

AKHBAR : SINAR AHAD

MUKA SURAT : 13

RUANGAN : NASIONAL

## Jangka hayat produk vaksin Covid-19 *convidecia* dilanjutkan

PUTRAJAYA - Bahagian Regulatori Farmasi Negara (NPRA) telah meluluskan permohonan variasi daripada Solution Biologics Sdn Bhd berhubung pengemaskinian tempoh jangka hayat produk bagi vaksin Covid-19 *convidecia recombinant novel coronavirus vaccine (adenovirus type 5 vector) solution for injection*.

Pengarah Kanan Perkhidmatan Farmasi, Norhaliza A Halim berkata, tempoh jangka hayat baharu yang diluluskan adalah daripada 15 bulan kepada 18 bulan apabila disimpan pada suhu 2 darjah celsius sehingga 8 darjah celsius.

Jelasnya, pelanjutan jangka hayat itu melibatkan vaksin MAL21066050AZ yang dikilang di CanSino Biologics Inc, China dan MAL22126013ASZ yang dikilang di Solution Biologics Sdn Bhd, Malaysia.

"Pelanjutan tempoh jangka hayat produk telah diberikan berdasarkan data stabiliti terkini yang dikemukakan oleh pihak pengilang.

"Kelulusan pelanjutan jangka hayat ini adalah secara retrospektif, bermaksud kelulusan ini juga terpakai kepada semua stok termasuk semua stok yang telah diterima sebelum variasi pelanjutan tempoh jangka hayat ini diluluskan," katanya dalam kenyataan pada Sabtu.

Norhaliza berkata, Kementerian Kesihatan Malaysia (KKM) sentiasa akan memastikan semua produk farmaseutikal termasuk vaksin Covid-19 yang dibekalkan di Malaysia telah dinilai dari aspek kualiti, keselamatan dan keberkesanan oleh NPRA. - *Bernama*

AKHBAR : THE SUNDAY TIMES

MUKA SURAT : 11

RUANGAN : NATION / NEWS

LATEST STABILITY DATA

# SHELF LIFE OF COVID VACCINE EXTENDED

Convidecia can last 18 months when stored at 2°C to 8°C, says medicine regulator

KUALA LUMPUR

**T**HE National Pharmaceutical Regulatory Agency (NPRA) has approved an application from Solution Biologics Sdn Bhd to extend the shelf life of the Covid-19 vaccine, Convidecia Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector) Solution for Injection.

NPRA senior director (pharmaceutical services) Norhaliza A. Halim said the newly approved shelf life was from 15 months to 18 months when stored at a temperature of 2°C to 8°C.



Norhaliza A. Halim

She said the extension of the shelf life involved the vaccine with the registration numbers MAL21066050AZ, manufactured by CanSino Biologics Inc, China, and MAL22126013ASZ, manufactured by Solution Biologics Sdn Bhd, Malaysia.

"The extension of the product's shelf life has been given based on the latest stability data submitted by the manufacturer.

"The approval of this shelf life extension is retrospective, meaning that this approval also applies to all stocks, including all stocks that have been received before this shelf life extension was approved," she said in a statement yesterday.

Norhaliza said the Health Ministry was committed to ensuring that all pharmaceutical products, including the Covid-19 vaccines supplied in Malaysia, had been assessed in terms of quality, safety and ef-

fectiveness by the NPRA. **Berna-**

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