**MAKLUMAN PENGEMASKINIAN TEMPOH JANGKA HAYAT**

**VAKSIN COMIRNATY *(ADULT DOSE)* DARIPADA**

**12 BULAN KEPADA 15 BULAN**

Sukacita dimaklumkan bahawa pada 13 September 2022, NPRA telah meluluskan permohonan variasi daripada syarikat Pfizer (Malaysia) Sdn. Bhd, berhubung pengemaskinian tempoh jangka hayat produk untuk vaksin *COMIRNATY* seperti berikut:

1. ***COMIRNATY Concentrate for Dispersion for Injection (MAL21016022AZ)***
2. ***COMIRNATY Concentrate for Dispersion for Injection (MAL21036039ASZ)***

|  |  |
| --- | --- |
| **Kategori** |  **Deskripsi variasi yang diluluskan**  |
| MaVB-59 | Memanjangkan tempoh penyimpanan vaksin dari 12 bulan ke 15 bulan apabila disimpan pada suhu -90°C hingga -60°C |

Bersama ini dilampirkan senarai kelompok dengan tarikh luput baharu yang telah dikemaskini seperti di Lampiran A. Maklumat jangka hayat produk di sisip bungkusan juga telah dikemaskini dan boleh dimuat turun melalui laman sesawang NPRA.

Sekiranya terdapat sebarang pertanyaan lanjut, YBhg. Datuk/ Dato’/ Tuan/ Puan boleh menghubungi *One-Stop-Centre* di alamat npra@npra.gov.my atau di talian 03-7883 5400 (sambungan: 4435/4436/4437) atau 03-7801 8445/8446/8447/8449

Sekian, terima kasih.

**Senarai vaksin *COMIRNATY Concentrate for Dispersion for Injection (MAL21016022AZ & MAL21036039ASZ)* dengan Tarikh Luput Baru selepas Pelanjutan Jangka Hayat Vaksin ke 15 Bulan**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No** | **No. Kelompok** | **Tarikh Mengilang** | **Tarikh Luput dari sijil *Lot Release*** | **Tarikh Luput Baru** **(15 Bulan)** |
| 1 | EP2163 | 23-Dec-20 | 31-May-21 | 28-Feb-22 |
| 2 | EP9605 | 13-Jan-21 | 30-Jun-21 | 31-Mar-22 |
| 3 | ER7449 | 27-Jan-21 | 30-Jun-21 | 31-Mar-22 |
| 4 | ET9096 | 12-Feb-21 | 31-Jul-21 | 30-Apr-22 |
| 5 | ET3045 | 25-Feb-21 | 31-Jul-21 | 30-Apr-22 |
| 6 | EX2405 | 4-Mar-21 | 31-Aug-21 | 31-May-22 |
| 7 | EX6564 | 15-Mar-21 | 31-Aug-21 | 31-May-22 |
| 8 | FA5715 | 31-Mar-21 | 31-Aug-21 | 31-May-22 |
| 9 | EW0198 | 6-Apr-21 | 30-Sep-21 | 30-Jun-22 |
| 10 | FC3558 | 9-Apr-21 | 30-Sep-21 | 30-Jun-22 |
| 11 | FD0927 | 21-Apr-21 | 30-Sep-21 | 30-Jun-22 |
| 12 | FD5996 | 30-Apr-21 | 30-Sep-21 | 30-Jun-22 |
| 13 | FE2083 | 11-May-21 | 31-Oct-21 | 31-Jul-22 |
| 14 | FE2625 | 11-May-21 | 31-Oct-21 | 31-Jul-22 |
| 15 | EY0584 | 16-May-21 | 31-Oct-21 | 31-Jul-22 |
| 16 | FE3064 | 20-May-21 | 31-Oct-21 | 31-Jul-22 |
| 17 | FC5029 | 26-May-21 | 31-Oct-21 | 31-Jul-22 |
| 18 | FF4222 | 2-Jun-21 | 31-Oct-21 | 31-Jul-22 |
| 19 | FE3430 | 2-Jun-21 | 31-Oct-21 | 31-Jul-22 |
| 20 | FE8163 | 2-Jun-21 | 31-Oct-21 | 31-Jul-22 |
| 21 | FF0884 | 10-Jun-21 | 30-Nov-21 | 31-Aug-22 |
| 22 | FF8871 | 10-Jun-21 | 30-Nov-21 | 31-Aug-22 |
| 23 | FG1807 | 15-Jun-21 | 30-Nov-21 | 31-Aug-22 |
| 24 | FG2872 | 15-Jun-21 | 30-Nov-21 | 31-Aug-22 |
| 25 | FG4421 | 15-Jun-21 | 30-Nov-21 | 31-Aug-22 |
| 26 | FG3716 | 30-Jun-21 | 30-Nov-21 | 31-Aug-22 |
| 27 | FG2975 | 30-Jun-21 | 30-Nov-21 | 31-Aug-22 |
| 28 | FG8643 | 1-Jul-21 | 30-Nov-21 | 31-Aug-22 |
| 29 | FG9019 | 6-Jul-21 | 31-Dec-21 | 30-Sep-22 |
| 30 | FH2528 | 16-Jul-21 | 31-Dec-21 | 30-Sep-22 |
| 31 | FG7900 | 26-Jul-21 | 31-Dec-21 | 30-Sep-22 |
| 32 | FG6272 | 2-Aug-21 | 31-Dec-21 | 30-Sep-22 |
| 33 | FH3253 | 5-Aug-21 | 31-Jan-22 | 31-Oct-22 |
| 34 | FH4763 | 9-Aug-21 | 31-Jan-22 | 31-Oct-22 |
| 35 | FH8773 | 10-Aug-21 | 31-Jan-22 | 31-Oct-22 |
| 36 | FK0112 | 11-Aug-21 | 31-Jan-22 | 31-Oct-22 |
| 37 | FK5475 | 12-Aug-21 | 31-Jan-22 | 31-Oct-22 |
| 38 | FJ5973 | 25-Aug-21 | 31-Jan-22 | 31-Oct-22 |
| 39 | FH4750 | 25-Aug-21 | 31-Jan-22 | 31-Oct-22 |
| 40 | FH4752 | 27-Aug-21 | 31-Jan-22 | 31-Oct-22 |
| 41 | FK6858 | 27-Aug-21 | 31-Jan-22 | 31-Oct-22 |
| 42 | FJ4188 | 27-Aug-21 |  30-Apr-22 | 31-Oct-22 |
| 43 | FK9414 | 1-Sep-21 | 28-Feb-22 | 30-Nov-22 |
| 44 | FL3560 | 3-Sep-21 | 31-May-22 | 30-Nov-22 |
| 45 | FH3221 | 8-Sep-21 | 31-May-22 | 30-Nov-22 |
| 46 | FL5324 | 9-Sep-21 | 31-May-22 | 30-Nov-22 |
| 47 | FL7476 | 13-Sep-21 | 31-May-22 | 30-Nov-22 |
| 48 | FL1940 | 15-Sep-21 | 31-May-22 | 30-Nov-22 |
| 49 | FL1939 | 15-Sep-21 | 31-May-22 | 30-Nov-22 |
| 50 | FK8888 | 16-Sep-21 | 31-May-22 | 30-Nov-22 |
| 51 | FK0892 | 17-Sep-21 | 31-May-22 | 30-Nov-22 |
| 52 | 210961 | 21-Sep-21 | 31-May-22 | 30-Nov-22 |
| 53 | FM3809 | 23-Sep-21 | 31-May-22 | 30-Nov-22 |
| 54 | FK6268 | 29-Sep-21 | 31-May-22 | 30-Nov-22 |
| 55 | FM3802 | 30-Sep-21 | 31-May-22 | 30-Nov-22 |
| 56 | FL4210 | 18-Oct-21 | 30-Jun-22 | 31-Dec-22 |
| 57 | FN1430 | 26-Oct-21 | 30-Jun-22 | 31-Dec-22 |
| 58 | FM9090 | 3-Nov-21 | 31-Jul-22 | 31-Jan-23 |
| 59 | 34513TB | 3-Nov-21 | 31-Jul-22 | 31-Jan-23 |
| 60 | 1K077A | 4-Nov-21 | 31-Jul-22 | 31-Jan-23 |
| 61 | 1K077-1A | 5-Nov-21 | 31-Jul-22 | 31-Jan-23 |
| 62 | 1F1044A | 8-Nov-21 | 31-Jul-22 | 31-Jan-23 |
| 63 | 1F1044A | 8-Nov-21 | 31-Jul-22 | 31-Jan-23 |
| 64 | 1F1045A | 9-Nov-21 | 31-Jul-22 | 31-Jan-23 |
| 65 | 1K078A | 10-Nov-21 | 31-Jul-22 | 31-Jan-23 |
| 66 | 35559TB | 15-Nov-21 | 31-Jul-22 | 31-Jan-23 |
| 67 | FM9281 | 17-Nov-21 | 31-Jul-22 | 31-Jan-23 |
| 68 | FP8233 | 19-Nov-21 | 31-Jul-22 | 31-Jan-23 |
| 69 | 1F1053A | 24-Nov-21 | 31-Jul-22 | 31-Jan-23 |
| 70 | 1F1054A | 24-Nov-21 | 31-Jul-22 | 31-Jan-23 |
| 71 | SDWE5 | 6-Dec-21 | 31-Aug-22 | 28-Feb-23 |
| 72 | 1F1060A | 8-Dec-21 | 31-Aug-22 | 28-Feb-23 |