HPRA Safety Update

COVID-19 Vaccines, Overview of National Reporting Experience
Publication date: 17 February 2023 (Safety Update #19)

Highlights from this update:

- Since the start of COVID-19 vaccination in Ireland and up to 31 January 2023, a total of 20,835 reports of suspected side effects have been notified to the HPRA. The number of COVID-19 vaccines doses administered over that time is reported as 8,056,180, of which 4,637,411 were administered as a booster.[1,2]

- Whilst not experienced by everyone, all vaccines have some side effects, the vast majority of which are mild to moderate in nature. Side effects need to be continuously balanced against the benefits of vaccines, given the risk of COVID-19 illness and related complications, and as scientific evidence shows they reduce deaths and hospitalisations due to COVID-19.

- This safety update focuses on mRNA vaccines (Comirnaty® and Spikevax®) as the most used vaccines in Ireland today. Overall, the national reporting experience for mRNA vaccines continues to support the favourable assessment that the benefits outweigh the risks. An overview of national reports of suspected side effects received is provided in this safety update on page 7.

- The wide uptake of COVID-19 vaccines during the COVID-19 pandemic has led to the rapid accumulation of extensive safety data from clinical trials, other studies and reports of suspected side effects made by members of the public and healthcare professionals. These data have established the safety profiles of these vaccines. On 08 December 2022, the European Medicines Agency (EMA) published a final COVID-19 vaccine safety update, and any further important changes recommended by the EMA's safety committee will be included in their meeting highlights. The HPRA continues to encourage healthcare professionals and members of the public to report suspected side effects. High-level information on the number of reports of suspected side effects the HPRA receives will continue to be published on our COVID-19 vaccines safety webpage.

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[1]*Health Service Executive Vaccination Programme overview as of 31 January 2023* *https://www.hse.ie/eng/services/news/newsfeatures/covid19-updates/vaccination-programme-dashboard-31-january-2023.pdf*

[2]*Government of Ireland GeoHive Vaccinations https://covid-19.geohive.ie/pages/vaccinations*

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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. All vaccines have some side effects, the vast majority of which are mild to moderate in nature. These side effects need to be continuously balanced against the expected benefits in preventing COVID-19 illness.

Reports included in the overview are those notified to the HPRA on a voluntary basis by healthcare professionals and members of the public, with reporting of suspected side effects to COVID-19 vaccines (www.hpra.ie/report) encouraged. Any reports of Irish cases received by the HPRA from the company (i.e., the licence holder, to date, BioNTech, Moderna, AstraZeneca, Janssen, Novavax) 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.

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 for COVID-19 vaccines is accessible here.

AUTHORISED COVID-19 VACCINES

COVID-19 vaccines currently authorised for use in the European Union (EU) by the EMA are listed below. Please note that not all authorised vaccines may be offered as part of the vaccination programme in Ireland. For further details on the vaccination programme in Ireland please refer to the HSE website.

mRNA vaccines:

- Comirnaty® Original (licence holder: BioNTech Manufacturing GmbH) is authorised for use in individuals aged 6 months and older as a primary vaccination course consisting of two separate doses, with a third dose recommended for those aged 5 years and older who are severely immunocompromised. A booster dose may be administered three months after the primary course in individuals aged 5 years and older. Different doses are used for those aged 6 months to 4 years and 5 to 11 years.
  - Comirnaty® is also available as two adapted vaccines:
    - Comirnaty® Original/Omicron BA.1 is authorised for use in individuals aged 12 years and older as a booster dose.
    - Comirnaty® Original/Omicron BA.4-5 is authorised for use in individuals aged 5 years and older as a booster dose.

  For further information on this vaccine click here.

- Spikevax® Original (*previously COVID-19 Vaccine Moderna®)* (licence holder: Moderna Biotech Spain, S.L.) is authorised for use in individuals aged 6 months and older as a primary vaccination course consisting of two separate doses, with a third dose recommended for those aged 6 years and older who are severely immunocompromised. A booster dose may be administered three months after the primary course in individuals aged 6 years and older. Different doses are used for those aged 6 months to 5 years and 6 to 11 years.
  - Spikevax® is also available as two adapted vaccines:
    - Spikevax® Original/Omicron BA.1 (licence holder: Moderna Biotech Spain, S.L.) is authorised for use in individuals aged 6 years and older as a booster dose.
    - Spikevax® Original/Omicron BA.4-5 (licence holder: Moderna Biotech Spain, S.L.) is authorised for use in individuals aged 12 years and older as a booster dose.

  For further information on this vaccine click here.

Adenoviral vector vaccines:

- Vaxzevria® (licence holder: AstraZeneca AB) is authorised for use in individuals 18 years and older as a vaccination course consisting of two separate doses. A booster dose may be administered three months after the primary course.
  For further information on this vaccine click here.

- Jcovden® *(previously COVID-19 Vaccine Janssen®)* (license holder: Janssen-Cilag International NV) is authorised for use in individuals aged 18 years and older as a vaccination course consisting of a single dose administration. A booster dose may be administered two months after the primary vaccination course.
  For further information on the vaccine click here.

Recombinant adjuvanted vaccine:

- Nuvaxovid® (licence holder: Novavax CZ, a.s.) is authorised for use in individuals 12 years and older as a primary vaccination course consisting of two separate doses. A booster dose may be administered six months after the primary vaccination course in individuals aged 18 years and older.
  For further information on this vaccine click here.

- VidPrevtyn Beta® (licence holder: Sanofi Pasteur) is authorised for use in individuals 18 years and older as a booster dose, administered four months after prior vaccination with either an mRNA or adenoviral vector vaccine.
  For further information on this vaccine click here.

Inactivated adjuvanted vaccine:

- COVID-19 Vaccine Valneva® (licence holder: Valneva Austria GmbH) is authorised for use in individuals 18 to 50 years of age as a primary vaccination course consisting of two separate doses.
  For further information on this vaccine click here

OVERVIEW OF SUSPECTED SIDE EFFECT REPORTS

Number of reports received

Since the start of vaccinations in Ireland and up to the 31 January, the HPRA has received 20,835 reports describing suspected side effects[3,4] in association with COVID-19 vaccines.

A breakdown of reports received by year is provided below:

2021	17,902
2022	2,852
2023	81

A breakdown of reports received by vaccine type is provided below:

mRNA vaccines (Comirnaty® and Spikevax®)	13,800
Adenoviral vector vaccines (Vaxzevria® and Jcovden® *[previously Janssen]*)	6,695
Recombinant adjuvanted spike protein vaccine (Nuvaxovid®)	6
Brand unknown/not specified	345

Doses administered by vaccine type, as of 31 January, were reported as follows:[1]

- mRNA vaccines: 6,012,359 Comirnaty®, 585,104 Spikevax®.
- Adenoviral vector vaccines: 1,217,060 Vaxzevria®, 241,206 Jcovden® *[previously Janssen]*.
- Recombinant adjuvanted spike protein vaccine: 458 Nuvaxovid®

Further information on vaccination, including doses administered, is available from covid-19.geohive.ie.

Regularly reported suspected side effects

The majority of reports recently received by the HPRA are associated with mRNA vaccines (Comirnaty® and Spikevax®), which are the most common type of vaccine currently in use.

The most regularly reported suspected side effects notified to the HPRA in relation to mRNA vaccines include the following:[5]

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[3]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.
[4]In accordance with EU guidance, reports are valid if the minimum reporting criteria are met. These include an identifiable reporter, an identifiable patient, one or more suspected medicine known to have been administered and one or more suspected adverse reaction.
[5]Terms listed as frequently reported are presented according to standard coding classification system (MedDRA) adopted for use in the EU, and grouped by system organ class (SOC) and listed alphabetically. It should be noted that regular reporting of a side effect is not the same as the incidence of occurrence.

mRNA vaccines (Comirnaty® and Spikevax®)

10% or more of reports describe side effects such as:

- Fever, pain (non-specific), tiredness
- Headache
- Nausea

1% to less than 10% of reports describe side effects such as:

- Diarrhoea, tingling sensation in mouth, vomiting
- Dizziness, drowsy, fainting/feeling faint, migraine, numbness/reduced sensations, tingling/pins and needles/tremor
- Back pain, joint/limb pain, muscle pain/weakness/spasm/stiffness, neck pain
- Blurred vision
- Chest discomfort/pain, chills, general discomfort, feeling unwell, feeling hot/cold, flu-like symptoms, lack of energy/feeling weak, swelling including of legs/arms/face, underarm pain
- Cough, shortness of breath, sore throat
- Difficulty carrying out daily tasks (such as temporarily unable to attend work, need to stay in bed)
- Feeling anxious, insomnia/trouble sleeping
- Increased heart rate/racing heart, increased blood pressure
- Injection site redness, pain, itchiness, swelling, rash, difficulty moving injected arm
- Lack of appetite
- Menstrual disturbances
- Painful/swollen lymph nodes
- Skin red/red rash, sweating, general rash, itching, itchy rash, hives
- Subsequent diagnosis of COVID-19
- Tinnitus (ringing in the ears), vertigo-like symptoms

The majority of regularly reported suspected side effects are consistent with the types of events typically observed following vaccination, including those described in the product information for the individual mRNA vaccines, and are mild to moderate in nature.

A full breakdown of all suspected side effects described in reports is provided on page 12.

Further information on how reports received by the HPRA are processed, including how safety signals are evaluated, is given on page 16.

TOPICS OF INTEREST, INCLUDING EMA RECOMMENDATIONS

In this section, topics of interest including recent recommendations from the EMA's safety committee are described.

These topics should be reviewed together with the approved product information, which describes the established safety profile, including known side effects, of a COVID-19 vaccine. The product information includes the package leaflet, and provides up to date evidence-based information on any expected side effects, as well as any relevant guidance. The product information for each authorised vaccine is available from the HPRA website.

Topics of interest;

- Vaccination of children and adolescents (up to 17 years)
- Booster (including adapted vaccines)
- Myocarditis and pericarditis
- Reports which included a fatal outcome
- Product information updates for mRNA vaccines (Comirnaty® and Spikevax®)
- Product information updates for recombinant adjuvanted vaccine (Nuvaxovid®)

Vaccination of children and adolescents (up to 17 years of age)

- The HPRA closely monitor reports of suspected side effects received in children (up to 11 years) and adolescents (aged 12 to 17 years). As of 31 January 2023, the HPRA received 512 reports of suspected side effects following vaccination, 125 of which related to a child, with the remainder relating to an adolescent. As of that date, 790,000 doses had been administered to children and adolescents as part of the national vaccination programme.[1]
- Overall, the reports received are consistent with the types of reports received for adults, with most being mild to moderate in nature. The most regularly reported include dizziness/fainting, headache, fever, nausea/vomiting and tiredness. Of the reports received which include information on outcome, many of the suspected side effects had resolved or were resolving at the time of reporting. A breakdown of all suspected side effects by type is available on page 15.

Reports following a booster dose with original or adapted mRNA vaccines

- The HPRA closely monitor reports of suspected side effects received following a booster dose, including those associated with adapted Comirnaty® and Spikevax® vaccines. 'Adapted' vaccines provide broader protection against new variants of COVID-19 and are available targeting both the original strain and variants BA.1 or BA.4-5 (for more information on adapted vaccines, see EMA website here).
- Up to 31 January, the HPRA has received 2,147 reports of suspected side effects following a booster dose, the vast majority of which are associated with Comirnaty® or Spikevax®, with 118 describing use of an adapted vaccine. Of these reports, 727 were received in 2021, 1369 in

2022, and 51 in 2023. Over 4.5 million booster doses have been administered as part of the national vaccination programme.[2]

- Overall, the reports received are consistent with the types of reports received after the primary vaccination course with the majority mild to moderate in nature. The most regularly reported include headache, fever, pain, swollen lymph nodes and tiredness.

Reports of myocarditis and pericarditis

- Myocarditis and pericarditis are inflammatory conditions of the heart and are very rare side effects of Comirnaty® and Spikevax® (meaning that up to one in 10,000 vaccinated people may be affected). Whilst the risk of myocarditis and pericarditis following vaccination is very rare, those vaccinated (or their parents/caregivers) should seek immediate medical attention if symptoms indicative of myocarditis or pericarditis occur. The symptoms can vary but may include chest pain, breathlessness and/or a forceful heartbeat that may be irregular (palpitations).
- Myocarditis and pericarditis can develop within just a few days after vaccination, with most cases occurring within 14 days. They occur more often after the second dose as compared to the first, and more often in younger males. Available data suggest that the course of myocarditis and pericarditis following vaccination is not different from myocarditis or pericarditis in general. For Comirnaty®, the risk of myocarditis and pericarditis appears to be lower in children (5 to 11 years) than adolescents (12 to 17 years).
- For mRNA vaccines, up to 31 January, the HPRA received a total of 135 reports describing suspected side effects of myocarditis (51 reports), pericarditis (61 reports) or a combination of both (23 reports). Of these, 112 occurred following vaccination with Comirnaty® and 23 following Spikevax®. In relation to dose, 46 cases occurred after the first dose, 56 after the second dose, and 25 after a booster or third dose (information on dose was not reported in eight cases). Most cases occurred within 14 days of vaccination, with 90 reported in males and 45 reported in females. The median age of cases was 39 years (range 12 to 87 years). In five cases, the report concerned an adolescent (12 to 17 years) and where outcome information is available on these cases, they have been reported as recovered/recovering. Reports received by the HPRA describe symptoms such as chest pain/discomfort, palpitations, dizziness, irregular heartbeat and shortness of breath.
- In its August 2022 update, the EMA's safety committee recommended that product information for Nuvaxovid® also be updated to include myocarditis and pericarditis as possible side effects. Up to 31 January, the HPRA has not been notified of any reports describing myocarditis or pericarditis following vaccination with Nuvaxovid®.
- All reports of myocarditis and pericarditis notified to the HPRA are carefully reviewed. However, it can be expected that medical events due to various causes will continue to occur, including following vaccination, but which are not all necessarily caused by the vaccine. Myocarditis and pericarditis can also occur for other reasons, such as due to an immune disorder or following a viral infection, such as COVID-19. If you experience symptoms following a COVID-19 vaccine, it is important that you follow the advice given in the package leaflet.

Reports which included a fatal outcome

- The HPRA closely monitor reports of suspected side effects received that describe a fatal outcome. Up to 31 January, a total of 124 reports have been received describing an individual who was known to have been vaccinated and subsequently passed away. Of these, 101 were reported with an mRNA vaccine, 14 with adenoviral vector vaccines and the remaining nine were reported with brand unknown/not specified. Where age was given, the majority (approximately two-thirds) describe an individual aged 75 years and over, with the median age of the individuals being 80 years. Of those, 68 deaths occurred in males and 56 in females. For a number of reports, the cause of death was unconfirmed at the time of reporting, with post-mortem results awaited.
- It is important to note that the HPRA receives reports based on a reporter's suspicion that an adverse experience may be associated with a vaccine. As such, these are referred to as 'suspected' side effects. With over 8 million COVID-19 vaccine doses administered in Ireland since 2020, it can be expected that fatalities due to progression of underlying disease or natural causes will continue to occur, including following vaccination. This does not mean that the vaccine caused the deaths. However, it is important that such reports are carefully evaluated. Further information on how all reports received are evaluated is described in more detail on page 16.

Product information updates for mRNA vaccines (Comirnaty® and Spikevax®)

A summary of product information updates as recommended by the EMA's safety committee since the last HPRA safety update is provided below. A copy of the production information for both vaccines is available on the EMA website: Comirnaty® (please refer to page 199 in the link provided for package leaflet), Spikevax® (please refer to page 118 in the link provided for package leaflet). [6]

- In its July 2022 update, the EMA's safety committee recommended that product information for Spikevax® be updated to include extensive swelling of the vaccinated limb as a possible side effect based on reports received. How often this event may occur following vaccination is uncertain. The HPRA has received reports of swelling at the site of vaccination, the majority of which were mild. The EMA have advised that in general, extensive swelling of the vaccinated limb is a condition that does not require treatment and resolves after some days

- In its November 2022 update, the EMA's safety committee recommended that product information for Comirnaty® and Spikevax® be updated to include heavy menstrual bleeding (or heavy periods) as a possible side effect. How often this event may occur following vaccination is uncertain. The available data reviewed involved mostly cases which appeared to be non-serious and changes which were temporary in nature. The EMA stated there is no evidence to suggest any impact on reproduction and fertility, and available data provide robust reassurance about the use of mRNA COVID-19 vaccines before and during pregnancy. For further information on the review by the EMA's safety committee please see the meeting highlights from October 2022. Up to 31 January, the HPRA was notified of 351 reports

[6] *Current as of 17 February 2023. Page number is subject to change as product information is updated.*

describing heavier menstrual bleeding following vaccination with Comirnaty® and 67 reports following vaccination with Spikevax®. Menstrual disorders in general are quite common and they can occur for a wide range of reasons. This includes some underlying medical conditions. Any person who experiences postmenopausal bleeding or is concerned about a change to their periods should consult their doctor.

- In its November 2022 update, the EMA's safety committee recommended that product information for Spikevax® be updated to include urticaria (hives/raised itchy rash) as a possible side effect. This rash may appear with acute onset (within a few days of vaccination) or delayed onset (up to two weeks post vaccination). The frequency (how often this event may occur) is 'uncommon', meaning it may affect up to 1 in 100 people. Up to 31 January, the HPRA was notified of 59 reports describing hives following vaccination with Spikevax®.

- At its January 2023 meeting, the EMA's safety committee recommended that product information for Comirnaty® be updated to include dizziness as a possible side effect. The frequency (how often this event may occur) is 'uncommon', meaning it may affect up to 1 in 100 people. Up to 31 January, the HPRA was notified of 1095 reports describing dizziness following vaccination with Comirnaty®.

Product information updates for recombinant adjuvanted vaccine (Nuvaxovid®)

A summary of product information updates as recommended by the EMA's safety committee since the last HPRA safety update is provided below. A copy of the production information is available on EMA website: Nuvaxovid® (please refer to page 27 for package leaflet).[6]

- In its July 2022 update, the EMA's safety committee recommended that product information for Nuvaxovid® be updated to include paraesthesia (tingling/pins and needles) and hypoaesthesia (numbness/reduced sensations in the skin) as possible side effects. How often these events may occur following vaccination is not yet known. Up to 31 January, the HPRA has not been notified of any reports describing tingling/pins or numbness/reduced sensations following vaccination with Nuvaxovid®.

- In its July 2022 update, the EMA's safety committee recommended that product information for Nuvaxovid® be updated to include anaphylaxis (a severe allergic reaction) as a possible side effect. How often this may occur following vaccination is uncertain. Up to 31 January, the HPRA has not been notified of any reports describing anaphylaxis following vaccination with Nuvaxovid®.

BREAKDOWN OF SUSPECTED SIDE EFFECTS BY CATEGORY

A full breakdown of all suspected side effects to mRNA vaccines (Comirnaty® and Spikevax®) described in reports received by the HPRA is provided below. Most reports received recently are associated with mRNA vaccines, which are the most common type of vaccine currently being used in Ireland.

Whilst the vast majority of reports notified to the HPRA describe expected events (i.e., known side effects of a vaccine or vaccination process), reports can also be received for events that are unexpected and/or are considered serious, as they required medical care or intervention. Such reports may describe events not caused by the vaccine and may have occurred coincidentally. However, all reports are carefully reviewed and if there is cause to do so, a further analysis is carried out to determine if a vaccine may have had a contributory role. If it is determined that a vaccine is a contributory factor, the public and healthcare professionals will be informed and the relevant product information will be updated.

Please read the following explanatory note in relation to understanding the data presented in the suspected side effect tables:

- A single report describes at least one suspected side effect for a vaccinated individual. Reports often describe several suspected side effects for an individual, which may include more than one category, or more than one in a specific category. For example, a single report that describes chills, fatigue and nausea in an individual, includes three suspected side effects, two in general symptoms (chills and fatigue) and one in gastrointestinal (nausea). As such, there are more suspected side effects in each category and overall, as compared to the number of reports received.
- The breakdown summary includes all suspected side effects as they are reported to the HPRA. This includes cases for which a diagnosis is reported as provisional, or for which there is more than one possible diagnosis at the time of reporting. In other cases, a diagnosis may not be available, and only signs and symptoms or laboratory test results are given. Reports are also received from members of the public, and the HPRA follows up to medically confirm these reports, where consent is provided and more information is required. For each report, all events are 'coded'[7] as suspected side effects in the national pharmacovigilance database using the exact information (verbatim) given in the report. The HPRA follows up with the reporter to collect any further information which may be relevant to the assessment of the case.
- The description of suspected side effects in this update, including the number and category, reflect 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 reports are further evaluated.
- Please refer to the section 'Understanding the data presented within this safety update' on page 3 for further interpretation guidance. Background information on the evaluation of suspected side effect reports is available on page 16.

Of the 20,835 reports notified to the HPRA as of 31 January 2023, over 95% have been submitted to EMA's Eudravigilance database, and as such, additional anonymised information on these reports, is publicly available through the following link www.adrreports.eu. See page 16 for further details. Reports of suspected side effects notified to the HPRA are carefully evaluated and validated reports are submitted onwards to Eudravigilance within defined regulatory timelines. Please note that a small number of reports received by the HPRA do not meet reporting requirements to EudraVigilance (for example, reports for which the brand of vaccine is unknown, or which describe

[7] *Medical Dictionary for Regulatory Activities (MedDRA) https://www.meddra.org/*

a medication error without an associated suspected adverse reaction). Follow up for information to validate such reports is undertaken by the HPRA, as appropriate.

Suspected side effects to mRNA vaccines

A breakdown of suspected side effects described in the 13,800 reports notified to the HPRA is provided below by category. Each report describes at least one suspected side effect for a vaccinated individual. Reports often describe several suspected side effects for an individual, including more than one in a specific category. As such, there are more suspected side effects in each category and overall, as compared to the number of reports received.

Category	Suspected side effects
General symptoms and local reactions *e.g., chills, fatigue, 'flu-like' feeling, fever, injection site pain or swelling*	15,795
Nervous system *e.g., dizziness, headache, lack of energy, pins & needles, fainting or feeling faint*	8,921
Muscles, tissue, bones or joints *e.g., general muscular pain or weakness*	6,118
Gastrointestinal *e.g., nausea, vomiting, diarrhoea*	4,267
Skin *e.g., rash, itchy rash*	3,538
Reproductive system, obstetrics or gynaecology related *e.g., menstrual disturbance*	2,295
Respiratory *e.g., cough, shortness of breath*	1,927
Behavioural, emotional and mental health *e.g., insomnia, trouble sleeping*	1,582
Social circumstances *e.g., need to rest in bed or take a break from normal daily activities*	1,301
Cardiac (heart) related *e.g., palpitations*	1,268
Procedural issues and complications *e.g., injection site bruising*	1,154
Blood and lymphatic system *e.g., swollen glands*	1,056
Eye *e.g., eye pain, vision blurred*	1,014
Abnormal clinical or laboratory result (i.e., where information is provided on results of relevant tests) *e.g., high temperature (via thermometer), increased heart rate or blood pressure (via BP monitor)*	963
Infection *e.g., local or general such as influenza or cold sore*	858
Blood vessel related (i.e., veins/arteries) *e.g., pale complexion*	751
Ear related e*.g., earache, tinnitus*	619
Metabolism and nutrition disorders *e.g., decreased appetite*	431
Immune system related *e.g., hypersensitivity, allergic reaction*	243
Kidney related *e.g., change in frequency of urination*	129
Endocrine (hormone) *e.g., thyroid function change*	41
Liver related *e.g., jaundice, inflammation*	35
Cysts and polyps *e.g., benign skin growth*	20
Conditions present at birth	<5
Medical procedures	<5

Suspected side effects in children and adolescents (up to 17 years) following vaccination with an mRNA Vaccine

A breakdown of suspected side effects described in the 512 reports notified to the HPRA concerning children and adolescents (up to 17 years) following vaccination is provided below by category. Each report describes at least one suspected side effect for a vaccinated individual. Reports often describe several suspected side effects for an individual, including more than one in a specific category. As such, there are more suspected side effects in each category and overall, as compared to the number of reports received.

Category	Suspected side effects
General symptoms and local reactions *e.g., tiredness, weakness, chest pain, feeling hot*	438
Nervous system *e.g., dizziness, headache, fainting or feeling faint*	356
Gastrointestinal *e.g., nausea, vomiting, abdominal pain*	204
Skin *e.g., rash, sweating*	166
Muscles, tissue, bones or joints *e.g., limb, muscle, joint pain*	118
Respiratory *e.g., shortness of breath*, *nosebleed*	104
Behavioural, emotional and mental health *e.g., trouble sleeping*	62
Procedural issue or complications *e.g., injection site bruising*	59
Social circumstances *e.g., need to rest in bed or take a break from normal daily activities*	54
Reproductive system, obstetrics or gynaecology related *e.g., menstruation disturbance*	53
Blood vessel related (i.e., veins/arteries) *e.g., pale complexion*	52
Infection *e.g., chest infection*	52
Cardiac (heart) related *e.g., palpitations/racing heart*	45
Eye *e.g., vision blurred*	44
Abnormal clinical or laboratory result (i.e., where information is provided on results of relevant tests) *e.g., changes in heart rate*	37
Blood and lymphatic system *e.g., swollen glands*	26
Metabolism and nutrition disorders *e.g., decreased appetite*	19
Ear related e*.g., earache, tinnitus*	17
Immune system related *e.g., hypersensitivity, allergic reactions*	13
Kidney related *e.g., inflammation*	9
Liver related	<5

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. This supports early detection and monitoring of possible safety signals in relation to reported side effects.

The EMA also make available anonymised information on all reports, based on global safety experience, publicly available through the following link www.adrreports.eu. The EMA also publish regular safety updates for COVID-19 vaccines, as well as highlights from meetings of the EMA's safety committee (Pharmacovigilance Risk Assessment Committee), which describe safety issues under review, as well as recommendations to revise product information. These are available via 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.