

Setting international standards for medicines

16 MARCH 2012 | GENEVA: In a world of increased globalization of medicine production and distribution, international pharmaceutical standards are becomingly increasingly important to safeguard quality and improve access to medicines.

At a meeting hosted by the World Health Organization (WHO) in Geneva earlier this month, countries showed unprecedented commitment to working together to strengthen international standards. For the first time in 10 years, representatives from pharmacopoeias from 23 countries came together and committed to working further towards harmonization and strengthening WHO's role when developing global standards for the production and testing of medicines.

“This is a significant milestone in the goal towards global access to quality medicines,” says Dr Sabine Kopp, from the Department of Essential Medicines and Health Products at WHO. “Countries are showing genuine willingness to share information and harmonize development of their own pharmacopoeial standards within the international context.”

A pharmacopoeia (from the Greek meaning "drug-making") is a reference containing compliance specifications for pharmaceutical medicines. Usually published by government authorities in each country, a pharmacopoeia provides the standards for an independent check of the quality of a medicine at any time during its shelf-life.

First attempts at standardizing the composition of drugs worldwide dates back to 1874. Following work in the early 1900s by the Belgian Government and the League of Nations, WHO took on the job of developing an international pharmacopoeia in 1947. “Our ancestors had a vision that all medicines would be tested using the same set of specifications for checking their quality. We should not lose this dream,” says Dr Kopp.

Since the publication of the first volume in 1951, the International Pharmacopoeia published by WHO has evolved to focus on the needs of developing countries, with priority given to medicines listed on the WHO Model List of Essential Medicines as well as new medicines for diseases including HIV and malaria.

Harmonization of standards has become increasingly important for public health for several reasons, one of the most important being to combat falsified and substandard medicines. “The latest incident in Pakistan where 125 died due to contamination of heart medicines with an antimalarial drug is very sad proof of the need for action,” says Dr Kopp. Testing of suspected medicines was a key element of the investigation and this process exposed limitations to using pharmacopoeial tests. Tests done to International Pharmacopoeia standards are intended to be applicable internationally and pick up more contaminants than tests done to one single manufacturer's specifications.

Uniform global standards will also help to expand access to medicines in developing countries. When each country has its own specifications for medicines, this makes it very expensive for manufacturers to tailor their exports to each country's requirements. If standards are not harmonized, the costs of checking quality also increase.

Last week's meeting has released momentum for greater collaborative work and sharing of information between world pharmacopoeias. Future projects discussed include a new internet-based system for information exchange, hosted by WHO, as well as a guide to "good pharmacopoeial practices", currently under development by a group of representatives from Argentina, Brazil, the European Pharmacopoeia, India, Japan, Mexico, the Russian Federation, Ukraine, the United Kingdom of Great Britain and Northern Ireland and the United States Pharmacopeia.

Opportunities for further collaboration this year include the International Pharmaceutical Federation (FIP) Centennial congress in Amsterdam on 3-8 October 2012 and the International Conference of Drug Regulatory Authorities (ICDRA) conference in Tallinn, Estonia also in October.

Quality assurance of medicines:

http://www.who.int/medicines/areas/quality_safety/quality_assurance/en/index.html

The International Pharmacopoeia:

<http://www.who.int/medicines/publications/pharmacopoeia/overview/en/index.html>

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