EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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

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COMIRNATY (tozinameran) timeline

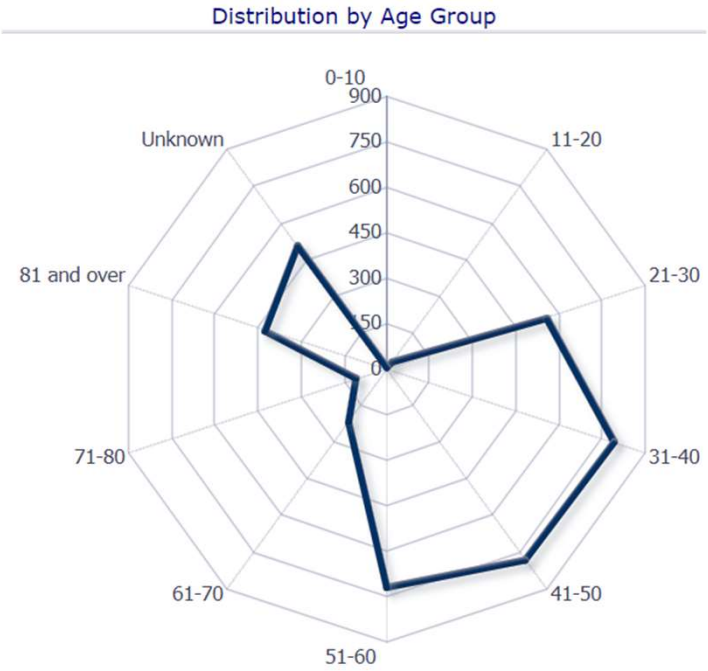
1 Preliminary data from post-marketing surveillance on adverse events following immunization

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.

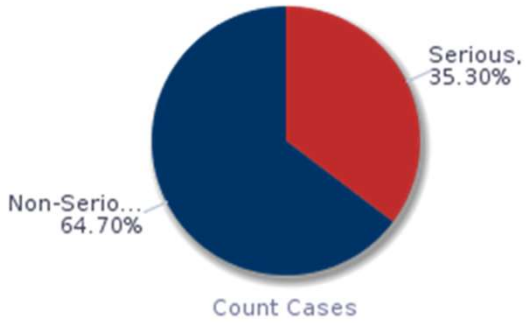
Overall, no issues have been identified to date for which additional action beyond close monitoring is deemed necessary based on the information provided in the EV case reports.

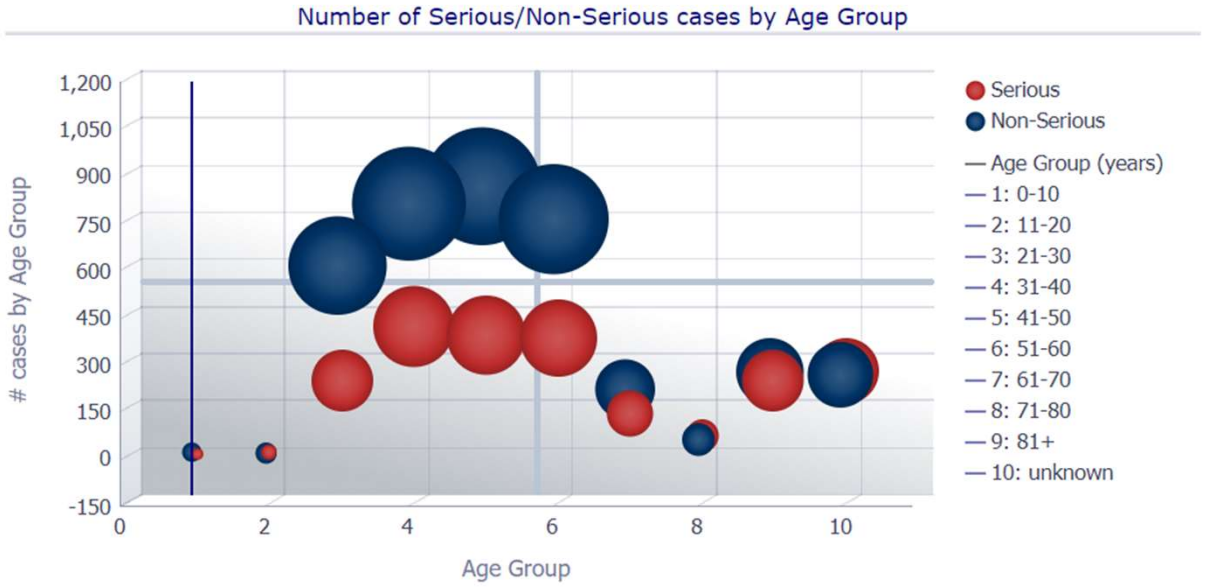
EudraVigilance (EV) data as of 14 Jan (1)



EV data as of 14 Jan (2)

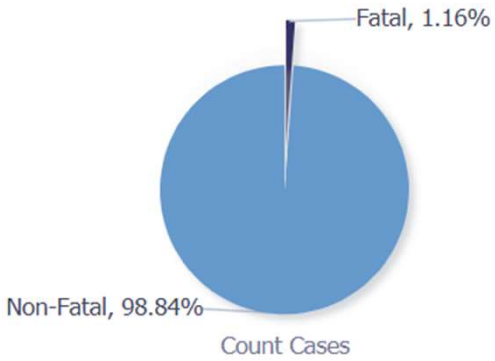
	# Cases
Serious	2,168
Non-Serious	3,973
	6,141





EV data as of 14 Jan (3)

	# Cases
Fatal	**71**
Non-Fatal	**6,070**
	6,141



Fatal by Age Group

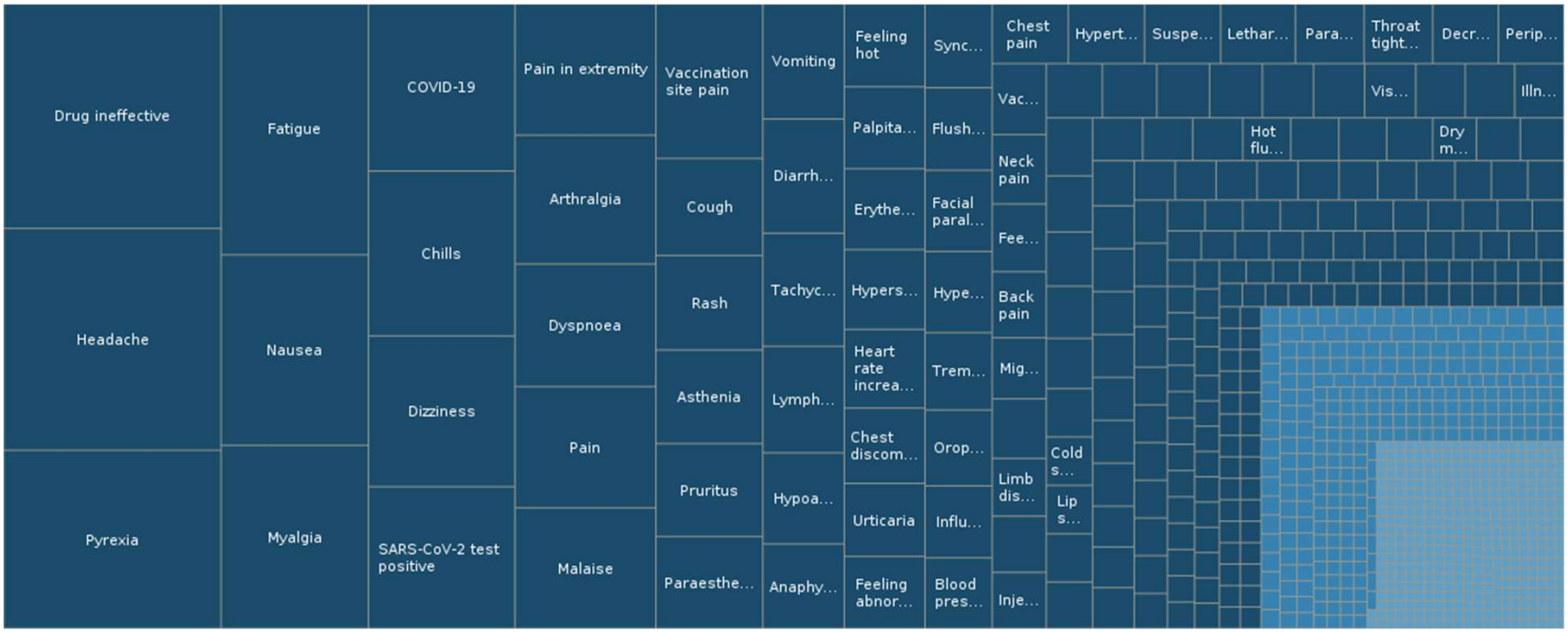
Age Group	Fatal	Non-Fatal	
0-10		11	**11**
11-20	1	31	**32**
21-30	1	564	**565**
31-40		797	**797**
41-50	2	789	**791**
51-60	2	726	**728**
61-70	1	217	**218**
71-80	11	102	**113**
81 and over	23	407	**430**
Unknown	3	505	**508**
Grand Total	**44**	**4,149**	**6,141**

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

COMIRNATY in the adrreports website

COVID-19 MRNA VACCINE PFIZER-BIONTECH (TOZINAMERAN)

EUROPEAN MEDICINES AGENCY

Many thanks and any questions?

Further information

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