World Health Organization

SIXTY-THIRD WORLD HEALTH ASSEMBLY
Agenda item 11.3

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# Measures to ensure access to safe, efficacious, quality and affordable medical products

## Draft resolution proposed by the delegations of India and Thailand

The Sixty-third World Health Assembly,

PP1 Recalling the Constitution of WHO, which states that "the objective of WHO shall be the attainment by all peoples of the highest possible level of health";

PP2 Recalling the principles of the Global strategy and plan of action on public health, innovation and intellectual property as adopted by the World Health Assembly in resolution WHA61.21;

PP3 Emphasizing the importance of ensuring access to affordable medicines, technologies and other health products among people in need while ensuring the quality, safety and efficacy of medical products[1] and promoting the rational use of medicines;

PP4 Concerned about reports of medical products with compromised quality, safety and efficacy, and stressing the need to ensure the availability of safe, efficacious, quality and affordable medical products;

PP5 Recognizing that falsely labelled or substandard medical products can have serious consequences for the health of the population;

PP6 Noting that the term and definition of "counterfeit" relates to infringement of intellectual property rights and should not be equated with medical products with compromised quality, safety and efficacy;

PP7 Noting that the definition in the Agreement on Trade-related Aspects of Intellectual Property Rights definition that "counterfeit trademark goods" shall mean any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such

[1] The term "medical products" hereafter should be understood to include vaccines, diagnostics and medicines in accordance with resolution WHA59.24.

a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation;[1]

PP8 Recognizing that issues of protection and enforcement of intellectual property rights are distinct from issues of quality, safety and efficacy of medical products;

PP9 Seriously concerned about numerous incidences of intellectual property enforcement measures that have resulted in unwarranted seizures of generic medicines, affecting timely access to efficacious affordable medical products for people in developing countries, including least-developed countries;

PP10 Recognizing that infringement of intellectual property rights is being confused with the issues of quality, safety and efficacy;

PP11 Recognizing that high prices of medical products result in inequitable access and facilitate proliferation of medical products with compromised quality, safety and efficacy;

PP12 Resolving to take immediate steps to promote the availability of affordable, quality, safe, and efficacious medical products;

PP13 Recognizing the need to promote measures to address quality, safety and efficacy of medical products that do not themselves become barriers to timely availability of affordable medical products and production of generic medical products;

PP14 Recognizing that the International Medical Products Anti-Counterfeiting Taskforce, or its Terms of Reference, has not been approved by any governing body of WHO and that there are conflicts of interest in its composition,

1. URGES Member States:

(1) to take measures to strengthen national drug regulatory authorities by enhancing their capacity to ensure for all, and particularly to vulnerable groups, access to safe, efficacious, quality and affordable medical products;

(2) to address the basic causes of the circulation of medicines with compromised safety, efficacy and quality such as weak regulatory capacity, unethical promotion of medicines, and high prices of medical products;

(3) to take measures to remove barriers to access to quality, safe, efficacious and affordable medical products;

(4) to ensure incorporation of public health safeguards, including as reaffirmed by the Doha Declaration on the TRIPS Agreement and Public Health, in their domestic intellectual property legislation;

[1] Agreement on Trade-related Aspects of Intellectual Property Rights Article 51, footnote 14(a).

(5) to implement trade, intellectual property and other policies without constraining policy space for health, including access to quality, safe, efficacious and affordable medical products and production of generic medical products;

(6) to refrain from applying measures to enforce intellectual property rights, such as the seizure of medical products in transit, that result in creating barriers to legitimate trade of generic medicines and impeding access to medical products, particularly in developing countries;

(7) to promote close collaboration among the national drug regulatory authorities to share information inspection techniques and testing methods;

2. REQUESTS the Director-General:

(1) to provide support to Member States, upon request, in strengthening their national drug regulatory authorities with a focus on enhancing their capacity, technical knowledge, infrastructure, facilities, and promoting robust systems to ensure that medical products available in their jurisdiction are of quality, safe and efficacious;

(2) to provide support for the development of new techniques and test methods for the use of national drug regulatory authorities to ensure the quality, safety and efficacy of medical products;

(3) to replace WHO's involvement in the International Medical Products Anti-Counterfeiting Taskforce with an effective programme to address the issues of quality, safety and efficacy as detailed in this resolution and ensure that the new programme avoids conflicts of interests, is evidence-based, transparent and Member-driven;

(4) to advocate that WHO does not get involved with infringement of intellectual property rights and other measures that could potentially undermine availability of quality, safe, efficacious and affordable medical products and production of generic medical products;

(5) to create measures to ensure that intellectual property enforcement does not inhibit access to affordable medical products;

(6) to report on implementation of this resolution to the Sixty-fourth World Health Assembly and subsequently biennially, through the Executive Board.

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