EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Media and Public Relations

Press release

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

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

Scaled-up processes for BioNTech/Pfizer's COVID-19 vaccine

EMA has approved an increase in batch size and associated process scale up at Pfizer's vaccine manufacturing site in Puurs, Belgium. The recommendation by the Agency's Committee for Human Medicines (CHMP) is expected to have a significant impact on the supply of Comirnaty, the COVID-19 vaccine developed by BioNTech and Pfizer, in the European Union.

Based on the review of the data submitted by BioNTech Manufacturing GmbH, the application to increase the batch size of the finished product manufactured at the Puurs site has been approved. EMA's decision reaffirms that the Puurs facility is capable of consistently producing high-quality vaccines and enables Pfizer/BioNTech to scale up the production process at this site.

The changes described will be included in the publicly available information on this vaccine on EMA's website.

New filling manufacturing line for COVID-19 vaccine Moderna

The CHMP also recommended the approval of a new filling line at Moderna's finished product manufacturing site for the EU in Rovi, Spain. The new line will enable an increase in finished product fill activities, to synchronize with the active substance scale-up process at the active substance manufacturing site (Lonza, Visp) approved last month.

The changes described will be included in the publicly available information on this vaccine on EMA's website.

EMA is in continuous dialogue with all 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 or increase the capacity of existing sites for the manufacture of high-quality COVID-19 vaccines.

Notes

1. This press release, together with all related documents, is available on the Agency's website
2. Increase in vaccine manufacturing capacity and supply for COVID-19 vaccines from AstraZeneca, BioNTech/Pfizer and Moderna.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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