

DECISIONS

WHA63(1) Composition of the Committee on Credentials

The Sixty-third World Health Assembly appointed a Committee on Credentials consisting of delegates of the following Member States: Angola, Austria, Bangladesh, Eritrea, Israel, Nauru, Nicaragua, Oman, Singapore, The former Yugoslav Republic of Macedonia, Trinidad and Tobago, Zambia.

(First plenary meeting, 17 May 2010)

WHA63(2) Election of officers of the Sixty-third World Health Assembly

The Sixty-third World Health Assembly elected the following officers:

President:	Mr M. Zenaidi (Tunisia)
Vice-Presidents:	Dra. M.I. Rodríguez (El Salvador) Dr R. Sezibera (Rwanda) Professor R. Akdağ (Turkey) Mrs G.A.A. Gidlow (Samoa) Professor Mya Oo (Myanmar)

(First plenary meeting, 17 May 2010)

WHA63(3) Election of officers of the main committees

The Sixty-third World Health Assembly elected the following officers of the main committees:

Committee A:	Chairman	Dr M. Mugitani (Japan)
Committee B:	Chairman	Dr W. Jayantha (Sri Lanka)

(First plenary meeting, 17 May 2010)

The main committees subsequently elected the following officers:

Committee A:	Vice-Chairmen	Mr U. Scholten (Germany) Dr D. Chiriboga (Ecuador)
	Rapporteur	Dr P. Mishra (Nepal)
Committee B:	Vice-Chairmen	Dr G.J. Komba-Kono (Sierra Leone) Dr N. El Sayed (Egypt)
	Rapporteur	Dr A.-P. Sanne (Norway)

(First meetings of Committees A and B, 17 and 19 May 2010, respectively)

WHA63(4) Establishment of the General Committee

The Sixty-third World Health Assembly elected the delegates of the following 17 countries as members of the General Committee: Burkina Faso, Cape Verde, Chad, Chile, China, Cuba, Democratic Republic of the Congo, Estonia, France, Jamaica, Jordan, Libyan Arab Jamahiriya, Russian Federation, Spain, United Kingdom of Great Britain and Northern Ireland, United Republic of Tanzania, United States of America.

(First plenary meeting, 17 May 2010)

WHA63(5) Adoption of the agenda

The Sixty-third World Health Assembly adopted the provisional agenda prepared by the Executive Board at its 126th session, with the deletion of four items and the transfer of one item from Committee B to Committee A.

(Second plenary meeting, 17 May 2010)

WHA63(6) Verification of credentials

The Sixty-third World Health Assembly recognized the validity of the credentials of the following delegations: Afghanistan, Albania, Algeria, Andorra, Angola, Antigua and Barbuda, Argentina, Armenia, Australia, Austria, Azerbaijan, Bahamas, Bahrain, Bangladesh, Barbados, Belarus, Belgium, Benin, Bhutan, Bolivia (Plurinational State of), Bosnia and Herzegovina, Botswana, Brazil, Brunei Darussalam, Bulgaria, Burkina Faso, Burundi, Cambodia, Cameroon, Canada, Cape Verde, Central African Republic, Chad, Chile, China, Colombia, Comoros, Congo, Cook Islands, Costa Rica, Côte d'Ivoire, Croatia, Cuba, Cyprus, Czech Republic, Democratic People's Republic of Korea, Democratic Republic of the Congo, Denmark, Djibouti, Dominican Republic, Ecuador, Egypt, El Salvador, Equatorial Guinea, Eritrea, Estonia, Ethiopia, Fiji, Finland, France, Gabon, Gambia, Georgia, Germany, Ghana, Greece, Guatemala, Guinea, Guinea-Bissau, Guyana, Haiti, Honduras, Hungary, Iceland, India, Indonesia, Iran (Islamic Republic of), Iraq, Ireland, Israel, Italy, Jamaica, Japan, Jordan, Kazakhstan, Kenya, Kiribati, Kuwait, Kyrgyzstan, Lao People's Democratic Republic, Latvia, Lebanon, Lesotho, Liberia, Libyan Arab Jamahiriya, Lithuania, Luxembourg, Madagascar, Malawi, Malaysia, Maldives, Mali, Malta, Marshall Islands, Mauritania, Mauritius, Mexico, Micronesia (Federated States of), Monaco, Mongolia, Montenegro, Morocco, Mozambique, Myanmar, Namibia, Nepal, Netherlands, New Zealand, Nicaragua, Niger, Nigeria, Norway, Oman, Pakistan, Palau, Panama, Papua New Guinea, Paraguay, Peru, Philippines, Poland, Portugal, Qatar, Republic of Korea, Republic of Moldova, Romania, Russian Federation, Rwanda, Saint Lucia, Samoa, San Marino, Sao Tome and Principe, Saudi Arabia, Senegal, Serbia, Seychelles, Sierra Leone, Singapore, Slovakia, Slovenia, Solomon Islands, Somalia, South Africa, Spain, Sri Lanka, Sudan, Suriname, Swaziland, Sweden, Switzerland, Syrian Arab Republic, Tajikistan, Thailand, The former Yugoslav Republic of Macedonia, Timor-Leste, Togo, Tonga, Trinidad and Tobago, Tunisia, Turkey, Turkmenistan, Tuvalu, Uganda, Ukraine, United Arab Emirates, United Kingdom of Great Britain and Northern Ireland, United Republic of Tanzania, United States of America, Uruguay, Uzbekistan, Vanuatu, Venezuela (Bolivarian Republic of), Viet Nam, Yemen, Zambia, Zimbabwe.

(Sixth plenary meeting, 19 May 2010)

WHA63(7) Election of Members entitled to designate a person to serve on the Executive Board

The Sixty-third World Health Assembly, after considering the recommendations of the General Committee, elected the following as Members entitled to designate a person to serve on the Executive Board: Armenia, Barbados, China, Ecuador, Mongolia, Morocco, Mozambique, Norway, Seychelles, Timor-Leste, United States of America, Yemen.

(Seventh plenary meeting, 20 May 2010)

WHA63(8) United Nations Joint Staff Pension Fund: appointment of representatives to the WHO Staff Pension Committee

The Sixty-third World Health Assembly nominated Dr A.A. Yoosuf (Maldives) as a member and Mr R. Chacon (Guatemala) as an alternate member of the WHO Staff Pension Committee for a three-year term until May 2013.

(Seventh plenary meeting, 20 May 2010)

WHA63(9) Selection of the country in which the Sixty-fourth World Health Assembly would be held

The Sixty-third World Health Assembly, in accordance with Article 14 of the Constitution, decided that the Sixty-fourth World Health Assembly would be held in Switzerland.

(Eighth plenary meeting, 21 May 2010)

WHA63(10) Substandard/spurious/falsely-labelled/falsified/counterfeit medical products

The Sixty-third World Health Assembly,

Reaffirming the fundamental role of WHO in ensuring the safety, quality and efficacy of medical products;

Noting the work of WHO in ensuring safety, quality and efficacy of medical products,

1. DECIDED to establish a time-limited and results-oriented working group on substandard/spurious/falsely-labelled/falsified/counterfeit medical products comprised of and open to all Member States;¹
2. REQUESTED the Director-General to convene and facilitate the work of the working group;
3. DECIDED that the working group will examine the following matters from a public health perspective, excluding trade and intellectual property considerations:

¹ And, where applicable, regional economic integration organizations.

- (a) WHO's role in measures to ensure the availability of quality, safe, efficacious and affordable medical products;
- (b) WHO's relationship with the International Medical Products Anti-Counterfeiting Taskforce;
- (c) WHO's role in the prevention and control of medical products of compromised quality, safety and efficacy such as substandard/spurious/false-labelled/falsified/counterfeit medical products from a public health perspective, excluding trade and intellectual property considerations;
- (d) any issue or issues raised in the proposals contained in documents, A63/A/Conf.Paper No.4 Rev.1, A63/A/Conf.Paper No.5 and A63/A/Conf.Paper No.7,¹ starting with those issues referred to in subparagraphs (a)–(c) above;

4. DECIDED that the working group shall make specific recommendations in relation to the issues set out in paragraph 3 above and report to the Sixty-fourth World Health Assembly, and shall report on progress in implementing this decision to the Executive Board, at its 128th session.

(Eighth plenary meeting, 21 May 2010)

Agenda item 11.20

**A63/A/Conf.Paper No.4 Rev.1
18 May 2010**

**Plan of work to support the prevention and control
of falsified medical products**

**Draft resolution proposed by the delegation of Ecuador on
behalf of the Union of South American Nations (UNASUR)²**

The Sixty-third World Health Assembly,

PP1 Considering resolutions WHA41.16 and WHA47.13 on the need to provide guidelines to Member States on the development of their own structures and the adoption of national measures to prevent and control falsified medical products;

PP2 Bearing in mind the Conference of Experts on the Rational Use of Drugs (Nairobi, 25–29 November 1985) which first addressed this issue at the international level;

PP3 Aware of the risks that falsified medical products entail for the population;

¹ Included below.

² Argentina, Bolivia (Plurinational State of), Brazil, Chile, Colombia, Ecuador, Guyana, Paraguay, Peru, Suriname, Uruguay and Venezuela (Bolivarian Republic of).

PP4 Observing that the falsification of medical products has an international dimension and that the prevention and control of this problem necessitates cooperation at the regional and subregional levels and between countries;

PP5 Reaffirming that health authorities must perform an important function in applying health regulations that strengthen a chain of safe, high-quality and efficacious medical products,

DECIDES:

- (1) to establish an intergovernmental working group comprising delegates of Member States and the Secretariat to consider and implement cooperation at the regional and subregional levels and between countries, with a view to preventing and controlling falsified medical products from a public-health perspective, excluding commercial and intellectual property considerations;
- (2) that the working group should examine the following topics:
 - (a) education measures such as training of consumers and public-health sector stakeholders;
 - (b) measures to strengthen the chain of production and distribution of medical products, specifically in relation to regulation and inspection;
 - (c) action strategies at the national, subregional and regional levels providing for mechanisms to improve sharing of information and experiences between countries;
 - (d) strategies to improve the capacity of the health sector to apply health regulation measures;
- (3) that, with the approval of Member States, the working group should be authorized to form technical subgroups of an ad hoc and provisional nature, and to invite experts to examine specific issues.

Agenda item 11.20

**A63/A/Conf.Paper No.5
19 May 2010**

Counterfeit medical products

Draft resolution proposed by the delegations of Algeria, Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Cape Verde, Central African Republic, Chad, Comoros, Congo, Côte d'Ivoire, Equatorial Guinea, Ethiopia, Gabon, Gambia, Ghana, Guinea, Guinea-Bissau, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritius, Namibia, Niger, Nigeria, Rwanda, Senegal, Sierra Leone, South Africa, Swaziland, Togo, Uganda, United Republic of Tanzania, Zambia and Zimbabwe

The Sixty-third World Health Assembly,

PP1 Having considered the report on counterfeit medical products;¹

PP2 Recalling resolution WHA41.16 on the rational use of drugs requesting the Director-General to initiate programmes for the prevention and detection of export, import and smuggling of falsely labelled, spurious, counterfeited or substandard pharmaceutical preparations;

PP3 Recalling resolution WHA47.13 on the rational use of drugs requesting the Director-General to support Member States in their efforts in combating the use of counterfeit drugs;

PP4 Recalling resolution WHA52.19 on the revised drug strategy and in particular the request to the Director-General to develop and disseminate uniform guidelines on the regulatory control, export, import and transit conditions of pharmaceutical products; and to develop standards of practice for entities involved in international trade in pharmaceuticals and pharmaceutical starting materials;

PP5 Recalling the continuous and repeated request from drug regulatory authorities of Member States that met in the framework of the International Conferences of Drug Regulatory Authorities to WHO to assist Member States to adopt measures to combat counterfeit medicines;

PP6 Concerned about the situation in which counterfeit medical products continue to move in international commerce, representing a major threat to public health, especially in the poorer areas of developing countries where regulatory capacities and law enforcement authorities are weak, and in which counterfeit medical products pose a challenge to the credibility and effectiveness of health systems;

PP7 Recognizing that the primary focus of combating the manufacture, distribution and use of counterfeit medical products is the protection of public health and that the main victims of counterfeiters are patients and the general public;

PP8 Recognizing that combating counterfeit medical products is one specific aspect of assuring quality, safety and efficacy of medical products;

PP9 Recognizing the importance of ensuring that combating counterfeit medical products does not result in hindering the availability of legitimate generic medicines;

PP10 Recognizing the various initiatives and progress achieved since 1988 by specific WHO guidelines for combating counterfeit medical products, and improvement of guidelines on import procedures for pharmaceutical products, inspection of drug distribution channels and good distribution practices for pharmaceutical products;

PP11 Aware of the importance of ensuring effective collaboration among patients, health professionals, the private sector and government institutions to combat counterfeit medical products effectively;

PP12 Cognizant of the importance of ensuring international collaboration and exchange of information in order to combat counterfeit medical products effectively;

¹ Document A63/23.

PP13 Noting with satisfaction that the Director-General has intensified activities aimed at strengthening international collaboration to combat counterfeit medical products and that WHO has a leading role in these activities;

PP14 Recognizing the contribution of all parties concerned to the fulfilment of their responsibilities in compliance with the components of resolutions WHA41.16, WHA47.13 and WHA52.19 that specifically focus on combating counterfeit medical products, and encouraging all parties to continue that action;

PP15 Inviting bilateral agencies, multilateral bodies inside and outside the United Nations system, and voluntary organizations to collaborate and to provide support to developing countries in setting up and carrying out programmes aimed at combating counterfeit medical products, and acknowledging the work of those countries that are already doing so;

PP16 Requesting governments, pharmaceutical manufacturers and other concerned parties to cooperate in the detection, investigation and prevention of the increasing incidence of counterfeited or other substandard medical products moving in international commerce;

PP17 Aware of the public health impact of counterfeit medicines in achieving Millennium Development Goal 8 as it relates to international collaboration, in particular Target 8.E on the availability and access to quality medicines,

1. URGES Member States:

- (1) to reaffirm their commitment to develop, implement and monitor national policies and to take all necessary measures in order to ensure access to medical products that meet regulatory standards;
- (2) to establish and enforce legislation and regulations that prevent counterfeit medical products from being manufactured, exported, imported or traded in international transactions as well as to regulate and monitor the supply and distribution systems;
- (3) to establish effective mechanisms of coordination and collaboration, including exchange of information among health, law enforcement and other relevant authorities in order to improve prevention, detection, investigation and prosecution of cases of counterfeit medical products;
- (4) to promote awareness among health professionals and consumers of the risks posed by the use of counterfeit medical products including those acquired through unauthorized outlets including Internet sites;

2. REQUESTS the Director-General:

- (1) to continue to address counterfeit medical products as an integral part, within the existing framework, of standard setting for quality, safety and efficacy;
- (2) to provide support to Member States in developing and implementing policies and programmes aimed at combating counterfeit medical products, including facilitating the exchange of information at the international level and the development of tools, guidelines, training and awareness initiatives, and methodology for evaluation and monitoring;
- (3) to continue the development and dissemination of independent and timely information on instances of counterfeit medical products;

- (4) to cooperate with Member States, at their request, and with international organizations and other relevant parties in detecting, monitoring and analysing cases of counterfeit medical products and their impact on public health;
- (5) to report to the Sixty-fifth World Health Assembly, through the Executive Board, both on progress achieved and problems encountered in the implementation of this resolution.

Agenda item 11.3**A63/A/Conf.Paper No.7
18 May 2010****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 products¹ 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;
- (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;

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

(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.
