HSE NATIONAL IMMUNISATION OFFICE

IMMUNISATION BULLETIN 54

THIS EDITION COVERS

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- Adapted vaccines for booster vaccination
- Comirnaty® Ready to Use (RTU) formulation (0.3ml/30 mcg)
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HSE National Immunisation Office
immunisaiton.ie
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IMMUNISATION BULLETIN 54

Welcome to Bulletin 54 from the HSE National Immunisation Office.

New mRNA COVID-19 vaccine formulations for people aged 12 years and older

New mRNA COVID-19 vaccine formulations are becoming available and will be used in the COVID-19 vaccination programme.

These are:

- **Adapted vaccines for booster vaccination ONLY.** These vaccines will be supplied to HSE vaccination clinics, GPs and retail Pharmacists
  - **Comirnaty® Original/Omicron BA.1 (referred to as Comirnaty® BA.1)**
  - **Comirnaty® Original/Omicron BA.4-5 (referred to as (Comirnaty® BA.4-5)**
  - **Spikevax® Original/Omicron BA.1 (referred to as Spikevax® BA.1)**
  - There is no change in the groups eligible for Booster vaccination.

- **Comirnaty® Ready to Use Formulation (0.3ml/30 mcg). This vaccine will be supplied to HSE vaccination clinics.**

VACCINATORS SHOULD COMPLETE THE MODULE ON HSELAND ENTITLED "NEW MRNA VACCINE FORMULATIONS" PRIOR TO ADMINISTRATION OF THESE VACCINES.

Adapted vaccines for booster vaccination

Three adapted bivalent mRNA COVID-19 vaccines have been recommended for use for booster vaccination by the National Immunisation Advisory Committee (NIAC), following approval by the European Medicines Agency. These vaccines are recommended and approved as booster doses only. **They should not be used for primary vaccination.**

The vaccines are:

- Comirnaty® BA.1
- Comirnaty® BA.4-5
- Spikevax® BA.1

These vaccines come as ready to use formulations and do not require dilution.

	Colour of vial cap	Formulation	Dose volume
Comirnaty BA.1	Grey	Ready to use, DO NOT DILUTE	0.3ml
Comirnaty BA.4-5	Grey	Ready to use DO NOT DILUTE	0.3ml
Spikevax BA.1	Blue	DO NOT DILUTE	0.5ml

Adapted vaccines for booster vaccination (cont. from page 2)

Summary of NIAC Recommendations

- Authorised bivalent mRNA vaccines are preferentially recommended for all those aged 12 years and older eligible for an adapted bivalent booster vaccination.
- An interval of at least four months (4-6 months) is recommended from the time of the last COVID-19 vaccine or confirmed SARS-COV-2 infection.
- In exceptional circumstances an interval of three months may be used (e.g., in a person scheduled to commence chemotherapy).
- They may be co-administered with influenza vaccine where appropriate
- The adapted bivalent mRNA booster vaccines should be given as follows:

Aged 12-29 years

- Comirnaty BA.1
- Comirnaty BA.4-5

Aged 30 years and older

- Spikevax BA.1
- Comirnaty BA.1
- Comirnaty BA.4-5

Those for whom an adapted bivalent mRNA vaccine is contraindicated or declined should be offered an alternative vaccine.

Adapted Booster Vaccine effectiveness

- Adapted vaccines are bivalent and contain mRNA based on the spike protein of the ancestral virus, as in the original vaccine, as well as mRNA based on the spike protein of the variant strain, either Omicron BA.1 or Omicron BA.4/5.
- They are adapted to better match circulating variants
- They are expected to give broader protection against different variants, although their impact on future variants is unpredictable
- In studies comparing the original vaccine, neutralising antibody levels induced by adapted vaccines were similar against the original COVID-19 strain and higher against Omicron.
- The extent that the higher antibody levels induced by the adapted vaccines will increase protection against COVID-19 variant disease is not known.
- While bivalent mRNA booster vaccines may offer advantage compared with the original vaccine, timely booster vaccination is more important than which vaccine is administered. **A booster dose of original mRNA COVID-19 vaccine offers significant protection against severe COVID-19 disease,** and should be used for booster vaccination if adapted booster vaccines are unavailable.

Reactogenicity and safety

- As the adapted vaccines are adaptations of the original COVID-19 vaccine for which the safety profile is well established, it is expected that their safety profile will be similar.
- Limited clinical data on BA.1 adapted vaccines shows local and systemic reactogenicity profiles similar to that of the original vaccines. Long-term follow up data is not available. The limited numbers of study participants precludes exclusion of very rare side effects.
- In authorising the BA.4-5 bivalent vaccine, the European Medicines Agency based their recommendations on safety of the bivalent BA.1 mRNA COVID-19 vaccine and long term data on previous mRNA vaccines.

Read more **here.**

Comirnaty® Ready to Use (RTU) formulation (0.3ml/30 mcg)

A new formulation of the original Comirnaty® 30mcg vaccine is now available. Like the Comirnaty® 30mcg vaccine formulation (purple cap) this vaccine contains mRNA for the SARS-CoV 2 spike protein of the original/ancestral SARS-CoV 2 strain. However, this vaccine comes as a ready to use formulation and does not need dilution.

Colour of vial/cap: the vial has a grey cap
Dose: 0.3mls
Ready to use. Does not require dilution

Indication: primary vaccination of individuals aged 12 years and older, including the additional dose for people who are immunocompromised. The vaccine can also be used for booster vaccination, however adapted vaccines are now available as booster does and these adapted vaccines should preferentially be used for booster vaccinations.

Note that unlike the Comirnaty® 30mcg formulation that requires dilution (purple cap), Comirnaty ® RTU formulation (grey cap) contains Trometamol and therefore the vaccine is contraindicated in individuals with a history of anaphylaxis to Trometamol.

A quick reference guide for COVID-19 mRNA vaccines has been developed.

Download the Quick Reference Guide to COVID-19 Vaccines **here.**

COVID-19 Vaccine Quick Reference Guide

PRIMARY VACCINATION INCLUDING ADDITIONAL DOSES FOR IMMUNOCOMPROMISED

	Comirnaty® *	Comirnaty® RTU (ready to use) *	Spikevax® *	Comirnaty® 10 micrograms *
NCCS Name	Comirnaty original PRIMARY CONC 0.3ml.	Comirnaty PRIMARY RTU 0.3ml.	Spikevax Original PRIMARY 0.5ml.	Comirnaty 5-11 0.2ml.
SmPC Name	Comirnaty 30 micrograms/ dose concentrate for dispersion for injection	Comirnaty 30 micrograms/ dose dispersion for injection	Spikevax 0.2 mg/mL dispersion for injection	Comirnaty 10 micrograms/ dose concentrate for dispersion for injection
Vial cap colour	**Purple cap**	**Grey cap**	**Red cap**	**Orange cap**
Age	12 years and older	12 years and older	30 years and older	5 - 11 years
Indication	PRIMARY OR ADDITIONAL DOSES	PRIMARY OR ADDITIONAL DOSES	PRIMARY OR ADDITIONAL DOSES	PRIMARY OR ADDITIONAL DOSES
Dose volume (dose)	0.3ml (30mcg)	0.3ml (30mcg)	0.5ml (100mcg)	0.2ml (10mcg)
Dilution	1.8ml Sodium Chloride	**DO NOT DILUTE READY TO USE**	**DO NOT DILUTE READY TO USE**	1.3ml Sodium Chloride
Doses per vial	6	6	10	10

**Can also be used as booster doses. Note that the booster dose of Spikevax is 0.25ml*

COVID-19 Vaccine Quick Reference Guide

ADAPTED BOOSTER VACCINES

	Comirnaty® RTU (ready to use) Original/Omicron BA.1	Comirnaty® RTU (ready to use) Original/Omicron BA.4 BA.5	Spikevax® Original/Omicron BA.1
NCCS Name	Comirnaty ADAPTED BOOSTER RTU 0.3ml.	Comirnaty ADAPTED BOOSTER RTU 0.3ml.	Spikevax Adapted BOOSTER 0.5ml.
SmPC Name	Comirnaty Original/Omicron BA.1 (15/15 micrograms)/dose dispersion for injection	Comirnaty Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection	Spikevax bivalent Original/Omicron BA.1 (50 micrograms/50 micrograms)/ mL dispersion for injection
Vial cap colour	**Grey cap**	**Grey cap**	**Blue cap**
Age	12 years and older	12 years and older	30 years and older
Indication	**USE FOR BOOSTER ONLY** NOT FOR PRIMARY OR ADDITIONAL DOSES	**USE FOR BOOSTER ONLY** NOT FOR PRIMARY OR ADDITIONAL DOSE	**USE FOR BOOSTER ONLY** NOT FOR PRIMARY OR ADDITIONAL DOSE
Dose volume (dose)	0.3ml (30mcg)	0.3ml (30mcg)	**0.5ml (50mcg)**
Dilution	**DO NOT DILUTE READY TO USE**	**DO NOT DILUTE READY TO USE**	**DO NOT DILUTE READY TO USE**
Doses per vial	6	6	5

THERE IS NO CHANGE TO THE GROUPS ELIGIBLE FOR COVID-19 BOOSTER VACCINES.

Frequently Asked Questions

Is there any change in the groups eligible for booster vaccination?

No there is no change in the groups eligible for booster vaccination.

What advice should I give to someone who recently had a booster dose of original mRNA Comirnaty (purple cap) or Spikevax (red cap)?

You should advise them that they have received an approved and appropriate vaccine. A booster dose of original mRNA COVID-19 vaccine offers significant protection against severe COVID-19 disease and hospitalisation. **Revaccination with an adapted booster vaccine is not recommended.**

Are there any additional contraindications and precautions to the new mRNA COVID-19 vaccine formulations?

The adapted vaccines (Comirnaty® BA.1, Comirnaty® BA.4-5) and Comirnaty® 30mcg Ready to Use contain Trometamol. Therefore they are contraindicated in individuals with anaphylaxis to Trometamol. Spikevax® BA.1 also contains Trometamol (as does Spikevax®) and so this vaccine is also contraindicated in individuals with anaphylaxis to Trometamol.

What intervals are recommended between the last dose of a COVID-19 vaccine and a booster dose of adapted COVID-19 vaccines (Comirnaty BA.1, Comirnaty BA.4-5 and Spikevax BA.1)?

- Interval between the last dose of a COVID-19 vaccine and booster dose: at least 4 months (4-6 months). In exceptional circumstances a 3 month interval may be used.
- Interval between COVID-19 infection and booster dose: at least 4 months (3 months in exceptional circumstances)

Can Comirnaty BA.1, Comirnaty BA.4-5 and Spikevax BA.1 be administered as a booster dose in pregnancy?

Yes adapted vaccines can be administered as booster doses in pregnancy.

Can booster doses of Comirnaty RTU BA.1, Comirnaty RTU BA.4- and Spikevax RTU BA.1 be co-administered with the seasonal influenza vaccine?

Yes they can be co-administered with the influenza vaccine, in different limbs.
(Comirnaty® 30 mcg Ready to Use may also be co-administered with the seasonal flu vaccine).

What is the recommended interval for booster doses of COVID-19 vaccine?

The recommended interval for ALL booster doses (1st, 2nd and 3rd booster dose) is now at least 4 months since the last dose of a COVID-19 vaccine.

In exceptional circumstances a 3-month interval may be used. This applies to ALL age groups and ALL COVID-19 vaccines.

Frequently Asked Questions (cont. from page 5)

Which mRNA vaccine should I use as the additional dose in people who are immunocompromised at the time of primary vaccination?

The additional dose is part of an extended primary course (and not a booster dose) therefore the following vaccines should be used:

- Comirnaty (purple cap) 0.3mls
- Comirnaty Ready to Use (grey cap) 0.3mls
- Spikevax (red cap) 0.5mls (only for individuals aged 30 years and older)

What vaccines can I use for primary vaccination?

- Comirnaty (purple cap) 0.3mls
- Comirnaty Ready to Use (grey cap) 0.3mls
- Spikevax (red cap) 0.5mls (only for individuals aged 30 years and older)

Are all patients taking immunomodulatory treatment considered immunocompromised?

Yes, any patient who is prescribed immunomodulatory treatment can be immunocompromised.
These patients are all recommended an additional COVID-19 vaccine dose to complete the Primary COVID-19 vaccine schedule. The additional COVID-19 vaccine dose is only recommended if they have commenced the immunomodulatory treatment before or as the primary COVID-19 vaccine schedule is given.

The list in the immunisation guidelines Table 5a.2 below is not all inclusive.

Immunocompromise due to disease or treatment	Severe e.g., **Transplantation:** - Listed for solid organ or haematopoietic stem cell transplant (HSCT) - Post solid organ transplant at any time - Post HSCT within 12 months **Genetic diseases:** - APECED[2] - Inborn errors in the interferon pathway - Some B and T cell deficiencies **Treatment e.g.,** - Cyclophosphamide, Rituximab, Alemtuzumab, Cladribine or Ocrelizumab in the last 6 months

Colour coding of materials

To aid vaccinators when reviewing materials and training, the colour coding of our materials will reflect the colour of the vial cap:

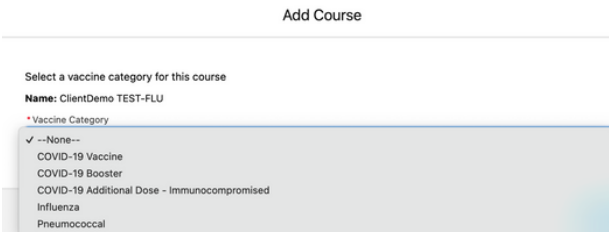
mRNA Vaccines	
Comirnaty® 30 micrograms*	
Spikevax®	
Comirnaty® 10 mcg (children aged 5-11)	
Comirnaty® Ready to Use	
Adapted mRNA Vaccines (Booster Only)	
Comirnaty® Ready to Use BA.1	
Comirnaty® Ready to Use BA.4-5	
Spikevax® Ready to Use BA.1	

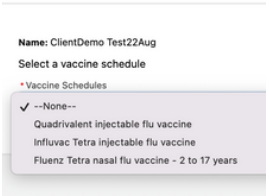
ALWAYS CHECK THE NAME OF THE VACCINE ON THE VACCINE VIAL LABEL BEFORE ADMINISTRATION.

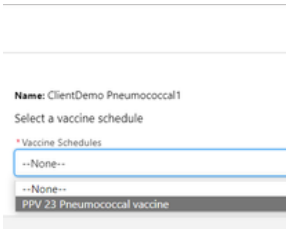
For more information visit NIO website **here**

Updates on COVAX - Sprint 22b

Sprint 22b added Influenza and Pneumococcal vaccine functionality into Covax.
For more details, see Influenza and Pneumococcal Training Trail on myTrailhead.







1. New categories and schedules of vaccines added for Influenza and Pneumococcal (PPV23).
2. Relevant Risk factors capturing enabled for Flu and Pneumococcal vaccines.
3. Extend Course' functionality in the administer vaccine flow if two dose of flu required.
4. New Extend Course' button if a Dose 2 of influenza vaccine is required for an already completed flu dose 1.
5. New consent and eligibility forms for Flu and Pneumococcal vaccines added.
6. 9i - aged 6 months - 4 years" priority group has been added to the picklist options for the 'Priority' field for LAIV or QIV in this age group.
7. Central adding of batch numbers for flu and pneumococcal vaccines.

HSE Flu Vaccination Pharmacy Finder - 2022/23 Influenza season

If you will be providing the HSE Flu vaccination programme in your pharmacy this season and you would like to take part in the HSE Flu Vaccine Finder on hse.ie to guide eligible people to book their flu vaccine with your pharmacy, please complete the online form. You can also use this form if you wish to withdraw from the service or need to update clinic times or any details. The information gathered will only be used for keeping this service up to date.

Add your pharmacy to the HSE Flu Vaccine Finder **here.**

Website

Visit our website **www.immunisation.ie** regularly for the most up to date information to support vaccinators and health professionals responding to queries.

Visit website here.

HSeLanD Vaccination Training Programme

COVID-19 vaccination training programme

You can access updates to the National Immunisation Office COVID-19 Vaccination Training Programme for

- Children 5 to 11
- Pfizer,
- Moderna,
- Janssen, and
- Nuvaxovid vaccine

through your HSeLanD account.

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.

Other immunisation training programmes

You will also find other programmes developed by our office by logging into your account on www.hseland.ie selecting **courses** then selecting **clinical skills** and finally selecting **National Immunisation Office**.

Our programmes cover topics like “Communicating about vaccines”, “HPV vaccine”, the “Flu vaccine”, “LAIV flu vaccine” and “vaccines in pregnancy”, "Vaccines - supporting people from Ukraine" and "Storing and Managing Vaccines".

Visit HSeLanD here.

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

Contact HSeLanD here.

Do you have queries?

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

Send your query here.

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

- Cliona Kiersey: mobile 087 9915452
- Achal Gupta: mobile 087 4064810

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

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