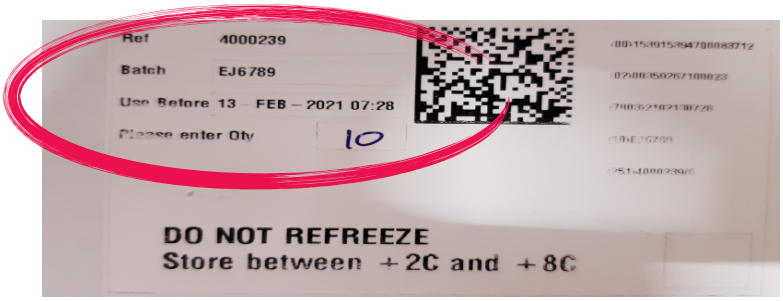
COVID-19 VACCINE BULLETIN 7

Welcome to the seventh bulletin from the HSE National Immunisation Office which highlights changes in clinical guidance for the COVID-19 vaccination programme. Bulletins will be published every week or more frequently, if required.

What information regarding the shelf-life of the vaccine should be recorded in the IT system/vaccination record?

Comirnaty® (Pfizer/BioNTech)

- The batch number should be recorded
- The "use before" date and time should be recorded (see table below)
- The batch number and expiry date of the saline diluent should also be recorded



"*Use before*" date and time **Maximum time from removal from ultra-low temperature (ULT) freezer to expiry, when stored at +2°C to +8°C**	**USE BEFORE** date and time = **120** hours from the time vials are removed by HSE National Cold Chain from ULT and stored at 2°C to 8°C (must be recorded on patient's notes). **Before** the 120 hours have passed, vials must be removed from fridge. They can be kept for up to **2** hours at room temperature in preparation for dilution. Within the 2 hours the vial must be diluted. **DISCARD** date and time = **6** hours from dilution (Must be written on the vial).

COVID-19 Vaccine Moderna®

- The batch number should be recorded
- The "use before" date should be recorded (see table below)

"*Use before*" date and time **30 days from date and time of arrival of the vaccines to vaccination site/clinic and stored at +2°C and + 8°C.**	The vaccine is transported by the HSE National Cold Chain service to vaccination sites/clinics frozen at -25ºC and -15ºC. At vaccination sites/clinics the vaccine is stored at +2°C and +8°C and thawed. If thawed and stored between +2°C and +8°C, the unopened vaccine has a shelf life of 30 days. This "use before" date and time is 30 days from date and time of delivery of vaccines by the NCCS van driver. The recipient must record the "use before" on the vaccine box. The vials must be discarded when the "use before" date and time has been reached.

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COVID-19 Vaccine AstraZeneca®

- The batch number should be recorded
- The expiry date should be recorded

Expiry date	The date the vaccine expires if stored at +2°C to +8 °C. This is 6 months from the date of manufacture and written on the vaccine label and box. The batch number and expiry date on the side of each vial should be recorded in the patient record.

National immunisation Advisory Committee Guidelines on COVID-19 vaccines chapter has been updated

Patients with planned immunosuppressive therapy should ideally complete vaccination two weeks before treatment. The recommended minimum interval for vaccines may be used.

In addition, updated information on the efficacy of COVID-19 vaccine AstraZeneca has been added.

Recent evidence shows that protection from COVID19 vaccine AstraZeneca starts from approximately 3 weeks after the first dose of vaccine with 76% protection overall against symptomatic COVID-19 disease for up to 90 days (12 weeks). Modelling showed no evidence of waning of protection in the first three months after vaccination. Higher efficacy of 82% was reported when the second dose was given after 12 weeks.

Read Updated Chapter Here

Updated information for women who are pregnant or breastfeeding and their doctors about COVID-19 vaccines including COVID-19 Vaccine AstraZeneca®

The Institute of Obstetricians and Gynaecologists in conjunction with the Irish Medicines in Pregnancy Service at the Rotunda Hospital and the National Immunisation Advisory Committee (NIAC) at the Royal College of Physicians of Ireland have updated their information for women who are pregnant or breastfeeding and their doctors about COVID-19 vaccines.

The information contained within the document now includes COVID-19 Vaccine AstraZeneca®.

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Resources on COVID-19 vaccination for the Travelling Community

HSE National Social Inclusion Office have updated the information available on their website on COVID-19.

There is now a section on the **Traveller COVID 19 sharing resources** for **Traveller COVID-19 vaccination resources**. As resources are developed nationally and regionally for Travellers this page will be updated.

For example, links to Pavee Point's two excellent Traveller COVID-19 vaccination videos entitled 'Travellers Take the Vaccine' are available on the page. We would encourage you to share the videos to your contacts.

Pavee Point video series: Travellers Take the Vaccine

Video 1: Watch Missie Collins, Traveller Primary Healthcare Worker, talking about her experience of getting the COVID-19 vaccine.

Watch It Here

Video 2: Watch Winnie McDonagh, Traveller Primary Healthcare Worker, talking about her experience of getting the COVID-19 vaccine.

Watch It Here

HPRA update

The HPRA have published their drug safety newsletter which is a Special Edition on COVID-19 Vaccines Safety Monitoring Activities.

The HPRA has established a dedicated online system for reporting of suspected adverse reactions to COVID-19 vaccines. The online system may be accessed via the HPRA website homepage (**www.hpra.ie/report**)

A specific COVID-19 downloadable report form is also available (**www.hpra.ie/report**), and can be completed and emailed to **medsafety@hpra.ie** or posted to the HPRA.

As much as possible of the following information should be included:

- Information on the person who has experienced the suspected reaction, including age, sex, pregnancy/breastfeeding status
- A description of the suspected adverse reaction, including, time to onset, clinical course and impact on the patient, any treatment administered, and outcome where known
- The brand name and dose of the vaccine
- The batch number of the vaccine administered
- Dates of initial and second (if applicable) vaccination
- Relevant medical history
- Any concomitant medications (including non-prescription medicines, herbal remedies, or contraceptives).
- Whether the person concerned was previously diagnosed with confirmed COVID-19
- Reporter (HCP or patient) details

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Early rate reductions of SARS-CoV-2 infection and symptomatic COVID-19 in recipients of Comirnaty® (Pfizer/BioNTech) COVID-19 Vaccine is Israel

Data from Israel reported in the Lancet this month, showed substantial early reductions in SARS-CoV-2 infection and symptomatic COVID-19 rates in healthcare workers following first vaccine dose administration.

The adjusted rate reduction of SARS-CoV-2 infection in vaccinated compared with unvaccinated individuals was 75% 15–28 days after first dose, and 30% 1–14 days after first dose.

For symptomatic COVID-19, adjusted rate reduction in vaccinated compared with unvaccinated individuals was 85% 15–28 days after first dose and 47% 1-14 days after a first dose.

Read More Here

Prevention of COVID-19 vaccination administration errors for safe practice

Correct vaccine

- Ask vaccine recipient which vaccine was received as a first dose
- Cross check this with the COVAX IT system or the patient's medical record
- The same vaccine should be used for both doses
- ***Remember there is no data on the interchangeability of COVID-19 vaccines***

Dosage intervals

- Each COVID -19 vaccine has a recommended dosing interval between first and second dose
- Check that the interval between first dose and second is correct before administering the vaccine

Read More Here

Drawing up the vaccines

- Do **not** withdraw excess amount of vaccine beyond the recommended dose
- Withdraw the correct dose as recommended
- Comirnaty® (Pfizer/BioNTech) vaccine 0.3ml for a single dose
- COVID-19 Vaccine Moderna® & COVID-19 Vaccine AstraZeneca® 0.5ml for a single dose
- *Remember lower or higher volumes than authorised doses should not be administered*
- ***Once a dose of vaccine has been withdrawn from a multidose vial it must NEVER be injected back into the vial***

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Handling the vaccine once in the syringe

- Keep out of direct sunlight
- Remember that if there are any air bubbles in the syringe when withdrawing the vaccine, the air bubbles should be removed prior to disconnecting the syringe and needle from the vaccine vial
- ***Remember mRNA vaccines, Comirnaty® (Pfizer/BioNTech) and COVID-19 Vaccine Moderna® are sensitive to agitation and light***

Co-administration

- Co-administration with other vaccines has not been studied
- Check have other vaccines been given in the last 14 days.
- ***Remember it is prudent to leave 14 days between COVID-19 vaccines and another vaccine***

Notification of vaccination errors

- You should follow the normal practice for notification of medication errors in your healthcare facility. HSE staff should enter details of medication errors into the NIMS system.
- In addition, all errors in vaccination for the COVID-19 vaccines should also be notified to the HPRA and to the National Immunisation Office at **immunisation@hse.ie**
- ***Remember to notify all vaccine administration errors.***

*Recommendations about COVID-19 vaccine are changing as more information becomes available so please check our **website** for the most up to date information.*