S.I. 14 of 2021

PUBLIC HEALTH ACT

(Act 13 of 2015)

Public Health (Emergency Use Authorisation of Vaccines and Medical Products) Regulations, 2021

In exercise of the powers conferred by section 26 of the Public Health Act, 2015 the Minister responsible for Health, makes the following regulations —

Citation

1. These regulations may be cited as the Public Health (Emergency Use Authorisation of Vaccines and Medical Products) Regulations, 2021.

Minister may authorise use of vaccines or medical products

2.(1) The Minister may, on the recommendation of the Public Health Commissioner, authorise the use of vaccines or medical products for emergency use for treatment, prevention, control or and suppression of any disease in a public health emergency as specified under Schedule 1 appended to the Act.

(2) The authorisation under subregulation (1) shall specify the details of the vaccine or the medical product and the infectious disease in respect of which the authorisation is issued.

(3) The authorisation under these regulations shall be issued in the Form specified in Schedule 1 appended to these regulations.

Conditions for Public Health Commissioner to consider in making recommendation

3. In making recommendations to the Minister, the Public Health Commissioner shall consider and ensure that —

(a) the vaccine or medical product does not cause any serious or life-threatening disease or condition;

(b) based on published scientific evidence, it is reasonable to believe that the vaccine or the medical product is effective in treating and preventing the spread of a serious disease;

(c) the known and potential benefits outweigh the known and potential risks of the vaccine or medical product;

(d) the vaccine or medical product shall only be used to treat or prevent the spread of serious disease in humans;

(e) that the patient can be administered with the vaccine or be treated by the medical product only on a voluntary basis;

(f) the vaccine or medical product for which an authorisation for emergency use is given, should have been approved, albeit under special conditions, in a jurisdiction recognised by Ministry of Health.

Declaration of authorised vaccine

4. It is hereby declared that the vaccines, the details of which are specified under Schedule 2, shall be the vaccines specified for the treatment, prevention, control or suppression of the diseases mentioned therein.

SCHEDULE 1

FORM

[Regulation 2]

AUTHORISED VACCINE/MEDICAL PRODUCT

1. Name of vaccine or Medical Product: .....

2. Commercial Name: .....

3. Manufacturer: .....

4. Date of Authorisation: .....

5. Use for the treatment, prevention, control or suppression of:

SCHEDULE 2

DECLARATION OF AUTHORISED VACCINES

[Regulation 4]

1. AUTHORISED VACCINE

1. Name of vaccine - COVID 19 VACCINE MRNA-1273
2. Commercial Name: MODERNA VACCINE
3. Manufacturer: ModernaTX, Inc., based at Cambridge - Massachusetts (USA)
4. Date of Authorisation: 21st of December 2020.
5. Use for the prevention of: Coronavirus Disease 2019.

2. AUTHORISED VACCINE

1. Name of vaccine - COVID 19 VACCINE, INACTIVATED
2. Commercial Name: VEROCELL
3. Manufacturer:
    1. Beijing Institute of Biological Products, China
    2. China National Pharmaceutical Group Corp (Sinopharm)
4. Date of Authorisation: 5th of January 2021
5. Use for the prevention of: Coronavirus Disease 2019

3. AUTHORISED VACCINE

1. Name of vaccine - COVID 19 VACCINE
2. Commercial Name: COVISHIELD (OXFORD-ASTRAZENECA)
3. Manufacturer: Serum Institute of India based in Pune - Maharashtra
4. Date of Authorisation: 13th of January 2021
5. Use for the prevention of: Coronavirus Disease 2019

MADE this 24th day of February 2021.

PEGGY VIDOT
MINISTER OF HEALTH