SIXTY-NINTH WORLD HEALTH ASSEMBLY **WHA69.20**

Agenda item 16.4 **28 May 2016**

Promoting innovation and access to quality, safe, efficacious and affordable medicines for children

The Sixty-ninth World Health Assembly,

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

Recalling resolutions 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;

Recalling also resolution WHA67.20 (2014) on regulatory system strengthening for medical products, and its relevance for promoting the safety, accessibility and affordability of medicines for children;

Concerned about the lack of access to quality, safe, effective and affordable medicines for children in appropriate dosage forms, and problems with rational use of children's medicines in many countries, and that, globally, children aged under five years still do not have secure access to medicines that treat pneumonia, tuberculosis, diarrhoeal diseases, HIV infection, AIDS and malaria, as well as medicines for many other infectious diseases, noncommunicable diseases and rare diseases;

Concerned also about the lack of research and development on age-appropriate dosage forms most suitable for children, as well as on new medicines for diseases that affect children, that are appropriate for use in all environments, including areas lacking access to clean water;

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, and in some circumstances, lack of packaging in child-proof containers;

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;

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

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[1] Document A69/42.

Noting that *The World Health Report 2010* identified the promotion of generic medicines as a key action that could be taken to improve access by making medicines more affordable, and recognizing the importance of accelerating generic availability and uptake following the expiration of patents;

Recalling the Convention on the Rights of the Child in which States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illnesses and rehabilitation of health,

1. URGES Member States:[1]

(1) to accelerate implementation of the actions laid out in resolution WHA60.20 on better medicines for children and WHA67.20 on regulatory system strengthening for medical products;[2]

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

(3) to take all necessary measures, including legislation, as appropriate, for the 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;

(5) to establish transparent and evidence-based processes for the design and updating of their national essential medicines list or its equivalent to include medicines for children, according to each country's health needs and priorities, taking into account the WHO Model List of Essential Medicines, including the WHO Model List of Essential Medicines for Children, and its transparent and evidence-based process, which considers public health relevance, evidence on efficacy and safety and comparative cost–effectiveness;

(6) to implement actions, with a focus on children, as agreed under Sustainable Development Goal 3, target 3b, which states: "Support the research and development of vaccines and medicines for the communicable and non-communicable 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 to the full the 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";

(7) to undertake analysis of their pharmaceutical supply systems, including through the use of the WHO standardized surveys, to identify inefficiencies in the cost and pricing structures of

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

[2] Taking into account the context of federated States.

medicines and sources of mark-ups on the prices of medicines, and to seek to reduce the price of children's medicines by promoting greater availability and use of generics, and identifying strategies to reduce prices including mark-ups on medicines, in order to increase the availability and affordability of medicines for children;

(8) to strengthen research and development on appropriate medicines for diseases that affect children, to ensure that high-quality clinical trials for these medicines are conducted in an ethical manner and to collaborate in order to facilitate innovative research and development on, formulation of, and timely regulatory approval of, provision of adequate and prompt information on, and rational use of, medicines for children, including generic medicines;

(9) to facilitate clinical trials of medicines for children based on sound ethics, needs and principles of patient protection, and to promote clinical trial registration in any registry[1] that provides data to the WHO International Clinical Trials Registry Platform and to make information on those trials publically available, including publication of summary and complete data of completed trials in accordance with national and regional legislative frameworks, as appropriate;

(10) to strengthen national regulatory systems including pharmacovigilance and post-market surveillance and to promote quality, ethical clinical trials of medicines for children and the accessibility and availability of quality, safe, effective and affordable medicines for children;

(11) to enhance the education and training of the health workforce in the rational use of medicines for children, including generic medicines, and to enhance the health education of the public, to ensure acceptance and understanding of the rational use of medicines for children;

2. REQUESTS the Director-General:

(1) to accelerate implementation of the actions laid out in resolutions WHA60.20 on better medicines for children, WHA67.22 on access to essential medicines and WHA67.20 on regulatory system strengthening for medical products;

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

(3) to consider appropriate representation of paediatric experts on the WHO Expert Committee on the Selection and Use of Essential Medicines;

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

(5) to continue to collaborate with governments,[2] other organizations of the United Nations system, including WTO and WIPO, donor agencies, nongovernmental organizations and the

[1] Including internationally-recognized open registries such as clinicaltrials.gov, among others, and national registries.

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

pharmaceutical industry, in order to encourage fair trade 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, as appropriate, upon request, standards for ethical and appropriate clinical trials of medicines in children, and to facilitate communication and coordination among Member States[1] to promote the sharing of paediatric clinical trial information;

(7) to support analysis and better understanding of the costs of research and development for medicines for children, including for rare diseases in children;

(8) to support countries in implementing relevant policies in line with the 2030 Agenda for Sustainable Development, including Goal 3 and related access to medicine targets, and to provide the necessary technical assistance in this regard, upon request;

(9) to report to the Seventy-first World Health Assembly on progress in the implementation of this resolution.

Eighth plenary meeting, 28 May 2016
A69/VR/8

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