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## **Access to essential medicines<sup>1</sup>**

### **Revision of the resolution EB134.R16 incorporating amendments by Bhutan, India, Oman, Syrian Arab Republic and Viet Nam**

The Sixty-seventh World Health Assembly,

PP1 Having considered the report on access to essential medicines;

PP2 Noting that WHO's definition of an essential medicine<sup>2</sup> contains the following elements: "Essential medicines are those that satisfy the priority health care needs of the population" and "Essential medicines are selected with due regard to their public health relevance, evidence of efficacy and safety, and comparative cost-effectiveness";

PP3 Recalling resolution WHA28.66 on prophylactic and therapeutic substances that relates to the formulation and implementation of medicines policies and pharmaceutical strategies; the Declaration of Alma-Ata in 1978 that recognized the provision of essential medicines as one of the pillars of primary health care, and subsequent resolutions in relation to essential medicines, such as resolution WHA54.11 on the WHO medicines strategy, WHA58.27 on improving the containment of antimicrobial resistance, WHA60.16 on progress in the rational use of medicines, WHA60.20 on better medicines for children, WHA60.29 on health technologies, WHA61.21 on the global strategy and plan of action on public health, innovation and intellectual property, and WHA64.9 on sustainable health financing structures and universal coverage, as well as WHA66.10 in which the Health Assembly endorsed the WHO global action plan for the prevention and control of noncommunicable diseases 2013–2020, and which includes Target (9) on the availability of essential medicines required to treat noncommunicable diseases;

PP4 Bearing in mind that the WHO medicines strategy, as set out in the Twelfth General Programme of Work 2014–2019, is based on the principles of evidence-based selection of a limited range of medicines, efficient procurement and distribution systems, affordable prices, and the rational use of medicines in order to promote better management and greater availability of medicines, more cost-effective use of health resources, and higher quality health care;

PP5 Considering that the effective implementation of the above principles is of critical importance to improving people's health, progressing towards universal health coverage and achieving the health-related Millennium Development Goals;

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<sup>1</sup> Document EB134.R16.

<sup>2</sup> WHO Expert Committee on the Selection and Use of Essential Medicines. Geneva: World Health Organization; in press (WHO Technical Report Series, No 985).

PP6 Welcoming WHO's regional actions in support of greater access to – and availability, affordability and rational use of – safe, effective and quality-assured essential medicines, including development of the Regional Office for the Western Pacific Regional Framework for Action on Access to Essential Medicines (2011–2016);

PP7 Acknowledging the complexity of the medicines supply chain and the challenges that countries encounter in this regard, the importance of good governance for medicines programmes,<sup>1</sup> and the consequences of the high costs of medicines, which are among the factors that make accessing care and treatment unaffordable;

PP8 Aware that shortages of essential medicines are a global problem that has an impact on the care of patients, the causes and implications of which vary from one country to another, and that there is insufficient information to determine the magnitude and specific characteristics of the problem;

PP9 Realizing the role of evidence-based clinical treatment guidelines to guide cost-effective treatment practices, the need for reliable and unbiased information to support rational prescribing, and the importance of increased health literacy to support patients and consumers to use medicines wisely;

PP10 Noting with concern that despite sustained efforts over a number of decades by Member States, the Secretariat and partners, most low-income countries are still facing a multitude of challenges in improving the availability, affordability and rational use of essential medicines;

PP11 Noting that the goal of Member States is to increase access to affordable, safe, effective and quality-assured essential medicines, including as appropriate, through the full use of the flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights in line with the Global Strategy and Plan of Action on Public Health Innovation and Intellectual Property;

PP12 Noting that support for research and development is important for the sustainable supply of future essential medicines, to address public health needs,

(OP.1) URGES Member States:<sup>2</sup>

(OP1.1) to ~~recognize the need and~~ [Bhutan] provide adequate resources, as required, for the development **and implementation** [Bhutan] of comprehensive national medicine policies, **to strengthened good governance of** [Bhutan] pharmaceutical systems **including** [Bhutan] regulatory, procurement and distributions systems and **to coordinated** [Bhutan] responses to address the complex and interrelated activities that affect access to essential medicines, in order to improve their availability, affordability, quality and rational use;

(OP1.2) to improve national policies for selection of essential medicines, **including critical medicines**, [India] particularly by using transparent, rigorous, evidence-based

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<sup>1</sup> In WHO's assessment instrument for measuring transparency in the public pharmaceutical sector (document WHO/EMP/MAR/2009.4), "good governance" refers to the formulation and implementation of appropriate policies and procedures that ensure the effective, efficient and ethical management of pharmaceutical systems, in particular medicines regulatory systems and medicine supply systems, in a manner that is transparent, accountable, follows the rule of law and minimizes corruption.

<sup>2</sup> And, where applicable, regional economic integration organizations.

processes based on the methods of health technology assessment in selecting medicines for inclusion in the national essential medicines lists according to each country's health needs and priorities;

(OP1.3) to encourage and support research on health systems regarding the procurement, supply and rational use of essential medicines;

(OP1.4) to promote collaboration and strengthen the exchange of information on best practices in the development, implementation and evaluation of medicine policies and strategies, that enhance access to affordable, safe, effective and quality-assured essential medicines;

(OP1.5) to place greater emphasis on medicines for children and to promote the availability, affordability, quality and safety of essential medicines for children through the development and manufacture of appropriate paediatric formulations and to facilitate market access to these medicines;

(OP1.6) to improve the education and training of health care professionals in order to support the implementation of national policies and strategies in relation to essential medicines, and to develop and implement evidence-based clinical practice guidelines and other interventions for the rational use of essential medicines;

(OP1.7) to strengthen the engagement with the general public and civil society to increase awareness and knowledge of essential medicines and public involvement, **as appropriate, and through transparent mechanisms and structures, [Viet Nam]** in enhancing access to and the rational use of these medicines;

(OP1.8) to identify key barriers to access to essential medicines and to develop strategies to address these barriers, making use of WHO's tools<sup>1</sup> and guidance as appropriate;

(OP1.9) to establish or strengthen, as appropriate, systems to monitor the availability (**using effective inventory management systems**) **[Bhutan]**, affordability and utilization of safe, effective and quality-assured essential medicines in public and private health facilities;

(OP1.10) to systematize information collection and strengthen monitoring mechanisms, in order to better detect and understand the causes of essential medicines shortages, and to develop strategies to prevent and mitigate the associated problems and risk caused by shortages;

**(OP1.11) to prevent countries in crisis to suffer from economic sanctions that will limit access to essential medicines and to ingredients for local production of medicines; [Syrian Arab Republic]**

(OP1.12~~1~~) 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

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<sup>1</sup> Including but not limited to: pharmaceutical sector country profiles, the assessment instrument for measuring transparency in the public pharmaceutical sector, the WHO/Health Action International tool for measuring medicine prices, availability, affordability and price components, and guidance on how to investigate drug use in health facilities.

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, in line with the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property;

(OP.2) REQUESTS the Director-General:

(OP2.1) to urge Member States to recognize the importance of effective national medicines policies, and their implementation under good governance, in order to ensure equity of access to affordable, safe, effective and quality-assured essential medicines and their rational use in practice;

(OP2.2) to facilitate and support the exchange of information and collaboration among Member States on best practices in the development and implementation of medicines policies;

(OP2.3) to support Member States in sharing best practices in the selection of essential medicines, and facilitating collaboration between the Secretariat and Member States in developing processes for the selection of medicines for national essential medicines lists consistent with the evidence-based methods used for updating the WHO Model List of Essential Medicines;

(OP2.4) to support Member States in building capacity for the evidence-based selection of essential medicines, the development and dissemination of, and adherence to, clinical practice guidelines and the promotion of other strategies for the rational use of affordable, safe, effective and quality-assured essential medicines by health care professionals and the public;

(OP2.5) to support Member States in developing and implementing their national medicines policies and supply systems especially with regard to regulation, financing, selection, procurement, distribution, pricing, reimbursement and use, in order to increase their efficiency and ensure the access to safe, effective and quality-assured essential medicines, including high price essential medicines;

(OP2.6) to support Member States in systematizing information collection and strengthening monitoring mechanisms, in order to better detect and understand the causes of essential medicines shortages, and in developing strategies to prevent and mitigate the associated problems and risk caused by shortages;

(OP2.7) to urge Member States to expedite progress towards the achievement of the Millennium Development Goals and universal health coverage by, inter alia, implementing national medicines policies for improving access to affordable, safe, effective, and quality-assured essential medicines;

(OP2.8) to provide, as appropriate, upon request, in collaboration with other competent international organizations, technical support, including, where appropriate, to policy processes to Member States that intend to make 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, in accordance with the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property;

**(OP2.9) to review/improve, in collaboration with other relevant organizations, procedures needed by Member States to implement the flexibilities within TRIPS and make these procedures more flexible. [Oman]**

**(OP2.109)** to report to the Sixty-ninth World Health Assembly, through the Executive Board, on the implementation of this resolution.

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