Press release

12 November 2019, Strasbourg, France

New secondary site of the EDQM: resilience and business continuity

The new secondary site of the EDQM, being opened and inaugurated on 15 November 2019, will enable the safe storage of contingency stocks of European Pharmacopoeia reference standards and ensure their distribution worldwide in the event of major incidents at its main site in Strasbourg.

European Pharmacopoeia (Ph. Eur.) reference standards are an indispensable component of the application of Ph. Eur. quality standards; they are used in pharmaceutical analysis, for example, for identification, purity tests or assays according to the corresponding monographs or general chapters of the Ph. Eur. These reference standards are essential for the quality control of medicines. Interruptions in their supply to health authorities, official medicines control laboratories and pharmaceutical manufacturers would mean blocking the release of medicines to the market in Europe and non-European countries which apply the Ph. Eur., thus depriving patients of their medicines.

The new site, based in Ars-Laquenexy, close to Metz in eastern France, is part of the EDQM's business continuity strategy based on the creation of a full backup stock in order to mitigate risks of disruptions to supplies of Ph. Eur. reference standards. Opening the ceremony, Ms Snežana Samardžić-Marković, Director General of Democracy of the Council of Europe, explained the reasons behind the investment for the building: "The reference standards produced by the EDQM are fundamental to guarantee that all patients in Europe and beyond have uninterrupted access to the good-quality medicines they need".

The Ph. Eur. reference standards are currently produced and stored by the EDQM in Strasbourg. The EDQM proposes a portfolio of about 3 000 reference standards which are used and distributed in more than 120 countries. Last year, more than 1 600 000 vials of reference standards were manufactured by the EDQM in order to create the contingency stock that will be stored in the new building. From a patient-safety perspective, the EDQM has a responsibility to anticipate risks and ensure that no disruptions in the availability of reference standards occur.

The new building has been designed with attention to aesthetics, functionality and the protection of the environment. The floor area is 2 770 m^2 (including technical spaces), of which 235 m^2 are dedicated to the preparation of samples required for laboratory studies carried out during the development of monographs and the establishment of reference standards. The overall storage capacity is 9 400 000 vials at +5°C, 2 211 840 at –20°C and 378 pallets. The new building will also have dedicated rooms to host backup computer servers for the EDQM and the Council of Europe.

Today, 38 countries and the European Union are involved in the work of the European Pharmacopoeia, which defines legally binding quality standards for medicines. This work is followed by 28 observer states, of which 22 are non-European states from all over the world, as well as the World Health Organization (WHO) and the Taiwan Food and Drug Administration. These standards serve as a scientific and technical reference for guaranteeing the same quality for medicines throughout Europe and beyond.

The inauguration of the new building is a testimony to the dynamism and added value of the EDQM, but also of the strength of the model of international co-operation set up by the Council of Europe in all fields related to fundamental human rights. Above all, it is also proof of the EDQM's commitment to protecting the fundamental right to access to good quality health inscribed in Council of Europe treaties such as the Social Charter.

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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 development, supporting 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] Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

1. There are 39 members of the European Pharmacopoeia Commission: *Austria, 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.