EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Media and Public Relations

Press release

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

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

Additional manufacturing site and scaled-up process for Comirnaty

CHMP has approved an additional manufacturing site for the production of Comirnaty, the COVID-19 vaccine developed by BioNTech and Pfizer. The site, located in Saint Remy sur Avre, France, is operated by Delpharm and will manufacture finished product. The site will allow to provide approximately up to 51 million additional doses in 2021.

EMA has also approved a new manufacturing line at BioNTech's manufacturing site in Marburg, Germany which increases the active substance manufacturing capacity by approximately 410 million doses in 2021.

Additional manufacturing site for Spikevax

The CHMP has also approved an additional manufacturing site for the production of Spikevax, the COVID-19 vaccine developed by Moderna.

The site, located in Bloomington, Indiana, United States (US), is operated by Catalent. The site will perform finished product manufacturing.

In addition to the new manufacturing facility for this vaccine, the CHMP has also approved several alternative sites responsible for batch control/testing and packaging of the finished product manufactured by Catalent.

On 30 July 2021, the CHMP already approved a scale-up of the active substance manufacturing process at two sites in the US (Moderna TX, Inc., Norwood, Massachusetts and Lonza Biologics, Inc., Portsmouth, New Hampshire). All together, these changes are estimated to allow the production of 40 million additional doses of Spikevax to supply the EU market in the third quarter of 2021.

These recommendations do not require a European Commission decision and the sites can become operational immediately.

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. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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