«05» February 2021

No 335-A

«ON DEFINING OF NEW VALIDITY DATA OF GOOD MANUFACTURING PRACTICE CERTIFICATES FOR MANUFACTURES IN THE REPUBLIC OF ARMENIA»

Taking into consideration the difficulties in conducting of GMP inspections due to the pandemic of coronavirus COVID-19 in the Republic of Armenia and the point 10 of the Article 2 of the Decree of the Government of the Republic of Armenia N199-n of February 28,

I ORDER:

- 1. To define the validity period of GMP certificates until on 30th of June 2021, given to manufacturers of Republic of Armenia during 2019-2020, except those certificates which expire after June 30, 2021.
- 2. From February 1 of this year, resume temporarily suspended inspections at manufacturing sites.
- 3. During the marketing authorization expertise of medicinal products and for issuance a permission for conducting clinical trials in the Republic of Armenia, GMP certificates issued by the regulatory authorities of foreign countries which expired after March 11, 2020 shall be considered valid with the terms fixed in the relevant document issued by the drug regulatory authority of the given state.
- 4. To Head of the Public Relations Department of the Ministry of Health Lilit Babakhanyan: to ensure the placement of this order on the official website of the Ministry of Health.
- 5. Entrust the supervision of this order to the Deputy of Minister of Health Artyom Smbatyan.
- 6. This order enters into force on the date of its official publication.

A. Avanesyan

05.02.2021