



Overview of safety monitoring for COVID-19 vaccines

EudraVigilance data, signal detection and evaluation – including PRAC evaluation of reports of deaths

EU-EEA NITAG COLLABORATION Webinar on COVID-19 safety

Presented 5.1.2e on 4 February 2021
5.1.2e





Lessons Learned H1N1

Lessons learned from A/H1N1 pandemic adapted to current emergency situation



Signal Detection Methods

- Rapid **detection, exchange, prioritisation** and **assessment** of safety **signals**
- Testing of additional **methodologies** specific for COVID-19



PhV Plan of the EU Regulatory Network for COVID-19 Vaccines

Enhanced monitoring activities to be carried out in the EU for COVID-19 vaccines, including **roles, responsibilities** and **interactions** of stakeholders involved



- Active surveillance of **vulnerable populations**
- Active data collection on **rare** and **severe** risks
- **ACCESS, ICMRA, pregnancy studies, int. cohorts**

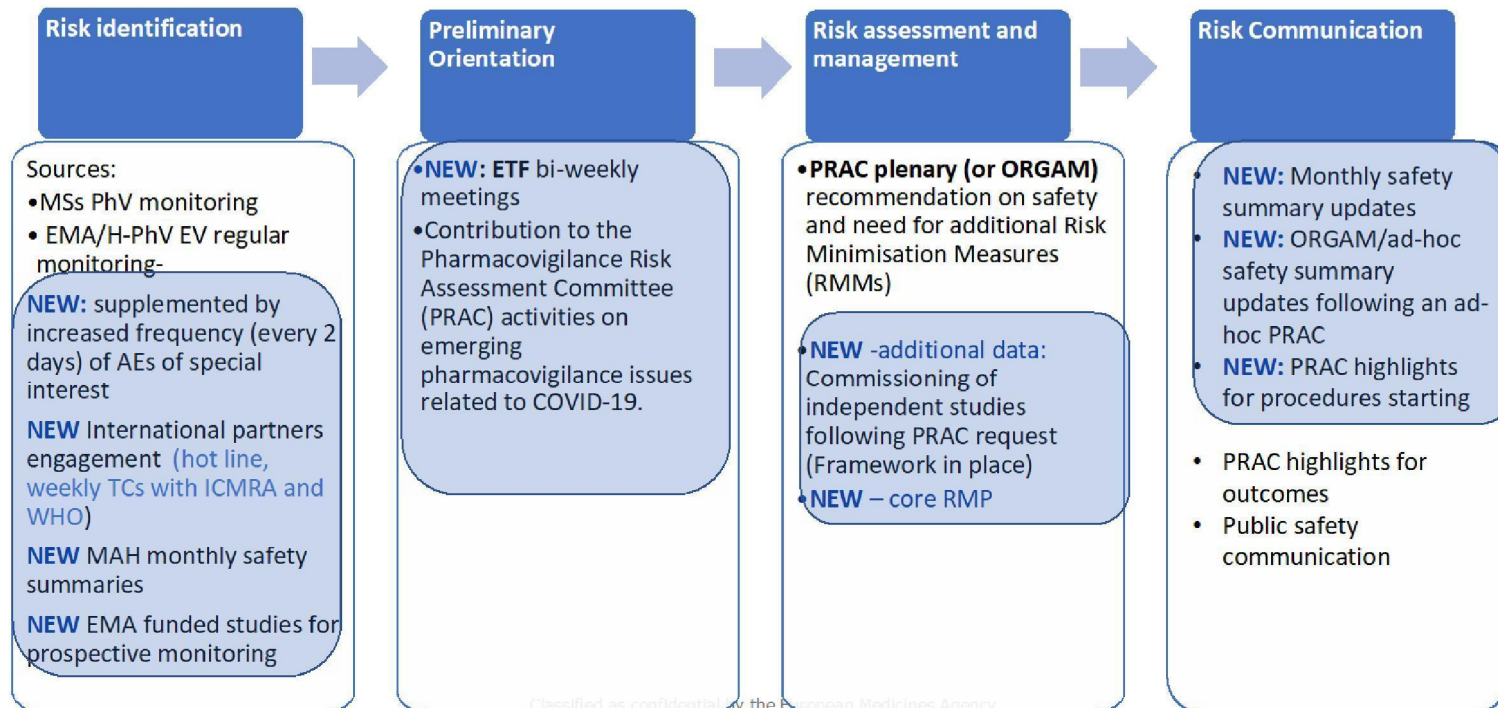
International And Research Centres Collaboration



- **Engage** and **communicate** with public, patients and HCP.
- **Enhanced communication** and **transparency** measures

Transparency & Communication

New elements introduced to strengthen PhV safety monitoring and risk communication



Safety update published by EMA

https://www.ema.europa.eu/documents/covid-19-vaccine-safety-update/covid-19-vaccine-safety-update-comirnaty-january-2020_en.pdf



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 January 2021

COVID-19 vaccine safety update

COMIRNATY

BioNTech Manufacturing GmbH

 Reuters

BRIEF-EMA Says Safety Data Collected On Comirnaty Use Consistent With Known Safety Profile Of Vaccine

Jan 29 (Reuters) - European Medicines Agency (EMA). * SAYS FIRST COVID-19 VACCINE SAFETY UPDATE PUBLISHED. * HAS RELEASED ITS FIRST ...

2 hours ago



B Bloomberg

Pfizer, BioNTech Covid Vaccine Safe for the Elderly, EMA Says

The European Medicines Agency's safety panel analyzed deaths in light of other medical conditions the people had, as well as the fatality rate ...

1 hour ago

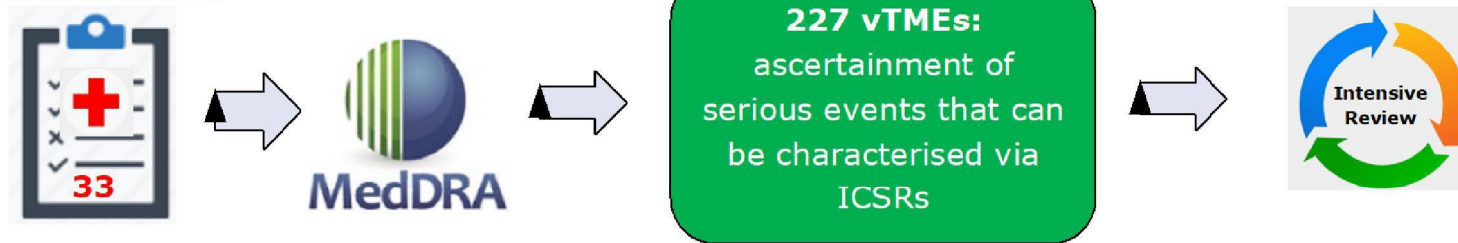


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Prioritisation – MedDRA Mapping



AESIs



vaccine Targeted Medical Events (vTMEs): Dedicated list of MedDRA PTs mapped from AESIs proposed for Covid-19 vaccines



Objective: Facilitate assessment of events that warrant analysis irrespective of statistical criteria routinely used to prioritise signal review. Events will be subject to intensive monitoring



Internal tool → not intended as a comprehensive list
Dynamic subject to continual review



Prioritisation

- **AESIs** combination of seriousness criteria, likelihood to be related/listed for vaccines, immuno-mediated etc.
- ✓ **intensive manual review of case narratives (every other day).**
- **Remaining events:** non-vTMEs, DMEs, IMEs, fatal, events with high background incidence rate etc.
- ✓ **Weekly screening – eRMRs produced for each vaccine and implemented with additional methods for prioritisation**
- **COVID19 vaccine dashboard** with descriptive analyses (serious, fatal, country, age-group, batch, fatal etc.)
- **OE analysis:** to support both detection and strengthening of signals
- ✓ **weekly updates: observed (EV) vs Expected (coverage data)**





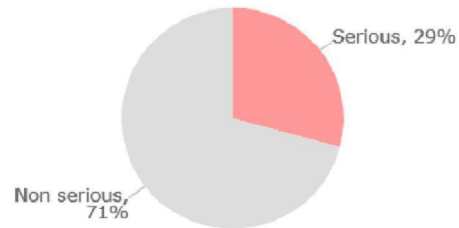
COMIRNATY (tozinameran) – Timeline



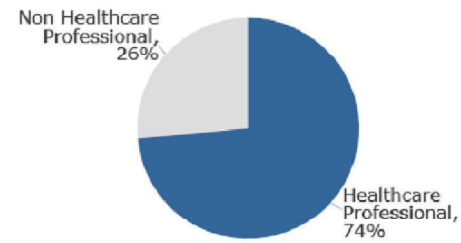


COMIRNATY - EV case reports as of 3 Feb

	# Cases
Serious	9,914
Non serious	24,097



	# Case [△] _▽
Healthcare Professional	25,001
Non Healthcare Professional	9,010



Fatal cases in Norway (14 Jan 2021)



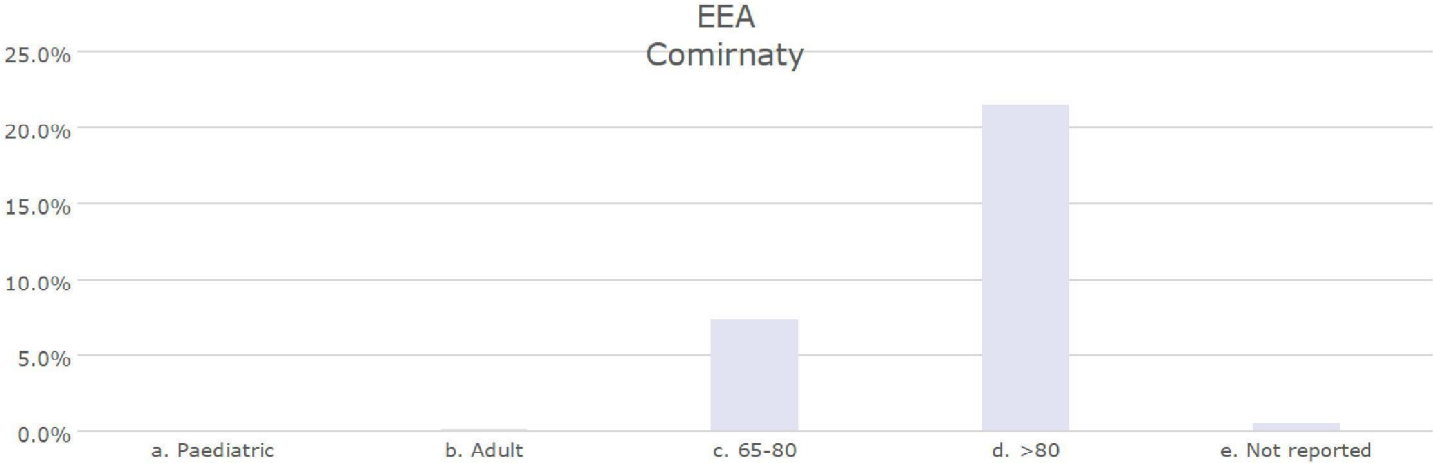
- Notification from the Norwegian Medicines Agency (NOMA), informing on 23 deaths in elderly people who received the Comirnaty
- NOMA published first weekly report, concluding that some of the fatal reports associated with Covid-19 vaccination suggest that common adverse reactions of mRNA vaccines, such as fever and nausea, may have contributed to fatal outcome in some frail patients.
 - Approximately 42000 people have been vaccinated in Norway to 14/01/2021.
 - Elderly and people in nursing homes with severe underlying medical conditions are being vaccinated.

EMA actions

- Information to IRN, PRAC, EMA international partners
- Communication with PRAC Rapp and NO colleagues
- LTT updated
- Info to management and PRAC Rapporteur:
 - EudraVigilance review of NO fatal cases;
 - Norway mortality data;
 - Member states exposure data.

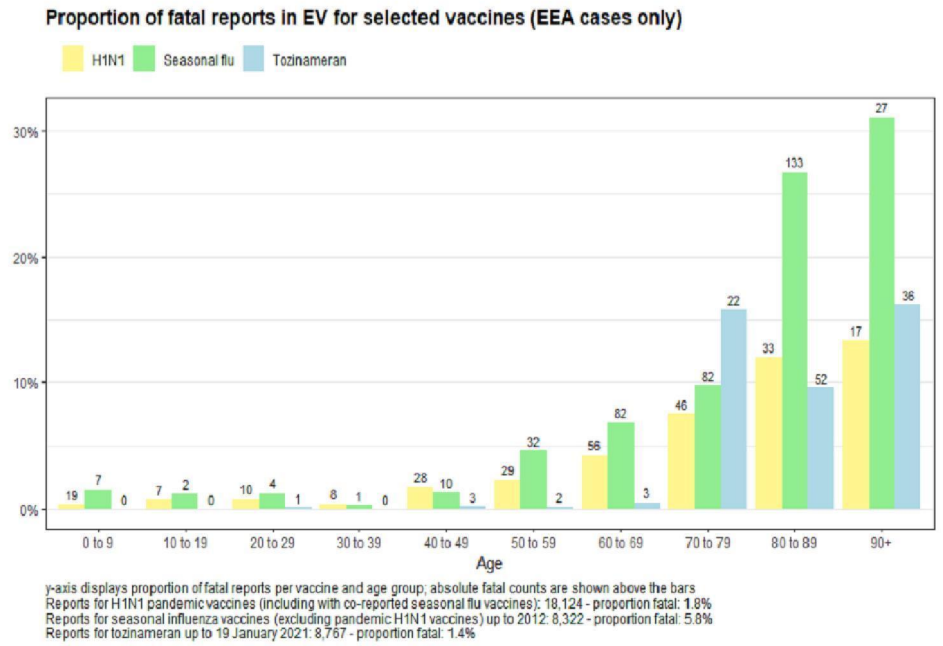
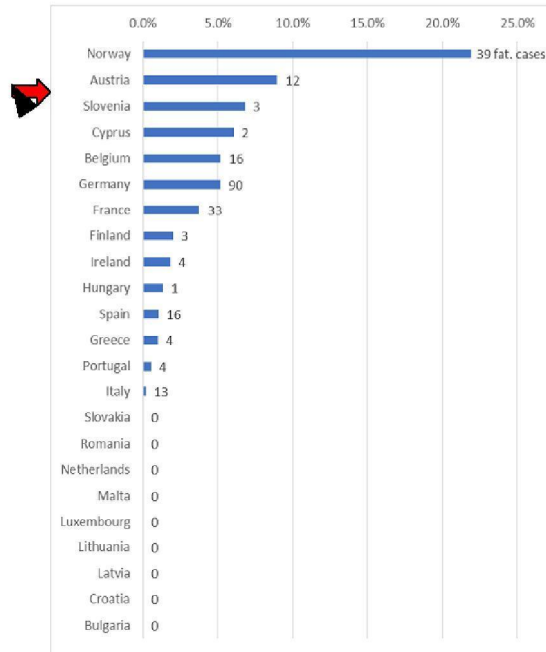


NO cases fatal cases stratified by age





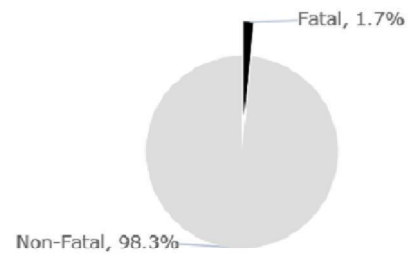
Data into context: comparison in EV





COMIRNATY - Number of fatal case reports as of 3 Feb

# Cases	
Fatal	566
Non-Fatal	33,445



Distribution by patient age group

0-9	
10-19	
20-29	1
30-39	
40-49	8
50-59	20
60-69	26
70-79	67
80-89	231
>90	191
Not reported	22



COMIRNATY – Fatal cases (as of 03/02/2021) (1)

- Fatal cases: 566 spontaneous case reports (majority in elderly patients, polymedicated, with multiple comorbidities).

28 Jan - PRAC assessment of all fatal cases (following NO notification):

- **Overall, having assessed the data submitted by the MAH as well as the EudraVigilance overview of fatal cases provided by EMA, the PRAC Rapporteur concluded that the fatal case reports in persons ≤65 years of age and in persons > 65 years of age does not raise a safety concern.**
- **The MAH will report on the fatal cases in the MSSRs.**



COMIRNATY (as of 03/02/2021) (2)

- Identified risks/Labelled events:
 - Anaphylaxis: anaphylactic reaction (317 spontaneous cases), anaphylactic shock (51 spontaneous cases);
 - Facial paralysis (195 spontaneous cases)

These events are closely followed in the MSSRs (Monthly Safety Summary Reports) from the MAH.



COMIRNATY – Other AESIs

- EV close monitoring of AESIs (Adverse Events of Special Interest);
- Informing the PRAC Rapporteur (NL) of relevant cases as they arise;
- Liaising with other regulators as needed.
- Timely exchange of information, transparency and communication.

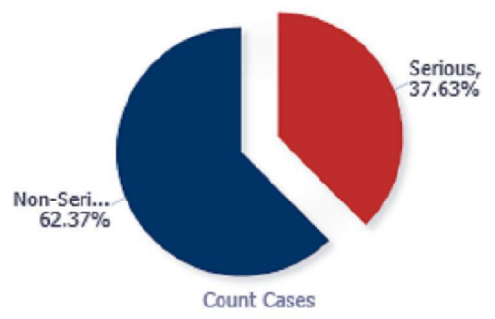
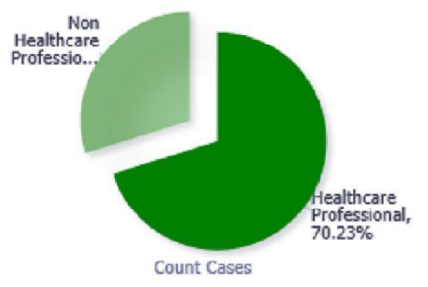
Overall, no issues have been identified to date for which additional action beyond close monitoring is deemed necessary based on the information provided in the EV case reports.



COVID-19 Vaccine Moderna

	# Cases
Healthcare Professional	420
Non Healthcare Professional	178
<i>598</i>	

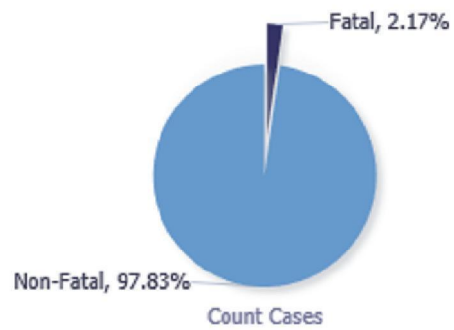
	# Cases
Serious	225
Non-Serious	373
<i>598</i>	





COVID-19 Vaccine Moderna

	# Cases
Fatal	13
Non-Fatal	585
<i>598</i>	



Fatal by Age Group

Age Group	Fatal	Non-Fatal	
11-20		5	5
21-30		96	96
31-40		102	102
41-50		104	104
51-60		87	87
61-70	1	38	39
71-80	3	33	36
81 and over	8	36	44
Unknown	1	84	85
Grand Total	13	585	598



Number of cases by Reaction PT & Seriousness

Reaction PT	Serious	Non-Serious	△▽
Pyrexia	30	137	167
Headache	29	100	129
Myalgia	14	63	77
Fatigue	22	51	73
Chills	21	50	71
Injection site pain	14	46	60
Nausea	17	40	57
Asthenia	12	37	49
Vaccination site pain	3	43	46
Pain in extremity	17	28	45
Dizziness	22	22	44
Arthralgia	6	32	38
Malaise	4	34	38
Injection site erythema	13	18	31
Lymphadenopathy	8	23	31
Pain	15	14	29
Erythema	8	19	27
Anaphylactic reaction	23	1	24
Dyspnoea	19	5	24
Vomiting	6	15	21

- On 28 January 2021, PRAC assessed a review submitted by the MAH of reports of suspected anaphylaxis after administration of COVID-19 Vaccine Moderna at a single vaccination site in the United States (US).
- Based on the current information, no new safety concern regarding anaphylaxis was identified for COVID-19 Vaccine Moderna.



Any questions?

Further information

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