

Special Edition on COVID-19 Vaccines Safety Monitoring Activities

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COVID-19 Vaccines – What is authorised

On the recommendation of the European Medicines Agency (EMA), the European Commission (EC) granted a conditional marketing authorisation for the first vaccine against COVID-19, [Comirnaty](#)[®] manufactured by Pfizer/BioNTech, on 21 December 2020. This was followed by a conditional marketing authorisation for the vaccine manufactured by Moderna, known as [COVID-19 Vaccine Moderna](#)[®], on the 6 January. These two vaccines contain messenger RNA (mRNA) formulated in lipid nanoparticles, which enable delivery of non-replicating RNA into host cells to direct transient expression of a viral protein from SARS-CoV-2, which in turn elicits an immune response.

Additionally, the EMA has recommended granting a conditional marketing authorisation for the [Astra Zeneca COVID-19](#)[®] vaccine on 29th January. This is a monovalent vaccine composed of a single recombinant, replication deficient adenovirus (ChAdOx1) vector encoding the S glycoprotein of SARS CoV-2.

Further information on the licensing of COVID-19 vaccines is available on the HPRA website [here](#), along with the approved product information (Summary of Product Characteristics (SmPC) and Package Leaflet (PL)) for each COVID-19 vaccine. [Key facts on COVID-19 vaccines](#) and more information about how these [vaccines have been developed, authorised and monitored](#) in the EU can be found on the EMA website.

Importance of reporting suspected adverse reactions

The assessment of the available data related to the quality, safety and efficacy of currently approved COVID-19 vaccines considered that the benefits of vaccination outweigh the potential risks, allowing for their approval for use. Further studies are planned and/or ongoing, the findings of which will contribute to the ongoing evaluation of the benefits and risks associated with use of these vaccines. Certain adverse reactions, particularly those that occur rarely or very rarely, may only emerge during 'real-life' use, in larger and more heterogeneous populations. It is essential therefore, that the safety and effectiveness of all COVID-19 vaccines is closely monitored following approval.

To facilitate monitoring of national experience with COVID-19 vaccines, reporting of suspected adverse reactions to the HPRA is encouraged and reporters are asked to include as much detail as available to support evaluation.

How to report a suspected adverse reaction to a COVID-19 vaccine to the HPRA

The HPRA has established a dedicated online system for reporting of suspected adverse reactions to COVID-19 vaccines, with preferred reporting options described below.

- The online system may be accessed via the HPRA website homepage (www.hpra.ie/report) or directly via [this link](#).
- 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 address below.
- By email to medsafety@hpra.ie.

In order to facilitate the most thorough evaluation of suspected adverse reactions, the HPRA requests that, when submitting a suspected adverse reaction report, healthcare professionals include *as much as possible* of the following information (however, please note that non-availability of all this information should not discourage report submission):

- Information on the **person** who has experienced the suspected reaction, including age (or age group) and sex, and any additional available information such as weight/BMI, pregnancy/breastfeeding status, co-morbidities etc.
- 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 or concomitant conditions** e.g. food allergies, co-morbidities previous vaccine allergy.
- 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.

All adverse reaction reports received will be processed and entered into the HPRA's national pharmacovigilance database. Reports will subsequently be sent to EudraVigilance (EV), the European Medicines Agency's database of suspected adverse reactions, where the data are analysed to detect new safety signals. Anonymised data from the EV database are publically accessible for review at www.adrreports.eu.

The HPRA is publishing periodic overviews of national reporting experience on its website, with the first such [update](#) published on 21 January and the second [update](#) published on 04 February.

European Safety Monitoring for COVID-19 Vaccines

While the safety of COVID-19 vaccines is being monitored according to the guidelines that apply to all medicines and vaccines, the EMA together with EU medicines agencies, have outlined several additional measures for COVID-19 vaccines in a [Safety Monitoring Plan](#). In addition, for each vaccine, a specific risk management plan (RMP) is agreed at the time of approval by EU regulators, which sets out amongst other things, any specific safety monitoring activities for that vaccine. The RMP is a living document and will be continually updated as more information becomes available. For information the RMPs for the [Pfizer/BioNTech](#), [Moderna](#) and [Astra Zeneca](#) vaccines are available from the EMA website. As part of the enhanced monitoring approach, companies will provide monthly safety reports, in addition to the regular periodic updates routinely required, and have been requested to conduct additional studies where necessary.

Post-authorisation studies are underway or planned to monitor the safety and effectiveness of COVID-19 vaccines which include independent observational research. The EMA Advisory Group, which focuses on data sources and epidemiological methods to monitor the safety, effectiveness and coverage of COVID-19 vaccines is supporting the [ACCESS](#) project ('vACCine Covid-19

monitoring readinESS'). Key deliverables from the ACCESS project including publication of background rates in the general population for pre-specified adverse events of special interest, as well as several template protocols for monitoring vaccines using different types of data sources and data collection, to maximise participation by EU countries.

Together, these measures ensure a monitoring approach that will enable swift assessment of data emerging from a range of different sources and for appropriate regulatory action to protect public health to be taken if needed. The HPRA will communicate with healthcare professionals and the public on experience gained with use of the COVID-19 vaccines nationally (see above) and will highlight relevant regulatory updates as appropriate.

Extensive new safety and effectiveness data are expected from widespread use of COVID-19 vaccines in worldwide vaccination programmes. Procedures are in place to allow for the rapid review of all such data and product information (SmPC and PL) may be updated at regular intervals following these reviews. The European Medicines Agency (EMA) published its [first safety update](#) on the COVID-19 vaccine, Comirnaty®, on 29 January and its [first safety update](#) (under safety updates) on the COVID-19 Vaccine Moderna® on 5 February.

Healthcare Professionals (HCPs) are requested to monitor the HPRA and EMA websites throughout the coming months for updated information as it becomes available. HCPs can register to receive alerts from the HPRA via the HPRA homepage, or via this [link](#). Please see below also.

Key messages

Suspected adverse reactions to COVID-19 vaccines should be reported to the HPRA via the available [methods](#).

Further information on COVID-19 vaccines is available on the HPRA website [here](#) and EMA website [here](#).

Healthcare professionals (HCPs) are encouraged to register [here](#) for HPRA alerts to receive up to date information on COVID-19 vaccines.

Registering with the HPRA for safety alerts and updates

The HPRA website provides users with the option of registering their contact information with the HPRA to enable them to receive direct and immediate notification of alerts/updates by email. Users will be alerted to (depending on their recorded preferences) publications such as the HPRA Drug Safety Newsletter, Direct Healthcare Professional Communications (DHPCs) and alerts regarding new/updated safety/quality information on medicines/vaccines/medical devices etc.

To facilitate prompt access to these updates, users are encouraged to avail of this option by registering on the website:

- Go to the HPRA webpage www.hpra.ie
- Click on 'Register' in the 'My HPRA' box on the top right hand corner of the homepage
- Enter your details and click 'Register'
- You will be emailed a link to confirm registration to the email address nominated
- Once registration is confirmed, log in using your email address and password
- You will be brought to the 'My HPRA' page to manage your preferences
- Under 'My preferences', tick the stakeholder group (e.g. Healthcare Professionals), topics of interest that you wish to receive updates about (e.g. safety and quality) and products of interest (Medicines). Please note that at any time you, can log into 'My HPRA' to update your preferences.

Correspondence/comments should be sent **by email only** to the Pharmacovigilance Section, Health Products Regulatory Authority, medsafety@hpra.ie.