World Health Organization

EXECUTIVE BOARD
138th session
Agenda item 10.5

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Promoting the safety and accessibility of children's medication

Draft resolution proposed by China, Italy, Pakistan and Thailand

The Executive Board,

Having considered the report on addressing the global shortages of medicines, and the safety and accessibility of children's medication,[1]

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

The Sixty-ninth World Health Assembly,

(PP1) Recalling resolution WHA60.20 (2007) on better medicines for children and WHA67.22 (2014) on access to essential medicines, which identified actions for Member States and the Director-General in support of better access for children to essential medicines;

(PP2) Concerned that problems remain with safety, accessibility and affordability of children's medicines in many countries, and that, globally, children under 5 still do not have secure access to medicines that treat pneumonia, diarrhoeal diseases, HIV infection, AIDS and malaria, as well as medicines for many other infectious diseases, noncommunicable diseases and rare diseases;

(PP3) Aware that an important factor linked to morbidity and mortality of children, is the lack of safe, effective, affordable and quality-assured medicines for children;

(PP4) Noting that despite sustained efforts over a number of decades by Member States, the WHO Secretariat and partners, many countries are still facing multiple challenges in ensuring the availability, affordability, quality assurance and rational use of children's medicines;

(PP5) Acknowledging Goal 3 of the 2030 Agenda for Sustainable Development, "Ensure healthy lives and promote well-being for all at all ages" particularly noting the targets related to access to medicines,

[1] Document EB138/41.

(OP) 1. URGES Member States:

(1) to accelerate implementation of the actions laid out in resolution WHA60.20 on better medicines for children;

(2) to learn from successful experiences with medicines policies for children in other countries and formulate and implement national measures including legislation as appropriate, and pharmaceutical policies in support of access to medicines for children;

(3) to take all necessary measures, including legislation, establishment of national plans and organizational structures and capacity to enhance such measures in the framework of national pharmaceutical policies as appropriate, to improve children's health;

(4) to ensure that national health policies and plans incorporate consideration of the needs of children based on the national situation, with clear objectives for increasing access to children's medicines, and to report, as appropriate, on the progress made in this regard;

(5) to learn from the evidence-based and transparent process used to update the WHO Model List of Essential Medicines, which considers disease prevalence, evidence on efficacy and safety and comparative cost-effectiveness; to adapt lists, as appropriate consideration of the local burden of disease; to develop as appropriate a comprehensive, clinical evaluation system for children's medicines;

(6) to develop a national Essential Medicines List, which includes medicines for children, and to develop therapeutic formularies and guidelines with supporting independent prescribing advice;

(7) to implement actions agreed under Sustainable Development Goal 3, with a focus on children, which states: Support the research and development of vaccines and medicines for the communicable and noncommunicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use the full provisions in the Agreement on Trade Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all;

(8) to encourage research and development of appropriate medicines for diseases that affect children, and to ensure that high-quality clinical trials for these medicines are conducted in an ethical manner;

(9) to facilitate timely licensing of appropriate, high-quality and affordable medicines for children and innovative methods for monitoring the safety of such medicines, and to encourage the marketing of adequate paediatric formulations together with newly developed medicines;

(10) to collaborate in order to facilitate innovative research and development on, formulation of, regulatory approval of, provision of adequate prompt information on, and rational use of, paediatric medicines and medicines authorized for adults but not approved for use in children;

(11) to actively facilitate high-quality paediatric clinical trials, including trial registration through national and international trial registries and also full publication of all completed trials to help guide quality use of medicines for children;

(12) to strengthen regulatory capacity including pharmacovigilance to promote high-quality clinical trials for children and the availability of safe, effective and quality-assured medicines for children;

(13) to promote research into health systems and other factors that affect access to and rational use of medicines for children;

(14) to enhance the training in rational use of medicines for children for healthcare professionals, and to enhance the health education of the public, to ensure acceptance and understanding of rational use of medicines for children;

(OP) 2. REQUESTS the Director-General:

(1) to accelerate implementation of the actions laid out in resolution WHA60.20 on better medicines for children;

(2) to further develop and maintain the Model List of Essential Medicines which includes the list of Essential Medicines for Children (EMLc) using evidence based clinical guidelines in coordination with all relevant WHO programmes;

(3) to consider the establishment of a working group of paediatric medicines experts to advise the WHO and the Committee on Essential Medicines on the development and maintenance of the List of Essential Medicines for Children;

(4) to support Member States in taking appropriate measures through provision of training and strengthening regulatory capacity according to national circumstances, and in promoting communication and coordination between countries on paediatric clinical trial design, ethical approval and product formulation;

(5) to collaborate with governments, other organizations of the United Nations system, including WTO and WIPO, donor agencies, nongovernmental organizations and the pharmaceutical industry in order to encourage fair trade, manufacturing, research and development and supply in safe and effective medicines for children and adequate financing for securing better access to medicines for children;

(6) to support Member States in implementing existing standards for clinical trials of medicines in children, and to facilitate communication and coordination among Member States to promote the sharing of paediatric clinical trial data;

(7) to promote cooperation among Member States' governments, bodies of the United Nations system and pharmaceutical companies, in aspects such as procurement and pricing of medicines;

(8) to monitor the general situation and support countries in implementing policies in line with the "access to medicine targets" under the Sustainable Development Goal 3, and to provide policy development assistance to low-income countries or regions.

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