HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

COVID-19 VACCINES – SAFETY MONITORING ACTIVITIES

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 29 January 2021. 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 (www.hpra.ie), along with the approved product information i.e. 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 (www.ema.europa.eu).

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 (http://www.hpra.ie/homepage/about-us/report-an-issue).
- A specific COVID-19 downloadable report form, is also available at the link above, 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 2021.

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. For information, the RMPs for the Pfizer/BioNTech and Moderna 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.

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. Healthcare Professionals (HCPs) are requested to monitor the HPRA and EMA websites throughout the coming months for updated information as it becomes available.

Key Message

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 and EMA website.

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