Date of issuance: 26 February 2021

NOTIFICATION OF NON-COMPLIANCE

Notification no: NNC 001/2021

The following lot of COMIRNATY® Concentrate for Dispersion for Injection produced by PFIZER MANUFACTURING BELGIUM NV, BELGIUM, whose numbers appear on the labels of the final containers, does not meet the requirements on product delivery and storage specification as approved by the Drug Control Authority and required by PIC/S Good Manufacturing Practice.

Product Registration Holder: PFIZER (MALAYSIA) SDN. BHD

Lot no: EP2163

Expiry date: 31 May 2021

No. of doses:

3510 doses

No. of doses per container:

6

Receiving facility:

Hospital Permai Johor

Signature:

Name of authorized person:

DR HASENAH BINTI ALI

Director of National Pharmaceutical Regulatory Agency (NPRA)

Ministry of Health Malaysia