

## HPRA Safety Update

### COVID-19 Vaccines, Overview of National Reporting Experience Publication date: 04 November 2021 (Update #13)

---

#### Highlights from this update:

- Up to 26 October, a total of 15,705 reports of suspected side effects were notified to the HPRA. The number of COVID-19 vaccines administered as of that date was reported as 7,317,176, including 236,168 administered as a single dose, 3,571,557 as a first dose, and 3,509,451 as a second dose.<sup>1</sup>
- Whilst not experienced by everyone, 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 benefits in preventing COVID-19 illness. Overall, the national reporting experience continues to support the favourable assessment that the benefits of COVID-19 vaccines outweigh the risks. An overview of national reports received is provided in this safety update on page [5](#).
- On 29 October, the European Medicines Agency (EMA) published [highlights](#) from its monthly safety committee meeting, which included information on COVID-19 vaccines. Topics of interest are summarised on page [7](#) of this update.
- The next HPRA safety update is due for publication on 09 December.

---

<sup>1</sup><https://covid-19.geohive.ie/pages/vaccinations>

## CONTENTS

Understanding the data presented within this safety update.....	<a href="#">3</a>
Authorised COVID-19 vaccines.....	<a href="#">4</a>
Overview of suspected side effect reports.....	<a href="#">5</a>
Topics of interest, including EMA recommendations.....	<a href="#">7</a>
mRNA vaccines (Comirnaty® and Spikevax® [ <i>previously Moderna</i> ]).....	<a href="#">7</a>
Adenoviral vector vaccines (Vaxzevria® and COVID-19 Vaccine Janssen®).....	<a href="#">8</a>
COVID-19 vaccines - Common topics.....	<a href="#">9</a>
Breakdown of suspected side effects by category.....	<a href="#">11</a>
Background information on the evaluation of suspected side effect reports.....	<a href="#">15</a>

## 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](http://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) 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 is accessible from  
<https://www.hpra.ie/homepage/medicines/covid-19-updates/covid-19-vaccines-product-information>

### AUTHORISED COVID-19 VACCINES

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

mRNA vaccines:

- Comirnaty® (licence holder: BioNTech Manufacturing GmbH) is authorised for use in individuals aged 12 years and older as a vaccination course consisting of two separate doses, with a third dose recommended for those who are severely immunocompromised. The authorisation has been expanded to include booster doses, administered at least 6 months after the second dose, in individuals aged 18 years and older. For further information on this vaccine click [here](#).
- Spikevax® (*previously COVID-19 Vaccine Moderna*®) (licence holder: Moderna Biotech Spain, S.L.) is authorised for use in individuals aged 12 years and older as a vaccination course consisting of two separate doses, with a third dose recommended for those who are severely immunocompromised. The authorisation has been expanded to include booster doses, administered at least 6 months after the second dose, in individuals aged 18 years and older. For further information on this vaccine click [here](#).

Adenoviral vector vaccines:

- Vaxzevria® (licence holder: AstraZeneca AB) is authorised for use in individuals 18 years of age and older as a vaccination course consisting of two separate doses. For further information on this vaccine click [here](#).
- COVID-19 Vaccine Janssen® (License holder: Janssen-Cilag International NV) is authorised for use in individuals aged 18 years and older as a single dose administration. For further information on the vaccine click [here](#).

## OVERVIEW OF SUSPECTED SIDE EFFECT REPORTS

### Number of reports received

Up to 26 October, the HPRA received 15,705 reports describing suspected side effects<sup>2,3</sup> in association with COVID-19 vaccines, as follows:

mRNA vaccines (Comirnaty® and Spikevax®)	9463
Adenoviral vector vaccines (Vaxzevria® and COVID-19 Vaccine Janssen®)	6140
Brand unknown/not specified	102

Doses administered by vaccine type, as of 26 October, were reported as follows:<sup>1</sup>

- mRNA vaccines: 5,308,766 Comirnaty®, 570,330 Spikevax®.
- Adenoviral vector vaccines: 1,189,631 Vaxzevria®, 236,145 COVID-19 Vaccine Janssen®.

### Regularly reported suspected side effects

The most regularly reported suspected side effects notified to the HPRA include the following:<sup>4</sup>

<b>mRNA vaccines (Comirnaty® and Spikevax®)</b>
<b>10% or more of reports describe side effects such as:</b>
<ul style="list-style-type: none"><li>▪ Fever, tiredness</li><li>▪ Dizziness, headache</li><li>▪ Pain (non-specific)</li><li>▪ Nausea</li></ul>
<b>1% to less than 10% of reports describe side effects such as:</b>
<ul style="list-style-type: none"><li>▪ Abdominal pain, diarrhoea, tingling sensation in mouth, vomiting</li><li>▪ Drowsy, fainting/feeling faint, migraine, numbness/reduced sensations, tingling/pins and needles/tremor</li><li>▪ Back pain, joint/limb pain, muscle pain/weakness/spasm/stiffness, neck pain</li><li>▪ Blurred vision</li><li>▪ 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</li><li>▪ Cough, shortness of breath, sore throat</li><li>▪ Difficulty carrying out daily tasks (such as temporarily unable to attend work, need to stay in bed)</li><li>▪ Enlarged lymph nodes</li><li>▪ Feeling anxious, insomnia/trouble sleeping</li><li>▪ Increased heart rate/racing heart, increased blood pressure</li></ul>

<sup>2</sup>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.

<sup>3</sup>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.

<sup>4</sup>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.

- Injection site redness, pain, itchiness, swelling, rash
- Lack of appetite
- Menstrual disturbances
- Skin reactions, skin red/red rash, sweating, general rash, itching, itchy rash, hives
- Tinnitus (ringing in the ears), vertigo-like symptoms

#### Adenoviral vector vaccines (Vaxzevria® and COVID-19 Vaccine Janssen®)

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

- Chills, fever, tiredness
- Dizziness, headache
- Joint pain, muscle pain, other pain (non-specific)
- Nausea

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

- Abdominal discomfort/pain, diarrhoea, vomiting
- Back pain, bone pain, limb pain, muscle spasms/weakness/stiffness, neck pain
- Chest discomfort/pain, general discomfort, feeling unwell/ill, feeling hot/cold, flu-like symptoms, lack of energy/weakness, swelling including of legs/arms
- Cough, shortness of breath, sore throat, nose bleed
- Difficulty carrying out daily tasks (such as temporarily unable to attend work, need to stay in bed)
- Drowsy, fainting, headache, migraine, numbness/reduced sensations, tingling/pins and needles, tremor
- Ear pain, tinnitus (ringing in the ears), vertigo-like symptoms
- Enlarged lymph nodes
- Eye pain, vision blurred
- Hives, skin red, general rash, sweating/cold sweat, itching,
- Increased heart rate/racing heart
- Injection site pain, redness, swelling, bruising, difficulty moving injected arm
- Insomnia/trouble sleeping
- Lack of appetite
- Menstrual disturbances

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 vaccines, and are mild to moderate in nature.

In reports evaluated, which include information on outcome, approximately 30% of suspected side effects had resolved or were resolving at the time of reporting. For others, the suspected side effects had not yet resolved, or the outcome was reported as unknown, at the time of initial reporting. Information on reports with a fatal outcome is provided on page [10](#).

A full breakdown of all suspected side effects described in reports is provided on page [11](#). Further information on how reports received by the HPRA are processed, including how safety signals are evaluated, is given on page [15](#).

A link to the most recent EMA safety committee meeting highlights is provided in the highlights section on the cover page.

## Topics of interest, including EMA recommendations

In this section, topics of interest, including any new recommendations from EMA's safety committee, are described. The information provided should be considered together with the approved product information for a vaccine which describes 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 each authorised vaccine is available from the HPRA website [here](#).

Topics of interest included in this safety update, are as follows:

### mRNA vaccines (Comirnaty® and Spikevax®)

- [Vaccination of adolescents \(12 to 17 years\)](#)
- [Myocarditis and pericarditis](#)

### Adenoviral vector vaccines (Vaxzevria® and COVID-19 Vaccine Janssen®)

- [Thrombosis with thrombocytopenia syndrome \(TTS\)](#)

### Common topics

- [Multisystem inflammatory syndrome \(MIS\)](#)
- [Allergic type reactions \(also known as hypersensitivity\)](#)
- [Menstrual disturbances](#)
- [Deaths following vaccination](#)

### mRNA vaccines (Comirnaty® and Spikevax®)

#### Vaccination of adolescents (12 to 17 years)

- As the national vaccination programme continues, the HPRA are closely monitoring any reports of suspected side effects received in adolescents aged 12 to 17 years.
- As of 26 October, the HPRA has received 195 reports of suspected side effects following vaccination of an adolescent with an mRNA vaccine. A breakdown of all suspected side effects by type, reported in those aged 12 to 17 years is available on page [14](#). Overall, the reports received are consistent with the types of reports received for adults, with most being mild to moderate in nature. 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.

#### Reports of myocarditis and pericarditis

- Myocarditis and pericarditis, which are inflammatory conditions of the heart, are possible side effects of [Comirnaty®](#) and [Spikevax®](#). Cases that have been reported internationally primarily occurred within 14 days, more often in younger men and after the second dose. The clinical course of myocarditis and pericarditis following vaccination has been observed as similar to that which can occur in unvaccinated people, for example, when myocarditis or pericarditis develop after a viral infection, or due to an immune disorder.
- Current advice is that those vaccinated should seek immediate medical attention if symptoms indicative of myocarditis or pericarditis occur. These symptoms can vary but often include breathlessness, a forceful heartbeat that may be irregular (palpitations), and chest pain.

- For Comirnaty® and Spikevax®, as of 26 October, the HPRA received a total of 83 reports describing suspected side effects of myocarditis (28 reports), pericarditis (33 reports) or a combination of both (22 reports). Of these, 73 occurred following vaccination with Comirnaty® and 10 following Spikevax®. In relation to dose, 37 cases occurred after the first dose and 43 after the second dose (information not reported for three cases), with most occurring within 14 days of vaccination. Suspected cases were reported in 57 males and 26 females, with a median age of 35 years (range 12 to 81). In five cases, the report concerned an adolescent (i.e. aged 12 to 17 years).
- National reports received describe symptoms such as chest pain/discomfort, palpitations, dizziness, irregular heartbeat and shortness of breath. In a number of cases, possible alternative explanations (other than vaccination) for the individual developing the condition were described, or the diagnosis was provisional and not yet finalised at the time of reporting. In the majority of the cases, the individuals were still recovering or had ongoing symptoms at the time of initial reporting.
- 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.
- The EMA's safety committee continues to closely monitor data on the risk of myocarditis and pericarditis. The companies that manufacture Comirnaty® and Spikevax® have recently been asked to perform a comprehensive review of all available data, including new data in the public domain on the frequency and nature of myocarditis/pericarditis associated with each of the mRNA vaccines. The EMA's safety committee will assess all new data to determine whether there is a need to update current advice in the product information for these vaccines. Further information on the review is available through the EMA safety committee's meeting [highlights](#).
- Advice for healthcare professionals previously issued on this topic is available from the HPRA website [here](#).

### Adenoviral vector vaccines (Vaxzevria® and COVID-19 Vaccine Janssen®)

#### Reports of thrombosis with thrombocytopenia syndrome (TTS)

- Thrombosis with thrombocytopenia syndrome (TTS) is a very rare side effect associated with Vaxzevria® and COVID-19 Vaccine Janssen®. The syndrome involves an unusual combination of thrombosis (blood clots) together with thrombocytopenia (very low platelet levels).
- Vaccine recipients are reminded to seek immediate medical attention if they experience any of the following signs and symptoms: shortness of breath, chest pain, leg swelling, leg pain, persistent abdominal pain post vaccination, severe or persistent headaches, blurred vision, confusion, seizures (fits) or bruising beyond the site of vaccination after a few days.
- Healthcare professionals are advised that individuals diagnosed with thrombocytopenia within three weeks after vaccination should be actively investigated for signs of thrombosis. Similarly, individuals who present with thrombosis within three weeks of vaccination should be evaluated for thrombocytopenia. Healthcare professionals should be alert to the signs and symptoms of TTS and consult applicable guidance and/or appropriate specialists to diagnose and treat this condition. A second dose of Vaxzevria® is contraindicated in any person who experienced TTS following their first dose.
- As of 26 October, the HPRA has received ten reports that are suspected cases of TTS, and which mostly describe the unusual combination of blood clotting in combination with low platelets. In

relation to these suspected TTS cases, symptoms occurred between 1-5 weeks of vaccination with a first dose of Vaxzevria® or single dose of COVID-19 Vaccine Janssen®. The types of symptoms reported include shortness of breath, severe and/or persistent headache, unusual skin bruising, abdominal pain, leg pain and leg swelling. Cases occurred in both males and females, with a median age of 36 (age range, 21 to 63 years). In a small number, blood clots occurred in unusual locations, including in the brain (cerebral venous sinus thrombosis, CVST) and liver (hepatic and portal veins). Based on information currently available, the individuals are either discharged or recovering in hospital after receiving specialist medical care.

- Advice to healthcare professionals previously issued on this topic is available from the HPRA website [here](#).

## COVID-19 vaccines - Common topics

### Reports of multisystem inflammatory syndrome

- Multisystem inflammatory syndrome (MIS) is a very rare but serious inflammatory condition affecting many parts of the body and symptoms can include tiredness, persistent severe fever, diarrhoea, vomiting, stomach pain, headache, chest pain and difficulty breathing. MIS has previously been reported following COVID-19 disease, including in children and adolescents.
- In HPRA safety update [#11](#), it was highlighted that the EMA's safety committee had started a review of a small number of reports of MIS following COVID-19 vaccination, including in some individuals without a history of COVID-19 disease. The [review](#) has now been completed, and found that there was not enough evidence to support a link between these very rare cases of MIS and COVID-19 vaccination. The EMA will continue to closely monitor any new cases of MIS that are reported following COVID-19 vaccination.
- To date, no reports of MIS following COVID-19 vaccination have been notified to the HPRA.

### Reports of allergic type reactions (also known as hypersensitivity)

- Allergic type reactions are known side effects of both mRNA and adenoviral vector vaccines. The HPRA has received a number of such reports, mainly describing symptoms such as itchiness, hives and rash. In some cases, medical treatment and/or clinical observation of the individual was needed.
- The HPRA continues to monitor reports of anaphylaxis, which is a serious allergic reaction. All reports suggestive of anaphylaxis (e.g. sudden onset of symptoms such as low blood pressure, collapse, rapid heart rate, shortness of breath, swelling of lips/throat and itchy skin) are carefully reviewed. Cases are classified by the HPRA as anaphylaxis using a well-established set of clinical and laboratory criteria however, some reports do not contain sufficient detail for classification purposes.<sup>5</sup> Of the reports reviewed, 12 cases associated with an mRNA vaccine and a small number<sup>6</sup> of cases associated with an adenoviral vector vaccine are currently classified as

---

<sup>5</sup>Reports classified using Brighton Collaboration case definition for anaphylaxis <https://brightoncollaboration.us/category/pubstools/case-definitions/>. Some reports contain limited information and therefore it is not possible to classify according to the Brighton Collaboration case definition. In these case, the HPRA follows up with the reporter for the missing information.

<sup>6</sup>When the relevant number is less than five, it is described as a small number to avoid any potential, inadvertent identification of the individuals concerned.

anaphylaxis. In some cases the individual concerned had recovered at the time of reporting and the remaining cases are being followed-up for further information.

- Anaphylaxis is a known side effect, and information on managing this risk is described in the product information. As for all vaccines, COVID-19 vaccines should be administered under close supervision with appropriate medical treatment available in case of such a reaction. Those vaccinated should discuss any signs/symptoms of allergic reaction that they are concerned about with a healthcare professional.

### Reports of menstrual disturbances

- Menstrual disturbances are one of the more regularly reported side effects to the HPRA (see [pages 5 & 6](#)). In the vast majority of cases, reports are received directly from a vaccinated woman, and describe a recent disturbance in normal menstruation, such as a period arriving earlier or later than expected, or of a heavier nature than normal. Whilst less frequent, some reports that describe a bleeding event in a woman who is post menopausal have also been notified.
- Following evaluation of the available data in relation to menstrual disorders, the EMA's safety committee concluded that no specific pattern of menstrual disturbances could be found and there is currently no evidence suggesting a causal association or link between menstrual disturbances and vaccination with Cormiranty®, Spikevax® or Vaxzevria®. The review of reports following vaccination with COVID-19 Vaccine Janssen® is ongoing however no causal association has been found so far.
- The EMA has highlighted that generally, menstrual disturbances are very common and can occur with or without an underlying medical condition. In about half of the cases reviewed, the patient's medical history or other medication being used provided a possible explanation for their symptom. The EMA outlined that menstrual disturbances may occur due to a wide range of reasons, including stress or tiredness and conditions such as fibroids and endometriosis. Women who are concerned about prolonged or severe menstrual disturbances may wish to seek medical advice, in particular if unexpected vaginal bleeding, for example, in a postmenopausal woman, is experienced.

### Reports of deaths following COVID-19 vaccination

- A total of 90 reports have been received describing an individual who was known to have been vaccinated and subsequently passed away. Of these, 79 were reported with an mRNA vaccine, seven with adenoviral vector vaccines and the remaining four were reported with brand unknown/not specified. The majority of reports with a fatal outcome describe an individual aged 75 years and over (approximately 80%), with the median age of the individuals being 84 years. For a number of reports, the cause of death was unconfirmed at the time of reporting, with post mortem results awaited.
- Reports describing a death are carefully reviewed. However, 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.

## BREAKDOWN OF SUSPECTED SIDE EFFECTS BY CATEGORY

A full breakdown of all suspected side effects described in reports received by the HPRA is provided below by vaccine type (i.e. mRNA and adenoviral vector vaccines) and by category (i.e. the related body system).

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'<sup>7</sup> 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](#) with regard to further interpretation guidance. Background information on the evaluation of suspected side effect reports is available on page [15](#).

Of the 15,705 reports notified to the HPRA up to 26 October, just under 70% have now 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](http://www.adrreports.eu). See page [15](#) for further details.

---

<sup>7</sup> Medical Dictionary for Regulatory Activities (MedDRA) <https://www.meddra.org/>

## Suspected side effects to mRNA vaccines

A breakdown of suspected side effects described in the 9,463 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 <i>e.g. chills, fatigue, 'flu-like' feeling, fever, injection site pain or swelling</i>	11126
Nervous system <i>e.g. dizziness, headache, lack of energy, pins &amp; needles, fainting or feeling faint</i>	6363
Muscles, tissue, bones or joints <i>e.g. general muscular pain or weakness</i>	4339
Gastrointestinal <i>e.g. nausea, vomiting, diarrhoea</i>	3173
Skin <i>e.g. rash, itchy rash</i>	2538
Reproductive system, obstetrics or gynaecology related <i>e.g. menstrual disturbance</i>	1515
Respiratory <i>e.g. cough, shortness of breath</i>	1302
Behavioural, emotional and mental health <i>e.g. insomnia, trouble sleeping</i>	1030
Social circumstances <i>e.g. need to rest in bed or take a break from normal daily activities</i>	779
Cardiac (heart) related <i>e.g. palpitations</i>	770
Eye <i>e.g. eye pain, vision blurred</i>	690
Blood and lymphatic system <i>e.g. swollen glands</i>	663
Procedural issues and complications <i>e.g. injection site bruising</i>	584
Abnormal clinical or laboratory result (i.e. where information is provided on results of relevant tests) <i>e.g. high temperature (via thermometer), increased heart rate or blood pressure (via BP monitor)</i>	570
Blood vessel related (i.e. veins/arteries) <i>e.g. pale complexion</i>	480
Infection <i>e.g. local or general such as influenza or cold sore</i>	476
Ear related <i>e.g. earache, tinnitus</i>	420
Metabolism and nutrition disorders <i>e.g. decreased appetite</i>	286
Immune system related <i>e.g. hypersensitivity, allergic reaction</i>	140
Kidney related <i>e.g. change in frequency of urination</i>	89
Endocrine (hormone) <i>e.g. thyroid function change</i>	21
Liver related <i>e.g. jaundice, inflammation</i>	20
Cysts and polyps <i>e.g. benign skin growth</i>	9

## Suspected side effects to adenoviral vector vaccines

A breakdown of suspected side effects described in the 6,140 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 <i>e.g. chills, fatigue, 'flu-like' feeling, fever, injection site pain or swelling</i>	10656
Nervous system <i>e.g. dizziness, headache, lack of energy, pins &amp; needles, fainting or feeling faint</i>	5549
Muscles, tissue, bones or joints <i>e.g. general muscular pain or weakness</i>	3861
Gastrointestinal <i>e.g. nausea, vomiting, diarrhoea</i>	2947
Skin <i>e.g. rash, itchy rash</i>	1638
Respiratory <i>e.g. cough, shortness of breath</i>	886
Behavioural, emotional and mental health <i>e.g. insomnia, trouble sleeping</i>	784
Social circumstances <i>e.g. need to rest in bed or take a break from normal daily activities</i>	625
Eye <i>e.g. eye pain, vision blurred</i>	480
Reproductive system, obstetrics or gynaecology related <i>e.g. menstruation disturbance</i>	468
Metabolism and nutrition disorders <i>e.g. decreased appetite</i>	460
Blood vessel related (i.e. veins/arteries) <i>e.g. pale complexion</i>	435
Abnormal clinical or laboratory result (i.e. where information is provided on results of relevant tests) <i>e.g. high temperature (via thermometer), increased heart rate or blood pressure (via BP monitor)</i>	391
Cardiac (heart) related <i>e.g. palpitations</i>	364
Procedural issue or complications <i>e.g. injection site bruising</i>	356
Ear related <i>e.g. earache, tinnitus</i>	347
Infection <i>e.g. local or general such as influenza or cold sore</i>	244
Blood and lymphatic system <i>e.g. swollen glands</i>	179
Kidney related <i>e.g. increased frequency of urination</i>	69
Immune system related <i>e.g. hypersensitivity, allergic reactions</i>	55
Liver related <i>e.g. jaundice</i>	10
Endocrine (hormone) <i>e.g. thyroid function change</i>	8
Cysts and polyps	<5

## Suspected side effects in adolescents (aged 12 to 17 years) following vaccination with an mRNA Vaccine

A breakdown of suspected side effects described in the 195 reports notified to the HPRA concerning adolescents aged 12 to 17 years following vaccination with an mRNA vaccine 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 <i>e.g. tiredness, weakness, chest pain, feeling hot</i>	182
Nervous system <i>e.g. dizziness, headache, fainting or feeling faint</i>	143
Gastrointestinal <i>e.g. nausea, vomiting, abdominal pain</i>	93
Muscles, tissue, bones or joints <i>e.g. limb, muscle, joint pain</i>	56
Skin <i>e.g. rash, sweating</i>	56
Respiratory <i>e.g. shortness of breath, nose bleed</i>	39
Cardiac (heart) related <i>e.g. palpitations/racing heart</i>	29
Behavioural, emotional and mental health <i>e.g. trouble sleeping</i>	24
Social circumstances <i>e.g. need to rest in bed or take a break from normal daily activities</i>	22
Reproductive system, obstetrics or gynaecology related <i>e.g. menstruation disturbance</i>	19
Blood vessel related (i.e. veins/arteries) <i>e.g. pale complexion</i>	16
Eye <i>e.g. vision blurred</i>	15
Blood and lymphatic system <i>e.g. swollen glands</i>	13
Infection <i>e.g. chest infection</i>	11
Ear related <i>e.g. earache, tinnitus</i>	9
Procedural issue or complications <i>e.g. fall</i>	9
Abnormal clinical or laboratory result (i.e. where information is provided on results of relevant tests) <i>e.g. changes in heart rate</i>	9
Metabolism and nutrition disorders <i>e.g. decreased appetite</i>	8
Immune system related	<5
Kidney 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, publically available through the following link [www.adrreports.eu](http://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](http://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](#).