REPUBLIC OF CYPRUS
MINISTRY OF HEALTH

Press release

Increase in vaccine manufacturing capacity and supply for COVID-19 vaccines from AstraZeneca, BioNTech/Pfizer and Moderna

EMA's human medicines committee (CHMP) has adopted several important recommendations that will increase manufacturing capacity and supply of COVID-19 vaccines in the EU.

New manufacturing site for AstraZeneca's COVID-19 vaccine

A new manufacturing site has been approved for the production of **AstraZeneca's COVID-19 vaccine** active substance. The Halix site is located in Leiden, the Netherlands, and will bring the total number of manufacturing sites licensed for the production of the active substance of the vaccine to four.
New manufacturing site and more flexible storage conditions for BioNTech/Pfizer's COVID-19 vaccine.

A new site has also been approved for the production of **Comirnaty**, the COVID-19 vaccine developed by BioNTech and Pfizer. The facility, which is in the German city of Marburg, will produce both active substance and the finished product. There are currently three active substance manufacturing sites supplying the EU included in the marketing authorisation.

In addition to the new manufacturing facility for this vaccine, the CHMP has also given a positive opinion to allow transportation and storage of vials of this vaccine at temperatures between -25 to -15˚C (i.e. the temperature of standard pharmaceutical freezers) for a one-off period of two weeks. This is an alternative to the long-term storage of the vials at a temperature between -90 to -60˚C in special freezers. It is expected to facilitate the rapid roll-out and distribution of the vaccine in the EU by reducing the need for ultra-low temperature cold storage conditions throughout the supply chain.

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New manufacturing site and scaled-up processes for Moderna's COVID-19 vaccine

Already last week, CHMP recommended approving the addition of a new manufacturing site for the production of active substance and finished product intermediates for Moderna's COVID-19 vaccine. The addition of the new manufacturing lines at the Lonza facility, located in Visp, Switzerland, together with other changes to the manufacturing processes that were greenlighted by the Committee are intended to scale-up production capacity and increase supply of the vaccine for the EU market.

The changes described will be included in the publicly available information on these vaccines on EMAs website.

EMA is in continuous dialogue with the marketing authorisation holders of COVID-19 vaccines as they seek to expand their production capacity for the supply of vaccines in the EU. The Agency provides guidance and advice on the evidence required to support and expedite applications to add new sites for the manufacture of high-quality COVID-19 vaccines.

As for any medicine in the EU, COVID-19 vaccines can only be manufactured in approved sites that are included in the marketing authorisation following regulatory assessment.

This requires that a manufacturer has a manufacturing licence from the national competent authority of the Member State in which the pharmaceutical manufacturing site is located to ensure that the production process complies with the standards of good manufacturing practice (GMP). National competent authorities carry out GMP inspections in coordination with EMA to check that manufacturers comply with EU standards, the conditions of their licence and the marketing authorisation if obtained.

In addition, the marketing authorisation needs to submit strong evidence to demonstrate that the site is capable to consistently produce high-quality vaccines according to agreed specifications.

Once the appropriate data are available, the company applies to add the new manufacturing site to the marketing authorisation. This is done via a variation application. EMA is ready to assess such requests rapidly.

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Ministry of Health
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