

## NINTH MEETING

Friday, 23 January 2009, at 14:05

**Chairman:** Sir Liam DONALDSON  
(United Kingdom of Great Britain and Northern Ireland)

**TECHNICAL AND HEALTH MATTERS:** Item 4 of the Agenda (continued)

**Counterfeit medical products:** Item 4.11 of the Agenda (Documents EB124/14, EB124/14 Add.1 and EB124/14 Corr.1)

Dr GIMÉNEZ CABALLERO (Paraguay), speaking on behalf of the Latin American and Caribbean Group, said that WHO was the forum for discussing means of ensuring the quality, safety and efficacy of medicines and health products, taking into account respect for national legislation and objective information on potential risks and adverse effects on health. WHO should concentrate on the public health aspects of the issue and on ensuring access to high-quality medicines.

Adulteration of medicines, lack of quality testing and noncompliance with good manufacturing practices were issues should be tackled as part of broader efforts to guarantee the quality and safety of medicines and health products. The Board's treatment of the matter must be evidence-based; and actions must be approved and negotiated between Member States and aim to strengthen the capacity of regulatory authorities responsible for medicines at country level.

WHO was not a suitable forum for the discussion of enforcement of intellectual property rights. WHO should confine its work on the quality of medicines to the health aspects and should not deal with issues that fell within the mandate of other multilateral forums.

Ms FARANI AZEVÊDO (alternate to Dr Buss, Brazil) said that her Government's concern about the quality, safety and efficacy of medicines and other medical products was reflected in its health policies. WHO was the proper forum to discuss methodologies to protect public health and promote access to medicines but not to discuss the enforcement of intellectual property rights. The Secretariat should help Member States to strengthen their regulatory capacities in safeguarding health.

Other issues related to intellectual property were, rightly, of interest to WHO and integral to the Global strategy and plan of action on public health, innovation and intellectual property.<sup>1</sup> Any norms or definitions on quality, safety and efficacy of medicines must be inclusive, evidence-based and derived from a process driven by Member States: for that reason, Brazil did not support the draft resolution contained in document EB124/14.

No definition of counterfeiting of medical products should be used to hinder access to legitimate generic medicines, especially in countries, such as her own, where they formed part of public health policies. Defects of quality and noncompliance with good manufacturing practice were detrimental to public health, but they should not be considered counterfeiting.

The previous day, her Government had stated concern at the seizure by the Dutch customs authorities of a shipment of the generic medicine losartan, en route from India to Brazil. Losartan, widely used to treat arterial hypertension in Brazil, was not protected by patents in either country and could be imported into either. The seizure, requested by a company that allegedly owned intellectual

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<sup>1</sup> Resolution WHA61.21.

property rights over the medicine in the Netherlands, had not been authorized by the courts and the shipment had not actually entered Dutch territory. The Dutch authorities had acted according to the “precautionary principle”, which might be applied, for example, to prohibit the importation of foodstuffs because of claims of adverse health effects. The producer would have to disprove those claims, at a cost in both time and money. WTO had deemed the precautionary principle to be a non-tariff barrier to trade.

The Dutch authorities had seized and returned to India exported medicines that conformed to existing international standards. That was a blow to universal access to medicines, a distortion of the international intellectual property system and a setback to the spirit and provisions of the Doha Declaration on the TRIPS Agreement and Public Health. WHO should firmly oppose all such action. In that connection, she noted that the International Medical Products Anti-Counterfeiting Taskforce had sought to amend WHO’s position on generic medicines on the pretext of combating counterfeit medicines, in an attempt to impede legitimate trade in generics.

That action had cast doubt upon the commitment of European countries to the promotion of access to medicines for developing countries. Her Government defended the primacy of health over trade and the right to use the flexibilities of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to ensure universal access to medicines, as reaffirmed in WHO’s Global strategy on public health, innovation and intellectual property.

Dr KÖKÉNY (Hungary), speaking on behalf of the Member States of the European Union, said that counterfeit medical products endangered human health and undermined health-care systems. The European Union appreciated WHO’s success in organizing stakeholders to address the issue. The European Commission had investigated the distribution of pharmaceuticals, including counterfeit medical products. It had drafted legislation that took into account the principles developed by the International Medical Products Anti-Counterfeiting Taskforce and aimed to counter the health threats posed by counterfeit products. The international campaign against counterfeit medicines called for cooperation and clear principles from institutions that included health and customs authorities, the police and financial institutions. WHO had a key role to play in coordinating international anti-counterfeit efforts, and the European Union therefore welcomed its leadership in the Taskforce.

Mr ABDOO (alternate to Dr Wright, United States of America) said that counterfeit medicines put the health of people at risk because those products might contain too much, too little or the wrong active ingredient, or might actually be toxic. A coordinated international approach to address that crime was essential. He acknowledged the expert coordinating work of the International Medical Products Anti-Counterfeiting Taskforce on the public health aspects of counterfeiting. His Government took seriously all reports of suspected counterfeit products, it resourced investigations and follow-up actions, including product recalls, public awareness campaigns and liaison with international regulators and law enforcement agencies. It helped other countries to strengthen quality of manufacture in medicines; to detect counterfeit products and track down those responsible; to deal with the effects of toxic products; and to raise public awareness.

The process of defining the concept “counterfeit medical product” had been lengthy. He was concerned to note that the original version of the draft resolution prepared by the Secretariat had wrongly referred to “intellectual property rights” rather than “patents” in its preamble. That wording had widened the scope of the draft resolution in a way that was unacceptable to his Government. He asked the Secretariat to explain that mistake. He had a number of amendments to propose, and suggested that an informal drafting group might be set up with a view to accommodating diverse perspectives and reaching consensus on a draft resolution. He looked forward to hearing the views of other members.

Dr ADITAMA (alternate to Dr Supari, Indonesia), speaking on behalf of the Member States of the South-East Asia Region, commended WHO’s efforts to tackle the public health risks associated

with substandard, spurious or falsely labelled medicines. The Member States of the Region were committed to preventing the use of such medicines. Those were defined in the various national legislations, and infringement of the relevant standards was a criminal offence. The International Medical Products Anti-Counterfeiting Taskforce had been set up in 2006 pursuant to the Declaration of Rome (18 February 2006) in order to combat counterfeiting and protect public health. However, the Declaration did not appear to have been discussed or endorsed by the Executive Board and Health Assembly as the basis for establishing the terms of reference, function and membership of the Taskforce. In fact, the Taskforce appeared to be composed mainly of representatives of developed countries and the pharmaceutical industry, with inadequate representation of developing countries.

The Member States of the Region did not accept the principles and elements developed by the Taskforce for the drafting of national legislation to combat counterfeit medical products. The process had not been inclusive and, in any case, the drafting of legislation was the prerogative of national governments. WHO should strengthen drug regulatory authorities through an intergovernmental process that stressed the public health risks of substandard, spurious or falsely labelled medical products. The Member States of the Region did not wish to consider the draft resolution.

Dr REN Minghui (China) said that counterfeit medicines posed a serious threat to public health. Since 2001, his Government had enacted legislation and monitoring that covered drug development, manufacturing, distribution and quality assurance. In response to global counterfeiting, it had strengthened the training of inspectors and regulation and control of medicine. The results of quality assurance tests were published regularly, and an electronic network had been established to prevent the circulation of counterfeit medical products. His country welcomed the work of WHO and the International Medical Products Anti-Counterfeiting Taskforce to promote international cooperation and the exchange of information, and would continue to collaborate with other countries in combating counterfeiting.

His Government was not satisfied with the definition contained in paragraph 10 of the report and repeated in the draft resolution, particularly the statement that medical products not authorized in one country but authorized elsewhere were not to be considered counterfeit. In his view, even if a product was licensed in another country, its ingredients, dosage and formula were not necessarily safe or effective for all people in all regions. Under Chinese law, any medicine entering the Chinese market without regulatory authorization was considered counterfeit. He called on the Secretariat to conduct surveys of national legislation and, based on its findings, define more precisely what constituted a counterfeit medical product.

WHO and the Taskforce should pay more attention to the problem of Internet sales of counterfeit medicines, as should the report and the draft resolution. A mechanism should be set up for the exchange of information and cooperation on the issue. All Member States should be fully consulted in the negotiations on the draft resolution.

Professor ALI (alternate to Professor Haque, Bangladesh) endorsed the statements made by the members for Brazil, Indonesia and Paraguay. His Government appreciated the Secretariat's efforts to sensitize Member States to meeting quality and safety standards for medicines but had some concerns regarding the report and the proposed draft resolution. It was concerned by the focus on counterfeit medical products as a public health issue. The term "counterfeit" most often referred to violations of intellectual property; such matters related to trade and should be dealt with elsewhere, not by WHO. A better understanding of the impact of counterfeit medical products on public health was needed. Without independent verified data, it was premature for WHO to address the issue.

National drug regulatory agencies were losing their authority on the issue in favour of law enforcement agencies, which lacked understanding of matters relating to the quality, safety and efficacy of medical products; their decisions could affect the supply of medicines. The Member States should strengthen their role in the activities of the International Medical Products Anti-Counterfeiting Taskforce. The heavy involvement of the private sector could lead to conflicts of interest. It was of

concern that some organizations participating in the Taskforce were also engaged in intellectual property protection and enforcement.

The definition of counterfeit medical products agreed by the Taskforce lacked precision: it might be construed as including legally produced generic products within its scope and could adversely affect access to, and production of, medicines in developing countries. All Member States should participate in formulating definitions destined for national legislation and those should exclude issues of intellectual property infringement.

His Government could not accept the report or support the draft resolution because of the emphasis on combating counterfeit medical products as an end in itself rather than for their impact on public health. It would, however, continue to act on the safety, quality and efficacy of medical products.

Dr DJIBO (Niger), speaking on behalf of the Member States of the African Region, said that a counterfeit medical product was one that had been deliberately mislabelled with the intention to mislead, an area of grave concern for African countries, particularly given their lack of control laboratories. The magnitude of the problem was difficult to estimate; however, a lack of appropriate legislation, the absence or weakness of national pharmaceutical regulatory authorities, and weak enforcement of laws and sanctions all contributed to the existence of counterfeit medical products. An instrument to collect data at national level would be tested in Kenya and Uganda.

He commended the work of the International Medical Products Anti-Counterfeiting Taskforce and noted with satisfaction the revision made to the sixth preambular paragraph of the draft resolution. He asked how long the work of the Taskforce would continue and whether WHO envisaged further institutional measures in order to sustain anti-counterfeiting initiatives. The Secretariat should propose a better definition of counterfeit medical products and should actively facilitate the exchange of information on the issue.

Dr BIN SHAKAR (United Arab Emirates), speaking on behalf of the Member States of the Eastern Mediterranean Region and welcoming the report, noted the increasingly complex threat to public health posed by counterfeit medical products. He welcomed the improved definition of counterfeit medical products, but proposed replacing the first sentence of the new definition with the first sentence of the 1992 working definition; and the remainder of the definition should remain unchanged. The report should focus on the protection of public health. A distinction should be made between counterfeiting and any issue relating to infringement of intellectual property. Generic medicines should not be considered counterfeit, nor should substandard batches of legitimate products. His country was a hub of trade and investment, encountered counterfeiting and played its part in combating the problem. His Government had assessed the magnitude of counterfeiting of medical products and had instituted anti-counterfeiting legislation; modernized the system of import and export for medicines; developed training for technical monitoring; and equipped mobile teams with laboratory and detection tools.

Dr MOHAMED (Oman), noting paragraph 4 in the report and the 10-fold increase in incidents recorded since 2000, suggested that the duration of patent protection, 20 years, might be contributing to the rise in counterfeiting. He asked how the Secretariat would assist Member States in strengthening their legislation and regulatory agencies, in protecting their supplies of vaccines and life-saving medicines and in dealing with incidents of counterfeiting.

Ms MIKHAILOVA (alternate to Dr Starodubov, Russian Federation) welcoming the Secretariat's efforts, said that improved monitoring and control of medical products would require improved legislation, import controls and international cooperation. Her Government was working with the Commonwealth of Independent States in order to prevent the import or export of counterfeit medical products and protect the health and well-being of citizens. Cooperation agreements had been

signed in order to develop scientific and research activity, standards and legislation. The Russian Federation aimed to coordinate that work and establish a network of testing laboratories.

It would be useful to establish a standing structure under the aegis of WHO that would facilitate international surveillance and coordinate exchange of information among regulatory and medical authorities. Effective methods for rapid identification of counterfeit medical products were needed, as were uniform definitions that could be incorporated into national legislation.

Professor HARPER (alternate to Sir Liam Donaldson, United Kingdom of Great Britain and Northern Ireland) said that the International Medical Products Anti-Counterfeit Taskforce had contributed significantly to engaging stakeholders in order to tackle the growing prevalence of counterfeit medicines, including training for police forces, customs authorities and regulatory bodies. WHO had a key role in coordinating the international collaboration required to combat the manufacture and distribution of counterfeit medical products. As countries strengthened controls and legislation, counterfeiting activities would shift to countries where profits remained high but the threat of legal action was low. In those vulnerable countries, the risks to public health would increase.

The proposed draft resolution was an important step forward. The new definition clarified that action against counterfeiting should not be confused with issues of patenting and did not threaten legitimate generic products. The United Kingdom supported the formation of a drafting group to examine issues such as substandard and dangerous medicines, taking account of the views expressed by members.

Dr JAYANTHA (alternate to Mr de Silva, Sri Lanka) endorsed the statement made by the member for Indonesia.

The CHAIRMAN observed that, despite the divergent views expressed, it seemed to be generally agreed that a proper definition of counterfeit medical products was needed, referenced to a proper source; that it was not just a matter of profiteering but of concern for the health and safety of patients; that international bodies could not interfere in the functions of national or regional statutory regulatory authorities; that much work was already being done in Member States to thwart counterfeiting and reduce the risks to patients; and that a suitable role must be defined for WHO. When the need for action was particularly great, the symbolism of WHO's public statements could be more important than their content, as in the case of the draft resolution on the humanitarian situation in the Gaza Strip. A failure by the Board to adopt a resolution on counterfeit medical products would simply reassure the counterfeiters and allow their life-threatening activities to continue unabated. He therefore suggested that a drafting group should be set up to shorten the unusually long text, reduce the time spent debating the wording, and enable the resolution to be adopted. The Health Assembly might add further details. He asked participants who were not members of the Board and wished to take the floor to save their comments for the drafting group.

Ms FARANI AZEVÊDO (alternate to Dr Buss, Brazil) and Professor ALI (alternate to Professor Haque, Bangladesh) wanted to hear what Member States not represented on the Board had to say before deciding on how to proceed.

Dr CHAUHAN (India)<sup>1</sup> said that the incident concerning the seizure of generic medicines described by the member for Brazil had confirmed fears about the use of non-tariff barriers to obstruct access to generic products. His country therefore aligned itself with the statement by the member for Indonesia, and endorsed the views expressed by the members for Bangladesh, Brazil and Paraguay. He

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<sup>1</sup> Participating by virtue of Rule 3 of the Rules of Procedure of the Executive Board.

urged the Secretariat to provide detailed documentation enabling Member States to form a considered opinion on the matter of falsely labelled, spurious and substandard medical products before any drafting group was set up.

Dr SADRIZADEH (Islamic Republic of Iran)<sup>1</sup> expressed his concerns over how the draft resolution on counterfeit medical products and the report proposed to address the matter. If adopted, the draft resolution could serve the protection and enforcement of intellectual property rights through issues of public health. That would endorse the activities of the International Medical Products Anti-Counterfeiting Taskforce. The given definition of counterfeit medical products would prevent developing countries from gaining access to medicines and from gaining self-sufficiency in the manufacturing of pharmaceutical preparations, neither of which was acceptable. “Counterfeit” was a term used in trade agreements, mainly in connection with trademark violations, which was not a matter for WHO but for other specialized agencies operating under other rules and procedures.

The Organization should focus instead on falsely labelled, spurious and substandard medicines. Furthermore, the Taskforce had not been established by Member States or mandated by the Health Assembly to conduct discussions on counterfeit medical products. The Board should proceed with caution and seek comprehensive clarification and consultation, especially with regard to the unbalanced participation of stakeholders, the activities of the Taskforce, and of its views on counterfeit medical products.

Dr LANDOETA (Bolivarian Republic of Venezuela)<sup>1</sup> said that her Government was aware of the risks of counterfeit medical products in the mainstream supply chain, and supported the statements made by the member for Paraguay and the representative of the Islamic Republic of Iran. The word “counterfeit” could be misleading in the context of public health. It was used in the Agreement on Trade-Related Aspects of Intellectual Property Rights, and the definition proposed by the Taskforce could serve as a cover for the protection and enforcement of those rights. That would deprive most developing countries of access to medical products and prevent those countries from becoming self-sufficient manufacturers and suppliers of pharmaceuticals. Although that was not the aim of the Taskforce, it had lost its focus. The direct financing of its activities by special interests, together with the involvement of international law-enforcement agencies capable of interfering in a country’s sovereign affairs, cast doubt on its place within WHO. The right to health took precedence over business interests, and her country dissociated itself from the Taskforce and any other such initiative.

Mr SILBERSCHMIDT (Switzerland)<sup>1</sup> agreed with previous speakers that the main reason to combat counterfeit medical products was to protect public health; that to forego a resolution would allow those responsible to continue producing and distributing those harmful products; that discussions and negotiations on the matter should take place in intergovernmental forums such as the Executive Board and the Health Assembly; that the definition of counterfeit medical products needed refining; and that action must be coordinated with WHO’s work on quality, standards and safety. Much had been said about the mandate, inclusiveness, financing and other aspects of the Taskforce, but he had heard nothing about the technical quality of its work. He supported the proposal by the Chairman for a drafting group in order to produce a more generally acceptable version of the draft resolution for submission to the Health Assembly.

Dr TIPICHA POSAYANONDA (Thailand)<sup>1</sup> aligned herself with the statements made by the members for Brazil, Indonesia and Paraguay, and the representatives of the Islamic Republic of Iran and the Bolivarian Republic of Venezuela. She commended the report by the Secretariat but was

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unable to support the draft resolution as the elements developed by the Taskforce were unacceptable. As substandard, spurious and falsely labelled medical products seriously undermined public health, she expressed support for strengthening of the regulatory environment and holding discussions at the intergovernmental level.

Ms FASTAME (Argentina)<sup>1</sup> aligned herself with the statement made by the member for Paraguay, and condemned the illegal counterfeiting of medical products. WHO, however, was not the right forum for dealing with the enforcement of intellectual property rights. Regarding regulatory mechanisms, Article 1.1 of the Agreement on Trade-Related Aspects of Intellectual Property Rights stated: “Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice”. As such, her Government was opposed to guidelines and standards being developed to harmonize such mechanisms at a global level, and would not support the draft resolution in document EB124/14. The Agreement already contained a definition of trademark counterfeiting and there was no need to create a new one.

Mr VAYAS (Ecuador),<sup>1</sup> expressing support for the statement made by the member for Paraguay, also agreed that WHO was not the forum for discussing intellectual property rights. Such matters were dealt with by the relevant international organizations, for example under regulations established by the Agreement on Trade-Related Aspects of Intellectual Property Rights and WIPO’s Development Agenda. WHO should concentrate on its core mandate of ensuring the quality, safety and efficacy of medicines. It should take into account the high cost of medicines on local populations, and respect national legislation.

Dr GAD (Egypt)<sup>1</sup> expressed concern that the report in document EB124/14 failed to define clearly the issues regarding the role of WHO and the activities of the International Medical Products Anti-Counterfeiting Taskforce. WHO had a mandate to protect public health by supporting national regulatory authorities in order to ensure the safety and efficacy of medicines. In contrast, counterfeit medical products were a matter of trademark violation, dealt with under national legislation and by procedures governing the protection and enforcement of intellectual property rights or, at the international level, by the relevant organizations such as WTO and WIPO.

Substandard medicines were a far greater threat to public health than counterfeit medical products, and the two subjects must not be confused, above all at WHO. With regard to the Taskforce, he expressed concern about representation; conflicts of interest; objectivity of data; and that it had no mandate from WHO’s governing bodies to pronounce on issues that were the preserve of Member States. Hence, neither the draft resolution nor the report was a positive way forward.

Regarding the resolution on the situation in the Gaza Strip, it was a valuable contribution and contained language that his country expected WHO to act upon.

The CHAIRMAN expressed full agreement with the previous speaker’s closing remark and clarified his own earlier comment, saying that the reality was as important as the symbolism.

Mr SANTA CRUZ (Chile),<sup>1</sup> endorsing the statement made by the member for Paraguay, said that the draft resolution on counterfeit medical products was not ready for adoption. Its focus should be on products failing to meet the standards of quality, safety and efficacy rather than on intellectual property rights. Furthermore, there was too little transparency regarding the background, functioning, financing and composition of the Taskforce and the subject of its meetings. The matter should be addressed within WHO or by a working group formed by the Executive Board or the Health

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<sup>1</sup> Participating by virtue of Rule 3 of the Rules of Procedure of the Executive Board.

Assembly. Chile was ready to set up a group that would examine the subject, specify which situations needed addressing and even change the definition of counterfeit medical products which had underpinned relevant work since 1992. He acknowledged the existence of a problem; however, a drafting group formed hastily to resolve the matter at the present session of the Executive Board could only produce unsatisfactory results.

Dr KAMOTO (Malawi) said that the definition might be less than ideal but counterfeit products remained a major public health problem that must be addressed. Any consultative group established should find another definition of counterfeit products that would encompass substandard medicines. Africa was the dumping ground for such products and a global approach to the problem was desperately needed. Arguing about the composition of the Taskforce would not advance that agenda, she appealed to those Member States concerned about not being involved in it to put forward more constructive ideas.

Ms TRUCILLO (Uruguay)<sup>1</sup> said that, despite the interest in the availability of medicines of optimum quality and effectiveness, the subjects of counterfeiting and regulation concerned violations of intellectual property rights should be addressed in other forums, such as WIPO. She was therefore unable to support the draft resolution.

Dr BABB-SCHAEFER (Barbados)<sup>1</sup> said that the production of counterfeit medical products called for zero tolerance. Their consumption could have harmful consequences, including death. Barbados broadly supported the idea behind the draft resolution, since its central concern was to protect public health rather than enforce intellectual property rights. The sixth preambular paragraph, however, was a potential cause of confusion and should be deleted, since the issues of counterfeiting and the violation of intellectual property rights were sometimes inextricably linked. Although not all violations of intellectual property rights resulted in counterfeit products, all such products were violations of those rights.

Mr RAJALA (European Commission), responding to comments by the member for Brazil, said that the pharmaceutical shipment in Rotterdam (The Netherlands) appeared to be the subject of an intellectual property dispute raised by the rights holder and had been acted upon by customs authorities. The shipment was now on its way back to the country of origin in agreement with the parties. Brazil had also criticized European Union legislation, but the Board was perhaps not the appropriate forum for that. He strongly questioned the appropriateness of involving WHO in a trade dispute; such matters were dealt with in WTO which, unlike WHO, had the appropriate instruments and mechanisms. The European Commission was authorized to speak for the Member States of the European Union on trade matters and it was prepared to work with WHO in any follow-up envisaged on the issue.

Mr CHAN (International Pharmaceutical Federation – FIP), speaking at the invitation of the CHAIRMAN, said that his organization had been involved in the International Medical Products Anti-Counterfeiting Taskforce and had provided inputs for a number of technical documents on legislation, regulatory infrastructure, implementation, enforcement, technology development trends and communications to combat counterfeit medical products. Some of those practical tools had been useful in the countries in which the Federation worked. He urged Member States to support a draft resolution on counterfeit medical products and to reaffirm the pledge to ensure access to genuine

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medical products. The Federation promoted awareness among all health professionals and patients of the dangers of counterfeit medical products.

The Internet made information globally accessible, and increasingly, patients were researching their own medical issues and also trying to self-diagnose and self-treat based on what they read. In the worst cases, unsuspecting patients died, became sick or developed resistance to genuine antibiotics through the ingestion of counterfeit medical products. The phenomenon of counterfeit medical products would only be eradicated through an agreed framework of coordinated action at the global level.

Mr MWANGI (International Alliance of Patients' Organizations – IAPO), speaking at the invitation of the CHAIRMAN, said that his organization had worked closely on the issue of counterfeit medical products with WHO, through the International Medical Products Anti-Counterfeiting Taskforce and with the World Alliance for Patient Safety. It had produced a tool kit on patient safety that included information on how to identify potential counterfeit medical products and acquire safe and effective medicines. Coordinated action was needed by the Secretariat and Member States to communicate to patients the risks of counterfeit medical products and to keep patients safe, to encourage vigilance and to report suspect medicines. He reaffirmed his organization's commitment to action through the Taskforce and related bodies.

Dr DAHL-REGIS (Bahamas) said that the debate had reflected assumptions about the capacities of certain countries, particularly low- and middle-income countries and small-island States, to discharge regulatory functions. The criminal and trade activities to which many speakers had referred fell outside the sphere of health, and the report was not clear enough on what WHO was doing on the public health aspects of counterfeit medical products. The Board needed to look at how the Secretariat was providing technical support to countries and regions. All references to criminal and trade aspects of counterfeit medical products should be expunged from the report.

Dr ETIENNE (Assistant Director-General), responding to the many different views expressed, re-emphasized that counterfeit medical products constituted a serious public health problem of increasing frequency and severity. The relevant statistics had, however, been omitted from the document for the sake of brevity. She contrasted the definition of counterfeiting within the Agreement on Trade-Related Aspects of Intellectual Property Rights, in which the aggrieved party was the holder of intellectual property rights, and in the WHO context, wherein the real victims of counterfeiting were patients and, through loss of confidence, health systems and health authorities. The earlier definition of counterfeiting had failed to address three aspects: medical products, as well as medicines; cases in which the quantity of active ingredient in the counterfeit product did not match the amount stated on the label; and cases where a licensed manufacturer had masked substandard batches with forged manufacturing documents. She understood the concern of low-income and developing countries that nothing in the report or the draft resolution should be construed as to limit the use of generic medicines. That concern was addressed in the report, which also indicated that violations of patent rights must not be confused with counterfeiting. The discussion had shown the need for a fresh look at the nomenclature of counterfeiting and how it related to the definition of intellectual property rights.

The Secretariat had engaged in consultations on several occasions, including drug regulatory authorities, and through the International Medical Products Anti-Counterfeiting Taskforce, which entity brought together Member States, the industry and other stakeholders to discuss an important public health problem. In that, it did not differ from bodies and mechanisms that had assisted the Secretariat in working on other problems. Developing countries were fully represented in the Taskforce. Nevertheless, having heard the doubts raised about its legitimacy and transparency, she would seek ways of making it more transparent and turning it into a broader consultative group to let all Member States feel that they were contributing.

She further assured members that the Secretariat was fully alive to the notion that the quality, safety and efficacy of medicines was vital for ensuring the health of individuals and care of a high standard. To that end, it was working with drug regulatory authorities and Member States in the areas, inter alia, of advocacy and assistance with their legislative processes.

As to the question from the member for the United States about how reference to intellectual property rights had been made in the report, she said that its inclusion had been due to a drafting error devoid of any ulterior motive. The Secretariat was ready to respond to the needs and be guided by the recommendations of Member States, particularly on what mechanism was needed to take the process further. She appealed, however, for Member States to recognize that counterfeit medical products posed a serious public health problem that they could not afford to ignore.

The DIRECTOR-GENERAL said that developing countries were not alone in being affected by substandard, poor quality or falsified medicines, although the impact was greater there than in developed countries. She assured Member States that WHO would remain within its area of competency, public health, and would not digress into areas for which it had no mandate, such as trade or intellectual property disputes. On the other hand, she needed sharper guidance on how to proceed, given the diversity of comments.

The CHAIRMAN said the Board had conducted a debate of great quality with carefully argued positions. The Secretariat had provided reassurances that there was no hidden agenda to extend WHO's action beyond its purview. He asked for views on the proposal to form a consultative group to reconsider the draft resolution.

Professor ALI (alternate to Professor Haque, Bangladesh) said that, while he was grateful for the efforts made to provide clarification, he did not accept the proposal to set up a consultative group. Since the underlying premise of the report and the draft resolution was unacceptable, there could be no effective discussion. Instead, the Secretariat should identify counterfeiting as a public health concern and address the root causes, with the focus on strengthening drug regulatory authorities. Any discussion should be conducted inclusively and supported by independent and verifiable data. He asked whether the International Medical Products Anti-Counterfeiting Taskforce had ever been endorsed by the Health Assembly, and how Member States could be expected to critique the work of an entity whose legitimacy had been questioned by several of them. Dissatisfaction with the report should be recognized and any further discussion on the draft resolution deferred.

Dr DAHL-REGIS (Bahamas), while agreeing that WHO needed to communicate the importance of the item under consideration, also supported the position expressed by the member for Bangladesh. Referring to her earlier question on the technical support that was being made available to countries and regions, she requested a more detailed response from the Secretariat.

Ms FARANI AZEVÊDO (alternate to Dr Buss, Brazil) expressed appreciation to the Chairman for his leadership of the current discussion; however, she could not support the solution that he had put forward. The course of action suggested by the member for Bangladesh was preferable. Too many problems still remained that made the drafting of a resolution feasible at the present time, most notably, the need to define "counterfeit" in relation to WHO's mandate. Both the discussion and the report built on technical work that had been carried out by the International Medical Products Anti-Counterfeit Taskforce, a group that was not under the control of the Member States, and had not been critically assessed. It was also unclear whether the Taskforce had considered WHO guidelines, the role of patents and of pricing that stimulated counterfeiting. Matters that were within the remit of other organizations, such as WIPO and the WTO, should not be included in WHO's agenda. Counterfeit medical products had a political as well as a health dimension. One solution might be to hold a full open-ended discussion, possibly on the basis of a revised report that would be prepared by

the Secretariat. The discussion should focus on all the issues related to counterfeiting and falsification, including: access to medicines; research and development in developing countries; capacity-building; and substandard products.

Dr GIMÉNEZ CABALLERO (Paraguay) drew attention to the role of logistics in improving access to medicines and medical products through estimates of demand, selection of products, procurement, good warehousing and distribution practices, ensuring rational use, strict quality control and the strengthening of regulatory institutions. His Government was determined to combat all types of counterfeiting and had appointed representatives with legal authority to serve on relevant bodies at all levels. He agreed with the members for Bangladesh and Brazil on the need for further discussion before a resolution could be adopted, and supported the establishment of a working group with a mandate to draw up a proposal for submission to either the Sixty-second or the Sixty-third World Health Assembly.

Dr ADITAMA (alternate to Dr Supari, Indonesia) expressed support for the comments made by the member for Bangladesh. He was unable to agree to the establishment of a working group. The Secretariat should take note of the discussions and, if necessary, prepare a new report or proposal based on them.

Dr BIN SHAKAR (United Arab Emirates), speaking on behalf of the Member States of the Eastern Mediterranean Region, expressed support for the Chairman's suggestion that the Board should establish a working group to review the content of the draft resolution.

Mr HOHMAN (alternate to Dr Wright, United States of America) endorsed the comments of the member for Brazil concerning the Chairman's efficient handling of the discussion. The debate had persuaded him that his earlier suggestion regarding the establishment of a small informal group would not be practicable because of the time available. The issue of counterfeit medical products had important public health aspects, with regard to which WHO had a legitimate role. However, several members had expressed concern about related aspects and appropriate discussion forums. On that basis, he supported the proposals made by the members for Bangladesh, Brazil, Indonesia and Paraguay, namely, that the Director-General should be requested to prepare further material on the matters that had been discussed. The deliberations might then be continued, through an intergovernmental process if so decided, to a stage where the matter could be considered by the Sixty-second World Health Assembly. If that suggestion was approved by the Board, the Director-General would then need to take into consideration a possible overlap with the intergovernmental process currently under way.

Dr KÖKÉNY (Hungary) said that, despite the marked divergence in the views of several delegations, it was necessary to send a strong message regarding patient safety and public health. Regardless of the definition of counterfeiting, it constituted a growing scourge in both developed and developing countries and must be eliminated. He therefore endorsed the proposal by the member for the United States that the Director-General should be requested to further clarify all the issues involved and suggested that the Board should take a decision on it.

Dr MOHAMED (Oman) pointed out that, during the deliberations of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property, issues of trade, intellectual property and patents had all been discussed in the context of their linkage with public health. He asked whether it was necessary to reopen the discussion and, in particular, to establish an intergovernmental working group, as the member for the United States had suggested.

The DIRECTOR-GENERAL remarked that, in 30 years of attending WHO meetings, she had never heard such a robust, substantive and high-quality discussion. There had been marked divergence of opinion in the first round of the discussion, but, after listening to further comments from members, she had noted some points of convergence. In effect, the members for Bangladesh, Brazil, Hungary, Indonesia, Paraguay and the United States had all been asking the Secretariat to identify the public health concerns and focus on what the Secretariat was doing to support Member States in strengthening their drug regulatory authorities in that regard. The member for Indonesia had requested the Secretariat to prepare a new report addressing the public health dimension of the issue of counterfeit medical products. That report would, she hoped, be submitted to the Sixty-second World Health Assembly, without a draft resolution, because there did not yet appear to be a convergence on the issues. The revised report should provide Member States with more information, which, in turn, should enable them to agree on a way forward. The member for Oman had drawn attention to the linkage between the content of the Board's discussions and WHO's previous work in connection with the Global strategy and plan of action on public health, innovation and intellectual property. Therefore, if the Board so agreed, the Secretariat would consider the Global strategy and plan of action, which the Health Assembly had already adopted, in order to identify points that might be relevant to the revised report. After considering the revised report, the Health Assembly could advise her on what further action she should take. If followed, that procedure would obviate the need for an intergovernmental process.

Dr VIROJ TANGCHAROENSATHIEN (Thailand)<sup>1</sup> said that he looked forward to the revised report. He urged the Director-General to carry out a thorough investigation of the role, function and public health interests of the members of the International Medical Products Anti-Counterfeit Taskforce. He cited the example of the National Institute of Health and Clinical Excellence in the United Kingdom and the terms of reference with which its members had to comply in order to avoid any possible conflict of interest.

Replying to a request for clarification from the DIRECTOR-GENERAL, he confirmed that the information requested should be provided in a document separate to the revised report.

The CHAIRMAN said that in the absence of any objection, he took it that the Board endorsed the procedure outlined.

**It was so agreed.**

**Human organ and tissue transplantation:** Item 4.12 of the Agenda (Document EB124/15)

Dr KÖKÉNY (Hungary), speaking on behalf of the European Union, the candidate countries Croatia, The former Yugoslav Republic of Macedonia and Turkey, the countries of the Stabilisation and Association Process and potential candidates Albania and Bosnia and Herzegovina, as well as Armenia and Ukraine, and recalling resolution WHA57.18, proposed a resolution on human organ and tissue transplantation which read:

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<sup>1</sup> Participating in virtue of Rule 3 of Rules of Procedure of the Executive Board.

The Executive Board,  
Having considered the report on human organ and tissue transplantation,<sup>1</sup>

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

The Sixty-second World Health Assembly,  
Recalling resolutions WHA40.13, WHA42.5 and WHA44.25 on organ procurement and transplantation and WHA 57.18 requesting an update of the Guiding Principles;

Having considered the report on human organ and tissue transplantation;

Aware of the growing magnitude and utility of human cell, tissue and organ transplantation for a wide range of conditions in low- as well as high-resource countries;

Committed to the principles of human dignity and solidarity which condemn the buying of human body parts for transplantation and the exploitation of the poorest and most vulnerable populations and the human trafficking that result from such practices;

Determined to prevent harm caused by the seeking of financial gain or comparable advantage in transactions involving human body parts, including organ trafficking and transplant tourism;

Convinced that the voluntary, non-remunerated donation of organs, cells and tissues from deceased and living donors helps to ensure a vital community resource;

Conscious of the extensive cross-boundary circulation of cells and tissues for transplantation;

Sensitive to the need for surveillance of adverse events and reactions associated with the donation, processing and transplantation of human cells, tissues and organs as such and for international exchange of such data to optimize the safety and efficacy of transplantation;

1. ENDORSES the updated WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation as attached to the WHO report EB124/15, hereby also called “the Guiding Principles”;

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

(1) to take account of the Guiding Principles in the formulation of their own policies and to implement these Guiding Principles in the law governing human cell, tissue and organ donation and transplantation where appropriate;

(2) to foster public awareness and understanding of the benefits created by the voluntary, non-remunerated provision of cells, tissues and organs as such from deceased and living donors, in contrast to the physical, psychological and social risks to individuals and communities caused by trafficking in material of human origin and transplant tourism;

(3) to oppose the seeking of financial gain or comparable advantage in transactions involving human body parts, organ trafficking and transplant tourism, including by encouraging health-care professionals to notify health authorities when they become aware of such practices;

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<sup>1</sup> Document EB124/15.

<sup>2</sup> Refers also to regional economic integration organizations where appropriate.

- (4) to sustain equitable access to transplantation services, which provides the foundation for public support of voluntary donation;
  - (5) to improve the safety and efficacy of donation and transplantation by collaborating to harmonize global practices;
  - (6) to establish and support national or multinational authorities to provide oversight, organization and coordination of donation and transplantation activities, with special attention to maximizing donation from deceased donors and to protecting the health and welfare of living donors;
  - (7) to collaborate in collecting data including adverse events and reactions on the practices, safety, quality, efficacy, epidemiology and ethics of donation and transplantation;
  - (8) to recognize and implement globally consistent coding systems for human cells, tissues and organs as such in order to facilitate national and international traceability of materials of human origin for transplantation;
3. REQUESTS the Director-General:
- (1) to disseminate the updated Guiding Principles as widely as possible to all interested parties;
  - (2) to aid the efforts of Member States and nongovernmental organizations towards global harmonization of donation and transplantation practices, including the prevention of organ trafficking and transplant tourism;
  - (3) to continue collecting and analysing global data on the practices, safety, quality, efficacy, epidemiology and ethics of donation and transplantation of human cells tissues and organs;
  - (4) to facilitate Member States' access to appropriate information on the donation, processing and transplantation of human cells, tissues and organs, including data on severe adverse events and reactions;
  - (5) to provide, in response to requests from Member States, technical support for developing national legislation and regulation on, and suitable systems for, donation and transplantation of cells, tissues or organs, in particular by facilitating international cooperation;
  - (6) to review the Guiding Principles periodically in the light of national experience with their implementation and of developments in the field of transplantation of human cells, tissues and organs;
  - (7) to report to the Health Assembly at least every four years on actions taken by the Secretariat, as well as by Member States and other partners, to implement this resolution.

He commended WHO's provision of a global knowledge base on transplantation, following extensive consultation with experts. He also welcomed the revision of the WHO Guiding Principles on Human Organ Transplantation, as contained in the annex to the report, which provided an essential framework to support progress in transplantation of cells, tissues and organs. In particular, he welcomed the addition of the two new Guiding Principles.

The following countries were cosponsors of the draft resolution: Argentina, Austria, Belgium, Brazil, Bulgaria, Colombia, Cyprus, Czech Republic, Denmark, El Salvador, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Japan, Latvia, Lithuania, Luxembourg, Mali, Malta, Mexico, Netherlands, New Zealand, Paraguay, Poland, Portugal, Republic of Moldova, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden and the United Kingdom of Great Britain and Northern Ireland.

Dr MAIGA (alternate to Mr Touré, Mali), speaking on behalf of the 46 Member States of the African Region, commended the report. She said that human organ and tissue transplantation was unfortunately practised in only a handful of countries in the African Region. The obstacles to advancing the use of organ transplants in Africa were many and included the lack of human and financial resources, especially kidneys and corneas; insufficient technical capacity; the absence of political and legal frameworks; and dysfunctional health systems. Low-income and middle-income countries were easy targets for the exploitation of poor and vulnerable people without legal protection. Transplant tourism and commercialization of the human body encouraged financial gain over the well-being of donor and recipient.

The transplantation rate in sub-Saharan Africa was only 0.2 per 1 million persons, dramatically lower than the rate elsewhere. African countries had a duty to catch up in this field and needed to establish legal frameworks before carrying out human organ and tissue transplantation.

She emphasized the need to strengthen collaboration between countries and with all stakeholders. The need for corneal transplantation was well established in her Region: the challenge was to raise public awareness of such possibilities and of procedures for acquiring and using immunosuppressant medicines at a lower cost. Increased access to organ transplants required the drawing up practical guides on how to arrange for kidney transplants in emerging countries. She endorsed the draft resolution.

Dr GARBOUJ (alternate to Dr Abdesselem, Tunisia), speaking on behalf of the Member States of the Eastern Mediterranean Region, said that the increased demand for organs and tissue and their limited availability had led to organ trafficking; indeed some countries in the Region were now destinations for transplant tourism. He commended the efforts of WHO to provide guidance; its emphasis on reducing the need for organ transplants; and the clarifications of, and additions to, the Guiding Principles. Increased awareness, encouraged by many organizations, and WHO's support for national initiatives, and combat of unethical practices, should all help to reduce trafficking.

Tunisia had undertaken public awareness campaigns, amended national legislation, established organ transplant banks and focused on policies related to transplants from deceased donors. Member States in the Region had established a network for exchange of information. A declaration of principle had been issued in Kuwait by experts from 17 Member States of the Region, banning organ trafficking and encouraging organ transplantation. In certain countries, religious and civil society leaders were promoting public awareness. The role of the media remained important in reinforcing ethical standards. The countries of the Region supported the revised Guiding Principles and would continue to cooperate with WHO on establishing guidelines and increasing awareness regarding transplantation.

Mr FISHER (Denmark) said that the report and Guiding Principles dealt appropriately with two areas of concern previously raised by Denmark, namely: the criminal exploitation of poor and powerless people; and the removal of tissue and organs from living minors and legally incompetent persons. The use of living donors in accordance with the Guiding Principles would reduce waiting time and thus reduce the illegal trade in organs. Transparency and registration, with national legislation regulating transplantation, were the most important ways of countering criminal and unethical practices. Countries that registered all transplantation activities in well-established regional or international registries were thus in control of those activities. A global system for coding transplantation material, registration of activities and cooperating with existing registries must be developed. National legislation should be based on Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, and on procurement, testing, processing, preservation, storage and distribution of human tissues and cells. He also emphasized the directive of the European Parliament and of the Council on Standards of quality and safety of human organs intended for transplantation, proposed by the European Commission in December 2008. In that context, he supported the draft resolution.

Dr REN Minghui (China) said that his Government attached great importance to managing transplantation. In March 2007, with the support of the Secretariat, China had regulated organ transplantation, set forth the rights of recipients and donors, established an organ donation system and clarified relevant government functions. The Ministry of Health had approved a system for evaluation of hospitals and health professionals, and reduced the number that practised transplantation. China had been a destination for transplant tourism, but that had been explicitly prohibited since July 2007. China was currently examining how to set up a national system to manage donation allocation, transplantation and registration, in accordance with the Guiding Principles. It would also regulate the taking of donations from living donors. China supported the revised Guiding Principles and would continue to work with the Secretariat in order to legislate and combat illegal activities. He expressed support for the draft resolution, but had difficulties with specific subparagraphs and would discuss those informally with the sponsor.

Mr ABDOO (alternate to Dr Wright, United States of America) said that the report and, in particular, the Guiding Principles raised international awareness of human rights, and ethical and safety issues. WHO was to be congratulated on its leadership role in promoting those issues. While living organ donation had been the subject of serious abuses of human rights at the global level, it could have substantial health benefits for the recipient. Living donation was acceptable where diligent efforts had been made to ascertain that an offer to donate was truly altruistic. While he supported the Guiding Principles in general, he was concerned about the use of the word “endorses” in the draft resolution. He proposed that it be replaced with “welcomes”, since the Board should not be obliged to endorse each new review or revision of the Guiding Principles by means of a resolution.

Dr MAHILLO DURÁN (Spain)<sup>1</sup> welcomed the draft resolution. The Spanish National Transplant Organization was a WHO collaborating centre and housed the Global Observatory on Donation and Transplantation. Current activities examined the practice, security and quality of allogeneic transplants as well as related ethical aspects such as living donors; transplant tourism; trade in cells, tissues and organs; and trafficking in human beings that targeted the poorest and most vulnerable people. The shortage of available organs had caused many countries to establish systems to improve supply, but it had also boosted the trade in human organs, particularly from living donors unrelated to recipients. In that context, the Guiding Principles, and a resolution supporting them, could represent the legal and ethical framework for acquiring and transplanting organs, cells and tissues for therapeutic purposes. That would encourage donation while providing tools with which to prevent trade and trafficking.

The updated version of the Guiding Principles advanced the process through recognition of all the key elements, notably issues of consent, the protection of minors, donation and remuneration, coercion and compensation, and the setting of standards and procedures. The adoption of a supporting resolution might encourage countries to take the Guiding Principles into account when formulating pertinent legislation and establishing national and international mechanisms for the supervision, organization and coordination of donation and transplantation activities.

**The meeting rose at 17:00.**

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<sup>1</sup> Participating by virtue of Rule 3 of the Rules of Procedure of the Executive Board.