**SIXTY-SEVENTH WORLD HEALTH ASSEMBLY** **WHA67.20**

**Agenda item 15.6** **24 May 2014**

# Regulatory system strengthening for medical products

The Sixty-seventh World Health Assembly,

Having considered the report on regulatory system strengthening; [1]

Welcoming the efforts of the Director-General, and recognizing the pivotal role that WHO plays in supporting countries in strengthening their regulatory systems of medical products for human use, [2] and in promoting equitable access to quality, safe, efficacious, and affordable medical products;

Recalling the Constitution of the World Health Organization, which affirms that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition;

Recalling also United Nations General Assembly resolution 67/81 on global health and foreign policy, which, inter alia, recognized the importance of universal coverage in national health systems, especially through primary health care and social protection mechanisms, in the provision of access to health services for all, in particular for the poorest segments of the population;

Recalling further resolutions WHA45.17, WHA47.17, WHA52.19, WHA54.11, WHA59.24, WHA63.12, and WHA65.19, all of which encompass aspects of the need to promote the quality, safety, efficaciousness and affordability of medicines, including blood products;

Reaffirming resolution WHA65.19 on substandard/spurious/falsely-labelled/falsified/counterfeit medical products, which establishes a new Member State mechanism for international collaboration, from a public health perspective, excluding trade and intellectual property considerations, to prevent and control substandard/spurious/falsely-labelled/falsified/counterfeit medical products and to promote access to affordable, safe and quality medical products;

Recognizing that effective regulatory systems are an essential component of health system strengthening and contribute to better public health outcomes, that regulators are an essential part of the health workforce, and that inefficient regulatory systems themselves can be a barrier to access to safe, effective and quality medical products;

Recognizing also that effective regulatory systems are necessary for implementing universal health coverage, responding to the dual burden of infectious and noncommunicable diseases, and

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[1] Document A67/32.

[2] For the purpose of this resolution, medical products include medicines, vaccines, diagnostics and medical devices.

achieving Millennium Development Goal 4 (Reduce child mortality), Goal 5 (Improve maternal health) and Goal 6 (Combat HIV/AIDS, malaria and other diseases);

Aware that health systems need to promote access to essential medical products and that, in order to ensure universal access to health care, rational use of medicines and the sustainability of health systems, urgent action is needed by the international community, Member States and relevant actors in health systems;

Very concerned by the impact on patients of medical products of compromised quality, safety and efficacy, in terms of poisoning, inadequate or no treatment, contributions to drug resistance, the related economic burden, and erosion of public trust in the health system;

Aware of the regulatory challenges presented by the ever-increasing complexities of medical product supply chains and welcoming the work plan of the Member State mechanism on substandard/ spurious/falsely-labelled/falsified/counterfeit medical products;

Emphasizing WHO's role in strengthening regulatory systems for medical products from a public health perspective, and in supporting national drug regulatory authorities and relevant regional bodies in this area, and in particular in developing countries;

Recalling WHO's Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, in particular element three, which calls for establishing and strengthening regulatory capacity in developing countries as one effective policy for building and improving innovative capacity, and element six, which promotes establishing and strengthening mechanisms to improve ethical review and regulate the quality, safety and efficacy of health products and medical devices;

Noting with appreciation the many existing national and regional efforts to strengthen regulatory capacity (including through a variety of models), improve regulatory coherence and convergence among regulatory authorities, and enhance good governance, including transparency in decision-making, leading to the improved availability of quality, safe, efficacious and affordable medical products, such as the European Union regulatory framework for medical products, work under way in PAHO following the adoption by its Directing Council in 2010 of resolution CD50.R9 on strengthening national regulatory authorities for medicines and biologicals, the African Medicines Regulatory Harmonization Initiative, and the regulatory harmonization and cooperation work in ASEAN;

Noting the ongoing collaboration between national and regional regulatory authorities in promoting cooperation among regulatory authorities at the regional and global levels;

Recognizing the significant investments made in the procurement of medicines through national health budgets and global health initiatives;

Also recognizing the essential role of WHO's prequalification programme in facilitating procurement of medical products with assured quality, safety and efficacy;

Stressing that the strengthening of regulatory systems should complement the efforts of the Secretariat and Member States to promote access to affordable medical products with assured quality, safety and efficacy;

Recalling the WHO good clinical practices that focus on the protection of human research subjects;

Recalling also WHO's ongoing reform agenda and welcoming in this regard the establishment in November 2012 of the Health Systems and Innovation cluster,

1. URGES Member States:[1]

(1) to strengthen national regulatory systems, including – as appropriate and voluntarily – by:

(a) undergoing self-evaluations, including with WHO support, to identify the strengths and opportunities for improvement in regulatory system functions, as a first step towards formulating plans for regulatory system strengthening, including through WHO-coordinated institutional development plans;

(b) collecting data on regulatory system performance to enable analysis and benchmarking for improved systems in the future;

(c) developing strong legal foundations and political leadership to underpin a regulatory system with a clear focus on patient safety and transparency in decision-making;

(d) identifying and developing a core set of regulatory functions to meet country and/or regional needs, such as market control and postmarket surveillance;

(e) developing needed competencies as an integral part of, although not limited to, the health workforce, and encouraging the development of the regulatory field as a profession;

(f) facilitating the use of relevant guidance and science-based outputs of WHO expert committees and good regulatory practices at the national, regional and international levels;

(g) devising and implementing strategies to address the increasing complexities of supply chains;

(2) to engage in global, regional and subregional networks of national regulatory authorities, as appropriate, recognizing the importance of collaboration to pool regulatory capacities to promote greater access to quality, safe, efficacious and affordable medical products;

(3) to promote international cooperation, as appropriate, for collaboration and information sharing, including through electronic platforms;

(4) to support regulatory systems for medical products with appropriate funding as an essential component of the health system;

(5) to support regulatory system strengthening as an essential component of the development or expansion of local or regional production of quality, safe and efficacious medical products;

[1] And, where applicable, regional economic integration organizations.

(6) to achieve access to and rational use of quality, safe, efficacious and affordable essential medicines, noting the growing emergence of resistance, and as a foundation for achieving broader access to quality, safe, efficacious and affordable medical products;

(7) to support WHO's institutional capacity relating to promoting access to and rational use of quality, safe, efficacious and affordable medical products in the context of universal health coverage;

(8) to strengthen the national and regional initiatives of regulatory authorities to improve regulatory capacities for review of medical products, promoting WHO's long-term objective of supporting the strengthening of national regulatory authority capacity among Member States;

(9) to support WHO's prequalification programme, including exploring modalities in consultation with Member States[1] for improved sustainability of this critical programme;

(10) to identify the need to strengthen regulatory system capacity, collaboration and cooperation in the technically complex areas where substantial gaps may still exist, such as the regulation of biotherapeutic products, blood products, and in vitro diagnostics;

2. REQUESTS the Director-General:

(1) to continue to support Member States upon their request in the area of regulatory system strengthening, including, as appropriate, by continuing to:

(a) evaluate national regulatory systems;

(b) apply WHO evaluation tools;

(c) generate and analyse evidence of regulatory system performance;

(d) facilitate the formulation and implementation of institutional development plans; and

(e) provide technical support to national regulatory authorities and governments;

(2) to continue to develop appropriate norms, standards and guidelines, including taking into account national, regional and international needs and initiatives, in accordance with WHO