SEA/RC62/R6	MEASURES TO ENSURE ACCESS TO SAFE, EFFICACIOUS, QUALITY AND AFFORDABLE MEDICAL PRODUCTS

The Regional Committee,

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

Recalling the principles of the Global Strategy and Plan of Action on public health, innovation and intellectual property as adopted by World Health Assembly resolution WHA61.21,

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

Concerned about reports of compromised safety, efficacy and quality, and stressing the need to effectively address the availability of safe, efficacious, quality and affordable medical products,

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

Recalling resolutions WHA41.16 (Rational use of drugs), WHA47.13 (Implementation of WHO’s revised drug strategy: Rational use of drugs; and WHO’s Action Programme on Essential Drugs), WHA52.19 (Revised drug strategy), and WHA57.14 (Scaling up treatment and care within a coordinated and comprehensive response to HIV/AIDS),

Stressing the urgent need to proactively take measures for the detection and prevention of illicit trade in falsely labelled and substandard medical products, which become a threat to public health,

Recognizing that national regulatory authorities in developing countries often lack capacity to detect and prevent distribution of falsely labelled and substandard medical products,

Noting that the term and definition of “counterfeit” relates to infringement of intellectual property rights and should not be equated with substandard medical products,

Recognizing the need to separate the issues of protection and enforcement of intellectual property rights from the availability, safety, efficacy and quality of medical products,
Seriously concerned about numerous incidences of intellectual property enforcement measures that have resulted in unwarranted seizures of medicines, affecting timely access to affordable medical products and generic production in developing countries,

Recalling the Doha Declaration on the TRIPS Agreement and Public Health, that “the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health” and that “the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all”.

Noting the TRIPS Agreement’s 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 a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation,

Agreeing to take immediate steps to ensure the availability of safe, efficacious and affordable quality medical products,

1. URGES Member States:
   (a) To take measures to strengthen the national regulatory authorities by enhancing their capacity to ensure for all, and particularly to vulnerable groups, access to safe, efficacious, quality and affordable medical products;
   (b) to ensure incorporation of public health safeguards, including as mandated by the Doha Declaration on the TRIPS Agreement and Public Health, in their domestic intellectual property legislation;
   (c) to implement trade and intellectual property policies without constraining policy space on health, including access to safe, efficacious, quality and affordable medical products;
   (d) to take measures to address barriers related to access to safe, efficacious, quality and affordable medical products;
   (e) 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 and obstructing access to medical products, particularly in developing countries;
   (f) to promote close collaboration among the national drug regulatory authorities to share information, intelligence, inspection techniques and testing methods;
   (g) to raise awareness of the public and regulatory agencies of the emerging problems of falsely labelled and substandard medical products entering the legitimate supply chains; and

2. REQUESTS the Regional Director:
   (a) to support Member States in strengthening the national regulatory authorities with a focus on enhancing their capacity, technical knowledge, infrastructure, facilities, and robust systems to ensure that medical products available in their jurisdiction are safe, efficacious and of quality;

2 WHA60.30, WHA59.24 and Declaration on TRIPS Agreement and Public Health (Para 4)
3 TRIPS Agreement Art 51, Footnote 14(a)
(b) to advocate that WHO does not support intellectual property policies that could potentially undermine availability of safe, efficacious, quality and affordable medical products; and

(c) to collaborate with other related intergovernmental organizations and streamline resources and information on illicit trade in medical products; and

(d) to support the development of new techniques and test methods for the use of national drug regulatory authorities to ensure the quality of medical products.