

**DRAFT RESOLUTION**

**WHA65.XX Substandard/Spurious/Falsely-Labelled/Falsified/Counterfeit Medical Products**

The Executive Board,

RECOMMENDS to the Sixty-fifth World Health Assembly the adoption of the following resolution:

The Sixty-fifth World Health Assembly,

PP1 Having considered the report of the Working Group of Member States on Substandard/Spurious/Falsely-Labelled/Falsified/Counterfeit Medical Products and its recommendations;

PP2 Welcoming the outcome of the Working Group of Member States on Substandard/Spurious/Falsely-Labelled/Falsified/Counterfeit Medical Products;

PP3 Reaffirming the fundamental role of WHO in ensuring the availability of safe, quality and efficacious medical products;

PP4 Recognizing that many people in the world lack access to safe efficacious, quality and affordable medicines and that such access is an important part of a health system;

PP5 Recognizing the importance of ensuring that combating SSFFC medical products does not result in hindering the availability of legitimate generic medicines;

PP4 Recognizing the need to promote access to affordable, safe, efficacious and quality medicines, including through the full implementation of the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property<sup>1</sup>;

PP5 Acknowledging the need for improving access to affordable, quality, safe and efficacious medicines as an important element in the effort to prevent and control medicines with compromised quality, safety and efficacy and in the decrease of SSFFC medical products;

PP6 Taking note of resolution 20/6 of the United Nations Commission on Crime Prevention and Criminal Justice entitled "Countering fraudulent medicines, in particular their trafficking";

---

<sup>1</sup>See paragraph 11(xii) of the Rio Political Declaration on the Social Determinants of Health

PP7 Expressing concern regarding the lack of sufficient financing of WHO's work in the area of quality, safety and efficacy of medicines;

PP8 Recognizing the need to enhance support to national and regional regulatory authorities to promote the availability of quality, safe and efficacious medical products.

OP1 REAFFIRMS the fundamental role of WHO in ensuring the safety, quality and efficacy of medical products, in promoting access to affordable, quality, safe and efficacious medicines, and in supporting national drug regulatory authorities in this area, in particular in developing countries and least developed countries.

OP2. REITERATES that WHO should continue to focus on and intensify its measures to make medical products more affordable, strengthening national regulatory authorities and health systems which includes national medicine policies, health risk management systems, sustainable financing, human resource development and reliable procurement and supply systems; and to enhance and support work on prequalification and promotion of generics, and efforts in rational selection and use of medical products. In each of these areas, WHO's function should be: information sharing and awareness creation; norms and standards and technical assistance to countries on country situation assessment; national policy development; and capacity building, supporting product development and domestic production;

OP3. FURTHER REITERATES that WHO should increase its efforts to support Member States in strengthening national and regional regulatory infrastructure and capacity;

OP4. DECIDES to establish a new Member State<sup>2</sup> mechanism for international collaboration among Member States, from a public health perspective, excluding trade and intellectual property considerations, regarding "SSFFC medical products" in accordance with the goals, objectives and terms of reference annexed to the present Resolution;

OP5. Further decides to review the Member State mechanism after three years of operation;

OP6. URGES Member States<sup>2</sup> to:

- (1) participate and collaborate with the Member State mechanism referred to in OP4;
- (2) provide sufficient financial resources to strengthen the work of WHO in this area;

OP7. REQUESTS the Director-General:

- (1) to support the Member State mechanism referred to operative paragraph 4.
- (2) to assist Member States in building capacity to prevent and control "SSFFC medical products".

= = =

---

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