World Health Organization

EXECUTIVE BOARD
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Regulatory system strengthening for medical products

Draft resolution proposed by Australia, Mexico, Nigeria, South Africa, Switzerland and United States of America

The Executive Board,

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

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

The Sixty-seventh World Health Assembly,

(PP1) 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**;

(PP2) Recalling the WHO Constitution, 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;

(PP3) Recalling also United Nations General Assembly Resolution 67/81 on global health and foreign policy, which recognized the importance of universal coverage in national health systems, especially through primary health care and social protection mechanisms, to provide access to health services for all, in particular for the poorest segments of the population;

(PP4) 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;

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[1] Document EB134/29.

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

[(PP4bis) Reaffirming WHA65.19 which establishes a new Member States mechanism for international collaboration from a public health prospective to prevent and control substandard/spurious/falsely-labelled/falsified/counterfeit medical products and to promote access to affordable safe and quality medical products;]

(PP5) Recognizing that effective regulatory systems are an essential component of ~~strong~~ 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;

(PP6) 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 Goals 4, 5 and 6;

(PP7) Aware that health systems need to **promote** ~~avoid the lack of~~ access to essential ~~medicines~~ **medical products** and ~~the proliferation of substandard, spurious, falsely-labelled, falsified, and counterfeit (SSFFC) medical products~~ in order to ensure universal access to health care, rational use of medicines and the sustainability of health systems, ~~and aware that~~ urgent action is needed by the international community, Member States and relevant actors in health systems;

(PP8) Very concerned by the impact on patients of ~~unsafe, poor quality~~ 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;

(PP9) Aware of the **regulatory challenges presented by** ever-increasing complexities of medical product global supply chains;

(PP10) 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 developing countries**;

(PP11) 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;

(PP12) ~~Welcoming~~ **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 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 the Association of Southeast Asian Nations (ASEAN);

(PP13) Also ~~welcoming~~ **noting with appreciation** the ~~intensive and~~ ongoing collaboration between **some** national regulatory authorities **including at the global level** in setting standards including the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) among others, and encouraging a continued emphasis of effort in ~~developing better~~ **strengthening** regulatory systems **in accordance with WHO principles and guidelines**;

(PP14) 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;

(PP15) Recalling the WHO ~~and ICH~~ good clinical practices that focus on the protection of human research subjects;

(PP16) Recalling WHO's ongoing reform agenda and welcoming in this regard the establishment in November 2012 of the Health Systems and Innovation cluster,

(OP) 1. URGES Member States:[1]

(1) to strengthen national regulatory systems by, as appropriate:

(a) undergoing self-evaluations, including **with** ~~through~~ WHO **support** ~~– coordinated evaluations~~, 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 systems 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~~, including with reference to WHO identified functions~~, to meet country and/or regional needs (e.g. market control, postmarket surveillance);

(e) developing needed competencies as an integral part **of**, **although not limited to,** ~~of~~ 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,** ~~including~~ the *Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use* (ICH);

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

(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 ~~networking approaches~~ **collaboration** to pool regulatory capacities to promote greater access to quality, safe, efficacious and affordable medical products;

(3) to **promote** ~~strengthen~~ international cooperation**, as appropriate, for** convergence and information sharing, including through electronic platforms~~, to achieve the common goal of securing supply chains for and access to quality, safe, efficacious and affordable medical products~~;

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

(5) to support regulatory systems strengthening as an essential prerequisite to the development or expansion of local or regional production of **quality, safe and efficacious** medical products ~~meeting international standards for quality, safety and efficacy~~;

(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 systems capacity, collaboration and convergence in the technically complex areas where substantial gaps may still exist such as regulation of biotherapeutic products ~~**that are similar in terms of quality, safety and efficacy to a licensed reference biotherapeutic products**~~, blood products, and in vitro diagnostics;

~~(10) to engage in international networks of national regulators to monitor development of new medicines for human use based on gene therapy, somatic cell therapy and tissue engineering in order to identify at an early stage the need to develop or adapt regulatory environments;~~

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

(OP) 2. REQUESTS the Director-General:

(1) to continue to support countries in the area of regulatory systems strengthening ~~through~~ **including by** developing **appropriate** ~~and promoting relevant global~~ norms and standards **[**taking account the standards created by existing regional and international initiatives**]**; continue evaluating national regulatory systems; continue applying and improving WHO evaluation tools; continue generating and analysing evidence of regulatory systems performance; continue facilitating the formulation and implementation of institutional develpment plans; and continue providing 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 systems strengthening as an integrated part of health systems development, recognizing that WHO's support on this critical area, particularly for developing countries, may be required, as appropriate, well into the future;

(3) to prioritize support to establishing and strengthening regional and subregional networks of regulatory authorities as appropriate, including strengthening areas of regulation of health products which 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 ~~securing~~ **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 (ICDRAs) 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 engage the relevant global donor community and global health programmes on~~ **to raise awareness of** the importance of ~~strong~~ **effective** regulatory systems within the health systems context**]**;

~~(8) to assess the role that regulatory systems have played in implementation of the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property when following up on instructions from the 133rd Executive Board in reviewing and evaluating the success of the GSPOA;~~

(9) to increase support and guidance for strengthening the capacity to regulate increasingly complex biological products with the focus on biotherapeutic products ~~that~~

~~are similar in terms of quality, safety and efficacy to a licensed reference 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;

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

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