Press release

12 November 2020, Strasbourg, France

COVID-19 vaccines: release of guidelines critical for co-ordinated independent batch control by EU OMCLs

The European Directorate for the Quality of Medicines & HealthCare (EDQM) has published three new Official Control Authority Batch Release (OCABR) guidelines outlining the tests to be performed by Official Medicines Control Laboratories (OMCLs) in the EU OCABR Network as part of the independent control of pandemic COVID-19 vaccine batches. They were adopted by the full OCABR Network and are in force from 12 November 2020.

The guidelines, which can be downloaded here, are for:

- Pandemic COVID-19 vaccine (Non-Replicating Chimpanzee Adenovirus-Vectored Vaccine);
- Pandemic COVID-19 vaccine (Non-Replicating Human Adenovirus-Vectored Vaccine);
- Pandemic COVID-19 vaccine (mRNA Vaccine).

These are expected to address the vaccines currently predicted to arrive first on the European market. Additional guidelines are under development to address other vaccine types which are under development for the COVID-19 pandemic and are intended for the European market (e.g. recombinant protein-based vaccines).

As part of OCABR, OMCLs will perform the prescribed tests and make a careful review of the batch release protocol from the manufacturer. The protocol will include data on all the quality control tests for batch release performed by the manufacturer, as approved in the marketing authorisation. Only batches that are compliant with the approved quality standards will be released.

Independent control of each batch of COVID-19 vaccine, before it reaches the patient, is an important part of the EU regulatory network strategy to ensure the availability of vaccines that meet the appropriate quality requirements and to protect public health. COVID-19 vaccines are eligible for EU OCABR according to Article 114 of EU Directive 2001/83/EC, as amended.

Presently, there are no COVID-19 vaccines with a marketing authorisation in the EU. The guidelines have been prepared based on current knowledge. Once the relevant marketing authorisations have been approved, they will be reviewed and updated accordingly, including the addition of a model protocol for the manufacturer's data submission.

The availability of these guidelines at an early stage will help anticipate the launch of the first vaccines and allow OMCLs and manufacturers to take the necessary steps to prepare for OCABR, thus preventing delays in availability while still ensuring their quality and safety.

Background

In line with EU regulations, batches of vaccines and blood-derived products on the EU market are eligible to be tested by Official Medicines Control Laboratories (OMCLs) before being placed on the market. The process, called Official Control Authority Batch Release (OCABR), involves independent analytical control and document review, in addition to the controls carried out by the manufacturer.

The European OMCL Network was established in 1995 by the European Commission and the Council of Europe in order to promote co-ordination and avoid duplication of effort between

Press release

European countries' laboratories in the field of quality control of identical medicinal products on the market.

Today, the OMCL Network brings together laboratories from more than 40 countries. Operating independently of manufacturers, and thus without any conflicts of interest, this network makes it possible to pool resources and latest technologies with a view to saving public money and sharing expertise and best practices across European laboratories. Its work gives member states the support they need to monitor the quality of medicines and to ensure that no substandard products reach European patients, potentially putting their health or the efficacy of their treatments at risk.

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Note for the Editor: Further information is available on the internet site **https://www.edqm.eu/**.

The EDQM is a leading organisation that protects public health by enabling the development, supporting the implementation and monitoring the application of quality standards for safe medicines and their safe use. Our standards are recognised as a scientific benchmark worldwide. The European Pharmacopoeia is legally binding in member states.[1] The EDQM also develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

1. There are 40 members of the European Pharmacopoeia Commission: *Austria, Albania, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Republic of Moldova, Montenegro, Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine, United Kingdom and the European Union.*

A political organisation set up in 1949, the Council of Europe works to promote democracy and human rights continent-wide. It also develops common responses to social, cultural and legal challenges in its 47 member states.