HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

1st HPRA Safety Update

COVID-19 Vaccines, Overview of National Reporting Experience

Publication date 21 January 2021

Highlights from the 1st HPRA safety update

- Up to 18 January, a total of 257 reports of suspected side effects were notified to the HPRA
- The cumulative total doses administered of COVID 19 vaccines was reported as 77,303 (dose 1) up to 13 January [1]
- Of the reports notified to the HPRA, the most commonly reported suspected side effects are in line with those typically associated with vaccination, including the types of side effects described in COVID-19 vaccine product information [2]
- National reporting experience to date supports the favourable assessment that the benefits of COVID-19 vaccines outweigh any risks

Understanding the data presented within this safety update

This update includes an overview of reports of ***suspected side effects*** notified to the HPRA safety monitoring system and is provided as an enhanced transparency measure for members of the public and healthcare professionals.

Reports included in the overview are those notified to the HPRA on a voluntary basis by healthcare professionals and members of the public. Reporting of all suspected side effects to COVID-19 vaccines (www.hpra.ie/report) is encouraged. Reports received by the HPRA from the company (i.e. the licence holder, to date, BioNtech and Moderna) responsible for the vaccine are also included within this update.

This overview provides an up-to-date summary of national reporting experience.

However, it is important to understand that conclusions on the safety of a vaccine cannot be drawn based on the information provided, given well-established and known limitations in interpreting such data in isolation, examples of which are described below.

[1] https://covid19ireland-geohive.hub.arcgis.com/

[2] https://www.hpra.ie/homepage/medicines/covid-19-updates/covid-19-vaccines-product-information

Causation

- The HPRA receives reports based on ***suspicion*** that an adverse experience may be associated with vaccination. This does not mean the vaccine ***caused*** the adverse experience**.** As such, these are referred to as ***"suspected"*** side effects.
- Reports may describe coincidental events, which have occurred post-vaccination, but would have occurred even if vaccination had not taken place (e.g. they may be due to an underlying medical condition, or be signs and symptoms of another illness).
- Each individual report is carefully reviewed, however, the totality of data from all sources (e.g. clinical and epidemiological studies and literature) must be considered as part of ongoing safety monitoring to ensure ***evidenced based conclusions*** are drawn.

Number/volume

- As the HPRA system is based on voluntary reporting, ***not all*** suspected side effects will be reported. As such, the number and types of reports notified can vary for a variety of reasons.
- An increased number of reports is expected for COVID-19 vaccines, given public interest as well as HPRA calls encouraging reporting. This is known as ***stimulated reporting***.
- A single report may describe more than one suspected side effect in an individual (e.g. headache and nausea reported together), therefore, the number of side effects may exceed the total number of reports received.

Comparisons

- The type and number of reports received for different COVID-19 vaccines are ***not directly comparable*** as, for example, the vaccines have not been used in the vaccination programme for the same length of time, and will have been administered to different numbers of people, with different underlying medical conditions and across different settings.
- Each vaccine is authorised on the basis that its benefits-risk profile has and continues to be favourable.

Changes to data over time

- The description of suspected side effects in this update reflects available information known at the time by the HPRA. These data may undergo changes as more information about individual reports becomes available through follow-up, and as more data are reported and evaluated.

For these reasons, the information in this report is not sufficient in isolation to draw conclusions on the safety profile of a vaccine. Like all vaccines, some side effects are to be expected, with the vast majority mild or moderate in intensity and resolving within a few days. Vaccines are approved for use on the basis of robust scientific evidence that demonstrates their benefits outweigh any risks.

Always refer to the product information for information on the established safety profile, including known side effects of a COVID-19 vaccine.

This includes the Package Leaflet (for members of the public) and Summary of Product Characteristics (for healthcare professionals).

Product information is accessible from www.hpra.ie/homepage/medicines/covid-19-updates

Authorised COVID-19 vaccines

COVID-19 vaccines currently authorised for use in the European Union by the European Medicines Agency include:

- Comirnaty® (licence holder: BioNTech), granted conditional marketing authorisation on 21 December 2020. For further information on this vaccine click here.

- COVID-19 Vaccine Moderna® (licence holder: Moderna), granted conditional marketing authorisation on 6 January 2021. For further information on this vaccine click here.

Overview of suspected side effect reports, per COVID-19 vaccine

Up to 18 January, the HPRA received 257 reports in association with approved COVID-19 vaccines.[3]

Comirnaty® (BioNTech Covid-19 mRNA vaccine)

Overall, the national reporting experience to date supports the favourable benefit/risk profile for this vaccine.

Commonly reported suspected side effects (reported as 1% or more of all suspected side effects) are listed here:

- Dizziness, headache, numbness, tingling/pins and needles
- Weakness, tiredness, feeling unwell, chills, fever
- Itchiness, rash, hives
- Nausea, diarrhoea, vomiting
- Joint pain, muscle pain, pain in limb, injection site pain
- Enlarged lymph nodes
- Rapid heart beat
- Transient increases in blood pressure

These reports are consistent with the types of events typically observed following vaccination, including those described in the product information for this vaccine. The majority were mild to moderate in nature and had resolved/were resolving at the time of reporting.

Other events reported to the HPRA, and that are described in the product information for this vaccine as occurring rarely or at an unknown frequency, include the following:

Allergic type reactions

- Allergic reactions have been known to occur with this vaccine, including a very small number of cases of severe allergic reactions (anaphylaxis) reported from use in vaccination campaigns elsewhere.
- The HPRA has received a relatively small number of reports describing signs and symptoms of allergic type reactions, including itchy rash, throat tightness and swelling of the face or tongue.
- All individuals were reported to have recovered, and in some cases there was a period of medical observation and/or treatment was administered, such as with oral anti-histamines.

[3] Of these, one report was made for which the brand of vaccine was unknown. A single report may contain more than one suspected side effect for an individual (e.g. rash and hives reported together). Therefore, the total number of suspected side effects will exceed the total number of reports.

- Based on currently available information, none of the reports received to date have been confirmed by the HPRA as anaphylaxis.
- As for all vaccines, Comirnaty® should be given under close supervision with appropriate medical treatment available in case of such a reaction.

Facial paralysis/palsy

- In the product information for this vaccine, weakness in muscles on one side of face (also known as acute peripheral facial paralysis or palsy) is reported to have occurred rarely in less than 1 in 1,000 people.
- The HPRA has received a small number of reports describing facial paralysis or conditions associated with temporary weakness in the muscles on one side of the face, such as Bell's palsy.
- At the time of reporting, the onset of symptoms in these cases was recent and the HPRA is following for further information for each report, including to confirm if symptoms have resolved.

COVID-19 Vaccine Moderna®

The reports received in association with this vaccine have been consistent with those typically observed with other vaccines and included in the product information. Given a very small number have been received to date, further details are not available at this time.

Background information on the evaluation of suspected side effect reports

As for all medicines and vaccines, suspected side effect reports in association with COVID-19 vaccines submitted to the HPRA are recorded and stored on the HPRA's national adverse reactions database. They are subsequently submitted (with any personal identifiers and contact details removed) to the EudraVigilance database operated and managed by the European Medicines Agency (EMA). EudraVigilance provides for the transfer of reports from national regulatory agencies such as the HPRA and marketing authorisation holders to the EMA, and supports early detection and monitoring of possible safety signals in relation to reported side effects.

The EMA also make available anonymised information on global safety reporting experience publically available through the following link (www.adrreports.eu) and regularly publish recommendations made by the EMA Safety Committee (www.ema.europa.eu).

Information from side effect reports, together with additional safety data (e.g. from the scientific literature, cumulative safety data analysis, epidemiological studies etc.) are assessed on an on-going basis, in conjunction with our EU counterparts to consider their impact on the known safety profile of the COVID-19 vaccines and any need for regulatory changes to support safe and appropriate use.

Partially anonymised details of reports are also shared with other bodies also involved in safety monitoring of medicines, in accordance with the legislative provisions, including GDPR (please see the HPRA privacy statement here). These bodies include the World Health Organisation (WHO) and as appropriate, the company(ies) that hold the licence(s) for the medicine(s) concerned (i.e. marketing authorisation holders or 'MAHs'). Sharing of this information ensures that the information is available to all parties responsible for the ongoing safety monitoring of medicines.

Further information to support interpretation of the data provided in this update is available here.