World Health Organization

EXECUTIVE BOARD
138th session
Agenda item 10.5

EB138/CONF./3
26 January 2016

Promoting the safety and accessibility of children's medication

Draft resolution proposed by China 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 and accessibility 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, especially those under the age of five, is the lack of 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 learn from successful experiences with medicines policies for children in other countries, and formulate legislation and national policies in support of access to medicines for children in their own country;

(2) to take all necessary, appropriate and feasible administrative and legislative measures to improve children's health, including, where appropriate, establishment of national plans and organizational structures and capacity to enhance such measures;

(3) to formulate and establish national health plans based on the domestic disease burden borne by children, and with clear targets for increasing access to children's medicines, and to report periodically to WHO on progress made as part of reporting on efforts to meet the Goals of the 2030 Agenda for Sustainable Development;

(4) 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;

(5) to develop a national Essential Medicines List for Children, with supporting prescribing advice and national policies to improve the accessibility of essential medicines for children, as appropriate to national circumstances;

(6) to consider, as appropriate, adapting national legislation in order to make full use of the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to that agreement, in order to promote access to essential medicines for children, in line with the global strategy and plan of action on public health, innovation and intellectual property;

(7) to actively facilitate high-quality paediatric clinical trials, and their registration in WHO's clinical trial registry platform, as well as publishing clinical data that helps to guide quality use of medicines for children;

(8) to eliminate unnecessary regulatory barriers as well as strengthen capacity and streamline the ethical and regulatory approval and monitoring processes of paediatric clinical trials;

(9) to enhance the training of rational use of medicines in 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 support Member States in taking appropriate administrative and legislative measures according to national circumstances, and in promoting communication and coordination between countries;

(2) 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;

(3) 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 for children;

(4) 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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