

EB120.R13 Better medicines for children

The Executive Board,

Having considered the report on progress in the rational use of medicines, including better medicines for children,¹

RECOMMENDS to the Sixtieth World Health Assembly the adoption of the following resolution:²

The Sixtieth World Health Assembly,

Having considered the report on better medicines for children;

Recalling resolutions WHA39.27, WHA41.16 and WHA47.13 on the rational use of drugs, WHA41.17 on ethical criteria for medicinal drug promotion, WHA43.20 and WHA45.27 on the WHO Action Programme on Essential Drugs, WHA47.12 on the role of the pharmacist in support of the WHO revised drug strategy, WHA49.14 and WHA52.19 on the revised drug strategy, WHA54.11 on the WHO medicines strategy, and WHA58.27 on improving the containment of antimicrobial resistance;

Recognizing the efforts of WHO in collaboration with governments, other organizations in the United Nations system, universities, the private sector, nongovernmental organizations and funding agencies in areas related to improving access to better medicines for children;

Aware of the core components of WHO's global framework for expanding access to essential medicines;

Wishing to promote evidence-based selection and use of medicines for children by health providers and carers;

Aware that there are regional initiatives to address inadequate access to essential medicines for children;

Wishing to ensure better access to essential medicines for children as a prerequisite for achieving health outcomes as set out in the internationally agreed health-related development goals, including those contained in the Millennium Declaration;

Aware that the lack of access to essential medicines of assured quality continues to pose significant risks of high morbidity and mortality in children, especially those under five years of age;

Concerned that children can be further disadvantaged by lack of physical and economic access to essential medicines, especially in vulnerable communities;

Recognizing that many countries do not have the requisite capacity to regulate and control medicines for children;

¹ Document EB120/37.

² See Annex 6 for the financial and administrative implications for the Secretariat of this resolution.

Aware that many manufacturers of essential medicines have neither developed nor produced appropriate dosage forms and strengths of medicines for children;

Concerned that there is insufficient investment in the clinical trials, development and manufacture of medicines for children;

1. URGES Member States:

(1) to take steps to identify appropriate dosage forms and strengths of medicines for children, and to encourage their manufacture and licensing;

(2) to investigate whether currently available medicines could be formulated to make them suitable for use in children;

(3) 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;

(4) 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;

(5) to promote access to essential medicines for children through inclusion, as appropriate, of those medicines in national medicine lists, and procurement and reimbursement schemes, and to devise measures to monitor prices;

(6) 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;

(7) to use mechanisms including, where appropriate, existing international trade agreements that might impact health, in order to ensure children's access to essential medicines, where applicable;

2. REQUESTS the Director-General:

(1) to promote the development, harmonization and use of standards for clinical trials of medicines for children; to revise and regularly update the Model List of Essential Medicines in order to include missing essential medicines for children, using evidence-based clinical guidelines; and to promote application of such guidelines by Member States and international financing bodies, with initial focus on treatments for HIV/AIDS, tuberculosis, malaria and chronic diseases;

(2) to ensure that all relevant WHO programmes, including but not limited to that on essential medicines, contribute to making safe and effective medicines as widely available for children as for adults;

(3) to promote the development of international norms and standards for quality and safety of formulations for children, and of the regulatory capacity to apply them;

- (4) to make available evidence-based treatment guidelines and independent information on dosage and safety aspects of essential medicines for children, progressively to cover all medicines for children, and to work with Member States in order to implement such guidelines;
- (5) to collaborate with governments, other organizations of the United Nations system, donor agencies and nongovernmental organizations 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 report to the Sixty-second World Health Assembly, and subsequently as appropriate, through the Executive Board, on progress achieved, problems encountered and specific actions needed to further promote better access to medicines for children.

(Twelfth meeting, 29 January 2007)