IFPMA

STATEMENT

Pharmaceutical trade associations welcome latest announcement of largest number of regulatory agencies recognized under the WHO Listed Authorities Framework

21 MAY 2024, GENEVA –Pharmaceutical trade associations at international, European and US-level have welcomed the recognition of the European Medicines Regulatory Network (EMRN) and the United States Food and Drug Administration (FDA) as WHO Listed Authorities, as well as the expanded scope of functions of the Health Sciences Authority (HSA) of Singapore. Following the previous announcement in October, this represents another crucial step in enhancing international cooperation to promote access and supply of safe, effective and quality medical products. The framework also provides for the optimal use of limited resources by facilitating reliance on the work products and decisions of trusted agencies in the decision-making of regulatory authorities, the WHO Prequalification Programme and procurement agencies.

Janis Bernat, Director, Scientific and Regulatory Affairs at the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), said:

“We congratulate the listed authorities for this recognition and commend WHO for their leadership in this area. Regulatory reliance serves as a beacon of efficiency and collaboration, enabling regulatory authorities worldwide to leverage each other's evaluations while maintaining accountability for patient safety. The WLA framework is a recognition of the transformative potential of regulatory reliance in expediting access to safe, effective, and quality-assured medicines.”

Pär Tellner, Director, Regulatory Affairs, Drug development and Manufacturing at the European Federation of Pharmaceutical Industries and Associations (EFPIA), said:
“EFPIA congratulates the formal recognition of the European Medicines Regulatory Network, comprised of European Commission, the European Medicines Agency (EMA) and the medicines regulatory authorities of 30 countries as WLA by WHO. It is a testament to their existing classification of stringent regulatory authorities (SRAs) for medicines including highly functioning national regulatory authorities (NRA's) for vaccines as benchmarked by WHO. The WLA framework is crucial for regulatory convergence and harmonisation, which EFPIA considers essential for delivering high-quality medicines and vaccines to people globally.”

Janet Vessotskie, Deputy Vice President of Science and Regulatory Advocacy at PhRMA, said:
“The United States leads the world in the introduction of new medicines thanks in part to the human drug review program by the U.S. FDA. International regulatory cooperation enables collaboration across borders so patients can get faster access to new medicines. We appreciate the WHO’s leadership on designing a

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transparent framework to recognize regulatory authorities that apply science-based, globally recognized standards to ensure the quality and safety of new biopharmaceutical products."

About IFPMA

The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) represents over 90 innovative pharmaceutical companies and associations around the world. Our industry's almost three million employees discover, develop, and deliver medicines and vaccines that advance global health. Based in Geneva, IFPMA has official relations with the United Nations and contributes industry expertise to help the global health community improve the lives of people everywhere.

For more information, visit ifpma.org.

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