

# COVID-19 VACCINE BULLETIN 43

Welcome to Bulletin 43 from the HSE National Immunisation Office which highlights changes in clinical guidance for the COVID-19 vaccination programme.

## COVID-19 vaccines for people with immunocompromise associated with a sub-optimal response to vaccination

The RCPI National Immunisation Advisory Committee (NIAC) have recommended that people with immunocompromise due to disease or treatment at the time of vaccination, should receive the following COVID-19 vaccines:

- A primary course of a COVID-19 vaccine e.g. 2 doses of Comirnaty® or Spikevax®
  - An additional dose of COVID-19 vaccine if aged 5 years and older (to extend the primary vaccination course)
- AND
- If they are aged 16 years and older, a booster dose of a COVID-19 vaccine

Conditions associated with immunocompromised are outlined below:

Underlying condition	Very high risk	High risk
Cancer	<ul style="list-style-type: none"> <li>- Receiving or within 6 weeks of receiving systemic cytotoxic chemotherapy, targeted therapy, monoclonal antibodies or immunotherapies</li> <li>- Receiving treatment or pending treatment for a haematological cancer</li> <li>- Undergoing or within 6 weeks of surgery or radical radiotherapy for lung or head and neck cancer</li> <li>- Advanced/ metastatic cancer</li> </ul>	Haematological <sup>1</sup> - within 5 years of treatment
Chronic kidney disease	On dialysis, or eGFR <15ml/min	eGFR <30ml/min
Immunocompromise due to disease or treatment	<p><b>Severe e.g. Transplantation:</b></p> <ul style="list-style-type: none"> <li>- Listed for solid organ or haematopoietic stem cell transplant (HSCT)</li> <li>- Post solid organ transplant at any time</li> <li>- Post HSCT within 12 months</li> </ul> <p><b>Genetic diseases:</b></p> <ul style="list-style-type: none"> <li>- APECED2</li> <li>- Inborn errors in the interferon pathway</li> <li>- Some B and T cell deficiencies</li> </ul> <p><b>Treatment e.g., -</b></p> <ul style="list-style-type: none"> <li>- Cyclophosphamide, Rituximab, Alemtuzumab, Cladribine or Ocrelizumab in the last 6 months</li> </ul>	Other e.g. High dose systemic steroids <sup>2</sup> HIV, not on treatment or CD4 count

<sup>1</sup> Includes e.g., leukaemia, lymphomas, blood dyscrasias or other malignant neoplasms affecting the bone marrow or lymphatic systems

<sup>2</sup> The following doses of prednisolone (or equivalent dose of other glucocorticoid) are likely to be immunosuppressive:

- Adults and children ≥10kg: ≥40mg/day for more than 1 week, or ≥20mg/day for 2 weeks or longer
- Children <10 kg: 2mg/kg/day for 2 weeks or longer

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## COVID-19 vaccines for people with immunocompromise associated with a sub-optimal response to vaccination (continued from page 1)

### Timing of the additional dose

The **additional dose** is recommended:

- 28 days after the primary course for children aged 5-11 years
- 2 months after the primary course for people aged 12 years and older

If someone has had breakthrough COVID-19 infection since their last dose they should wait at least 3 months before receiving their additional dose.

### Timing of the booster dose

A **booster dose** is recommended only for people aged 16 years and older at least 3 months after an additional dose. If someone has had breakthrough COVID-19 infection since their additional dose, they should wait at least 3 months before receiving their booster dose.

Refer to the Quick Reference Guide for COVID-19 Vaccines for the most up to date interval recommendations:

[See Quick Reference Guide](#)

Refer to the COVID-19 Chapter from the Immunisation Guidelines for Ireland from NIAC for additional information:

[See NIAC chapter](#)

Read the NIAC Advice to CMO:

[Read more here](#)

**Quick Reference Guide for COVID-19 Vaccines**

This is a summary of information. The full clinical guidance and other questions should be consulted at <https://www.hse.ie/eng/immunisation>

Age	Primary course (2 doses)	Additional dose (1 dose)	Booster dose (1 dose)
5-11 years	28 days	28 days	Not applicable
12-15 years	28 days	28 days	Not applicable
16-17 years	28 days	28 days	3 months
18 years and older	28 days	28 days	3 months

*Note: For people aged 16 years and older, an additional dose is recommended for people aged 16 years and older.*

### Frequently asked questions



**Why is an additional dose recommended for people with immunocompromise due to disease or treatment?**

Data indicates that those with severe immunocompromise do not have adequate protection following a primary COVID-19 vaccine course. There is evidence that protection can be enhanced by an additional dose.

[Read NIAC advice here](#)



**What's the difference between the additional dose and a booster dose for people who are immunocompromised?**



The additional dose of COVID-19 vaccine is an extended primary vaccination course. Data indicates that those with severe immunocompromise do not have adequate protection following a primary COVID-19 vaccine course. There is evidence that protection can be enhanced by an additional dose. This additional dose is part of the primary vaccination course (an extended primary vaccination course).

The booster dose is required to enhance protection against severe disease because of waning immunity and reduced protection against the Omicron variant strain after primary vaccination.

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## Comirnaty® (Pfizer BioNTech)

There are 2 Comirnaty® (Pfizer BioNTech) vaccines available in Ireland.

Appearance of vial	Name of vaccine	Licensed for	Available from
	Comirnaty® (Pfizer BioNTech)	12 years and older <b>only</b>	HSE vaccination clinics <b>and</b> participating GP practices <b>and</b> participating Pharmacies
	Comirnaty® (10 micrograms/dose concentrate) for children aged 5-11	5-11 year olds <b>only</b>	HSE vaccination clinics <u>only</u>

**Children aged 5-11 years should only receive the Comirnaty® 10 microgram/dose formulation (orange cap). This vaccine is only available from HSE vaccination clinics. It is NOT AVAILABLE IN GENERAL PRACTICE OR PHARMACIES. DO NOT administer the vaccine for those 12 years and older (purple cap) to children aged 5-11 years.**

## How can you ensure the right formulation of Comirnaty® is given to the appropriate age group?

The following checks are routinely recommended before COVID-19 vaccination:

- ✓ Is this a primary course, an additional dose for a person who is immunocompromised?
- ✓ Is this a booster dose?
- ✓ What is the age of the person?
- ✓ Is vaccination recommended for this age group?
- ✓ What is the recommended vaccine for this age-group?
- ✓ What is the recommended dose?
- ✓ What is the recommended interval since the last dose?
- ✓ Has this person had COVID-19 infection? What is the recommended interval since COVID-19 infection?



**Refer to the Comirnaty® (Pfizer/BioNTech) Vaccine Formulations Guide before administering a Comirnaty® vaccine (see table on next page)**

[See more here](#)

**Read frequently asked questions for vaccinators on Comirnaty 10 microgram/dose concentrate formulation for children aged 5-11**

[Read FAQs here](#)

**See also clinical guidance for vaccinators**

[Read more here](#)

# Comirnaty® (Pfizer/BioNTech) Vaccine Formulations Guide

A Quick Reference Guide to dosing, dilution, and storage information.

(Refer to [www.immunisation.ie](http://www.immunisation.ie) and Summary of Product Characteristics for full guidance)



Formulation	12 years and older Dilute to use	5-11 year olds Dilute to use
Vial	Multi-dose Vial	Multi-dose Vial
Vial Cap Colour	<u>Purple Plastic Cap</u>	<u>Orange Plastic Cap</u>
Dosage	30 mcg (Thirty microgram)	10 mcg (Ten microgram)
Dilution	Dilution required	Dilution required
Amount of Diluent Needed Per Vial	1.8ml	1.3ml
Vial Size	2ml	2ml
Doses per Vial	6 doses per vial (after dilution)	10 doses per vial (after dilution)
Injection Volume per Dose	0.3ml	0.2ml
Fill Volume per Vial	0.45ml	1.3ml
Refrigeration Storage Time (+2°C to +8°C)	1 month (within shelf life)	Up to 10 Weeks (within shelf life)
Room Temperature (≥8°C to +30°C)	Up to 2 hours prior to dilution	Up to 12 hours prior to dilution
After Dilution (+2°C to +30°C)	Discard by 6 hours after dilution	Discard by 12 hours after Dilution
Package Size	195 vials	10 vials

For any questions regarding deviation in practice from that recommended in the guidance please contact the National Immunisation Office .

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## Comirnaty® (Pfizer BioNTech) (continued from page 5)

### Children with additional needs

Some children getting their COVID-19 vaccine may need:

- more time at their appointment
- a quieter appointment time with fewer people

If a child has additional needs, parents and guardians are advised to call HSELive to arrange one of these options.

Freephone: [1800 700 700](tel:1800700700)

### Shelf-life of Comirnaty®

Since 10 September 2021 a new shelf-life at Ultra-Low Temperature storage conditions is approved in the European Union (EU) for Comirnaty (purple cap). The Product Information was updated with the new shelf-life for the frozen vial. The shelf-life was extended from 6 months to 9 months. The storage conditions remain unchanged (-90°C to -60°C).

The extension in the Expiry Date on the vial and on the printed paperwork from NCCS is solely due to an extension in shelf-life in Ultra-Low Temperature freezer.

Comirnaty (purple cap) SmPC states Thawed vial **1 month at 2°C to 8°C** within the 9-month shelf life.

The **Use Before** has not changed. There was no extension to the **Use Before** date which is the applicable date for storage of the vials at +2°C to +8°C.

The vials that you have in stock will have a printed expiry date but this is only applicable if stored in ULT freezers. While this date has been extended by 3 months, this is not applicable to the **Use Before** recommended for the thawed vials.

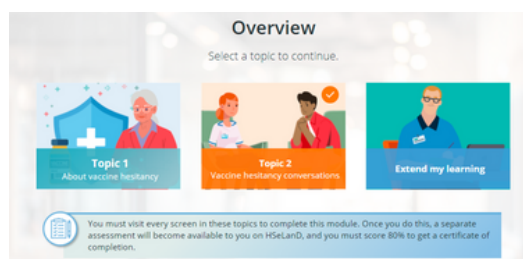
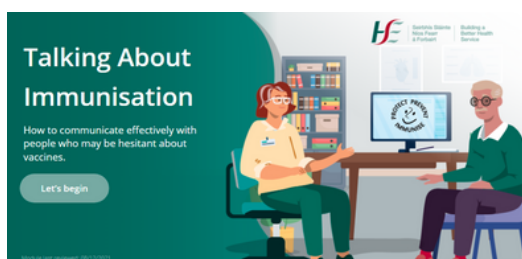
**Please note:** any expired vaccines, including COVID-19 vaccines must be given to the NCCS driver at your next scheduled delivery so they can be returned to the NCCS and should not be disposed of locally.

[See GP Vaccine Return form here](#)

## New e-learning module on HSeLand Communicating with people who are hesitant about vaccines

We have developed a new e-learning module to support you in communicating with people who may be hesitant about vaccines.

The e-learning module is called **“Talking about Immunisation”** and is available from [www.hseland.ie](http://www.hseland.ie)





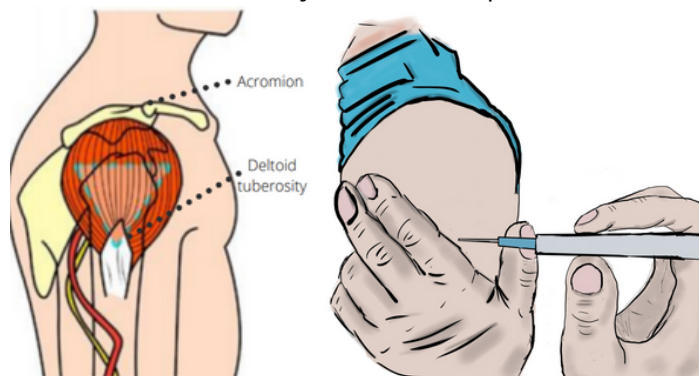
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## Reminder about IM Injection Technique

All vaccinators must be competent in IM injection technique which includes correct landmarking of the injection site to ensure the vaccine is given in the correct area of the Deltoid muscle.



Below is a reminder of IM injection technique. **Note: COVID-19 vaccine should be given IM only.**



Summary sheet outlining  
the IM injection technique

[Click here](#)

When vaccinating children aged 5-15 years, the same intramuscular injection technique should be followed as for adults.

The injection site must be landmarked correctly to avoid injury associated with administration of the vaccine in the wrong site.

Several supporting documents, training videos and modules are available on correct IM injection technique.



Watch Training video

[Click here](#)

Training is also included in HSELand modules

[Click here](#)

More IM Injection Technique materials

[Click here](#)

**Please contact your clinical lead or line manager if you need additional support or training.**

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## Comirnaty® (10 micrograms/dose concentrate) for children aged 5-11

### Clinical Trial and Real World Data

We have developed a new webpage and will be adding to it as additional information becomes available:

[Click here](#)

## Frequently asked questions



### Who is recommended to receive a booster dose of COVID-19 vaccine?

The RCPI National Immunisation Advisory Committee (NIAC) recommends a booster dose of COVID-19 vaccine for people aged 16 years and older who have an interval of:

- at least 3 months since their last dose of COVID-19 vaccine
- OR
- at least 3 months since they tested positive for COVID-19



### Can a booster dose of COVID-19 vaccine be given to 12-15 year olds?

No. The NIAC have not recommended a booster dose of COVID-19 vaccine for 12-15 year olds.



### If someone has a contraindication or a precaution to an mRNA vaccine, what are their options for vaccination (primary vaccination, additional dose, and booster)?

For individuals who have a contraindication or precaution to an mRNA vaccine (including pregnant women), consideration can be given to a viral vector vaccine. COVID-19 vaccine Janssen is available through HSE vaccination clinics. Note that COVID-19 vaccine Janssen is licensed and recommended from the age of 18 years only.



### Do you need to leave an interval between COVID-19 infection and vaccination with a non-COVID-19 vaccine (e.g. the vaccines given in the schools immunisation programme)?

After COVID-19 infection, vaccines can be administered from when the person finishes the recommended period of isolation. The exception to this is COVID-19 vaccines (information about intervals between COVID-19 disease and a COVID-19 vaccine is available from the [Quick Reference Guide](#)).

If the vaccinee has an acute febrile illness, the vaccination should be delayed until recovery.

[Download Quick Reference Guide](#)

## Stay up to date with the latest advice



Read COVID-19 Frequently Asked Questions for Health Professionals

[See more here](#)

Complete the e-learning Programme on HSELand

[See more here](#)

See also clinical guidance for vaccinators

[Read more here](#)

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## Pneumococcal polysaccharide vaccine

Pneumococcal infection is responsible for 50% of community acquired pneumonia and bacteraemia where the overall mortality rate can be as high as 25%. It can also cause a wide variety of other infections including sinusitis, osteomyelitis, bronchitis and otitis media.

Over the years streptococcus pneumoniae has become resistant to many medications making the treatment of pneumococcal infections much more difficult. Prevention of disease through vaccination is now more important than ever.

### **Pneumococcal polysaccharide vaccine (PPV):**

PPV contains purified polysaccharide from 23 of the most common capsular types of streptococcus pneumoniae. This vaccine is recommended for those aged 65 years and older and "at-risk" adults and children 2 years of age and older.

### **Those with the following conditions are at higher risk of invasive pneumococcal disease and should be vaccinated with PPV23:**

- Everybody aged 65 years and over and
- Everybody aged 2 years and over with;
  - Diabetes
  - Chronic lung, heart, liver, or kidney disease
  - Cancer patients under hospital supervision
  - Chronic neurological disease
  - Children aged 2 to less than 5 years of age with a history of invasive pneumococcal disease
  - Coeliac disease
  - Down Syndrome
  - Cochlear implants or are about to get cochlear implants
  - Immune deficiency because of a disease or treatment, including cancer patients
  - HIV infection
  - Absent spleen or a non-functioning spleen
  - CSF leaks, either congenital or complicating skull fractures or neurosurgery
  - Intracranial shunt

PPV23 vaccination is **not** recommended for healthy children and adults as they are at low risk of pneumococcal disease.

## How many doses of PPV are required?

We have developed an algorithm to guide you in determining the numbers of doses required:

[See more here](#)

### **Aged 65 years and older**

**One** PPV23 pneumococcal vaccine is recommended for anyone aged 65 years or older irrespective of immune status.

### **Aged less than 65 years of age**

- **One dose is required for those at risk**
- **A booster** vaccination is recommended 5 years after the first vaccination for some individuals: those whose antibody levels are likely to decline rapidly e.g. those who have asplenia, hyposplenism, immunosuppression including HIV infection, chronic renal disease, nephrotic syndrome or renal transplant.
- Patients with these conditions who received their dose of PPV23 at less than 65 years of age require one further PPV23 booster at or after 65 years of age (five years after the previous dose)

If PPV23 was given during chemotherapy or radiotherapy a further dose vaccine is recommended 3 months after treatment.

PPV is available to order for GP practices  
from the National Cold Chain Service

[Order PPV](#)



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## Seasonal Influenza vaccine

**Seasonal influenza vaccination is the best way to protect individuals at risk of severe influenza, and prevent the need for hospital care and treatment in ICU.**

It is especially important this season, given the burden on health services, that people at risk of the complications of influenza are protected.

The vaccine and its administrations are free for at-risk groups through GPs and Pharmacies.



[Click to find a pharmacy offering flu vaccines](#)



**Reminder: This influenza season, the flu vaccination programme has been extended to include people aged 50-64.**

**Flu vaccine is also strongly recommended for healthcare workers, to protect them and their vulnerable patients against influenza.**

**IF YOU ARE 50 OR OVER  
YOU CAN NOW GET  
THE FREE FLU VACCINE**

If you are **50 or older**, **pregnant**, **have a long term medical condition** or are a **health care worker** you can get your free flu vaccine through participating GPs and Pharmacies.

[www.hse.ie/flu](http://www.hse.ie/flu)

Scan the QR code to find a pharmacy giving flu vaccines near you



**Protect yourself.  
Protect others.**

[Click for more information](#)

[Click to print poster](#)

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## Website

Visit our website [www.immunisation.ie](http://www.immunisation.ie) regularly for the most up to date information to support vaccinators and health professionals responding to queries.

Our dedicated COVID-19 Vaccination section contains

- Information from the National Immunisation Advisory Committee
- Clinical guidelines
- COVID-19 vaccine studies
- IM injection technique reminders
- Dedicated pages for the licensed COVID-19 vaccines

[Visit here](#)

## HSeLanD COVID-19 Vaccination Training Programme

We have developed a HSeLanD training programme for the **Children 5-11 COVID-19 vaccination programme**.

You can access updates to the National Immunisation Office COVID-19 Vaccination Training Programme for Children 5 to 11, Pfizer, Moderna, and Janssen vaccine through your HSeLanD account.

[Visit HSeLanD](#)

We would encourage you to log in and complete the updated content in each programme to refresh your knowledge and ensure you are up to date with your COVID-19 Vaccination Training.

If you have any issues with the platform please contact HSeLanD directly.

[Contact HSeLanD](#)

## Do you have queries?

Clinical queries from healthcare professionals can be directed to our HSE email address.

[Send your query](#)

Should vaccines be exposed to temperatures outside of parameters please contact the National Immunisation Office pharmacists immediately. Contacts include:

- Mariangela Toma: mobile 087 7575679
- Cliona Kiersey: mobile 087 9915452
- Achal Gupta: mobile 087 4064810

**The National Immunisation Office is not involved in the allocation or delivery of COVID-19 Vaccines.**

**Queries that are not clinical or technical cannot be answered by the National Immunisation Office**

Read about the role of the National Immunisation Office in supporting the COVID-19 vaccination programme on our [website](#).

Recommendations about COVID-19 vaccine are changing as more information becomes available so please visit our [website](#) for the most up to date information.