Press release

3 November 2020, Strasbourg, France

New EDQM document on recombinant viral vectored vaccines to support COVID-19 vaccine developers

A broad range of technologies are being evaluated in the development of COVID-19 vaccines, from conventional approaches, such as live attenuated and inactivated vaccines, to more recent technologies, such as nucleic acid vaccines and recombinant viral vectored vaccines. Currently, limited guidance is available covering the quality of such new technologies.

The EDQM has drafted a text on the control of viral vectored vaccines in order to support COVID-19 vaccine developers currently working on candidate vaccines based on this technology. This work was accomplished in collaboration with the European Pharmacopoeia (Ph. Eur.) Group of Experts on vaccines for human use (Group 15), which is composed of experts from licensing authorities, national control laboratories, academia and industry from Europe and beyond (including the United States Food and Drug Administration, Health Canada and the Therapeutic Goods Administration, Australia).

This new text provides a series of analytical strategy options for the control of recombinant viral vectored vaccines. It includes recommendations on tests that may be conducted at different manufacturing stages of viral vectored vaccines and can be used by COVID-19 vaccine developers as an aid in building appropriate analytical strategies during the development of their candidate vaccines. The principles described in this document can also be used for other recombinant viral vectored vaccines.

This document, entitled "Recombinant viral vectored vaccines for human use", is not binding and will be updated to adapt to the evolving situation and to take into account experience with new constructs or products. Stakeholders are encouraged to contribute to this process by submitting relevant comments and data via the address: VaccinesTF@edqm.eu.

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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.*

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