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More flexible storage conditions for BioNTech/ Pfizer's COVID-19 vaccine

EMA's human medicines committee (CHMP) has recommended a change to the approved storage conditions of Comirnaty, the COVID-19 vaccine developed by BioNTech and Pfizer, that will facilitate the handling of the vaccine in vaccination centres across the European Union (EU).

This change extends the approved storage period of the unopened thawed vial at 2-8°C (i.e. in a normal fridge after taking out of deep-freeze conditions) from five days to one month (31 days). The change was approved following assessment of additional stability study data submitted to EMA by the marketing authorisation holder. Increased flexibility in the storage and handling of the vaccine is expected to have a significant impact on planning and logistics of vaccine roll-out in EU Member States.



The changes described will be included in the publicly available information on Comirnaty and will be implemented by the marketing authorisation holder in updated product labelling. Users are reminded to always refer to the label and package leaflet of the supplied

product for the correct storage information.

EMA is in continuous dialogue with the marketing authorisation holders of COVID-19 vaccines as they seek to make manufacturing improvements to enhance vaccine distribution in the EU.