Beat: News

European Commission - vaccine against COVID-19

BioNTech and Pfizer

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USPA NEWS - European Commission authorises first safe and effective vaccine against COVID-19

Today, the European Commission has granted a conditional marketing authorisation (CMA) for the COVID“‘19 vaccine developed by BioNTech and Pfizer, making it the first COVID-19 vaccine authorised in the EU. This authorisation follows a positive scientific recommendation based on a thorough assessment of the safety, effectiveness and quality of the vaccine by the European Medicines Agency (EMA) and is endorsed by the Member States.

The President of the European Commission, Ursula von der Leyen, said: “Today we add an important chapter to a European success story. We approved the first safe and effective vaccine against COVID-19. More vaccines will come soon. Doses of the vaccine approved today will be available for all EU countries, at the same time, on the same conditions. The upcoming European vaccination days will also be a great moment of unity. This is a good way to end this difficult year, and to start turning the page on this pandemic. We are all in this together.“

Stella Kyriakides, Commissioner for Health and Food Safety, said: “This is a big day for Europe. It is a day of true European solidarity in action. After months of work, we are seeing our EU Vaccines Strategy bear fruit “‘ access to safe, effective and affordable vaccines at the same time for all Member States. Today we witness what can be achieved collectively when we work together in a strong European Health Union. A Europe that cares and that supports. A Europe that leaves no stone unturned.“

BioNTech and Pfizer made a formal application for a conditional marketing authorisation on 1 December. This followed the analysis of their data in a “˜rolling review' by EMA as from 6 October. Thanks to this rolling review, EMA managed to assess the conditional marketing authorisation application very rapidly. This procedure, specifically designed for emergency situations, ensures as swift an assessment as possible while ensuring that all requirements in terms of safety, effectiveness and quality of the vaccine are fully and thoroughly evaluated.

On the basis of EMA's positive opinion, the Commission has verified all the elements supporting the marketing authorisation and consulted Member States before granting the conditional market authorisation.

The BioNTech/Pfizer vaccine is based on messenger RNA (mRNA) technology. This allows cells to manufacture harmless fragments of viral proteins that the human body uses to build an immune response to prevent or fight subsequent, natural infection. When a person is given the vaccine, their cells will read the genetic instructions and produce fragments of the “˜spike protein', a protein on the outer surface of the virus which it uses to enter the body's cells, to replicate, and cause disease. The person's immune system will then treat this protein as foreign and produce natural defences “” antibodies and T cells “” against it.

Next steps

The Commission, the Member States and the company are now working towards the delivery of the first doses on 26 December, so that the EU vaccination days can start on 27 “‘ 28 “‘ 29 December.

Deliveries will continue in December and on a steady weekly basis during the following months. Distribution of the full 200 million doses is scheduled to be completed by September 2021. The Commission and the Member States are working to activate the additional 100 million doses.

Background

A conditional marketing authorisation (CMA) is an authorisation of medicines on the basis of less complete data required for a normal marketing authorisation. Such a CMA may be considered if the benefit of a medicine's immediate availability to patients clearly outweighs the risk linked to the fact that not all the data are yet available. However, once a CMA has been granted, companies must

provide within certain deadlines further data including from ongoing or new studies to confirm that the benefits continue to outweigh the risks.

On 1 December 2020, EMA received an application for a CMA for the vaccine developed by BioNTech and Pfizer. However, and since 6 October, EMA has already been assessing data on the vaccine's safety, effectiveness and quality and results from laboratory studies and clinical trials in the context of a rolling review. This rolling review and the assessment of the CMA application allowed EMA to quickly conclude on the safety, effectiveness and quality of the vaccine. EMA recommended granting the conditional marketing authorisation as the benefits of the vaccine outweigh its risks.

The European Commission has verified whether all necessary elements "" scientific justifications, product information, informational material to healthcare professionals, labelling, obligations to marketing authorisation holders, conditions for use, etc. - were clear and sound. The Commission also consulted the Member States, as they are responsible for the vaccines marketing and the use of the product in their countries. Following the Member States' endorsement and on the basis of its own analysis, the Commission decided to grant the conditional market authorisation.

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