**CABINET OF MINISTERS OF UKRAINE**

**DECREE**

**of February 8, 2021 № 95**

**Kyiv**

**Some issues of state registration of vaccines or other medical immunobiological products for specific prevention of acute respiratory disease COVID-19 caused by coronavirus SARS-CoV-2 subject to obligations for emergency medical use**

According to Article 92 of the Law of Ukraine “On Medicines”, the Cabinet of Ministers of Ukraine **decides**:

1. To approve the Procedure for the state registration of vaccines or other medical immunobiological products for specific prevention of acute respiratory disease COVID-19 caused by coronavirus SARS-CoV-2 subject to obligations for emergency medical use (attached)

2. To specify that:

Issues of the responsibility of manufacturers of vaccines or other medical immunobiological products for specific prevention of acute respiratory disease COVID-19 caused by coronavirus SARS-CoV-2, supplied through the COVAX mechanism, and requirements to texts of instructions for use of such vaccines and labelling of the immediate and outer (if any) packaging of such vaccines are be regulated by agreements signed by Ukraine trough the COVAX mechanism. The Expert Center of Ministry of Health of Ukraine shall conduct free of charge an expert evaluation of the benefit/risk balance and verification of the authenticity of registration materials during the state registration of vaccines or other medical immunobiological products for specific prevention of acute respiratory disease COVID-19 caused by coronavirus SARS-CoV-2 subject to obligations for emergency medical use, which are to be supplied through the COVAX mechanism;

registration of vaccines or other medical immunobiological products for specific prevention of acute respiratory disease COVID-19 caused by coronavirus SARS-CoV-2, subject to obligations for emergency medical use, the development and/or production of which has been carried out in a state recognized by the Verkhovna Rada of Ukraine as an aggressor state, is prohibited.

**D. Shmygal**

**Prime Minister of Ukraine**