

AKHBAR : THE STAR

MUKA SURAT : 6

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## Shelf life of seven Covid-19 vaccines extended

**PUTRAJAYA:** The National Pharmaceutical Regulatory Agency (NPRA) has approved a variation application for the extension of the shelf life of seven Covid-19 vaccine products from April 28 to Dec 20 last year.

The Health Ministry's Pharmacy Services senior director, Norhaliza A Halim, announced the new shelf life for the products, namely Comirnaty (Pfizer), CoronaVac (Sinovac) and Convidecia (Cansino), in a detailed statement yesterday.

The new shelf life approved for the products ranges from 12 months to 24 months, depending on the storage temperature.

"The approval of this shelf life extension is retrospective, meaning it also applies to all stocks including those received before this shelf life extension variation was approved," she said, according to Bernama.

She added that the shelf life of pharmaceutical products, including vaccines, is determined based on the stability study conducted by the manufacturer at a specific storage temperature in real time.

The stability study involves a series of tests such as physical characteristics, potency, purity and sterility to confirm that the product still meets the specified specifications when stored for a certain period of time, and data collection for the stability study will usually be completed within two to three years.

Norhaliza said since there is an urgent need for Covid-19 vaccines, conditional registration has been granted to the registered vaccines and the manufacturers have also been allowed to file rolling submissions of their products' stability test data.

"The most recent data will be submitted to NPRA through a variation application and will be evaluated to ensure that the quality of the vaccine remains the same as when it was approved," she said.

Norhaliza said the expiry date on the vaccine label may indicate that the product has expired but consumers can check the actual expiry date, which is after the extension, at the NPRA website <https://npa.gov.my/index.php/en/consumers/information/vaccine-covid-19-update.html>.