

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Preliminary data from post-marketing surveillance on adverse events following immunization

Dr. Irina Caplanusi

Pharmacovigilance Office, European Medicines Agency

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An agency of the European Union





COMIRNATY (tozinameran) timeline



1 Preliminary data from post-marketing surveillance on adverse events following immunization
Classified as internal/staff & contractors by the European Medicines Agency



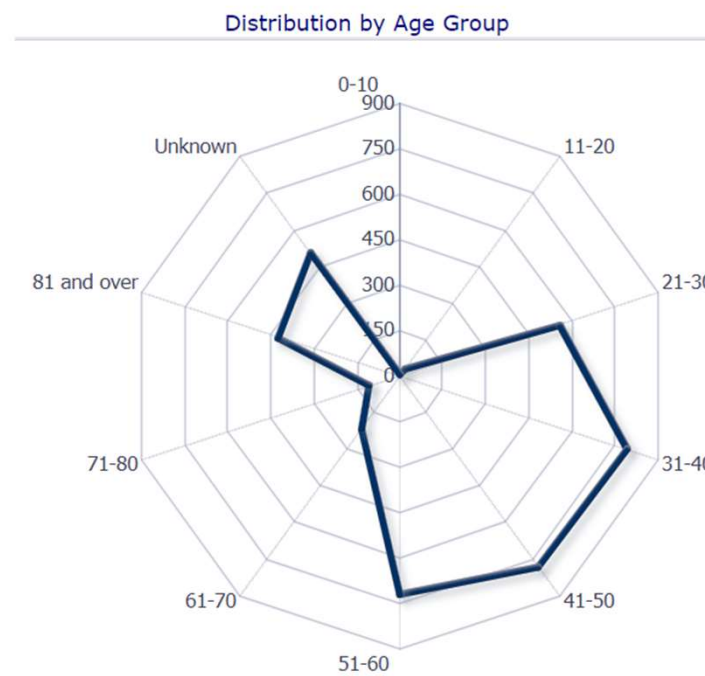
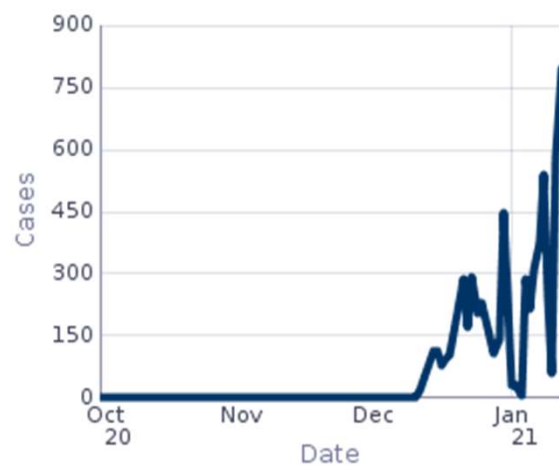
EMA signal detection activities COMIRNATY

- EV daily monitoring (tools, processes, methodology supporting intensive review);
- Informing the PRAC Rapporteur (NL) of relevant cases as they arise;
- Close monitoring of fatal cases, and adverse events of special interest;
- Liaising with other regulators as needed.
- Timely exchange of information, transparency and communication.

Overall, no issues have been identified to date for which additional action beyond close monitoring is deemed necessary based on the information provided in the EV case reports.



EudraVigilance (EV) data as of 14 Jan (1)

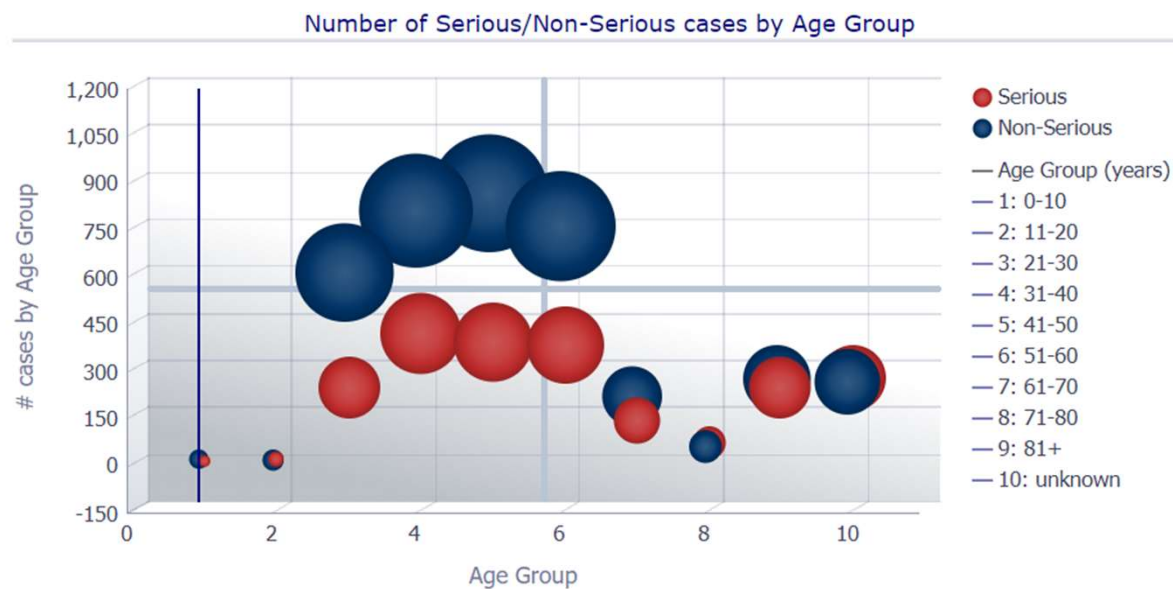
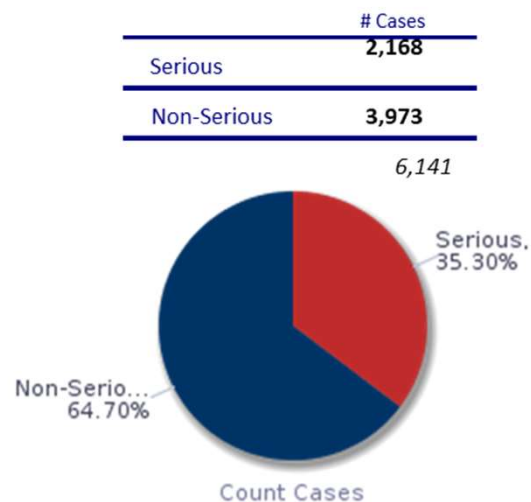


3 Preliminary data from post-marketing surveillance on adverse events following immunization

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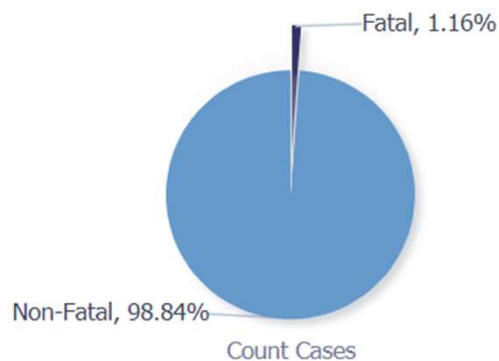
EV data as of 14 Jan (2)





EV data as of 14 Jan (3)

	# Cases
Fatal	71
Non-Fatal	6,070
<i>6,141</i>	



Fatal by Age Group

Age Group	Fatal	Non-Fatal	
0-10		11	11
11-20	1	31	32
21-30	1	564	565
31-40		797	797
41-50	2	789	791
51-60	2	726	728
61-70	1	217	218
71-80	11	102	113
81 and over	23	407	430
Unknown	3	505	508
Grand Total	44	4,149	6,141

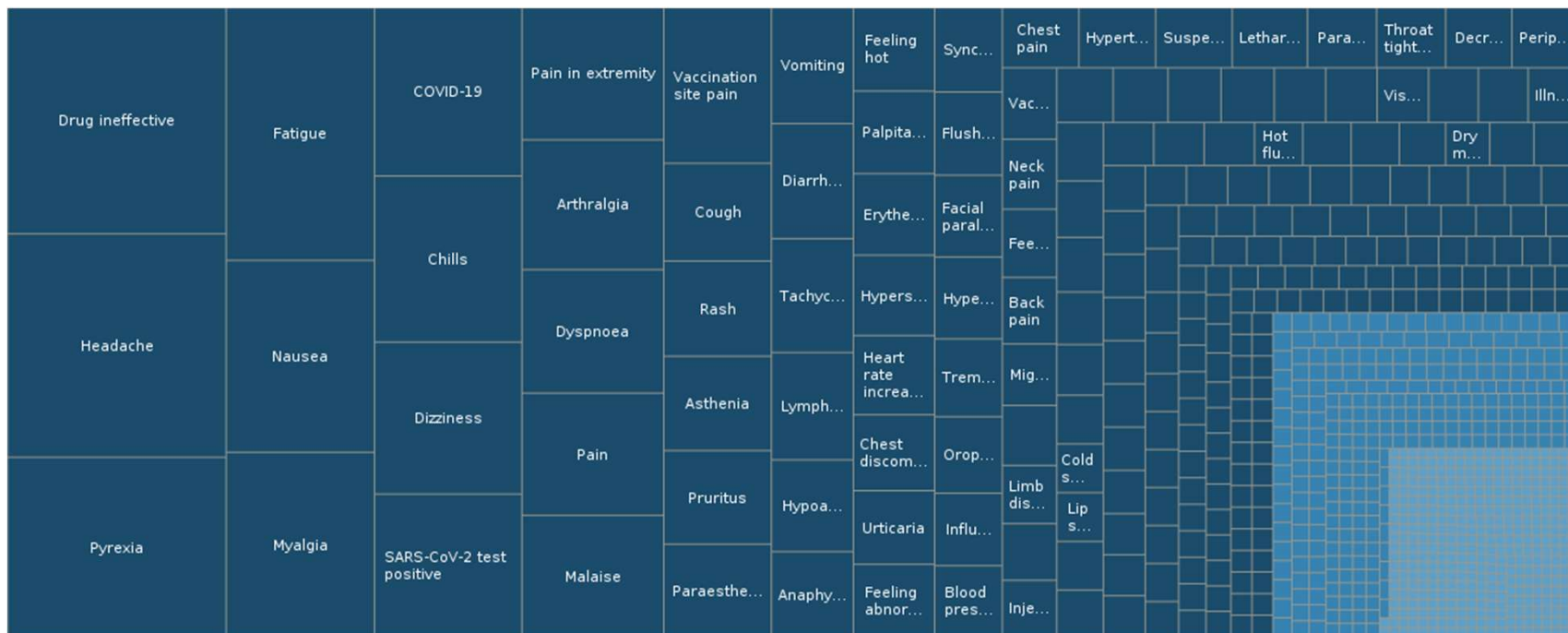


Events which triggered public attention (as of 17/01/2021)

- Identified risks/Labelled events:
 - Anaphylaxis: anaphylactic reaction (107), anaphylactic shock (22), anaphylactoid reaction (7)
 - Facial paralysis: 77 cases
- Fatal cases: 132 cases (majority in elderly patients, polymedicated, with multiple comorbidities).



EV number of serious cases (as of 17/01/2021)





European database of suspected adverse drug reaction reports

www.adrreports.eu

- provides public access to reports of suspected side effects contained in EV
- launched to comply with the [EudraVigilance Access Policy](#), aiming to support the monitoring of the safety of medicines and to increase transparency for stakeholders, including the general public.
- the figure displayed is always the total side effects reported up to the end of the previous week. **The figures are updated online every Monday.**



European database of suspected adverse drug reaction reports – Data source

- Each individual case refers generally to **one patient** (any follow-ups will complement the same case);
- The web reports refer to **spontaneous** cases in EV;
- A spontaneous case can refer to **serious** and/or **non-serious** side effects. **A side effect is classified as 'serious'** if it either results in death/ is life-threatening/ requires hospitalisation or prolongation of existing hospitalization/ results in persistent or significant disability/incapacity/ is a congenital anomaly/birth defect/ or results in some other medically important conditions;
- Only reports where medicines or active substances are reported as “**suspected**” by the reporter to have caused or contributed to the event are included.



European database of suspected adverse drug reaction reports

Understanding the reports

- All the information available on this website relates to medicines that have been assessed and the **benefits judged to outweigh the risks;**
- The suspected side effects **may not be related to or caused by the medicine;**
- Any individual case report should be seen **in the context of all available data;**
- The information is **only part of the information** used by the EMA and national medicines regulatory authorities to monitor the benefits and risks of an authorised medicine.

More comprehensive information about the possible side effects of a medicine



summary of product characteristics



patient information leaflet



Landing page – www.adrreports.eu



The screenshot shows the landing page of EudraVigilance. At the top, there is a blue header with the European Union flag logo on the left, the text "EudraVigilance - European database of suspected adverse drug reaction reports" in the center, and "Contacts | FAQ" and "English (en)" on the right. Below the header is a navigation menu with links: Home, About, Understanding reports, Search, Medicine safety, and Switch to Veterinary. The main content area features a section titled "Online access to suspected side-effect reports" with a photograph of white pills. To the right of the photo is a text box explaining that users can view data on suspected side-effects for authorised medicines in the EEA, and that access is granted by the name of the medicine or active substance. Below this is a search box with a magnifying glass icon and the text "Search for a report" and "Search here for suspected adverse drug reaction reports". A link below the search box reads "To consult the reports for COVID-19 vaccines, follow this link, then click on the letter 'C' and scroll down until 'COVID-19'". At the bottom left is a button labeled "How to report a side-effect". At the bottom right is a "Key information" section with two bullet points: the first states that information relates to suspected side effects, which are medical events observed after medicine use but not necessarily related to or caused by the medicine; the second states that information should not be interpreted as meaning the medicine causes the effect or is unsafe to use, and that only a detailed evaluation allows for robust conclusions.

Contacts | FAQ
English (en)

Home About Understanding reports Search Medicine safety Switch to Veterinary

Online access to suspected side-effect reports



On this website you can view data on suspected side-effects, also known as suspected adverse drug reactions, for authorised medicines in the European Economic Area (EEA).

For centrally authorised medicines, access to reports is granted both by the name of the medicine or the name of the active substance. For non-centrally authorised medicines, access is granted based on the name of the active substance only.

[To consult the reports for COVID-19 vaccines, follow this link, then click on the letter 'C' and scroll down until 'COVID-19'](#)

[How to report a side-effect](#)

Key information

- ✔ The information on this website relates to **suspected side effects**, i.e. medical events that have been observed following the use of a medicine, but which are **not necessarily related to or caused by the medicine**.
- ✔ Information on suspected side effects **should not be interpreted** as meaning that the medicine or the active substance causes the observed effect or is **unsafe to use**. Only a detailed evaluation and scientific assessment of all available data allows for robust conclusions to be drawn on the benefits and risks of a medicine.



COMIRNATY in the adrreports website

[COVID-19 MRNA VACCINE PFIZER-BIONTECH \(TOZINAMERAN\)](#)



Many thanks and any questions?

Further information

Irina.Caplanusi@ema.europa.eu

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

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