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## **Addressing the global shortage of medicines**

### **Draft resolution proposed by the delegations of Colombia, India, Kenya, South Africa, and United States of America**

The Sixty-ninth World Health Assembly,

**PP1** Having considered the report on global shortages of medicines and the safety and accessibility of children's medicines;

**PP2** Recommends to the Sixty-ninth World Health Assembly the adoption of the following resolution;

**PP3** Recalling the World Health Assembly resolutions WHA67.22 on access to essential medicines, WHA60.20 on better medicines for children, WHA67.20 on Regulatory system strengthening WHA67.21 access to biotherapeutic products, including similar biotherapeutic products, and ensuring their quality, safety and efficacy, WHA61.21 on global strategy and plan of action on public health, innovation and intellectual property, WHA65.19 on substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products, WHA65.17 on vaccines, WHA68.7 and WHA67.25 on antimicrobial resistance as well as resolutions WHA64.9 sustainable health financing structures and universal coverage, and also, recalling the Resolution A/HRC/RES/12/24 from the Human Rights Council on access to medicines;

**PP4** Noting with particular concern that for millions of people, the right to the enjoyment of the highest attainable standard of physical and mental health, including access to medicines, remains a distant goal, that especially for children and those living in poverty, the likelihood of achieving this goal is becoming increasingly remote [reference (A67/81)];

**PP5** Recognizing that the continuous supply of quality, safe, effective medicines is one of the building blocks of every well-functioning health system, which requires a reliable supply chain: and noting reports of global medicines shortages and stockouts that also infringe on patients' right to health; undermine public health prevention and treatment goals; and threaten governments' ability to scale up services towards achieving universal health coverage;

**PP6** Recalling the Agenda 2030 for Sustainable Development, which includes, inter alia, the commitment to achieve universal health coverage, financial risk protection, access to primary health-care services and access to safe, effective, quality and affordable medicines and vaccines for all by 2030;

**PP7** Acknowledging that Agenda 2030, supports 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, (A/RES/70/1 target 3.b);

**PP8** Noting that the challenges related to medicine shortages and stockouts are widespread, affecting medicine manufacturers, procurement agencies and countries at every economic level, and they appear to be escalating in severity, and the factors that affect the non-availability of medicines can be categorized into three areas: problems with the manufacture of the medicine, challenges with the procurement of medicines and problems with the supply chain which result in medicines being unavailable when patients access care; therefore interventions to address weaknesses in all three areas are critical to ensure that medicines are available at the point of care;

**PP9** Aware that the shortage of medicines is a global problem, 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;

**PP10** Noting also that the implications of these shortages in the case of infectious diseases goes beyond the individual patient and impacts public health as a shortage/stockout of antibiotics, antituberculosis drugs, antiretrovirals or vaccines may result in the spread of infection beyond the individual patient;

**PP11** Considering that there is a need for improved international collaboration on the management of shortages of medicines given that medicines shortages may increase risks of SSFFC medical products entering the supply chain;

**PP12** Concerned about the challenges that shortages of medicines pose to Member States, in relation to ensuring universal access to healthcare, research and development, rational use of medicines, and that the financial sustainability of health systems can be affected by technological pressure caused by high-cost medicines; and aware that urgent patient-centred action is needed by the international community, Member States and relevant actors in health systems,

1. URGES Member States:<sup>1</sup>

**(OP1)** to develop strategies that may be used to forecast, avert or reduce shortages, adapted to national priorities and contexts, including:

- (a) to implement effective notification systems that allow remedial intervention to circumvent medicine shortages;
- (b) to ensure that best practices for medicines procurement, distribution and contract management processes are in place to mitigate the risk of shortages;
- (c) to develop systems that are capable of monitoring medicine supply, demand, availability and alerting procurement departments to possible medicine availability problems;

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<sup>1</sup> And, regional economic integration organizations, as appropriate.

(d) to strengthen institutional capacity to ensure sound financial management of procurement systems, to prevent funding shortfalls for medicines;

(e) to promote, review and strengthen programmes, public policies, regulatory frameworks, systems and authorities that promote access to medicines and align policy frameworks to be responsive to medicines that are at risk of being unavailable at the point of care, through the appropriate regulatory strategies;

(f) to urge Member States to focus on health rights of everyone especially vulnerable groups and to ensure these groups have timely access to medicines in shortage;

(g) to seek to make medicines more affordable through the implementation of various strategies to manage prices such as price negotiations/regulation, voluntary/compulsory licences in order to decrease prices of medicines in shortage;

**(OP2)** calls upon manufacturers (active pharmaceutical ingredient and formulation), wholesalers, global, and regional procurement agencies and other relevant stakeholders to contribute to global efforts to address the challenges of medicines shortages, including through participation in notification systems;

**(OP3)** to advance gradually regional and international integration of national notification systems including but not limited to sharing of best practices, training for human capacity building where necessary with a view of establishing an international notification system for essential medicine shortages and stockouts;

2. REQUESTS the Director-General:

(1) to support Member States in addressing the global challenges of medicines shortages by developing a global medicine shortage notification system; which may include information to better detect and understand the causes of medicines shortages;

(2) to propose global best practices for the notification and management of shortages, including data standards, database management and regulatory/legislative strategies including the full use of TRIPS to minimize the impact of shortages;

(3) to develop an assessment of the magnitude and nature of the problem of shortages of medicines, including factors such as: market supply system failures and pressures, manufacturing and distribution challenges, and recommended solutions, to address the most important factors identified;

(4) to identify medicines that are at particular risk of being in short supply and develop strategies to ensure their availability at an affordable price in collaboration with global partners;

(5) to prioritize, the development of new or updated procurement and supply chain guidelines, to support the effective functioning of health systems and minimize the risk of shortages;

(6) to work with global partners to strengthen systems for supply chain management;

- (7) to support Member States in the implementation of surveillance systems that will monitor and report supply and demand of medicines, using standardized formats throughout the supply chain, to predict needs and shortages, and that also reduce the risk of SSFFC entering the supply chain;
- (8) to continue to support the Member State mechanism on SSFFC medical products;
- (9) to report on progress and outcome of the implementation of this resolution to the Seventy-first World Health Assembly.

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