Meet with ZWIERS!

BMW career event

March 24th, 2021

ZWIERS
Regulatory Consultancy

Agenda

- Intro to Regulatory Affairs
- RA-COVID19 Quiz
- Short story "BMW student → RA consultant"
- Question round

Regulatory affairs?

WORLD NEWS DECEMBER 21, 2020 / 12:23 AM / UPDATED 3 MONTHS AGO

EU clears Pfizer COVID-19 vaccine for first inoculations

By Bart H. Meijer 5 MIN READ

AMSTERDAM (Reuters) - The European Union geared up to start mass vaccinations against COVID-19 just after Christmas after the shot developed by Pfizer and its German partner BioNTech cleared regulatory hurdles on Monday.

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Regulatory Affairs?

Everything a company needs to do to obtain permission from the health authorities to bring a product to the market and maintain it.

Goal: safe, efficacious and high-quality products (with information) for the patient

How to get the product to the market?

RA actions

- ✓Advise on the required data/studies
- ✓Obtain permission to perform (human) studies
- ✓Review/evaluate the data/studies
- ✓Discuss issues with authorities and experts
- ✓Write justifications and dossier parts
- ✓Submit data, dossiers

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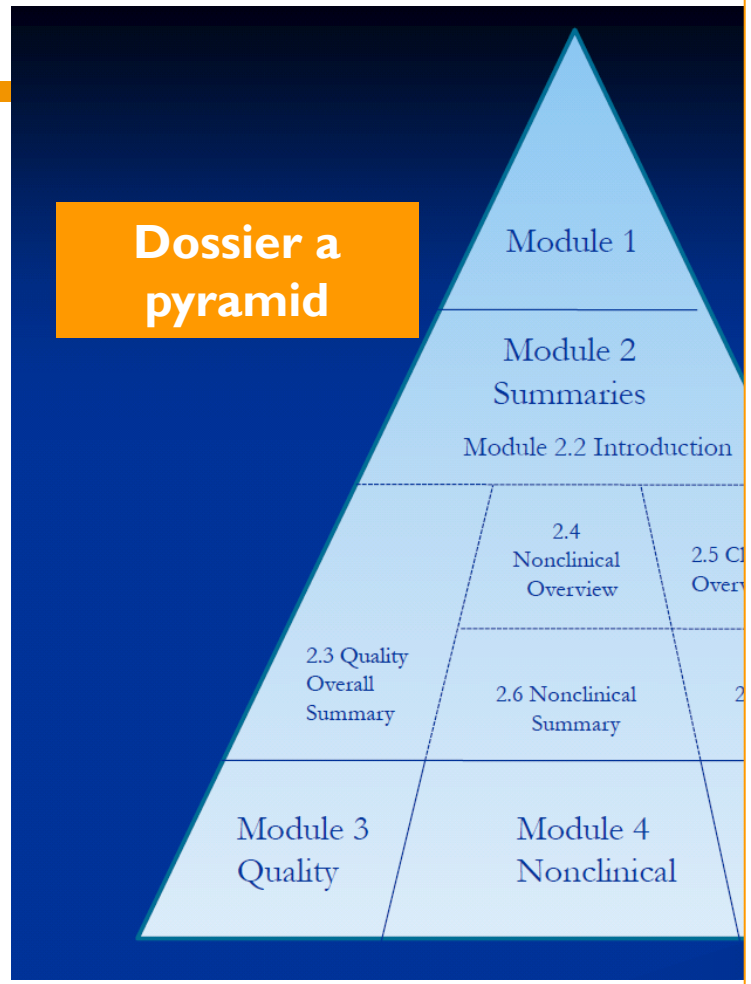

Package leaflet: Information for the user

Comirnaty concentrate for dispersion for injection
COVID-19 mRNA Vaccine (nucleoside modified)

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you receive this vaccine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Comirnaty is and what it is used for

Comirnaty is a vaccine used for preventing COVID-19 caused by SARS-CoV-2 virus.

Comirnaty is given to adults and adolescents from 16 years of age and older.

The vaccine causes the immune system (the body's natural defences) to produce antibodies and blood cells that work against the virus, so giving protection against COVID-19.

As Comirnaty does not contain the virus to produce immunity, it cannot give you COVID-19.

2. What you need to know before you receive Comirnaty

Comirnaty should not be given
- if you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you are given the vaccine if:
- you have ever had a severe allergic reaction or breathing problems after any other vaccine injection or after you were given Comirnaty in the past.
- you have ever fainted following any needle injection.
- you have a severe illness or infection with high fever. However, you can have your vaccination if you have a mild fever or upper airway infection like a cold.
- you have a bleeding problem, you bruise easily or you use a medicine to prevent blood-clots.
- you have a weakened immune system, because of a disease such as HIV infection or a medicine such as corticosteroid that affects your immune system

As with any vaccine, the 2-dose vaccination course of Comirnaty may not fully protect all those who receive it and it is not known how long you will be protected.

RA COVID19 QUIZ

QUESTION 1

- How much involvement did/does the Dutch Medicines Evaluation Board (MEB/CBG) have in approval of COVID vaccines?

A. None
B. MEB/CBG makes independent decisions
C. MEB/CBG relies on EMA

ANSWER I

- C. MEB/CBG relies on EMA

QUESTION 2

- Were new regulatory procedures/processes applied to COVID19 approval?

A. Yes
B. No

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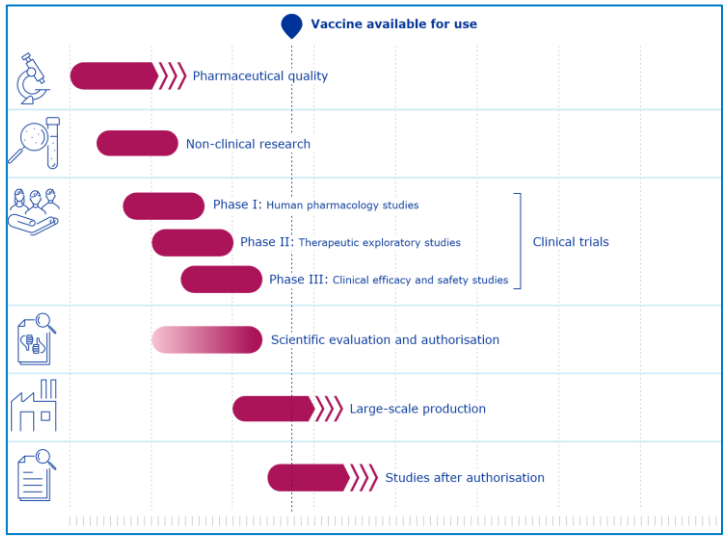
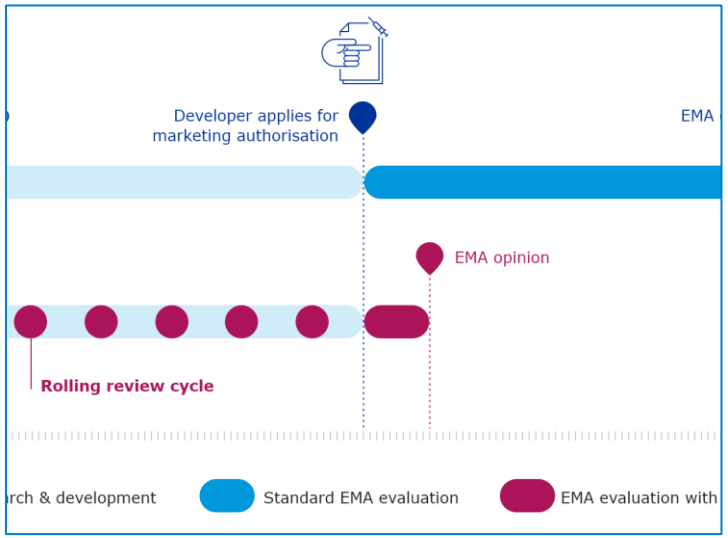
ANSWER 2

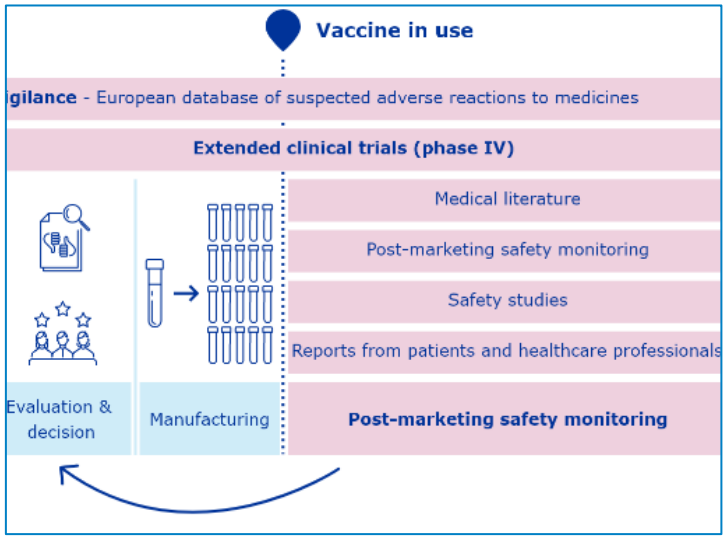
- B. No



Fast track development



Rolling review & accelerated assessment



Conditional approval

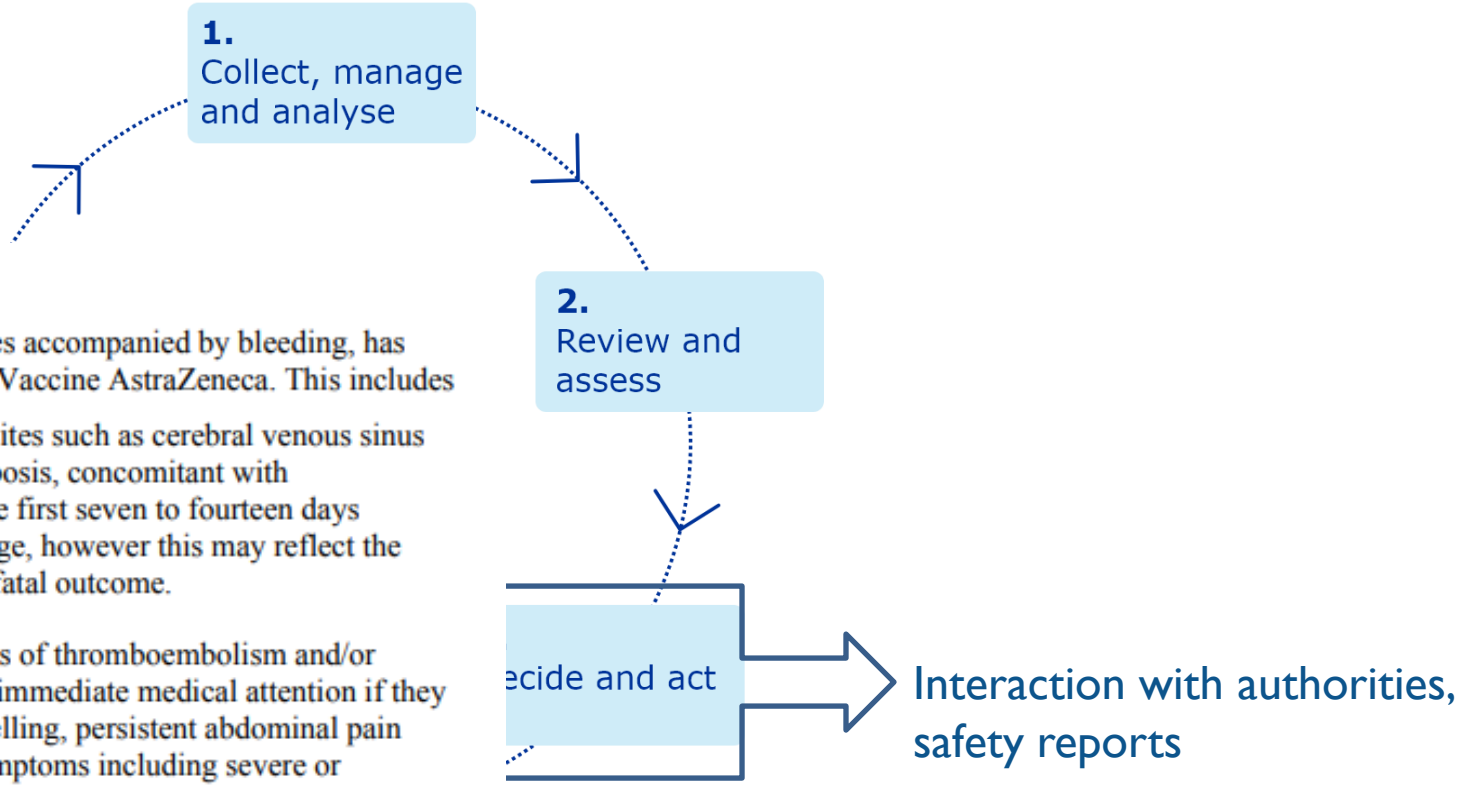
QUESTION 3

- Does the (thrombosis) safety finding associated with the AstraZeneca vaccine lead to regulatory actions?

A. All related actions are regulatory
B. Yes
C. No, no regulatory action involved

ANSWER 3

- B. Yes, several actions



Thrombocytopenia and coagulation disorders

A combination of thrombosis and thrombocytopenia, in some cases accompanied by bleeding, has been observed very rarely following vaccination with COVID-19 Vaccine AstraZeneca. This includes severe cases presenting as venous thrombosis, including unusual sites such as cerebral venous sinus thrombosis, mesenteric vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia. The majority of these cases occurred within the first seven to fourteen days following vaccination and occurred in women under 55 years of age, however this may reflect the increased use of the vaccine in this population. Some cases had a fatal outcome.

Healthcare professionals should be alert to the signs and symptoms of thromboembolism and/or thrombocytopenia. Those vaccinated should be instructed to seek immediate medical attention if they develop symptoms such as shortness of breath, chest pain, leg swelling, persistent abdominal pain following vaccination. Additionally, anyone with neurological symptoms including severe or persistent headaches or blurred vision after vaccination, or who experiences skin bruising (petechia) beyond the site of vaccination after a few days, should seek prompt medical attention.

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Short story

"BMW student → RA consultant"

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You!

- Think: what do I want? What am I good at?
- Type: regulatory attractive CV
- Talk: network
- Training?

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