LICENCE CONDITIONS ON VACCINE COLD CHAIN FOR LICENSEES INVOLVED IN THE HANDLING, STORAGE AND/OR TRANSPORT OF VACCINES

IMPOSED UNDER SECTION 13(1) OF THE HEALTHCARE SERVICES ACT 2020

1 Application

1.1 These licence conditions ("**LCs**") apply to all persons which have been licensed under the Healthcare Services Act 2020 (the "**HCSA**") and are involved in the handling, storage and/or transport of vaccines (such persons referred to as "**Licensee(s)**").

1.2 A breach of these LCs may result in regulatory action being taken against Licensees under section 20 of the HCSA, including but not limited to:

(a) suspension or revocation of the Licensee's HCSA licence;

(b) shortening the term of the Licensee's HSCA licence;

(c) a direction requiring the Licensee to rectify the contravention, or prevent a recurrence of the contravention; and/or

(d) a direction requiring the Licensee to pay a financial penalty.

1.3 For avoidance of doubt:

(1) the defined terms as used in these LCs shall have the meaning ascribed to them in the HCSA and any Regulations made thereunder, unless otherwise stated; and

(2) the requirements in these LCs are without prejudice, and in addition to the requirements imposed under the HCSA as well as any Regulations and other applicable licensing conditions, directions, codes of practice made thereunder.

2 Definitions

2.1 "**Vaccine Cold Chain**" means the systems, processes and equipment for the maintenance of vaccines within the Set Temperature Range (as defined in paragraph 2.2 below).

2.2 "**Set Temperature Range**" means (a) the temperature range specified or instructed by the relevant vaccine manufacturer, or (b) if no temperature range is specified or instructed by the vaccine manufacturer, from 2ºC to 8ºC (both values inclusive).

3 Requirements on Vaccine Cold Chain

3.1 The Licensee shall ensure that all vaccines are stored within the Set Temperature Range.

3.2 The Licensee shall ensure that no food or drinks are stored in any refrigerator or freezer used for the storage of vaccines ("**vaccine storage**").

3.3 The Licensee shall ensure that all vaccines are stored at the central compartment of a refrigerator or freezer (where the temperature is the most certain and stable) and are not stored in the door or at the bottom of the refrigerator or freezer (as the case may be).

3.4 The Licensee shall ensure that any refrigerator or freezer used for vaccine storage has a thermometer in the refrigerator or freezer at all times to measure the internal temperature of the refrigerator or freezer. For avoidance of doubt, a 'thermometer' shall include a temperature monitoring probe that is in the refrigerator or freezer, provided that the probe is linked to a display on the exterior of the refrigerator or freezer which displays the temperature measured by the probe.

3.5 The Licensee shall ensure that the thermometer referred to in paragraph 3.4 above is placed at the central compartment of the refrigerator or freezer and adjacent to the stored vaccines.

3.6 The Licensee shall ensure that the temperature of the refrigerator or freezer in which the vaccines are stored is monitored and recorded at least twice daily during the Licensee's operating hours.

3.7 When transporting vaccines, the Licensee shall ensure that either cold boxes or vaccine carriers with ice packs are used in the Vaccine Cold Chain.

3.8 The Licensee shall establish and implement processes on how to manage a break in the Vaccine Cold Chain. A break in the Vaccine Cold Chain refers to the exposure of any vaccines to temperatures outside of the Set Temperature Range due to reasons such as, but are not limited to, a breakdown or power failure of the refrigerator or freezer used to store the vaccines.

3.9 Without limiting paragraph 3.8, where any vaccines have been exposed to temperatures outside of the Set Temperature Range ("**affected vaccines**"), the Licensee shall:

(a) seek the advice of the relevant vaccine manufacturer on whether the affected vaccines can still be used on patients;

(b) ensure that none of the affected vaccines are used on patients until the vaccine manufacturer has provided advice that the affected vaccines can still be used on patients (see paragraph 3.9(a)); and

(c) separate the affected vaccines from the other vaccines which are not affected vaccines, while awaiting the advice of the vaccine manufacturer.