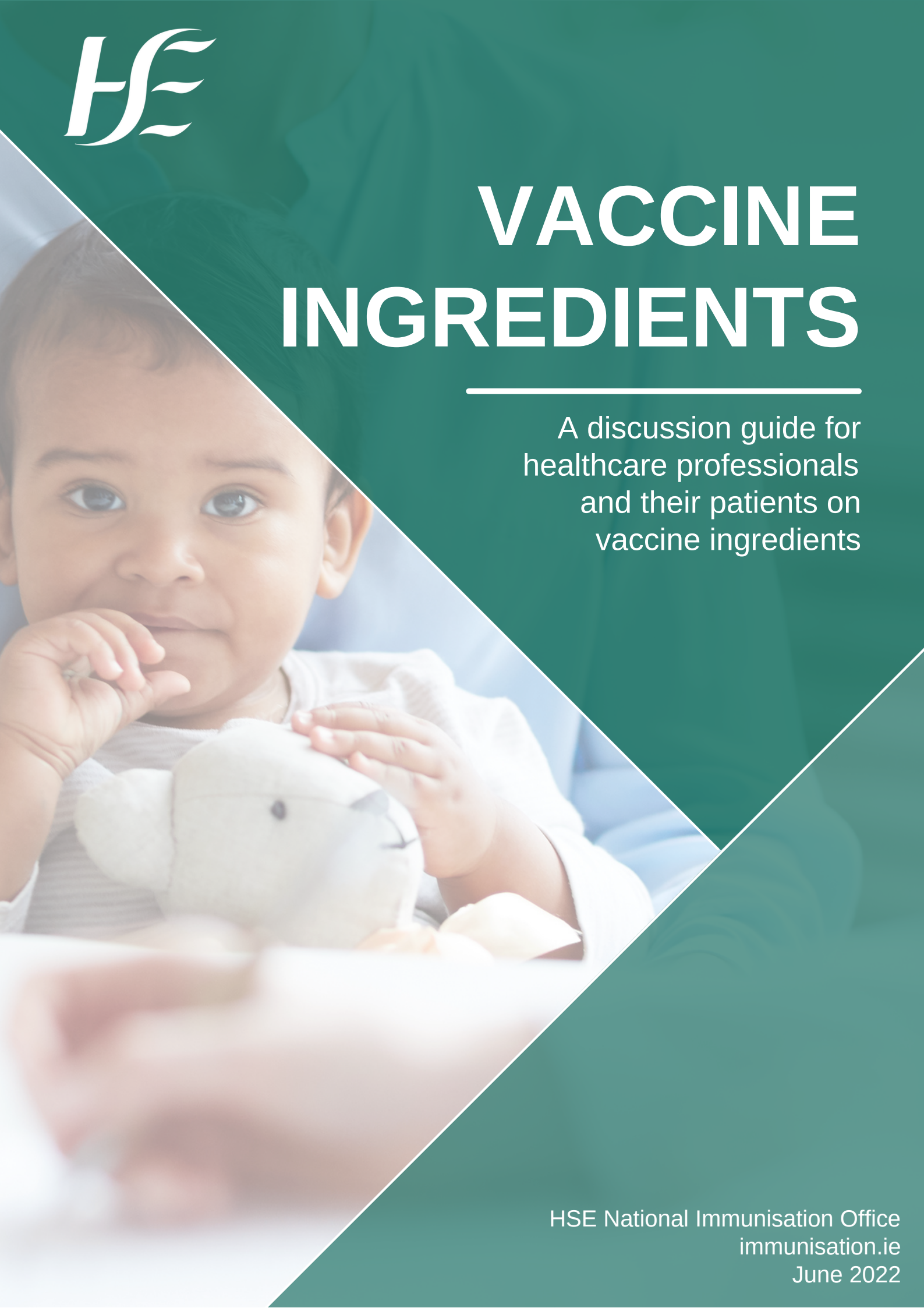

VACCINE INGREDIENTS

A discussion guide for healthcare professionals and their patients on vaccine ingredients

HSE National Immunisation Office
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VACCINE INGREDIENTS

What is in a vaccine?

Vaccines are made up of active ingredients and excipients. An excipient is an additive which is included in tiny amounts in a vaccine. Excipients have been used in vaccines and other medicines for many years and are known to be safe. Many of the excipients used in vaccines are naturally found in water, food and in our bodies.

Each vaccine contains the active ingredient and also has specific excipients. Each excipient serves a specific purpose:

- **The Antigen:** is the “active ingredient” and it provides immunity.
- **An Adjuvant:** found in some vaccines to give us a stronger immune response and may mean that a lower dose of antigen can be used. An example of an adjuvant is aluminium salts found in the 6 in 1 vaccine.
- **Stabilizers:** keeps the vaccine stable and prevent it from breaking into its different parts, an example of a stabiliser is gelatin.
- **Manufacturing by-products:** tiny amounts may be found in the vaccine after the manufacturing process. For example:
  - **Cell culture materials:** an example of this is egg protein as the antigen is grown in egg protein. (you will find more information about this below)
  - **Inactivating ingredients:** an example of this is formaldehyde which is used to kill or inactivate viruses (you will find more information about this below)
  - **Antibiotics:** an example of this is neomycin which is used to prevent contamination by bacteria. (you will find more information about this below)
- **Preservatives:** used in some vaccines that come in vials that contain more than 1 dose. Preservatives keep the vaccine safe and help them to last longer. Preservatives are not used in the vaccines given as part of the national immunisation programme in Ireland. None of the multi dose vials of COVID-19 vaccines used in Ireland contain preservatives.

Where can I find a list of the ingredients of a vaccine?

The list of ingredients or excipients for each vaccine can be found in the official licensed documentation for each vaccine. This is called the Summary of Product Characteristics (also called the SmPC). The list of excipients are usually listed in Section 6. The SmPC documents are available from the Health Products Regulatory Authority (HPRA) and European Medicines Agency (EMA).

More information
Visit **www.ema.europa.eu** (search under product information)
Find official licensed documentation on the Health Products Regulatory Authority (HPRA) website **www.hpra.ie**

This leaflet gives you information about vaccine ingredients

- Aluminium
- Antibiotics
- Eggs/ovalbumin
- Formaldehyde
- Gelatin
- Polysorbate 80
- Thiomerosal

There is also some information about cell lines. These are not ingredients found in vaccines but are used in the manufacture of some vaccines.

Aluminium

Aluminium is found in tiny amounts in the following vaccines used in Ireland.

- 6-in-1 vaccine: Infanrix Hexa (0.82 milligrams)
- Prevenar 13 (0.125 milligrams)
- MenB vaccine: Bexsero (0.5 milligrams)

Aluminium is an adjuvant. Aluminium is added to vaccines to increase the immune response to the vaccine.

Aluminium is the most abundant element on earth and is in the air we breathe, the water we drink and the food we eat. It is also found in medication such as antacids.

The biggest source of aluminium is in our diet (e.g. in fruits and vegetables, flour, cereals, nuts, honey, dairy products and baby formula). It has been used in vaccines for more than 80 years. Vaccines that contain aluminium have been given to more than 1 billion people.

Children normally consume from 0.7 - 2.3 mg/kg aluminium per week.
Infant formula contains 0.225 milligrams of aluminium/litre.
(A milligram is a tiny amount; there are 5,000 milligrams in a teaspoon measure).

Studies show that the level of aluminium in the blood does not change after getting a vaccine that contains an aluminium adjuvant.

Monitoring the safety of vaccines during the last 80 years has shown us that aluminium adjuvants are associated with local reactions only. Very rarely aluminium adjuvants may cause small itchy lumps (also called granulomas) to develop at the injection site, which normally get better on their own within a few months.

Aluminium in vaccines is not associated with any chronic medical illness.

Antibiotics

Traces of antibiotics are used in the following vaccines in Ireland:

- **MMR:** Neomycin
- **Infanrix hexa (6-in-1):** Neomycin + polymixins

Antibiotics like neomycin are used to prevent bacterial contamination during manufacture of the vaccine. The antibiotic is almost entirely removed during the vaccine purification process, but trace quantities may remain in some vaccines. These traces of antibiotics are unlikely to cause a severe allergic reaction. Antibiotics (e.g. penicillin and cephalosporins) that are most likely to cause severe allergic reactions are not used in the manufacture of vaccines.

Egg proteins and ovalbumin

Egg proteins and ovalbumin are used in the following vaccines in Ireland

- Inactivated influenza vaccines
- Live attenuated influenza vaccine (Fluenz Tetra)

During the manufacturing of the vaccine, influenza viruses are grown and incubated in eggs. The flu viruses are harvested and inactivated so that they cannot cause infection and these viruses are then used to make the vaccine.

Traces or very small quantities of egg proteins may remain in influenza vaccines as a result. Most people with egg allergy can receive these vaccines as the amount of egg protein in the vaccine is too small to cause any concern.

Formaldehyde

Formaldehyde can be found in tiny amounts in the 6-in-1 vaccine: Infanrix Hexa.

At birth an infant’s body naturally contains from 50 to 70 times more formaldehyde than found in one vaccine. As a child grows the amount of formaldehyde naturally found in their body also increases.

Formaldehyde in very small amounts is used to inactivate toxins from bacteria or kill viruses in the vaccine. Tiny amounts of formaldehyde can remain in the vaccine after manufacture. The body gets rid of the minuscule amounts of formaldehyde in any vaccine and it is not stored in the body.

Gelatin

Gelatin is used in the following vaccines used in Ireland.

- MMR (MMRVAXPRO) but not MMR (Priorix) vaccine
- The nasal flu vaccine (Live Attenuated Influenza Vaccine / Fluenz Tetra)

Gelatin is used as a preservative and a stabiliser. The gelatin in vaccines is purified and broken down by water. It is different from gelatin used in foods. Gelatin is safe to use in vaccines. Very rarely, in about one in 1 million children, gelatin may cause a severe allergic reaction (anaphylaxis).

People may also be have concerns because of religious reasons as gelatin is made from animal products (pork).

It may be helpful to know that The Irish Council of Imams has issued a statement to say that vaccination with vaccines containing porcine gelatin is permissible.

More information
Read the Irish Council of Imams statement **here**.

Scholars of the Islamic Organization for Medical Sciences have also determined that it is permitted for observers of Muslim faith to receive vaccines.

More information
Read 2001 letter from the World Health Organization Regional Office for the Eastern Mediterranean **here**.

Rabbi Abraham Adler, from the Kashrus and Medicines Information Service in the United Kingdom has advised:

“It should be noted that according to Jewish laws, there is no problem with porcine or other animal derived ingredients in non-oral products. This includes vaccines, injections, suppositories, creams and ointments”.

More information
Read more **here**.

Polysorbate 80

Polysorbate 80 is used in the following vaccines in Ireland

- Pneumococcal conjugate vaccine (PCV) Prevenar
- HPV vaccine Gardasil 9
- Virus vector COVID-19 vaccines
- Novavax COVID-19 vaccine

Polysorbate 80 is a common food additive e.g. in ice-cream and it is used in some vaccines as an emulsifier (to hold other ingredients together). Compared with its use in foods, there is very little polysorbate 80 in vaccines.

Thiomerosal

Some parents may ask about mercury in vaccines. Ethylmercury (thiomersal or thimerosol) is confused with methylmercury but both are chemically very different. Ethylmercury (thiomersal) was used as a preservative in some multi-dose vaccines. There is no thiomersal in any of the childhood vaccines used in the Irish Primary Immunisation programmes or any other vaccines used in Ireland. Methylmercury has never been used in vaccines, but it is present in fish and shellfish.

Summary table of types of vaccine ingredients

Ingredient	Example	Purpose	Other sources
Adjuvants	Aluminium salts	Enhances the immune response to the vaccine.	From drinking water, infant formula, or use of health products such as antacids, buffered aspirin, and antiperspirants
Stabilizers	Gelatin	Maintains effectiveness of the vaccine after manufacture.	From eating food and resides in body naturally
Manufacturing by-products	Formaldehyde	To kill viruses or inactivate toxins during the manufacturing process.	Resides in body naturally (more contained in the body than in vaccines).
Manufacturing by-products	Neomycin	Prevents contamination during vaccine manufacturing.	Antibiotics
Manufacturing by-products	Egg protein (influenza vaccines)	To grow the virus make the vaccine.	Foods containing eggs.

Vaccine manufacturing using foetal cell lines

Some people may have questions about foetal cell lines in vaccines. There are no foetal cells in any vaccine. In order to produce a vaccine to protect against a viral disease, such as rubella (German measles), the virus is grown in living cells. The best way to achieve this is using cell lines, i.e. cells which can be multiplied for many generations.

In the 1960's scientists derived cell lines from the tissue of a foetus (following an elective termination of pregnancy) in order to establish cell lines most suitable for vaccine production. These same foetal cells have continued to grow in the laboratory since then and are used to make vaccines today. No further sources of foetal cells are needed to make vaccines. Foetal cell lines are not contained in the vaccines themselves.

There are some vaccines used in Ireland that are manufactured using cell lines

- MMR vaccine (the Rubella component of the vaccine) Priorix and MMRVaxpro
- Viral vector COVID-19 vaccines (Vaxzevria® (AstraZeneca) and COVID-19 Vaccine Janssen (Johnson and Johnson)).

Cell lines are used in the manufacturing of these vaccines to grow the viruses that are then deactivated or rendered harmless to make the vaccine. Many years ago, these cell lines originated from elective termination of pregnancies (e.g. for MMR, from the 1960s). These same foetal cells have continued to grow in the laboratory since then and are used to make vaccines today. No further sources of foetal cells are needed to make vaccines. Foetal cell lines are not contained in vaccines themselves.

The Irish Catholic Bishops' Conference has issued a statement that if a more ethically acceptable alternative is not readily available to them, it is morally permissible for Catholics to accept a vaccine that involves the use of foetal cell-lines.

More information
Read statement **here**.

Further information and resources

If you are interested in reading more information visit:

- Children's Hospital of Philadelphia, Vaccine Education Centre, click **here**.
- University of Oxford, Vaccine Knowledge Project, click **here**.
- Resources from the Centers for Disease Control and Prevention, click **here**.
- Making the Vaccine Decision: Addressing Common Concerns, click **here**.