BioSpectrum the business of Bio & Health Sciences ASIA EDITION

WHO approves largest number of regulatory agencies for medical products

May 22, 2024 | News

Decision is based on the recommendation by the WHO technical advisory group



The World Health Organisation (WHO) has approved designation of 33 national and regional regulatory authorities as WHO Listed Authorities (WLAs) that can be relied on for fulfilling the highest level of regulatory standards and practices for quality, safety and efficacy of medicines and vaccines.

This listing makes a total of 36 regulatory authorities from 34 Member States now designated as WLAs since the launch of the initiative in March 2022.

The newly approved WLAs include: the US Food and Drug Administration (US FDA) and the European Medicines Regulatory Network (EMRN), which is composed of the European Commission, the European Medicines Agency (EMA) and the medicines regulatory authorities of the following 30 countries: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany (Federal Institute for Drugs and Medical Devices & Paul-Ehrlich-Institut), Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden.

Furthermore, the Health Sciences Authority (HSA) of Singapore, which was previously designated as a WLA in October 2023, was approved for an expanded scope of functions. WHO approval for HSA includes an additional regulatory function of market surveillance and control. With this inclusion, HSA's WLA status now covers all regulatory functions, for the product stream of medicines – including multisource (generics) and new medicines (new chemical entities) and biotherapeutics and similar biotherapeutic products.

The decision is based on the recommendation by the WHO technical advisory group on WHO Listed Authorities (TAG-WLA) following WHO performance evaluations confirming consistency of advanced performance by these authorities in line with international standards and best regulatory practices for ensuring the quality, safety and efficacy of medicines and vaccines.