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SCIENCE MEDICINES HEALTH

Pharmacovigilance and Public Safety Updates for COVID-19 Vaccines

PCWP & HCPWP Joint Meeting
2 March 2021

Georgy Genov & Priya Bahri, European Medicines Agency

New elements introduced to strengthen Pharmacovigilance (PhV), including risk communication

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Risk identification

Sources:

- Member states' monitoring
- EMA/EudraVigilance regular monitoring

NEW Supplemented by increased frequency (every 2 days) of adverse events of special interest

NEW International partners engagement (hot line, weekly teleconferences with ICMRA and WHO)

NEW Companies' monthly safety summaries

NEW EMA funded studies for prospective monitoring

Preliminary Orientation

NEW EMA Task Force on COVID-19 bi-weekly meetings

NEW Contribution to the Pharmacovigilance Risk Assessment Committee (PRAC) activities on emerging pharmacovigilance issues related to COVID-19.

Risk assessment and management

- PRAC recommendation on safety and need for additional risk minimisation measures (RMMs)

NEW Additional data: Commissioning of independent studies following PRAC request (framework in place)

NEW Core risk management plan

Risk Communication

- PRAC Highlights for outcomes
- Public safety communication

NEW Monthly/ ad-hoc safety summary updates

NEW PRAC Highlights for procedures starting

Pharmacovigilance communication and transparency for COVID-19 vaccines

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Regular EMA publications:

- Good pharmacovigilance practices
- European public assessment report (EPAR) with assessment reports, product information and summaries of assessment report and risk management plan
- Committee documents, incl. agenda and outcomes of Pharmacovigilance Risk Assessment Committee (PRAC)
- Public access of EudraVigilance as the data base of individual case safety reports (ICSRs) of suspected adverse reactions at http://www.adrreports.eu/ (EVDAS)

Additional 'pandemic' EMA publications:

- EU Pharmacovigilance Plan and Core Risk Management Plan for COVID-19 vaccines
- Key facts on vaccines/COVID-19 vaccines for general and interested audiences
- Risk management plans for COVID-19 vaccines
- Study plans and reports conducted under EMA/EU initiatives for COVID-19 vaccines
- COVID-19 vaccines safety updates

Public COVID-19 vaccines safety updates

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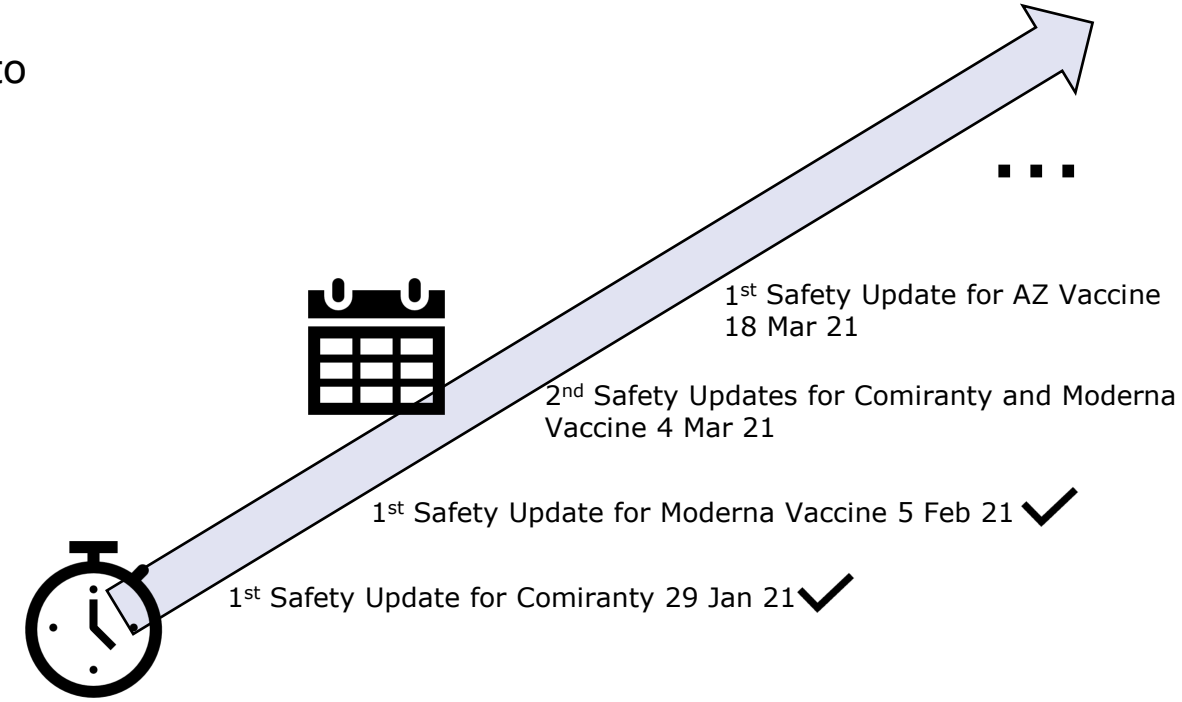
Goals:

- Timely transparency
- Meaningful communication to the public
- Useful for journalists and specialist stakeholders
- One place to go when interested in vaccine safety

Publication timelines:

- Monthly aligned with assessment of monthly company reports
- Ad hoc when needed given continuous safety monitoring



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28 January 2021

COVID-19 vaccine safety update

COMIRNATY

BioNTech Manufacturing GmbH

The latest safety data for this vaccine are in line with the known side effect profile, and the related reviews are presented in this update.
Reports of suspected severe allergic reaction have not identified new aspects regarding the nature of this known side effect.
No specific safety concern has been identified for vaccine use in frail elderly individuals.
The benefits of Comirnaty in preventing COVID-19 continue to outweigh any risks, and there are no recommended changes regarding the use the vaccine.

Safety updates provide the outcomes of the assessment of emerging data since marketing authorisation for COVID-19 vaccines. The assessments are carried out by EMA's safety committee (Pharmacovigilance Risk Assessment Committee (PRAC)). The safety updates are published regularly at Post-authorisation: Safety updates.

All published safety updates for Comirnaty are available at Comirnaty: safety updates.

Content:

1. Updates on safety of Comirnaty

On 28 January 2021, PRAC concluded that the safety data reviewed for Comirnaty are in line with the vaccine's known benefit-risk profile. The review covered all new safety data emerging since 21 December 2020, including the first Summary Monthly Safety Report[1] from the marketing authorisation holder. Specifically, the following was concluded by PRAC in relation to:

Severe allergic reaction (anaphylaxis)

Anaphylaxis is a known side effect of Comirnaty. The assessment of the reports of suspected anaphylaxis to date did not identify new aspects regarding the nature of this side effect. PRAC noted that a recent analysis in the United States estimated the frequency of anaphylaxis as approximately 11 cases per million doses of Comirnaty administered[2]. A frequency estimate appropriate for the EU product information could not yet be determined.

PRAC requested the marketing authorisation holder to continue reviewing all anaphylaxis cases for further assessment by the committee.

Information on managing the risk of anaphylaxis is already available in the product information.

Review of reports of suspected side effects with fatal outcome, specifically in frail elderly individuals

Given concerns which arose from Norway about deaths reported in frail elderly individuals after vaccination with Comirnaty, PRAC reviewed the current reports of suspected side effects with fatal outcome in individuals of any age. This review did not suggest a safety concern.

In many cases concerning individuals above 65 years of age, progression of (multiple) pre-existing diseases seemed to be a plausible explanation for death. In some individuals, palliative care had already been initiated before vaccination.

Before Comirnaty was granted a marketing authorisation in the EU, the safety of the vaccine was carefully assessed through large clinical trials across age groups including study participants that were 75 years of age and older, as detailed in the public assessment report.

PRAC concluded that based on the current data there was no need to amend the product information regarding how Comirnaty should be used, including in frail elderly individuals. PRAC requested that the marketing authorisation holder continues reviewing all reports of suspected side effects with fatal outcome thoroughly.

1. Summary Monthly Safety Reports will be compiled by the marketing authorisation holders for COVID-19 vaccines to support timely and continuous benefit-risk evaluations. The submission of such reports complements the submission of periodic safety update reports (PSURs).

2. Centres for Disease Control and Prevention (CDC) COVID-19 Response Team, Food and Drug Administration: Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine: United States, December 14–23, 2020. MMWR. 2021; 70 (2): 46-52 (epub 6 Jan 2021).

2. Other information for Comirnaty

Comirnaty is a vaccine that has been authorised in the European Union (EU) for use in people aged 16 years and older to protect against developing COVID-19 when infected with the coronavirus SARS-CoV-2. COVID-19 is a potentially severe disease that may result in death.

Comirnaty contains a molecule called mRNA, which the body uses to temporarily produce the SARS-CoV-2 spike protein. The mRNA is broken down shortly after vaccination. The spike protein does not cause COVID-19.

Before Comirnaty was granted a marketing authorisation in the EU, the efficacy and safety of the vaccine was assessed through pre-clinical studies and large clinical trials. More than 18,000 participants have been given the vaccine in clinical trials.

The most common side effects known for Comirnaty will not be experienced by everybody, are usually mild or moderate, and get better within a few days after vaccination.

More information on how Comirnaty works and its use is available in the medicine overview for Comirnaty. This includes information on use in pregnant and breastfeeding women and immunocompromised individuals.

Information in all EU/EEA languages is available in the product information, which includes the summary of product characteristics and the package leaflet.

3. How safety is monitored

As for all COVID-19 vaccines, all relevant new information emerging on Comirnaty is collected and promptly reviewed. This is in line with the pharmacovigilance plan for COVID-19 vaccines of the EU regulatory network.

Collecting suspected side effects

The EU regulatory network continuously monitors reports of suspected side effects observed in vaccinated individuals. These reports are collected and recorded in EudraVigilance, a system operated by EMA for managing and analysing information on suspected adverse reactions to medicines.

Vaccinated individuals and healthcare professionals should report suspected side effects via the national reporting systems. For more information, see Reporting side effects. Information on how to report side effects in your Member State is available in the package leaflet and the list of national competent authorities.

You may visit EudraVigilance – European database of suspected drug reaction reports and search for "COVID-19 mRNA Vaccine PFIZER-BIONTECH (Tozinameran)" to see all suspected side effects reported for Comirnaty in the EU. Please note that these reports describe suspected side effects in individuals, i.e. these events may not necessarily have been caused or otherwise be related to the vaccine.

Planned and ongoing studies

The company that markets Comirnaty will continue to provide results from the main clinical trial, which is ongoing for up to two years, and conduct additional studies to monitor the safety and effectiveness of the vaccine as it is used in the vaccination campaigns and other clinical practice. For the list of planned or ongoing safety studies for Comirnaty, see the risk management plan.

A paediatric investigation plan (PIP) for Comirnaty is in place. This describes how the company will collect data on the vaccine's efficacy and safety for its potential use in children.

In addition, EMA and European authorities are coordinating observational studies in EU Member States looking at real-world data from clinical practice to monitor the safety and effectiveness of COVID-19 vaccines, including in pregnant women. For more details on the ongoing projects, see Treatments and vaccines for COVID-19: post-authorisation.

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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

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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Politik

COVID-19-Impfüberwachung: Keine neuen Sicherheitssignale

Amsterdam/Langen – Gut einen Monat nach dem Start der Impfungen mit dem Coronavakzin Comirnaty von Pfizer/Biontech hat die Europäische Arzneimittelagentur (EMA) keine Sicherheitsprobleme festgestellt. Die gemeldeten allergischen Reaktionen und Nebenwirkungen zeigten im Vergleich zu den Zulassungsstudien keine Auffälligkeiten, teilte die EMA heute mit.

Auch das für die Impfüberwachung in Deutschland zuständige Paul-Ehrlich-Institut (PEI) zieht ein durchaus positives Fazit des ersten Impfmonats: Bislang seien nur wenige gravierendere Nebenwirkungen bei den Coronaimpfungen aufgetreten, sagte PEI-Präsident Klaus Cichutek heute in Berlin.

National Institute for Public Health and the Environment
Ministry of Health, Welfare and Sport

Safety

Obviously, the health and safety of the people being vaccinated are our first priority. In the Netherlands, doctors assess whether the vaccination is suitable for a person of any age, old or young, especially in the case of vulnerable and elderly people. Last week, the EMA announced that further investigation of the deaths of frail elderly people in Norway and elsewhere has shown that there is no direct link between the deaths of these people and the vaccination they received.

Vulnerable elderly people

Everyone in the Netherlands over the age of 18 will be offered a COVID-19 vaccination. That includes elderly people and people in (extremely) vulnerable health. Vaccination of vulnerable elderly people started on 18 January. On average, an estimated two thousand people aged 80 years and older die each week in the Netherlands. These deaths will also include people who have recently been vaccinated. More information about side-effects of the COVID-19 vaccination can be found in the weekly overview on the Lareb website.

The COVID-19 vaccination campaign was established on the basis of the advisory opinion issued by the Health Council of the Netherlands, as decided by the Ministry of Health, Welfare and Sport (VWS). Everyone in the Netherlands over the age of 18 years old will be offered a COVID-19 vaccination. The COVID-19 vaccines used in the Netherlands have been assessed as safe and approved for use by both the European Medicines Agency (EMA) and the Medicines Evaluation Board (CBG-MEB) in the Netherlands.

Public COVID-19 vaccines safety updates

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Your input and feedback counts!

- PCWP and HCPWP members responded after November meeting
- Patient and healthcare professional members of the COVID-19 EMA Pandemic Task Force (COVID-ETF) participate in the pre-publication review of each safety update

Thank you!

Suggestions received mainly on:

- Comparative frequency data for allergic adverse reaction
- Use of the vaccines in certain patient populations, e.g. immunocompromised or rare disease patients
- Support to healthcare professionals when explaining safety profile to patients

Feedback welcome to priya.bahri@ema.europa.eu

Thank you for your attention

Further information

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