World Health Organization

SEVENTIETH WORLD HEALTH ASSEMBLY

A70/A/PSR/7
26 June 2017

COMMITTEE A

PROVISIONAL SUMMARY RECORD OF THE SEVENTH MEETING

Palais des Nations, Geneva
Friday, 26 May 2017, scheduled at 09:00

Chairman: Dr H. M. AL KUWARI (Qatar)

CONTENTS

COMMITTEE A

SEVENTH MEETING

Friday, 26 May 2017, at 10:05

Chairman: Dr H. M. AL-KUWARI (Qatar)

1. THIRD REPORT OF COMMITTEE A (document A70/70)

The RAPPORTEUR read out the draft third report of Committee A.

The report was adopted.[1]

2. PREPAREDNESS, SURVEILLANCE AND RESPONSE: Item 12 of the agenda (continued)

Antimicrobial resistance: Item 12.2 of the agenda (documents A70/12, A70/13 and EB140/2017/REC1, resolution EB140.R5) (continued from the fourth meeting)

The CHAIRMAN drew attention to the draft resolution on improving the prevention, diagnosis and clinical management of sepsis, contained in resolution EB140.R5, as amended in informal consultations by the delegations of Germany, Indonesia on behalf of the Member States of the South-East Asia Region, Ireland, the Russian Federation, Thailand and the United States of America, which read:

> The Seventieth World Health Assembly,
>
> **PP1** Having considered the report on improving the prevention, diagnosis and clinical management of sepsis,[2]
>
> **PP2** Concerned that sepsis continues to cause approximately six million deaths worldwide every year, most of which are preventable;
>
> **PP3** Recognizing that sepsis as a syndromic response to infection is the final common pathway to death from most infectious diseases worldwide;
>
> **PP4** Considering that sepsis follows a unique and time-critical clinical course, which in the early stages is highly amenable to treatment through early diagnosis and timely and appropriate clinical management;
>
> **PP5** Considering also that infections which may lead to sepsis can often be prevented through appropriate hand hygiene, access to vaccination programmes, improved sanitation and water quality and availability and other infection prevention and control best practices; and that forms of septicaemia associated with nosocomial infections are severe, hard to control and have high fatality rates;

[1] See page […]

[2] Document A70/13.

PP6 Recognizing that while sepsis itself cannot always be predicted, its ill effects in terms of mortality and long term morbidity can be mitigated through early diagnosis and appropriate and timely clinical management;

PP7 Recognizing also the need to improve measures for the prevention of infections and control of the consequences of sepsis, due to inadequate infection prevention and control programmes, insufficient health education and recognition of early sepsis, inadequate access to affordable, timely, appropriate treatment and care, and insufficient laboratory services, as well as the lack of integrated approaches to the prevention and clinical management of sepsis;

PP8 Noting that health care-associated infections represent a common pathway through which sepsis can lead to an increased burden on health care resources;

PP9 Considering the need for an integrated approach to addressing sepsis that focuses on prevention, early recognition through clinical and laboratory services, and timely access to health care, including intensive care services, with reliability in the delivery of the basics of care, including intravenous fluids and the timely administration of antimicrobials where indicated;

Acknowledging that:

(i) the inappropriate and excessive use of antimicrobials contributes to the threat of antimicrobial resistance;

(ii) the global action plan on antimicrobial resistance adopted in resolution WHA68.7 (2015),[1] as well as resolution WHA67.25 (2014), urged WHO to accelerate efforts to secure access to effective antimicrobials and to use them responsibly and prudently;

(iii) sepsis represents the most vital indication for the responsible use of effective antimicrobials for human health;

(iv) in the absence of appropriate and timely clinical management, including effective antimicrobials, sepsis would be almost universally fatal;

(v) ineffective or incomplete antimicrobial therapy for infections, including sepsis, may be a major contributor to the increasing threat of antimicrobial resistance;

(vi) the incidence of some resistant pathogens may be reduced by the use of appropriate vaccines; and

(vii) immunocompromised patients are most at risk from very serious forms of septicaemia;

PP10 Recognizing that many vaccine-preventable diseases are a major contributor to sepsis and reaffirming resolution WHA45.17 (1992) on immunization and vaccine quality, which urged Member States, inter alia, to integrate cost-effective and affordable new vaccines into national immunization programmes in countries where this is feasible;

PP11 Recognizing the importance of strong, functional health systems, which include organizational and therapeutic strategies in order to improve patient safety and outcomes from sepsis of bacterial origin;

PP12 Recognizing the need to prevent and control sepsis, to increase timely access to correct diagnosis and to provide appropriate treatment programmes;

PP13 Recognizing the advocacy efforts of stakeholders, in particular through existing activities held every year on 13 September[2] in many countries, to raise awareness regarding sepsis,

[1] See document WHA68/2015/REC/1, Annex 3.

[2] See document EB140/12 paragraph 10: civil society organizations promote a World Sepsis Day on 13 September.

(OP1) URGES Member States:[1]

(1) to include prevention, diagnosis and treatment of sepsis in national health system strengthening policies and processes, in the community and in health care settings according to ~~international~~ **WHO [Indonesia on behalf of the Member States of the WHO South-East Asia Region]** guidelines;

(2) to reinforce existing or develop new strategies leading to strengthened infection prevention and control programmes, including by strengthening hygienic infrastructure, promoting hand hygiene, and other infection prevention and control best practices, clean childbirth practices, infection prevention practices in surgery, improvements in sanitation, nutrition and delivery of clean water, access to vaccination programmes, provision of effective personal protective equipment for health professionals and infection control in health care settings;

(3) to continue in their efforts to reduce antimicrobial resistance and promote the appropriate use of antimicrobials in accordance with the global action plan on antimicrobial resistance,[2] including development and implementation of comprehensive antimicrobial stewardship activities;

(4) to develop and implement standard and optimal care and strengthen medical countermeasures for diagnosing and managing sepsis in health emergencies, including outbreaks, through appropriate guidelines with a multisectoral approach;

(5) to increase public awareness of the risk of progression to sepsis from infectious diseases, through health education, including on patient safety, in order to ensure prompt initial contact between affected persons and the health care system;

(6) to develop training for all health professionals on infection prevention and patient safety, and on the importance of recognizing sepsis as a preventable and time-critical condition with urgent therapeutic need and of communicating with patients, relatives and other parties using the term "sepsis" in order to enhance public awareness;

(7) to promote research aimed at innovative means of diagnosing and treating sepsis across the lifespan, including research for new antimicrobial and alternative medicines, rapid diagnostic tests, vaccines and other important technologies, interventions and therapies;

(8) to apply and improve the use of the International Classification of Diseases system to establish the prevalence and profile of sepsis and antimicrobial resistance, and to develop and implement monitoring and evaluation tools in order to focus attention on and monitor progress towards improving outcomes from sepsis, including the development and fostering of specific epidemiologic surveillance systems and to guide evidence-based strategies for policy decisions related to preventive, diagnostic and treatment activities and access to relevant health care for survivors;

(9) to engage further in advocacy efforts to raise awareness of sepsis, in particular through supporting existing activities[3] held every year on 13 September in Member States;

(OP2) REQUESTS the Director-General:

(1) **to develop sepsis prevention and management guidelines; [Indonesia on behalf of the Member States of the WHO South-East Asia Region]** to and draw attention to

[1] And, where applicable, regional economic integration organizations.

[2] See document WHA68/2015/REC/1, Annex 3.

[3] See document EB140/12 paragraph 10: civil society organizations promote a World Sepsis Day on 13 September.

the public health impact of sepsis, including by publishing a report on sepsis describing its global epidemiology and impact on the burden of disease and identifying successful approaches for integrating the timely diagnosis and management of sepsis into existing health systems, by the end of 2018;

(2) to develop sepsis prevention and management guidance; [Germany]

~~(2)~~**(3)** to support Member States, as appropriate, to define standards and establish the necessary guidelines, infrastructures, laboratory capacity, strategies and tools for reducing the incidence of, mortality from and long-term complications of sepsis;

~~(3)~~**(4)** to collaborate with other organizations in the United Nations system, partners, international organizations and other relevant stakeholders in enhancing access to quality, safe, efficacious and affordable types of treatments of sepsis, and infection prevention and control, including immunization, particularly in developing countries, while taking into account relevant existing initiatives;

~~(4)~~**(5)** to report to the Seventy-third World Health Assembly on the implementation of this resolution.

The financial and administrative implications of the draft resolution for the Secretariat were:

Resolution: Improving the prevention, diagnosis and management of sepsis	
A.	**Link to the General Programme of Work and the Programme budget**
1.	**Please indicate to which outcome in the Twelfth General Programme of Work, 2014–2019 and to which output in the Programme budget 2016–2017 this draft resolution would contribute if adopted.** Twelfth General Programme of Work, 2014–2019, category 3, outcome: increased access to interventions for improving health of women, newborns, children and adolescents; category 4, outcome: policies, financing and human resources are in place to increase access to people-centred, integrated health services; category 5, outcome: increased capacity of countries to build resilience and adequate preparedness to mount a rapid, predictable and effective response to major epidemics and pandemics. Programme budget 2016–2017, outputs: 3.1.1; 3.1.2; 3.1.4; 3.1.6; 4.2.3; and 5.2.2.
2.	**Please provide a short justification for considering the draft resolution, if there is no link to the results as indicated in the Twelfth General Programme of Work, 2014–2019 and the Programme budget 2016–2017.** Not applicable.
3.	**Please indicate the estimated implementation time frame (in years or months) for any additional deliverables.** 4.5 years.
B.	**Budgetary implications for implementation of additional deliverables**
1.	**Current biennium − estimated, additional budgetary requirements, in US$ millions:** None.
(i)	**Please indicate the level of available resources to fund the implementation of the proposed resolution in the current biennium, in US$ millions:** – **How much are the resources available to fund the proposed resolution in the current biennium?** US$ 0.40 million (in-kind staff contribution across regional offices and WHO headquarters).

– **How much would the financing gap be?**
US$ 1.68 million.

– **What are the estimated resources, not yet available, if any, which would help to close the financing gap?**
Zero.

2. 2018–2019 (if required): estimated budget requirements, in US$ millions:
US$ 5.03 million.

Level	Staff	Activities	Total
Country offices	0.00	1.20	1.20
Regional offices	1.35	0.48	1.83
Headquarters	1.20	0.80	2.00
Total	**2.55**	**2.48**	**5.03**

3. Future bienniums beyond 2018–2019 (if required) − estimated budgetary requirements, in US$ millions:
US$ 5.03 million.

The representative of the CONGO said that he supported the proposed amendments and wished to be added to the list of sponsors of the draft resolution.

In the absence of any objections, the CHAIRMAN took it that the Committee wished to approve the draft resolution.

The draft resolution contained in resolution EB140.R5, as amended, was approved.[1]

Implementation of the International Health Regulations (2005): Item 12.4 of the agenda (document A70/16) (continued from the fourth meeting)

The CHAIRMAN explained that, following informal consultations conducted under the chairmanship of the representative of Monaco, agreement had been reached on the text of a draft decision, which read:

The Seventieth World Health Assembly, having considered the report on implementation of the International Health Regulations (2005): global implementation plan,[2] mindful of the legally binding nature of the International Health Regulations (2005), recalling country ownership and WHO's leadership in the implementation of the International Health Regulations (2005) and aware of the urgency of implementation of the International Health Regulations (2005), decided:

(1) to take note of the report contained in document A70/16; and

(2) to request the Director-General:

(a) to develop, in full consultation with Member States, including through Regional Committees, a draft five-year global strategic plan to improve public health preparedness

[1] Transmitted to the Health Assembly in the Committee's fourth report and adopted as resolution WHA70.7.

[2] Document A70/16.

and response, based on the guiding principles contained in Annex 2 of document A70/16, to be submitted for consideration and adoption by the Seventy-first World Health Assembly through the Executive Board at its 142nd session;

(b) to continue to pursue and strengthen efforts in supporting Member States for the full implementation of the International Health Regulations (2005), including through building their core public health capacities.

The draft decision was approved.[1]

3. HEALTH SYSTEMS: Item 13 of the agenda (continued)

Principles of the donation and management of blood, blood components and other medical products of human origin: Item 13.2 of the agenda (document A70/19)

The representative of LEBANON said that she supported the 10 principles contained in the report by the Secretariat, in particular principle 2 (equity in donation) and principle 5 (financial neutrality). She welcomed the efforts made to reflect the fact that different types of medical product of human origin might require different operational systems and regulatory oversight adapted to their specificities, and that the manner in which countries implemented the principles might differ depending on the type of product in question. In that context, WHO must be actively engaged in devising international guidelines on the various steps of traceability for medical products of human origin.

The representative of PANAMA, expressing support for the 10 principles set out in the report, said that medical products of human origin should be subject to a uniform global regulatory framework. Donors and recipients should be well informed of the risks and benefits before giving consent, and strict quality control systems for medical products of human origin must be in place. She proposed adding "or any discrimination on grounds of religion or ethnicity" after "considerations of financial or social status" at the end of principle 8.

The representative of BAHRAIN said that she welcomed the framework of principles, which must be applied to all medical products of human origin. Those products must be subject to appropriate national regulatory oversight, adapted to their specificities. Comprehensive strategies for the management of medical products of human origin were needed, as was close collaboration among regulatory authorities. The Secretariat should offer guidance on the strategies and interventions that could be implemented to ensure compliance with the principles at the national, regional and global levels.

The representative of MALAYSIA proposed adding the following sentence at the beginning of principle 2: "Voluntary, non-remunerated donation should be the basis for donation of blood, blood components and other medical products of human origin." Her delegation wished to be included in a drafting process to revise principles 1, 3, 5, 8 and 10. The Secretariat should hold additional consultations and capacity-building sessions to ensure that Member States fully understood and adhered to the principles, for which she expressed her support.

[1] Transmitted to the Health Assembly in the Committee's fourth report and adopted as decision WHA70(11).

The representative of ARGENTINA said that, while she acknowledged the value of establishing a set of shared principles, she had several concerns. The term "product" was not appropriate to refer to organs, tissues and cells, as it implied that they could potentially be commercialized, which was unacceptable given the ethical issues surrounding human biological materials. Since Member States were far from self-sufficient in organ and tissue donation, the voluntary nature of donation must be enshrined in countries' regulatory frameworks. She highlighted the importance of putting in place different standards to govern blood donation as opposed to organ, tissue and cell donation. Further work should therefore be done to improve the document.

The representative of SLOVAKIA, noting that blood components could be removed from blood and therefore become a base material, proposed that, in principle 2, the words "blood and plasma products" should be replaced by "blood, blood components and plasma products". Also, the document should distinguish between plasma as a blood component for transfusion, and plasma products for which plasma was a base material. She asked why the title of the report had been amended since its consideration by the Executive Board to include blood and blood components under the term "products", since blood and blood components were raw materials.

The representative of the ISLAMIC REPUBLIC OF IRAN highlighted the importance of setting more guidelines and standards to govern the use of medical products of human origin, as those currently in place did not meet the needs of manufacturers and regulators.

The representative of INDONESIA said that it would be difficult to achieve self-sufficiency in respect of plasma-derived medicinal products given the infrequent nature of donation and the lack of standards for blood and blood component safety in most developing countries. Consideration should be given to a payment-in-kind system for regular plasma donors who donated exclusively for plasma-derived medicinal product purposes; WHO should develop guidelines for such a system.

The representative of the CONGO, speaking on behalf of the Member States of the African Region, said that most African States did not yet have the requisite technology for transplants and that the use of blood and medical products of human origin in reproductive health remained limited. Steps had been taken to improve blood transfusion safety in the African Region, thereby decreasing the prevalence of certain diseases transmitted through blood transfusion. Self-sufficiency in blood and blood products would, however, be difficult to achieve. Resource-poor States should be given support, to facilitate the development of tissue and organ transplantation at the subregional level. The framework of principles could, however, be improved further.

The representative of the DOMINICAN REPUBLIC said that, given the growing demand for medical products of human origin, the framework of principles for promoting ethical practices was particularly important. The utmost care must be taken to ensure that the principles were applied rigorously, and in full compliance with the precept of voluntary, non-remunerated donation. In countries where efforts were being made to increase the availability and quality of medical products of human origin, in particular blood, special attention must be paid to upholding principle 2 on equity in donation.

The representative of CHINA said that the systems and norms in place in China for the donation and management of blood and organs were in line with the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation. WHO should establish a global regulatory mechanism for organ donation, so that data could be cross-checked between countries to identify the origins of donated organs. WHO should also continue to provide technical support to Member States to help developing countries use new technology and advanced administrative methods, and thereby strengthen their capacities to ensure the safety and security of blood and other medical products of human origin.

The representative of TUNISIA described the legislation in force in Tunisia, which was in line with the 10 principles, and said that efforts were being made to promote blood donation and improve the national blood transfusion system. She highlighted the importance of capacity-building to enable Member States to apply the principles successfully.

The representative of THAILAND said that the guiding principles were timely, given the shortage of medical products of human origin and Member States' limited capacities and resources to provide services in that regard. Given that different types of product might require different operational and regulatory systems, and that those systems ought to be consolidated with other national services, consideration should be given to the creation of a national coordinating mechanism for setting criteria and regulatory measures to guarantee the high quality of such medical products and the safety and equity of donors and recipients.

The representative of FRANCE said that she welcomed the revised principles. In particular, she reiterated France's commitment to the prior informed and voluntary consent of donors and welcomed the revised formulation of principle 5 on altruistic voluntary non-remunerated donation, which now mentioned resolution WHA63.22 (2010) and placed the necessary emphasis on donor protection.

The representative of IRAQ emphasized the need to tackle inappropriate practices with regard to blood donation. Efforts must be stepped up to manage the blood donation process more effectively and efficiently, including by establishing regional blood banks to guarantee supplies of blood and blood products. Donated blood and blood components must be healthy and safe. Safe transport of donations should be integrated into national health policy. Results-oriented strategies were needed to prevent communicable diseases being transmitted through unsafe blood donation. Laboratories must be better equipped to that end. Crisis response measures were in place but could be improved, in which regard support from the Organization would be appreciated. It was also important to provide services to migrants and refugees.

The representative of the RUSSIAN FEDERATION pointed out that the issue was not only important from the health perspective, but also in terms of international law, bioethics and criminal law. While expressing overall support for the 10 principles, she reiterated the suggestion made by her delegation at the 140th session of the Executive Board to replace the term "medical products of human origin" with "biological materials (products) of human origin", to avoid any overlap, confusion or incompatibility with existing terminology used in Member States' legislation. It would be useful to prepare a glossary on the subject, keeping in mind potential developments in biomedicine, and to discuss the matter further and draw up additional WHO guidance.

The representative of VIET NAM said that for developing countries with limited resources, establishing a sustainable blood donation management system required considerable work and financial and technical support at various levels, including to improve the legislative framework, ensure quality, safety, efficiency and professionalism, and establish a network of donors whose health was well monitored.

The representative of GERMANY said that the 10 principles, which were intended to cover all medical products of human origin, should not weaken existing international guiding principles and ethical standards in more specific areas such as organ donation. The principles should also address the distinction between different types of product of human origin. In order to safeguard organ donors and prevent organ trafficking and organ tourism, the principles should state clearly that the prohibition of financial gain and adherence to the principle of financial neutrality were indispensable in organ donation and transplantation, and that no deviation therefrom should be allowed.

The representative of INDIA, acknowledging the growth in demand for medical products of human origin, said that considerable inequalities in access to such products remained. While the attention given in the principles to equity among donors was welcome, greater focus should be placed on equity among recipients. If the majority of medical products of human origin were used in private sector medical care in urban areas, a net flow from poor to rich became inevitable. The need to expand publicly funded services that poor people could access should be stated clearly. Universal access to blood and blood products should be used as a test case to assess the impact of quality requirements and trade in medical products of human origin on their availability to poorer populations. Member States should also have the right to prioritize domestic use of medical products of human origin.

The representative of PAKISTAN said that all 10 principles were important and relevant. Their implementation by Member States would help promote ethical practices in the donation and management of blood, blood components and other medical products of human origin.

The representative of COLOMBIA, expressing support for the development of principles on the issue, which would help protect human rights, welcomed the inclusion of items such as haematopoietic stem cells from peripheral blood, bone marrow or umbilical cord blood. The consultative process through which the framework of principles had been developed would be beneficial in tackling the challenges faced in Colombia, which relied heavily on health tourism for its development, in terms of transparency, equitable access, and the quality and sustainability of the system. Any procedure involving the use of medical products of human origin should be trialled in order to ensure its safety, quality and effectiveness, not least to avoid unhelpful publicity of "miracle cures". The principles would be useful in preventing organ trafficking and transplant tourism, which undermined public confidence in voluntary donation and had an impact on national criteria for allocating organs, tissues and cells. Principle 5 on financial neutrality was particularly important. He sought clarification as to whether the principles were intended to replace or complement the existing WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation, as there seemed to be a discrepancy between them with regard to payment for cell donation.

The representative of MALDIVES said that blood transfusion services required quality assurance systems and good manufacturing practices, together with enhanced regulatory oversight and strengthened technical capacity for regulatory authorities and control laboratories. It was vital for donations of medical products of human origin to be entirely voluntary and for regulations to be strengthened to prevent misuse. He urged WHO to continue to provide technical support in relevant areas.

The representative of ECUADOR said that ensuring the availability of blood, blood components and other medical products of human origin in line with ethical principles was a priority for his Government. Quality assurance and vigilance systems were in place covering donor selection, traceability and the quality of products. The lack of universal health coverage was one of the main factors contributing to inequitable access to medical products of human origin. Altruistic voluntary donation was essential in order to protect donors from exploitation. Proper education was needed to raise awareness of the community benefits of voluntary donation. The donation and management of blood, blood components and other medical products of human origin should be the responsibility of each Member State's health system and carried out in line with best practice. He supported the comments made by the representative of Argentina concerning terminology. The Organization should increase its support to Member States in promoting ethical practices regarding medical products of human origin. Experience should be exchanged with a view to facilitating the implementation of the framework of principles.

The representative of LIBERIA emphasized the importance of tackling ethical issues to ensure that donors were not subject to exploitation, coercion or abuse.

The representative of KENYA said that his Government was committed to applying the framework of principles. He underscored the importance of ensuring that discussions on the donation and management of blood, blood components and other medical products of human origin were culturally sensitive in order to address preconceptions, taboos and beliefs about their use and to realize the full potential thereof.

The representative of the UNITED STATES OF AMERICA expressed support for the principles, which should be evaluated continuously to take account of advances in technology and recognize the role of Member States' national systems and experience. He encouraged the Secretariat to assist Member States in developing and implementing legal frameworks to regulate the use of medical products of human origin and in establishing systems to ensure safety, availability and quality by promoting best practice. Regulatory and public health monitoring frameworks should support the principles of ethics, safety, vigilance and surveillance, and his Government stood ready to share its experience with others.

The representative of AFGHANISTAN, welcoming the framework of principles, said that work had begun at the national level to draft regulations on medical products of human origin, in line with WHO guidance, which would bridge a regulatory gap that currently left donors and recipients vulnerable to organ trafficking. In that regard, he requested technical support from the Organization.

The representative of AUSTRALIA expressed support for the helpful revisions made to the principles since their consideration by the Executive Board at its 140th session and noted Australia's support for the concept of ethical principles when regulating donations and the use of components of the human body. Australia strongly recommended that legal consent from donors should remain a requirement in the procurement of medical products of human origin. The principles should be implemented within the context of each Member State's particular needs and system of governance.

The representative of SRI LANKA said that he welcomed the framework of principles for promoting ethical practices in the donation and management of medical products of human origin. A mechanism should be developed to ensure that all Member States had access to the most up-to-date blood screening technologies, to ensure maximum safety and prevent infections.

The representative of BANGLADESH said that advances in science and health care technology had led to greater availability of biological products. The framework of principles and policy options would ensure safety, quality and efficacy within and across national borders. The proposals concerning the procurement, manufacture and provision of medical products of human origin provided important guidance for Member States. The Secretariat should provide support for setting standards and developing guidelines for regulation, vigilance and surveillance systems for the manufacture and use of medical products of human origin.

The observer of the INTERNATIONAL FEDERATION OF THE RED CROSS AND RED CRESCENT SOCIETIES welcomed the framework of principles and policy options, and said that voluntary unpaid blood donors provided the foundation for a safe and sustainable blood supply. Voluntary systems helped guard against coercion and exploitation of vulnerable potential donors. Her Federation was working with WHO to develop a global framework to help achieve 100% voluntary blood donation in every country. She called for increased global commitment to support governments everywhere to provide essential blood services to their citizens.

The representative of MEDICUS MUNDI INTERNATIONAL – INTERNATIONAL ORGANISATION FOR COOPERATION IN HEALTH CARE, speaking at the invitation of the CHAIRMAN, welcomed the framework of principles but expressed concern that insufficient attention had been paid to the challenges that low- and middle-income countries would face in implementing them. Given the globalization of supply chains, a legally binding international instrument was required. When discussing choice and informed consent, consideration should be given to the gender, social and class dimensions of donation of blood and organs. The principles might not adequately protect the rights of women donors involved in assisted reproductive technologies and did not cover surrogacy, nor did they offer any guidance on the ethics of new procedures that were not life-saving, such as uterus transplants. Unless public health systems were strengthened, the recipients of donated organs would be predominantly those who could afford private health care.

The ASSISTANT DIRECTOR-GENERAL (Health Systems and Innovation), responding to points made, thanked the Member States and non-State actors for their support for the proposed set of guiding principles and for the efforts made by Member States since January 2017 to work with the Secretariat to improve the proposed framework. Furthermore, she noted the many national efforts to ensure the non-exploitation of donors, non-discrimination in respect of medical products of human origin and the safety and quality of medical products of human origin. The Secretariat had taken due note of the comments on the importance of sharing experiences and the suggestions regarding the proposed principles. The broad scope of medical products of human origins covered by the proposed framework meant that it had not been possible to go into detail with regard to specific types of cells, tissues and organs. The Secretariat proposed to work further with interested Member States to develop more specific guidance for particular types of medical products of human origin.

The Committee noted the report.

Addressing the global shortage of, and access to medicines, and vaccines: Item 13.3 of the agenda (document A70/20)

The representative of MALTA, speaking on behalf of the European Union and its Member States, said that the candidate countries the former Yugoslav Republic of Macedonia, Montenegro, Serbia and Albania, the country of the stabilization and association process and potential candidate Bosnia and Herzegovina, as well as Ukraine aligned themselves with her statement.

Shortages and temporary stock outs of medicines and vaccines could have serious consequences, and must therefore be addressed at the global level. A balance must be struck between the need to promote and finance the research and innovation of new medicines while ensuring that good quality, safe medicines were accessible and affordable to those in need, in line with target 3.8 of the Sustainable Development Goals. She expressed appreciation for WHO's efforts to develop technical definitions and hold consultations with all stakeholders to better understand the implications of shortages of medicines and vaccines. Attention should also be paid to evidence-based needs identification. She welcomed initiatives at the global, regional and national levels to develop alternative business models and strengthen regulatory systems to ensure that products could be registered and quality assured, and to improve the transparency of price-setting mechanisms and policies. Measures to encourage informal exchanges on shortages and prices, and to develop a global notification system and management plans for medicines and vaccines at risk of shortage, were also welcome. WHO had an important role in the Interagency Supply Chain Group and at the country level in advocating country ownership and organizing the in-country coordination of donors.

The representative of INDIA, supported by the representatives of the UNITED STATES OF AMERICA, BRAZIL and ALGERIA, requested a deferral of the discussion pending the continuation of informal discussions on terminology.

The representative of MONACO, supported by the representatives of the NETHERLANDS and SWITZERLAND, requested clarification regarding the informal discussions, about which her delegation had not been informed. The initiation of an informal consultation process without informing all delegations constituted a worrying lack of transparency.

The representative of INDIA said that he wished to clarify that an informal consultation process as such had not been initiated. His delegation had merely entered into a preliminary conversation with some others, in an effort to resolve differences regarding the terminology used in respect of access to medicine and shortages.

The representative of NORWAY, supported by the representative of MONACO, expressed concern that the objective of the informal discussions had not been clarified. He wished to know what terminology was being considered, since he was unaware that the discussion on agenda item 13.3 would result in a decision or resolution. The deadline for submitting drafts had passed and it was not desirable to start work on a text that had not been presented to the Health Assembly.

The representative of the OFFICE OF THE LEGAL COUNSEL said that, in line with Rule 48 of the Rules of Procedure of the World Health Assembly, formal proposals for draft resolutions or decisions must be presented by delegations by close of business on the opening day of the Health Assembly. Should the Committee wish to produce a text through a process it had initiated, however, it could do so.

The representative of the UNITED STATES OF AMERICA said that his understanding was that the Committee was not being asked to mandate an informal working group to draft a text, but rather was being asked to suspend the discussion on item 13.3 to allow time for Member States to consider the matter further.

The representative of ECUADOR, supported by the representatives of SWITZERLAND, MONACO and CANADA, said that the discussion should be resumed as soon as possible.

The CHAIRMAN suggested that, in a spirit of compromise, the discussion should be deferred until later in the day, without the initiation of an informal or formal consultation process. In the absence of any objections, she would take it that the Committee agreed to that suggestion.

It was so agreed.

(For continuation of the discussion, see the summary record of the eighth meeting.)

Evaluation and review of the global strategy and plan of action on public health, innovation and intellectual property: Item 13.4 of the agenda (document A70/21)

The representative of QATAR, speaking on behalf of the Member States of the Eastern Mediterranean Region, said that she welcomed the comprehensive external evaluation contained in document A70/21. Member States should promote research and development and strengthen international cooperation between the public and private sectors to create mutually beneficial partnerships. WHO should continue to provide technical support to promote the transfer of technology and the production of health products and to evaluate the outcomes of the global strategy and plan of action on public health, innovation and intellectual property. National regulatory agencies should be strengthened to improve access to health products. WHO should also support improved access to technical and scientific knowledge by widening the availability of libraries and databases.

The representative of SURINAME said that the review of the global strategy and plan of action on public health, innovation and intellectual property should take into account the needs of smaller countries, such as Suriname, when shaping the research agenda. The traditional knowledge of those countries could contribute to the discovery of new anti-infective agents and other medicines, but the populations of those countries needed assurance that they would benefit from sharing that knowledge. Resource poor countries had limited access to newly developed medicines and vaccines and access to some established medicines had been affected by price hikes. Her Government was therefore looking forward to participating in the work of the expert panel to review the global strategy and plan of action on public health, innovation and intellectual property.

The representative of BAHRAIN said that Member States must increase their efforts to implement the global strategy and plan of action on public health, innovation and intellectual property, given its importance to research and development and the transfer of technology in low- and middle-income countries. The Secretariat should provide further assistance to countries in the Eastern Mediterranean Region to boost research and development and enhance surveillance systems.

The representative of the RUSSIAN FEDERATION said that expanding the application of the Agreement on Trade-Related Aspects of Intellectual Property Rights, taking into account the interests of developing countries, would ensure that modern medicines and medical assistance could be accessible to all. Stimulating research and industrial potential would have a positive impact on epidemiology, in particular for HIV infection and viral hepatitis, and for noncommunicable diseases. He welcomed the comprehensive evaluation of the global strategy and plan of action on public health, innovation and intellectual property, and supported the inclusive approach to its review.

The representative of SWITZERLAND said that the external evaluation had been particularly valuable. He commended the approach taken by the external evaluation team, which had considered countries on the basis of income, rather than grouping the majority of countries together under the catch-all term “developing countries”, which would facilitate a targeted, needs-based approach to the provision of support. A similarly differentiated approach should be adopted during the overall programme review.

The representative of GERMANY, welcoming the external evaluation report, said that her Government was already implementing some of the recommendations, including capacity building, the transfer of technology and the strengthening and financing of health care systems.

The representative of IRAQ said that his Government was undertaking various measures to improve the national health system. The Secretariat, together with other concerned organizations, should support Member States in their efforts to encourage innovation and to strengthen industries for the development of vaccines, thereby enhancing health security at the national, regional and global levels. Action plans and strategies should be developed at the regional level, and WHO regional offices should receive the necessary support in that regard.

The representative of the UNITED STATES OF AMERICA said that he welcomed the evaluation and looked forward to receiving the review of the second stage evaluation of the global strategy and plan of action on public health, innovation and intellectual property.

(For continuation of the discussion, see the summary record of the eighth meeting.)

The meeting rose at 12:40.

= = =