134th session **EB134.R17**

Agenda item 9.5 **25 January 2014**

Regulatory system strengthening for medical products

The Executive Board,

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

RECOMMENDS to the Sixty-seventh World Health Assembly, the consideration and adoption of the following resolution:

The Sixty-seventh World Health Assembly,

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, which establishes a new Member State mechanism for international collaboration, from a public health perspective, to prevent and control substandard/spurious/falsely-labelled/falsified/counterfeit medical products and to promote access to affordable, safe and quality medical products;]

---

[1] Document EB134/29.

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

Recognizing that effective regulatory systems are an essential component of health systems 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 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 ever-increasing complexities of medical product global supply chains;]

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 the WHO 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 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 its 2010 resolution CD50.R9, the African Medicines Regulatory Harmonization Initiative, and the regulatory harmonization and cooperation work in ASEAN;

[Also noting with appreciation the ongoing collaboration between some national regulatory authorities, including at the global level, in setting standards, including the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use among others, and encouraging a continued emphasis of effort in strengthening regulatory systems in accordance with WHO principles and guidelines;]

Recognizing the significant investments made in the procurement of medicines through global health initiatives, national health budgets, and, in particular, the essential role of WHO's prequalification programme and national regulatory systems in assuring the safety, quality and efficacy of these medical products;

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 by, as appropriate:

(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 systems 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) **[implementing relevant guidance and science-based outputs of international regulatory harmonization and convergence efforts such as, where applicable, the Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use;]**

(g) **[implementing strategies to address the increasing complexities of global 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;

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

(3) to promote international cooperation, as appropriate, for convergence 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 prerequisite to the development or expansion of local or regional production of quality, safe and efficacious medical products;

(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 support WHO in its efforts to strengthen its prequalification programmes, including exploring modalities in consultation with Member States[1] for improved sustainability of this critical programme, [while also focusing on supporting national and regional initiatives to improve regulatory capacity for medical products][focusing on achieving longer term objectives of developing national regulatory authority capacity among Member States];]**

(9) to identify the need to strengthen regulatory system capacity, collaboration and convergence 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 countries in the area of regulatory system strengthening, including by developing appropriate norms and standards**[**, **taking into account the standards created by existing regional and international initiatives]**; continue to evaluate national regulatory systems; continue to apply and improve WHO evaluation tools; continue to generate and analyse evidence of regulatory systems performance; continue facilitate the formulation and implementation of institutional develpment plans; and continue provide technical support to national regulatory authorities and governments;

(2) to ensure that all relevant parts of the Organization, at all levels, are actively engaged and coordinated in the carrying out of WHO's mandate pertaining to regulatory system strengthening as an integrated part of health system development, recognizing that WHO's support in this critical area, particularly for developing countries, may be required, as appropriate, well into the future;

(3) to prioritize support for establishing and strengthening regional and subregional networks of regulatory authorities, as appropriate, including strengthening areas of

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

regulation of health products that are the least developed, such as regulation of medical devices, including diagnostics;

(4) to promote the greater participation of Member States in existing international and regional initiatives for collaboration, harmonization and convergence in accordance with WHO principles and guidelines;

(5) **[to strengthen the integration and coherence among WHO's prequalification programmes as an aid to assuring safe supply of quality medical products, engaging with Member States in the further refinement and improvement of the global prequalification model, while in parallel supporting the development of functional national and regional regulatory bodies and networks, leading to more global participation in the global prequalification programme;]**

(6) to increase support for and recognition of the significant role of the International Conference of Drug Regulatory Authorities in promoting the exchange of information and collaborative approaches among drug regulatory authorities, and as a resource to guide and facilitate further development of, and regulatory harmonization and convergence among, these authorities;

(7) to raise awareness of the importance of effective regulatory systems within the health system context;

(8) to increase support and guidance for strengthening the capacity to regulate increasingly complex biological products with the focus on biotherapeutic products, blood products and associated in vitro diagnostics, and, where appropriate, on new medicines for human use based on gene therapy, somatic-cell therapy and tissue engineering;

(9) to report to the Seventieth and Seventy-second World Health Assemblies, through the Executive Board, on progress in the implementation of this resolution.

Thirteenth meeting, 25 January 2014
EB134/SR/13

= = =