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European and Indian Pharmacopoeias to cooperate further on provision of strong quality standards for medicines

The EDQM/European Pharmacopoeia (Ph. Eur.) and the Indian Pharmacopoeia Commission (IPC) held a symposium on the quality control of medicines in the context of the pharmaceutical legislation and regulatory requirements that exist in Europe and India.

The event, which took place in Mumbai on 26 April, was attended by authorities and manufacturers alike, in particular those involved in the manufacture of APIs, from production, quality control and regulatory affairs. The programme covered an overview of the roles of the EDQM/ Ph. Eur. and the IPC in the quality control of medicines including harmonisation activities. Practical advice was also given on using and interpreting the European Pharmacopoeia General Chapters and Monographs, together with an overview of the policies and processes used to establish Pharmaceutical Reference Standards.

This symposium showed the importance for the main pharmacopoeias of the world to combine their resources and efforts, and make the best use of competences to better encompass worldwide developments. Indian expertise in the pharmaceutical sector plays an extremely important role for international cooperation and to this end, the European Pharmacopoeia Commission wished to express appreciation of the motivation and contribution of Indian experts participating in the work of its expert groups, since it granted Observer status to the IPC in 2016, to reflect India's considerable manufacturing expertise and Indian companies are among the world leaders in the production of generics and vaccines.

Dr. Keitel, Director of the EDQM, thanked the Indian authorities for the opportunity provided with the symposium in Mumbai and explained: "the European Pharmacopoeia, which currently includes more than 2800 quality standards, has been working on the basis of collaboration and pooling resources since 1964. In today's globalised pharmaceutical industry with complex supply chains, new risks and challenges, the cooperation and interaction with its Observers is crucial for the Ph. Eur. With the Indian pharmaceutical industry leading in the provision of high quality generics to the world, IPC is one of our most prominent partners.

The presence of the Ph. Eur. in Mumbai is a testimony to the global leading role of the Indian pharmaceutical industry, but it also represents an important step in the direction of supporting our industry in further improving its capacity of protecting global health through the provision of ever higher quality standards. The collaboration between the two Pharmacopoeias shows the commitment on both sides in making the best scientific resources available for the protection of health in India, in Europe and the rest of the world."

Discussions also covered the EDQM's Procedure for Certification of Suitability, or CEP as it is more commonly known. As sourcing of APIs is a global business and a key strategic challenge for pharmaceutical companies, with millions of people around the world relying on affordable, high-quality medicines, the EDQM's CEP offers industry and regulatory authorities a centralised and efficient procedure that supports manufacturers in accessing highly regulated markets, such as the European Union. There are currently more than 4200 valid certificates (CEP) granted to

manufacturers from more than 50 countries covering more than 1000 substances. Of these, 40% (1673) have been granted to Indian manufacturers - the No. 1 country in the world for CEPs.

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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 thirty-nine 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, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, "the former Yugoslav Republic of Macedonia", Turkey, Ukraine, United Kingdom and the European Union.*

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