

# COVID-19 VACCINE BULLETIN 42

Welcome to Bulletin 42 from the HSE National Immunisation Office which highlights changes in clinical guidance for the COVID-19 vaccination programme.

## Booster or additional dose vaccination after breakthrough COVID-19 infection

The National immunisation Advisory Committee has updated the definition of COVID-19 breakthrough infection, to include individuals who have symptoms and a positive antigen test.

### The advice is as follows:

If a person in a group for whom an additional or booster dose is recommended has had laboratory confirmed COVID-19 infection or a positive COVID-19 antigen test with symptoms after a completed primary vaccine course (i.e., a breakthrough infection), the additional or booster dose should be delayed for at least three months after the COVID-19 infection was diagnosed.

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## Checking a person's age before vaccination

As the COVID-19 vaccination programme for children continues, we want to remind you of the importance of always checking the person's age/date of birth before vaccinating them, to ensure the recommended vaccine is administered.

The Comirnaty® vaccine for children aged 5-11 years contains a different dose of vaccine compared to the formulation for older age groups.

The vaccine for children aged 5-11 years is only available through vaccination clinics. GPs and Pharmacists do not have supplies of this vaccine.

Different mRNA vaccines are recommended for different age groups. Those aged less than 30 years should receive Comirnaty®, and not Spikevax®. Those aged 30 and older may receive Spikevax® or Comirnaty®.

### Always check the person's age/date of birth before vaccinating.

Quick Reference Guide to COVID-19 Vaccines				
This is a summary of information, the full clinical guidance and NIAC guidelines should be consulted at <a href="http://www.immunisation.ie">www.immunisation.ie</a>				
Vaccine	Comirnaty® Children's formulation	Comirnaty® (Pfizer BioNTech)	Spikevax® (Moderna)	COVID-19 Vaccine Janssen® (only if cannot receive an mRNA vaccine)
Primary vaccination course (recommended for people aged 5 years and older)				
Age	5-11 years	≥12 years	≥30 years	≥18 years
Dose	0.2mls	0.3mls	0.5mls	0.5mls
Interval between dose 1 and dose 2	21 days	21-28 days	28 days	Not applicable
Timing since COVID-19 infection	4 weeks	4 weeks	4 weeks	4 weeks
Additional dose for immunocompromised (recommended for people aged 5 years and older)				
Age	5-11 years	≥12 years	≥30 years	≥18 years
Dose	0.2mls	0.3mls	0.5mls	0.5mls
Interval since finishing primary vaccination course	28 days	2 months	2 months	2 months
Timing since COVID-19 breakthrough infection	At least 3 months	At least 3 months	At least 3 months	At least 3 months
Booster dose for eligible groups*				
Age	Not recommended	≥16 years	≥30 years	≥18 years
Dose	-	0.3mls	0.25mls	0.5mls
Interval since finishing primary vaccination course	-	At least 3 months	At least 3 months	At least 3 months
Timing since COVID-19 breakthrough infection	-	At least 3 months	At least 3 months	At least 3 months

\*Recommended for people aged 16 years and older, including pregnant women (see [Chapter 5a](#), Immunisation Guidelines).  
For any questions regarding deviation in practice from that recommended in the guidance please contact the [National Immunisation Office](#).

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[See Quick Reference Guide](#)

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## Booster doses for people aged 16 years and older who are immunocompromised and have received an additional dose

### What are the recommendations?

Immunocompromised individuals aged 16 years and older, who have received an additional vaccine dose to complete their primary vaccination course, are recommended a booster dose of an mRNA vaccine at least 3 months after their last dose.

### What about people aged less than 16 years who are immunocompromised?

People aged 5-15 years who are immunocompromised, are recommended an additional dose of vaccine to complete their primary vaccination course. They are not recommended a booster dose at this time.

### What vaccine should be used as the booster dose?

The vaccines recommended are:

- **People aged 16-29 years:** Comirnaty®
- **People aged 30 years and older:** Comirnaty® or Spikevax®. Note that the dose of Spikevax® for the booster dose is 0.25mls

These recommendations apply regardless of the vaccines received for the primary course or the additional dose.

### What is the recommended timing of the booster dose?

The booster dose should be given at least 3 months after the last (the additional) dose. In exceptional circumstances e.g. starting chemotherapy, the booster dose can be given from 2 months after the last (the additional) dose.

### What is someone has had a breakthrough COVID-19 infection?

If a person has had laboratory confirmed COVID-19 infection, or a positive COVID-19 antigen test with symptoms after they received the additional dose, the booster dose should be delayed for at least three months after the COVID-19 infection was diagnosed.

## Children aged 12-15 years and booster doses

We have had several enquires as to whether booster doses are recommended for children aged 12-15 years. The National immunisation Advisory Committee has not recommended booster doses for this age group. Booster doses for this age group are also not licensed by the European Medicines Agency at this time.

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## Booster doses for those vaccinated abroad

The National immunisation Advisory Committee recommends an mRNA booster vaccine for people aged 16 years and older who have completed a primary vaccination course with any vaccine type. This includes people who were vaccinated abroad and are considered fully vaccinated.

### NIAC defines those as fully vaccinated as follows:

- Those who have documentary evidence of a complete COVID-19 vaccination course with a COVID-19 vaccine authorised by the FDA, MHRA or recommended by WHO should be considered fully vaccinated.
- Those who have partially completed a COVID-19 vaccine course with a vaccine authorised by the FDA, MHRA or recommended by WHO should be offered an EMA authorised COVID-19 vaccine to complete the series, and then should be considered fully vaccinated.
- Those who have received a partial or complete course of COVID-19 vaccine not authorised by the FDA, MHRA or recommended by WHO should be offered a complete course of an EMA authorised COVID-19 vaccine.



### COVID-19 vaccination given outside Ireland COVID-19 vaccine course

#### Complete

People who have documentary evidence of a complete COVID-19 vaccination course with a COVID-19 vaccine authorised by the

- EMA
- FDA
- MHRA or
- recommended by WHO

should be considered fully vaccinated if they are resident in Ireland.

Authorised and recommended vaccines	
COVID-19 Vaccines	Doses required
Comirnaty® (Pfizer BioNTech) COVID-19 mRNA Vaccine	2
SpikeVax® (COVID-19 Vaccine Moderna)	2
Vaxzevria® Vaccine (AstraZeneca)	2
COVISHIELD (interchangeable with Vaxzevria® Vaccine (AstraZeneca))	2
COVID-19 Vaccine Janssen®	1
Sinovac-CoronaVac COVID-19 vaccine	2
Sinopharm (Beijing): BBIBP-CorV (Vero Cells)	2
Bharat Biotech: Covaxin®	2
COVID-19 vaccine Nuvaxovid®	2
Covovax® vaccine NVX-CoV2373 (Novavax formulation)	2

An mRNA booster vaccine is recommended for people aged 16 years and older who have completed a primary vaccination course with any vaccine type. This includes people who were vaccinated outside of Ireland and are considered fully vaccinated.

#### Partially complete

Offer 1 EMA authorised COVID-19 vaccine to complete the vaccine course.

The minimum interval between the last vaccine dose and an EMA authorised COVID-19 vaccine is **28 days**.

#### Vaccines not authorised

The Sinopharm/WIPB COVID-19 vaccine, Sputnik V (Gamaleya) COVID-19 vaccine and CanSinoBIO COVID-19 are **not** currently WHO approved.

Anyone who has received these vaccines should be offered a complete course of an EMA approved vaccine.

## Chapter 5a COVID-19

**5a**  
**COVID-19**  
**NOTIFIABLE**

**COVID-19**  
**7 January 2022**

[Click to read more](#)

[Click to read NIAC chapter](#)

# COVID-19 VACCINE BULLETIN 42

## COVID-19 Vaccines: Important information regarding dates

### Comirnaty® (Pfizer BioNTech) and Spikevax® (Moderna):

Both Comirnaty® and Spikevax® vaccines are stored in frozen state in the National Cold Chain Service (NCCS) in freezers (ultra low temperature between -90°C and -60°C, and between -25°C and -15°C respectively) until they are ordered by vaccination sites. Vaccines are then transferred to the NCCS fridge and stored at temperature between +2°C and +8°C and are continuously stored at these temperatures to the point of delivery at the vaccination site. At the vaccination site the vaccines are stored in fridges that must be maintained at temperature between +2°C and +8°C until time of preparation for administration.

There are two dates and times that are important for vaccinators 1) **"USE BEFORE"** and 2) **"DISCARD"**

### 1 USE BEFORE date and time

The **USE BEFORE** date and time reflects the time by which the vial (which now is in its thawed state) must be diluted /reconstituted (**Comirnaty®**) for administration or administered (**Spikevax®**). The **USE BEFORE** date and time is calculated by NCCS based on the time the vials have been removed from the freezers in NCCS, and time allowed when stored unopened in the fridge at temperature between +2°C and +8°C.

**The USE BEFORE date and time determines the timelines within which the vials can be administered and the vials should not be administered after this time, irrespective of the expiry date.**

**Comirnaty®:** The **USE BEFORE** date and time will be printed on the label that has been affixed to the box by the National Cold Chain Service (NCCS). The vials must be returned for destruction to NCCS when the **USE BEFORE** date and time has been reached and the vial has not been reconstituted.

**Comirnaty® children aged 5-11 years:** The **USE BEFORE** date and time will be printed on the label that has been affixed to box by the NCCS. The vials must be returned for destruction to NCCS when the **USE BEFORE** date and time has been reached and the vial has not been reconstituted.

**Spikevax®:** The **USE BEFORE** date and time will be printed on the label that has been affixed to the box by the National Cold Chain Service (NCCS). The vials must be returned for destruction to NCCS when the **USE BEFORE** date and time has been reached and the vial has not been punctured.

### 2 DISCARD date and time

**DISCARD** time and date is the maximum time allowed from dilution or first puncture of a vaccine vial, to time of administration. The vaccine must NOT be administered once the **DISCARD** time and date has been reached.

The **DISCARD** time and date must be written on the vaccine vial at the time of dilution (**Comirnaty®** and **Comirnaty® for children aged 5-11 years**) or at the time of first puncture (**Spikevax®**).

**Continued on page 5**



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## COVID-19 Vaccines: Important information regarding dates

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Summary table:

	Comirnaty®	Comirnaty® children aged 5-11 years	Spikevax®
Use before date and time	AS PER NCCS LABEL	AS PER NCCS LABEL	AS PER NCCS LABEL
Discard time and date	6 hours	12 hours	19 hours

**PLEASE NOTE:** The expiry date is the date that the vaccine expires when stored in its frozen state. With respect to Comirnaty® (both presentations), it must be continuously remain between -90°C and -60°C in an ultra-cold temperature (ULT) Freezer and with respect to Spikevax®, it must continuously remain between -25°C and -15°C in a Freezer.

This is the date printed on the vial.

This date is superseded by the USE BEFORE date and time once it is removed from the freezer by the NCCS.

European Medicine Agency has approved the extension of the shelf -life of both Comirnaty® and Spikevax® and this is reflected in their SmPC. This extension is only applicable to the vial in its frozen state and does not affect the USE BEFORE date and time.

The expiry date should not be recorded in the person's record.

## Clinical Guidance for COVID-19 Vaccination

Comirnaty® (Pfizer BioNTech)

Spikevax® (COVID-19 Vaccine Moderna)

COVID-19 Vaccine Janssen®

Comirnaty® 10 mcg/dose for children 5-11 years (Pfizer BioNTech)

Version 33 13/01/2022

[Click for more information in Clinical Guidance](#)



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## Updated report on the safety of COVID-19 vaccines in pregnancy

Pregnant women with COVID-19 are at increased risk for severe illness and of adverse birth outcomes, including miscarriage, stillbirth and pre-term delivery. Data from the US has shown that women with symptomatic COVID-19 during pregnancy have a more than twofold increased risk for intensive care unit admission, invasive ventilation, and extracorporeal membrane oxygenation, and a 70% increased risk for death, compared with non-pregnant women with symptomatic infections.

mRNA vaccines, including booster doses are recommended in pregnancy to protect mothers and babies from these serious consequences. With high levels of transmission of COVID-19 in Ireland, it is especially important that pregnant women are protected.

The latest report from the Vaccine Safety Datalink (VSD) in the US supports the already considerable evidence on the safety of COVID-19 vaccines in pregnancy.

In a retrospective cohort of >40,000 pregnant women, COVID-19 vaccination during pregnancy was not associated with preterm birth or small-for-gestational-age at birth overall, stratified by trimester of vaccination, or number of vaccine doses received during pregnancy.

[Click to read more](#)

We have several resources to support those advising pregnant women about vaccination available on our website

**PREGNANT OR THINKING ABOUT PREGNANCY?**

### 6 REASONS TO GET THE COVID-19 VACCINE

**COVID-19 can be serious for you and your baby**

You are more likely to get very unwell and need treatment in intensive care than a woman who is not pregnant. COVID-19 in pregnancy can cause premature labour or stillbirth. Getting the vaccine helps protect you and your baby from serious illness and hospitalisation from COVID-19.

**The safety of the vaccine**

Hundreds of thousands of pregnant women have safely received COVID-19 vaccines. COVID-19 vaccines are not shown to have any negative effect on babies in the womb. They may help to protect your baby after birth as you may pass on antibodies to your baby.

**Any stage of pregnancy**

You can get the vaccine at any stage of pregnancy. You can get it in the early stages of pregnancy or if you are close to full-term, but the sooner you get it, the sooner you and your baby are protected. If you have already been vaccinated, you can get your booster dose at any stage of pregnancy.

**Protect you and your baby**

Your own body develops protection against COVID-19 after vaccination. Your body develops antibodies against COVID-19. They pass across the placenta to your baby. The vaccine itself is broken down in your body and disappears after a few days.

**Most side-effects are mild and short-lived**

Most side effects from the vaccine are mild, and go away after a few days. They include a sore arm, tiredness, a temperature and a headache. Serious side effects, like an allergic reaction are very rare.

**No effect on fertility**

COVID-19 vaccines have no effect on fertility. COVID-19 vaccines are closely monitored around the world. There is no information to suggest that COVID-19 vaccines have any effect on your ability to get pregnant or on fertility.

Talk to your Doctor or Midwife about COVID-19 vaccines or visit the HSE website. COVID-19 vaccines are available from participating GPs, Pharmacies, Central Vaccination Clinics and in some maternity hospitals.

Scan the QR code to visit the HSE website:

Version 1  
13th December 2021

**COVID-19 vaccination in pregnancy**  
Information for Healthcare Professionals working in Maternity Settings

HSE National Immunisation Office

[Click for more information](#)

# COVID-19 VACCINE BULLETIN 42

## COVAX update

Sprint 18 is scheduled for early to mid-February 2022.  
A full update on sprint changes will follow in a subsequent bulletin.

On the medical eligibility assessment, the pregnancy question is to be removed from the all receiving Spikevax and Comirnaty from sprint 18.

A separate question "Are you pregnant?" will be captured instead at the point of vaccination.

The pregnancy question will remain on the medical eligibility assessment for the COVID-19 vaccine Janssen. If a pregnant woman had anaphylaxis to the mRNA vaccine COVID-19 vaccine Janssen can be considered as an alternative.

For errors in relation to doses of booster or additional dose and Comirnaty children vaccinations, there is new guidance uploading to mytraillhead next week to resolve the data on COVAX and guide you to creating new courses.



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## Seasonal Influenza vaccine

The European Centre for Disease Control (ECDC) and the World Health Organization have reported that influenza activity continues to increase across the European region. Severe cases have been reported requiring treatment in intensive care.

[Click to read more](#)

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

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

**Of note 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

[Click to print poster](#)



**Protect yourself.  
Protect others.**

[Click for more information](#)

## Children's nasal flu vaccine

Hear from Tracey Wall, Director of Nursing at Children's Health Ireland (CHI) and others about the importance of the free nasal flu vaccine for children aged 2 to 17 years:



[Click to watch](#)



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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 **NEW** 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](#)

**ADVANCED WARNING: HSeLand will be offline from Tuesday 18th January at 17.00 until lunchtime on Wednesday 19th January.**

## 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

**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.