

PROVISIONAL SUMMARY RECORD OF THE SEVENTH MEETING

**Palais des Nations, Geneva
Saturday, 28 May 2016, scheduled at 14:00**

**Chairman: Dr PHUSIT PAKONGSAI (Thailand)
later: Dr M. ASADI-LARI (Islamic Republic of Iran)
later: Dr PHUSIT PRAKONGSAI (Thailand)**

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SEVENTH MEETING

Saturday, 28 May 2016, at 14:10

Chairman: Dr PHUSIT PRAKONGSAI (Thailand)
later: Dr M. ASADI-LARI (Islamic Republic of Iran)
later: Dr PHUSIT PRAKONGSAI (Thailand)

1. **COMMUNICABLE DISEASES:** Item 15 of the agenda (continued) [transferred from Committee A]

Global vaccine action plan: Item 15.2 of the agenda (document A69/34)

The representative of BURKINA FASO, speaking on behalf of the Member States of the African Region, recalled that the objective of the global vaccine action plan was to expand vaccination coverage in the period 2011–2020 to all people, irrespective of their location; its targets were ambitious, but remained achievable. Several challenges hindered implementation of the Expanded Programme on Immunization in the Region, including the accessibility, cost and availability of vaccines, especially during emergency situations such as the current yellow fever epidemic in Angola. To ensure the successful implementation of the global vaccine action plan, further efforts were required, including: a review of the criteria of the International Coordinating Group on Vaccine Provision for Epidemic Meningitis Control for releasing vaccine supplies; the establishment of regional stockpiles of vaccines; the facilitation of access to vaccination services by allocating sufficient funding; and the improvement of the accessibility and availability of vaccines – in keeping with the targets identified in the 2030 Agenda on Sustainable Development. The Member States of the Region were committed to implementing the recommendations of the WHO Strategic Advisory Group of Experts on immunization¹ and requested support from the Secretariat to that end; he urged the Health Assembly to endorse those recommendations.

The representative of the REPUBLIC OF KOREA acknowledged the efforts of the international community to achieve the goals of the global vaccine action plan. The issue of vaccination merited increased attention on the global health agenda in view of its pivotal role in ensuring global health security, including further investment in research and development for the production of safe and efficacious vaccines at the national, regional and international levels and the importance of strengthening surveillance systems. To support international efforts, her Government had decided to increase its contributions to the GAVI Alliance from US\$ 1 million to US\$ 4 million annually for the next three years. The Republic of Korea would continue its efforts to achieve the goals of the 2011–2020 Decade of Vaccines and the global vaccine action plan.

The representative of SAUDI ARABIA said that his Government supported the position of Eastern Mediterranean Region with respect to the global vaccine action plan and drew attention to the significant challenge currently faced by his country in relation to the elimination of measles, which posed a serious threat to global health security. Measles had not been accorded sufficient attention at the international level, and the conditions in the Region were conducive to its spread; the increase of

¹ See document A69/34, Annex 1.

areas affected by conflict and crisis hindered efforts to reach all those in need of vaccines. The lessons learnt from efforts to eliminate poliomyelitis could be usefully applied to efforts invested in eliminating measles, and he urged the Secretariat, Member States, regional offices and the industry to accord maximum attention to the issue.

The representative of SRI LANKA said that the national immunization programme continued to attain high coverage rates, resulting in the prevention and control of most vaccine-preventable diseases; for instance, no case of poliomyelitis, diphtheria or neonatal tetanus had been recorded. In 2015 Sri Lanka had introduced the inactivated poliovirus vaccine, and in the current year had made the switch from trivalent to bivalent oral poliovirus vaccine and introduced the human papillomavirus vaccine. Sri Lanka had prioritized strengthening vaccine-preventable disease surveillance and assessing the performance of the Expanded Programme on Immunization in reducing childhood morbidity and mortality. Innovative options for the financing of routine immunization services at the subnational level were required in order to ensure their sustainability. He endorsed the recommendations of the Strategic Advisory Group of Experts on immunization.

The representative of the RUSSIAN FEDERATION welcomed the progress achieved thus far, including the introduction of new vaccines and progress towards the elimination of poliomyelitis. She expressed appreciation of the efforts to review the situation in developing countries, WHO's prequalification process and the technical support required to ensure vaccine availability and accessibility, and broadly supported the recommendations of the Strategic Advisory Group of Experts on immunization, including the proposal to strengthen partnerships at all levels in the work against vaccine-preventable disease including measles and rubella and health systems. Special attention should be paid to populations living in post-conflict situations, where there was a higher risk of the spread of disease.

The representative of the UNITED REPUBLIC OF TANZANIA described the range of measures taken by his country to implement the global vaccine action plan, which included introducing new and under-utilized vaccines, increasing access to vaccines for marginalized populations through the "reach every child" strategy, and developing a comprehensive immunization plan for the period 2016–2020. His country had been certified as having eliminated maternal and neonatal tetanus in 2012 and, as a result of the high national oral poliovirus vaccination coverage, had also achieved "polio-free" certification in November 2015. WHO should continue to strengthen the capacity of developing countries to facilitate their participation in vaccine research and development. He welcomed the collaboration of WHO and UNIDO in the establishment of the African vaccine manufacturing initiative, and WHO's work on the prequalification process. His Government was committed to implementing the recommendations of the Strategic Advisory Group of Experts on immunization.

The representative of THAILAND said that the Secretariat and other development partners should continue to support Member States in strengthening national immunization programmes, as part of efforts towards ensuring universal health coverage. The Expanded Programme on Immunization should develop a list of critical priority actions to be taken at the country level. The success of immunization programmes must not lead to complacency. The potential financial impact and sustainability of new vaccines should be taken into serious consideration by WHO and the WHO Strategic Advisory Group of Experts on immunization before their introduction was recommended. Achievement of the goals of the global vaccine action plan depended to a large extent on the capacity of developing countries to develop and produce vaccines at a low cost; consideration should therefore be given to delinking the cost of research and development from the price of vaccines. Her Government was fully committed to implementing the global vaccine action plan and looked forward to the achievement of the targets related to the Decade of Vaccines.

The representative of the UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND fully supported the accelerated implementation of the global vaccine action plan and the recommendations of the Strategic Advisory Group of Experts on immunization. His Government was proud to be the largest donor to the GAVI Alliance, having committed to provide £1440 million in funding from 2016 to 2020. WHO should improve the management of the global vaccine stockpile, increase transparency in decision-making, and communicate decisions and actions more clearly. In spite of the continued high national vaccination coverage rates and its success in meeting WHO targets, his Government had not become complacent: the recent introduction of the meningococcal ACWY and B vaccines served as an example. All countries and partners were called on to ensure that progress in achieving the targets related to the Decade of Vaccines remained on track. Member States were urged to increase domestic financing for, and support to, immunization.

The representative of DENMARK, speaking also on behalf of Finland, Iceland, Norway, Sweden, Estonia, Latvia and Lithuania, thanked the GAVI Alliance and the Global Polio Eradication Initiative for their coordinated efforts to eradicate poliomyelitis. Although progress had been made in some countries and regions, the elimination strategies for maternal and neonatal tetanus urgently needed revision and additional funding. He welcomed the recommendations of the Strategic Advisory Group of Experts on immunization regarding accountability. Immunization plans that were consistent with the global vaccine action plan should be put in place at the country level and shared with the regional offices. The countries that were no longer qualifying for support from the GAVI Alliance must ensure the availability of sufficient domestic funding for immunization. In order to improve equitable health coverage, immunization programmes should form an integral part of strengthened health systems. He expressed concern at the challenges related to vaccine production and delivery and their concomitant effect on the successful implementation of national vaccination programmes. The recent Ebola and Zika virus outbreaks had highlighted the urgent need for increased efforts to develop new vaccines to prevent and respond to epidemics and pandemics. A coordinated approach was required to counter the dissemination of non-evidence-based information on the possible side effects of vaccines.

The representative of VIET NAM strongly supported the recommendations of the Strategic Advisory Group of Experts on immunization. Her Government had successfully implemented the Expanded Programme on Immunization; the national regulatory authority had been accredited by WHO, and Viet Nam was producing vaccines and satisfying national demand. Her Government was committed to implementing the global vaccine action plan, but she highlighted the need for additional support from the Secretariat in order to maintain the operation of the national regulatory authority, enhance national capacity to manufacture vaccines, and maintain high immunization coverage rates.

The representative of CHILE said that concerted and effective action was needed to advance the progress made towards the targets of the global vaccine action plan. Greater priority should be accorded to immunization programmes at the national level, with an emphasis on ensuring free universal access to vaccines. In the light of the increasing dissemination of incorrect information on the effects of vaccines, efforts must be made to promote their efficacy and safety. Noting the importance of communicating the fact that efforts to enforce immunization were based on technical, ethical and legal considerations, she called for support to tackle vaccine refusal. To address the availability and accessibility of vaccines, WHO should promote collective vaccine purchasing, and emphasize the importance of public-private partnerships in developing and producing vaccines in low- and middle-income countries, as well as the need for flexibility in relation to intellectual property protection.

The representative of LIBYA said that, in the light of the current emergency situation, his country was facing significant difficulties in achieving the targets of the global vaccine action plan. Noting that many other countries in the Eastern Mediterranean Region affected by crisis were facing similar challenges, he underscored the urgent need for support for such countries, including solutions to meet the vaccination needs of both the domestic and refugee populations. Given the increasing price of vaccines and the resultant unaffordability for many countries, he called on WHO and other partners to facilitate access to the lowest global price of vaccines for countries facing humanitarian crises. He requested information on how the Secretariat would take action to implement the provisions of resolution WHA68.6 (2015), including those relating to the reduction of vaccine prices. The right of every child and indeed every person, including those living in crisis situations, to be vaccinated with affordable vaccines must be upheld. He looked forward to further progress on the implementation of resolution WHA68.6 in the coming year.

The representative of the UNITED STATES OF AMERICA, noting that the global vaccine action plan was not on track, urged all countries to renew their commitment to achieving its targets. Urgent action was needed to ensure that global vaccine stockpiles were effectively managed by WHO; the current limited supply of yellow fever vaccine was of particular concern. The Secretariat should work with Member States to develop strategies for the vaccination of those living in areas affected by conflict and insecurity. She commended the efforts of Member States of the African Region, which had led to the Declaration on Universal Access as a Cornerstone for Health and Development in Africa at the Ministerial Conference on Immunization in Africa earlier in the year. She expressed support for the recommendations of the Strategic Advisory Group on immunization, in particular the need for global, regional and national partners to align their efforts to support countries in strengthening their leadership and accountability frameworks. She regretted that the monitoring framework for the sustainable development goals did not include an indicator that was aligned with the objectives of the global vaccine action plan. She urged the Secretariat, UNICEF and Member States to: provide guidance on reaching every child, building upon the successful results achieved in relation to poliomyelitis vaccination; conduct robust disease surveillance; provide effective outbreak response; devise culturally appropriate communication strategies; and implement accountability frameworks. The ability of Nigeria to harness the polio infrastructure and model to successfully control the recent Ebola outbreak affirmed the strong case for using polio assets more extensively to contribute to global health security.

The representative of CHINA said that his Government attached great importance to the global vaccine action plan, and welcomed the progress so far. Given the lengthy implementation period for the global vaccine action plan, WHO should regularly review the progress made and challenges remaining. In order to achieve the targeted results, international cooperation should be increased. Support should be provided to facilitate the introduction of new vaccines and technology transfer, and vaccinations should be provided free of charge to school-aged children. China stood ready to cooperate with other Member States in order to achieve the targets of the global vaccine action plan.

The representative of the PHILIPPINES expressed concern that, despite the progress made, challenges remained in attaining the goals of the global vaccine action plan. She highlighted the need to ensure equity and the importance of WHO's leadership role in ensuring that populations in areas affected by crisis and countries with a high burden of disease had access to affordable, life-saving vaccines. Her Government supported the recommendations of the Strategic Advisory Group of Experts on immunization.

The representative of SOUTH AFRICA said that the lack of availability, shortages and stock-outs of vaccines had wide public health implications and hindered progress towards the objectives related to antimicrobial resistance. In response to the need for urgent action to ensure that suppliers had sufficient capacity to respond to the global demand, the Secretariat should convene a team on vaccine market dynamics to develop strategies for securing vaccine supply. In view of the prohibitive cost of vaccines, especially for developing countries, the Secretariat should accelerate the work on vaccine pricing, including the establishment of a database of global vaccine prices. It should prepare guidelines on accessibility to affordable vaccines for populations in crisis situations. In addition, it should fast-track the objectives of the global vaccine action plan, particularly in relation to availability and affordability.

The representative of IRAQ, speaking on behalf of the Member States of the Eastern Mediterranean Region, said that the Region was on track for the achievement of the regional hepatitis B control target and the introduction of new and under-utilized vaccines. Several countries in the Region continued to face great challenges because of their security situation; more than 95% of the unvaccinated children in the Region were in those countries. As part of their commitments to implement the global vaccine action plan, countries and partners should allocate and mobilize more financial resources and establish a process for monitoring and accountability at national and subnational levels, through the National Immunization Technical Advisory Group. Significant support from partners, in terms of funding and technological transfer, would be needed to ensure access to immunization in countries in crisis and overcome the global shortage of some vaccines. Greater effort should be made to reduce the cost of new life-saving vaccines. Resources were also required to overcome the bottlenecks in maternal and neonatal tetanus elimination. Member States of the Region supported the recommendations of the Strategic Advisory Group of Experts and the proposal to present the assessment report to the World Economic Forum in Davos in order to mobilize necessary resources.

The representative of MALAYSIA said that the affordability of new vaccines and the rising numbers of vaccine refusals continued to hinder attainment of the targets in the global vaccine action plan. Malaysia had experienced a stock-out of a combination inactivated poliovirus and cellular pertussis vaccine, which had disrupted the vaccination schedule, and she urged the Secretariat to ensure that supply-side interventions were matched with demand-consolidation activities relating in particular to strengthening national decision-making and the national financing of immunization programmes.

The representative of INDONESIA said that it was important for WHO to put in place a proper mechanism for vaccine procurement in order to make vaccines available and affordable. Maternal and neonatal tetanus had been eliminated in Indonesia. Her Government encouraged WHO and its partners to facilitate technology transfer and capacity-building for vaccine manufacturing. All child health stakeholders were called on to support and mobilize resources in order to enable all children to have access to quality immunization services.

The representative of NIGER said that, despite efforts of her Government since 2010 to put in place an action plan for vaccines, including the highly effective campaign to introduce meningococcal A vaccine as part of its routine vaccination programme, there was an outbreak of more than 7000 cases of meningitis in 2015. The causative agent in more than 75% of the more than 470 deaths had been group C meningococci and group W meningococci in about 15%. The global shortage of vaccines against those strains and their exorbitant cost had posed serious difficulties for the authorities at that time. WHO's contribution was recognized but more was needed. The Organization should advocate wider availability of the tetravalent vaccine and a reduction in its cost.

The representative of THE GAVI ALLIANCE, speaking at the invitation of the CHAIRMAN, concurred that the Decade of Vaccines was not on course to achieve its objectives. Reaching underserved populations with life-saving vaccines was challenging, particularly in the context of humanitarian crises. In the second half of the Decade of Vaccines, emphasis on coverage and equity was needed to ensure that the key targets of the global vaccine action plan were met. Her organization planned to increase its efforts to help countries to plan for the transition away from eligibility for its support so as to ensure the sustainability of immunization systems. It was also important to build sustainable health systems in countries and to pursue an international approach to ensuring vaccine access in the event of disease outbreaks. The monitoring framework for the 2030 Agenda for Sustainable Development would provide an excellent platform to reinvigorate global commitment to the Action Plan. The GAVI Alliance advocated the inclusion of a specific immunization indicator in the monitoring framework and called for the support of Member States and others in that regard.

The observer of CHINESE TAIPEI welcomed the recommendations of the Strategic Advisory Group of Experts on immunization in connection with strengthening accountability in implementing plans and improving immunization coverage rates among unvaccinated children in marginalized regions. The Secretariat was encouraged to promote collaboration in immunization programmes, to support the international community in meeting vaccination coverage targets, and to coordinate efforts in increasing regional vaccine production capacity. Chinese Taipei stood willing to share its expertise regarding its immunization information system on vaccination coverage among children and its experiences in successfully implementing immunization programmes with its partners.

The observer of the INTERNATIONAL FEDERATION OF RED CROSS AND RED CRESCENT SOCIETIES called on Member States to take action by: sharing information on vaccine prices with WHO; engaging in shared leadership with civil society; and matching supply-side interventions with demand-side activities, including through dialogues with communities. He called on the Secretariat to: provide guidance to Member States and partners on the vital role that civil society organizations can play in the implementation of a critical package of health services, including immunizations, to populations living in areas of conflict; support better coordination between governments and civil society organizations with regard to the global vaccine action plan accountability framework; and provide more online course offerings related to immunization.

The representative of MSF INTERNATIONAL, speaking at the invitation of the CHAIRMAN, encouraged Member States to continue to share their price data with WHO. High prices were preventing her organization from being able to scale-up vaccinations for children in crisis-affected areas; pharmaceutical companies were offering no sustainable solution. In addition to accelerating competition among vaccine companies, WHO should use its expertise to facilitate a review of the pneumococcal conjugate vaccine candidates from emerging economy manufacturers in order to cut waiting times for the next product.

The representative of the INTERNATIONAL PHARMACEUTICAL STUDENTS' FEDERATION, speaking at the invitation of the CHAIRMAN, endorsed positive collaboration between national regulatory bodies, the pharmaceutical companies, health practitioners and medicine retailers. Member States should incorporate immunization training within all pharmacy curricula and provide research internships to pharmacy students. As pharmacists reached community members on a daily basis, Member States should include pharmacy students and professionals in public health campaigns to tackle vaccine hesitancy and educate the public on the rarity of adverse effects.

The ASSISTANT DIRECTOR-GENERAL (Family, Women's and Children's Health) said that tremendous progress had been made in four main areas of the global vaccine action plan, namely: the introduction of new vaccines, including the development of the new Ebola vaccine; polio eradication; the eradication of maternal and neonatal tetanus, particularly in India and the South-East Asia Region in general; and vaccine price sharing. Already 40 Member States had shared information on vaccine pricing with WHO, but much more needed to be done; the Secretariat would work on continuing to shape the market in order to drive down vaccine prices. Turning to the concerns expressed by Member States, she said that a global mid-term review on measles was under way to provide recommendations on how to strengthen control and elimination of measles, mumps and rubella. The Director-General had recently commissioned an evaluation on how to improve the management of vaccine stockpiling. The GAVI Alliance would focus on reducing inequity in vaccination coverage. A discussion had been initiated on how best to use the assets of the polio eradication programme to advance the other goals of the global vaccine action plan. The positive, high-level political commitment to vaccinations and immunization in Africa was encouraging. Plans were in place to develop the WHO workforce, particularly in countries experiencing emergencies and crises, and to devote more resources to promoting the health of women and children in displaced settings.

The Committee noted the report.

2. HEALTH SYSTEMS: Item 16 of the agenda (continued) [transferred from Committee A]¹

Follow-up to the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination – Report of the open-ended meeting of Member States: Item 16.2 of the agenda (document A69/40) (continued from the fourth meeting, section 2)

The CHAIRMAN invited the Committee to consider the following revised version of the draft resolution:

The Sixty-ninth World Health Assembly,

PP1 Recalling WHA66.22 and subsequent WHA decisions on the Follow-up of the Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination and noting progress made in the implementation of the Strategic Workplan agreed in WHA66.22;

PP2 Acknowledging that the 2030 Agenda for Sustainable Development includes the commitment to support the research and development of vaccines and medicines for the communicable and noncommunicable diseases that primarily affect developing countries, provide access to affordable medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all;

PP3 Recalling the Global strategy and plan of action on public health, innovation and intellectual property and its aims to promote innovation, build capacity, improve access and mobilize resources to address diseases that disproportionately affect developing countries;

¹ See the summary record of the General Committee, first meeting, section 2.

PP4 Noting with particular concern that for millions of people the right to the enjoyment of the highest attainable standard of physical and mental health, including access to medicines, remains a distant goal, that especially for children and those living in poverty, the likelihood of achieving this goal is becoming increasingly remote;

PP5 Noting the establishment of the High-Level Panel on Access to Medicines convened by the UN Secretary-General;

PP6 Underscoring that health research and development should be needs-driven and evidence-based and be guided by the following core principles: affordability, effectiveness, efficiency, and equity; and it should be considered as a shared responsibility;

PP7 Acknowledging the central role of the Global Observatory on Health Research and Development to consolidate, monitor and analyze relevant information on health research and development activities related to type II and III diseases and the specific research and development needs of developing countries in relation to type I diseases, as well as for potential areas where market failures exist, and also antimicrobial resistance and emerging infectious diseases likely to cause major epidemics, building on national and regional observatories (or equivalent functions) and existing data collection mechanisms, with a view to contributing to the identification and the definition of gaps and opportunities for health research and development priorities and supporting coordinated actions on health research and development;

PP8 Expressing concern at the significant gap in funding the Strategic Workplan agreed in WHA66.22, including the six selected demonstration projects,

(OP1) URGES Member States:¹

- (1) to make concerted efforts including through adequate and sustainable funding to fully implement the Strategic Workplan agreed in WHA66.22;
- (2) to create, operationalize and strengthen, as appropriate, national health research and development observatories or equivalent functions for tracking and monitoring of relevant information on health research and development and to provide regular information on relevant health research and development activities to the Global Observatory on Health Research and Development or to other existing data collection mechanisms which provide regular reports to the Global Observatory on Health Research and Development;
- (3) to provide support to the Director-General for the development of sustainable financing mechanisms for the full implementation of the Strategic Workplan agreed in WHA66.22;

(OP2) REQUESTS the Director-General:

- (1) to expedite the full implementation of the Strategic Workplan agreed in WHA66.22;
- (2) to expedite the further development of a fully functional Global Observatory on Health Research and Development;
- (3) to submit terms of reference and a costed workplan of the Global Observatory on Health Research and Development to the Seventieth World Health Assembly through the 140th session of the Executive Board under the CEWG related agenda item;
- (4) to expedite, as part of the development of the Global Observatory on Health research and development, the development of norms and standards for classification of health research and development, including common reporting formats, building on

¹ And, where applicable, regional economic integration organizations.

existing sources, in consultation with Member State experts and relevant stakeholders in order to collect and collate information systematically;

(5) to promote the Global Observatory on Health Research and Development among all stakeholders, including through regular open-access publications and outreach activities and encourage all stakeholders to regularly share relevant information on health research and development with the Global Observatory on Health Research and Development;

(6) to support Member States in their endeavours to establish or strengthen health research and development capacities including the monitoring of relevant information on health research and development;

(7) to establish a WHO Expert Committee on Health R&D to provide technical advice on prioritization of health research and development for Type II and III diseases and specific research and development needs of developing countries in relation to Type I diseases as well as for potential areas where market failure exists based, *inter alia*, on the analyses provided by the Global Observatory on Health Research and Development. The Expert Committee will, as needed, consult with all relevant stakeholders in carrying out its work as specified in its terms of reference, which will be formulated and submitted to the 140th session of the Executive Board for its consideration;

(8) to take into account the study conducted by the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases, and on the basis of the report of the CEWG, present a proposal with goals and an operational plan for a voluntary pooled fund to support research and development for Type III and Type II diseases and specific research and development needs of developing countries in relation to Type I diseases, to be submitted to the Seventieth World Health Assembly through the 140th session of the Executive Board;

The plan shall describe how the WHO Global Observatory on Health Research and Development, the WHO Expert Committee on Health Research and Development and the Scientific Working Group of a pooled fund will work together, with specific disease examples, and in line with the core principles of affordability, effectiveness, efficiency, equity and the principle of delinkage. The plan shall also provide options for sustainable funding;

(9) to promote and advocate for sustainable and innovative financing for all aspects of the Strategic Workplan agreed in WHA66.22 and to include, as appropriate, the Strategic Workplan in WHO financing dialogues for mobilizing sufficient resources to meet the objectives of WHA66.22;

(10) to promote policy coherence within WHO on its research and development related activities such as those in relation to the Research and Development Blueprint for Emerging Pathogens and the Global Action Plan on Antimicrobial Resistance in terms of application of the core principles of affordability, effectiveness, efficiency and equity and the objective of de-linkage identified in WHA66.22;

(11) to report to the Seventieth World Health Assembly, through the 140th session of the Executive Board, on the implementation of this resolution, and request the Seventieth World Health Assembly to consider convening another open-ended meeting of Member States in order to assess progress and continue discussions on the remaining issues in relation to monitoring, coordination and financing for health research and development, taking into account relevant analyses and reports.

The draft resolution, as amended, was approved.¹

The representative of INDIA, speaking as chairman of the drafting group that had successfully negotiated and finalized the draft resolution the previous day, expressed the hope that the adoption of the resolution would pave the way for accelerated development of the Global Health Observatory on Health Research and Development, implementation of the demonstration projects and the coordination mechanism, and the rapid overcoming of the funding difficulties that hindered the work of the Consultative Expert Working Group on Research and Development.

The representative of GERMANY, welcoming the approval of the draft resolution, said that her Government was committed, with its Group of Seven partners, to working together with WHO to contribute to the coordination of research and development efforts, and would support the further development of the Global Observatory with €500 000.

The representative of SWITZERLAND said that her country wished to be added to the list of sponsors of the resolution.

Health workforce and services: Item 16.1 of the agenda (documents A69/36, A69/37 and A69/37 Add.1) (continued)

- **Draft global strategy on human resources for health: workforce 2030** (document A69/38)
- **Framework on integrated people-centred health services** (documents A69/39 and EB138/2016/REC/1, resolution EB138.R2) (continued from the fourth meeting, section 2)

The CHAIRMAN invited the Committee to consider the following revised version of the draft resolution contained in resolution EB138.R2:

The Sixty-ninth World Health Assembly,

PP1 Acknowledging Sustainable Development Goal 3 (Ensure healthy lives and promote well-being for all at all ages) including target 3.8, which addresses achieving universal health coverage, including financial risk protection, access to quality essential health care services, and access to safe, effective, quality and affordable essential medicines and vaccines for all;

PP2 Recalling resolution WHA64.9 (2011) on sustainable health financing structures and universal coverage, which urged Member States to continue investing in and strengthening health-delivery systems, in particular primary health care and services, and adequate human resources for health and health information systems, in order to ensure that all citizens have equitable access to health care and services;

PP3 Reaffirming resolution WHA62.12 (2009) on primary health care, including health system strengthening, which requested the Director-General to prepare implementation plans for four broad policy directions, including putting people at the centre of service delivery **and also reaffirming the need to continue to prioritize progress on the implementation plans on the other three broad policy directions included in resolution WHA62.12 (2009): (1) dealing with inequalities by moving towards universal coverage; (2) multisectoral action and health in all policies; and (3) inclusive leadership and effective governors for health;**

¹ Transmitted to the Health Assembly in the Committee's fourth report and adopted as resolution WHA69.23.

PP4 Recalling resolution WHA63.16 (2010) on the WHO Global Code of Practice on the International Recruitment of Health Personnel and its recognition that an adequate and accessible health workforce is fundamental to an integrated and effective health system and for the provision of health services;

PP5 Recalling also resolution WHA64.7 (2011) on strengthening nursing and midwifery which emphasize the implementation of strategies for enhancement of interprofessional education and collaborative practice as part of people-centred care, and WHA66.23 (2013) on transforming health workforce education in support of universal health coverage;

PP6 Reaffirming resolution WHA60.27 (2007) on strengthening health information systems, which acknowledged that sound information is critical in framing evidence-based health policy and making decisions, and fundamental for monitoring progress towards internationally agreed health-related development goals;

PP7 Recalling resolutions WHA67.20 (2014) on regulatory system strengthening for medical products, WHA67.21 (2014) on access to biotherapeutic products, including similar biotherapeutic products, and ensuring their quality, safety and efficacy, WHA67.22 (2014) on access to essential medicines, ~~and~~ WHA67.23 (2014) on health intervention and technology assessment in support of universal health coverage **and WHA67.18 (2014) on traditional medicine,**

(OP1) ADOPTS the framework on integrated, people-centred health services;

(OP2) URGES Member States:

(1) to implement, as appropriate, the framework on integrated, people-centred health services at regional and country level, in accordance with national contexts and priorities;

~~(1)~~**(2) to implement proposed policy options and interventions for Member States in the framework on integrated, people-centred health services in accordance with nationally set priorities towards achieving and sustaining universal health coverage, including with regard to primary health care as part of health system strengthening;**

~~(2)~~**(3) to make health care systems more responsive to people's needs, while recognizing their rights and responsibilities with regard to their own health, and engage stakeholders in policy development and implementation;**

~~(3)~~**(4) to promote coordination of health services within the health sector and intersectoral collaboration in order to address the broader social determinants of health and to ensure a holistic approach to services, including health promotion, disease prevention, diagnosis, treatment, disease-management, rehabilitation and palliative care services;**

(5) to integrate where appropriate traditional and complementary medicine and modern health systems, based on national context and knowledge-based policies, while assuring the safety, quality and effectiveness of health services and taking into account a holistic approach to health;

(OP3) INVITES international, regional and national partners to take note of the framework on integrated, people-centred health services;

(OP4) REQUESTS the Director-General:

- (1) to provide technical support and guidance to Member States for the implementation, national adaptation and operationalization of the framework on integrated, people-centred health services, **paying special attention to primary health services as part of health system strengthening;**
- (2) to ensure that all relevant parts of the Organization, at headquarters, regional and country levels, are aligned, actively engaged and coordinated in promoting and implementing the framework on integrated, people-centred health services;
- (3) to perform research and development on indicators to trace global progress on integrated people-centred health services;
- (4) to report on progress **on the implementation of** ~~made in implementing~~ the framework on integrated people-centred health services to the Seventy-first and Seventy-third World Health Assemblies and at regular intervals thereafter.

The financial and administrative implications for the Secretariat of adoption of the draft resolution were the same as for resolution EB138.R2 adopted by the Board.

The representative of LIBERIA read out the proposed amendment to operative paragraph 2(5), which read as follows: “to integrate where appropriate traditional and complementary medicine and modern health systems, based on national context and knowledge-based policies, while assuring the safety, quality and effectiveness of health services and taking into account a holistic approach to health”.

The representative of KENYA said that a system was needed for monitoring the implementation of national policies on integrated people-centred health services at all levels of the health system. Given that the implementation of those services was part of primary health care and a strengthened health system, his Government supported the inclusion of a reference within the draft resolution and framework to the use of primary health care in the implementation of the integrated people-centred health services within a strengthened health system. He asked the Secretariat to provide countries with the support necessary to ensure that the framework was fully adapted at country level.

The representative of IRAQ said that primary health care was the best approach for adopting people-centred health services. Family health evidence-based practices should be the cornerstone of the model. Community needs should be the main parameter in the presentation of primary health care. Health promotion activities needed to be invigorated and priority given to people in crisis situations, vulnerable populations and high-risk groups.

The representative of CANADA accepted the new text of the draft resolution.

The draft resolution, as amended, was approved.¹

¹ Transmitted to the Health Assembly in the Committee’s fourth report and adopted as resolution WHA69.24.

3. **PROGRESS REPORTS:** Item 17 of the agenda (document A69/43) [transferred from Committee A]¹

Communicable diseases

- A. **Eradication of dracunculiasis (resolution WHA64.16)**

Noncommunicable diseases

- B. **Sustaining the elimination of iodine deficiency disorders (resolution WHA60.21)**

Promoting health through the life course

- C. **Strengthening of palliative care as a component of comprehensive care throughout the life course (resolution WHA67.19)**
D. **Contributing to social and economic development: sustainable action across sectors to improve health and health equity [follow-up of the 8th Global Conference on Health Promotion] (resolution WHA67.12)**
E. **Reproductive health: strategy to accelerate progress towards the attainment of international development goals and targets (resolution WHA57.12)**

Health systems

- F. **Health intervention and technology assessment in support of universal health coverage (resolution WHA67.23)**
G. **Access to essential medicines (resolution WHA67.22)**
H. **Access to biotherapeutic products, including similar biotherapeutic products, and ensuring their quality, safety and efficacy (resolution WHA67.21)**
I. **WHO strategy on research for health (resolution WHA63.21)**

Corporate services/enabling functions

- J. **Multilingualism: implementation of action plan (resolution WHA61.12)**

The representative of SWEDEN, speaking also on behalf of Denmark, Estonia, Finland, Iceland, Latvia, Lithuania and Norway, called for progress reports to contain clear information on their link to the results chain in the programme budget and explicit statements about their contribution towards key outcomes.

Regarding progress report C, he welcomed the policies adopted and looked forward to the development of new tools for palliative care for children. The Secretariat should also continue its work towards the introduction of palliative care monitoring mechanisms and its joint efforts with UNODC to draft legislation on the availability and accessibility of controlled medicines. Concerning progress report D, he welcomed the measures taken to strengthen the Secretariat's capacities to provide guidance and technical assistance for sustainable, multisectoral actions aimed at improving health and health equity; such efforts should continue. He asked when the casebook on country action (paragraph 28) would be published. Regarding progress report E, he expressed concern at the uneven progress and

¹ See the summary record of the General Committee, first meeting, section 2.

inequalities, for example, in access to contraception and safe abortion services. Urgent action was required to tackle gender-based and domestic violence against women and implement the WHO global plan of action to strengthen the role of the health systems to address interpersonal violence, in particular against women and girls, and against children, adopted in resolution WHA69.5. Sexual and reproductive health rights were central to the achievement of the 2030 Agenda for Sustainable Development.

The representative of THAILAND expressed great regret at the decision to consider all progress reports under one agenda item; the limited time for discussion of implementation of resolutions contrasted with the effort put into adopting them. In regard to progress report F, he welcomed the steps taken to strengthen the capacities of countries with limited resources for health intervention and technology assessment and the collaboration with other agencies. Given the large variations in progress made by countries reported in the 2015 Global Survey on Global Health Technology Assessment by National Authorities, the Secretariat should support Member States in establishing their own cost-effectiveness thresholds and devising normative guidelines to assess the attendant social and ethical impacts. Concerning progress report I, he urged the Secretariat to monitor closely the implementation of the WHO strategy on research for health. In respect of progress report A, he commended the impressive work towards the eradication of dracunculiasis.

Dr Asadi-Lari took the Chair.

The representative of MALI, speaking on behalf of the Member States of the African Region on progress report A, on the eradication of dracunculiasis, noted with concern that the new cases of human and canine infections had been reported by Chad in 2106. The report referred to the work undertaken with partners, but failed to detail the efforts made by Member States; that imbalance should be rectified. Member States in the Region remained concerned that cases of canine infections were noted in some of the eight countries yet to be certified as free of dracunculiasis. He welcomed the steps taken by the Secretariat to support the eradication of canine infections in Chad and efforts to prevent cross-border transmission. Further attention should, however, be paid to preventing transmission in refugee camps and countries in the midst of conflict; the Secretariat must find innovative ways to fill the US\$ 214 million funding gap for the period 2016–2020.

The representative of JAPAN welcomed the measures adopted by the Secretariat to facilitate access to essential medicines (progress report G), but called for pharmacovigilance and more appropriate use of medical products in order to prevent adverse medical effects. Scientific data on safety and efficacy must therefore be disseminated in a timely manner to all health-care providers to support that task. His Government would continue to assist the Secretariat's efforts in that area by sharing its expertise, best practices and lessons learnt.

The representative of the UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND welcomed the progress made towards the eradication of dracunculiasis (progress report A) and supported the increased research focus on interrupting canine transmission of the disease. The Secretariat should facilitate cross-border dialogue and, where appropriate, use other surveillance systems to help to identify and eradicate cases of dracunculiasis. Turning to progress report H, he noted the growing number of poor quality and fake medicines entering the market and urged Member States to remain vigilant. The Secretariat must strive to change the perception that the process of WHO pre-qualification for medicines, vaccines and diagnostic tests was time-consuming and expensive, particularly in the case of medications that had already been approved by a recognized international agency. Some form of agreement on an accelerated procedure for pre-qualification should therefore be established at the earliest opportunity.

The representative of SRI LANKA acknowledged the work on sustaining the elimination of iodine deficiency disorders (progress report B); decisive action by his Government had resulted in very low rates. Regarding progress report D, he welcomed the Secretariat's steps to promote sustainable action across sectors and raise awareness of the need to harmonize policy decisions in different sectors in order to improve health and health equity. Sri Lanka had recently adopted various policy measures to improve multisectoral action on health, including the establishment of a national health development network and council. However, the country continued to face challenges, such as demographic and epidemiological transitions and unhealthy lifestyles. In that connection, he thanked the Secretariat for its support during the mission of the United Nations Inter-Agency Task Force on the Prevention and Control of Non-Communicable Diseases to Sri Lanka in 2015 and urged it to provide the country with additional tools and guidelines to monitor future progress.

The representative of KENYA said that his country remained committed to dracunculiasis eradication and had adopted numerous measures to halt transmission of the disease. The last known indigenous case in Kenya had been reported in 1994, with the last imported case in 2005. Pre-certification activities had started in 2006 and it was hoped that the country would be certified free of dracunculiasis by the end of 2016.

The representative of the REPUBLIC OF KOREA expressed appreciation for the Secretariat's efforts to strengthen access to essential medicines and biotherapeutic products. Her Government had taken various steps to detect shortages and stock-outs of essential medications, including the establishment of a medicine-shortage management system, and remained committed to cooperating with other Member States to harmonize regulations of biotherapeutic products.

The representative of CHINA, referring to progress report G on access to essential medicines, said that her Government had established an indicator mechanism to monitor the implementation of resolution WHA67.22 at the national level. In respect of progress report J, she stressed the importance of language diversity to the work of WHO and called on the Secretariat to provide further information on the budget allocated for the recruitment of translation and language service staff.

The representative of SENEGAL welcomed the considerable drop in the number of cases of dracunculiasis, but called for additional steps to raise awareness of the disease among the general public in disease-endemic areas and ensure universal access to potable water. In order to eradicate dracunculiasis by 2020, greater efforts must be made to take account of the threats and constraints facing countries affected by the disease and provide those States with the appropriate human, material and financial support, where necessary.

The representative of the UNITED STATES OF AMERICA urged the Secretariat to continue promoting the detection and prevention of dracunculiasis, particularly in Chad where the number of cases of canine infections remained high. Regarding palliative care, he welcomed the progress made towards the implementation of resolution WHA67.19 and efforts made to integrate palliative care into all aspects of medical treatment. Further collaboration between WHO and the International Narcotics Control Board, the United Nations Commission on Narcotic Drugs and the Economic and Social Council would be required to facilitate appropriate access to controlled narcotics required for the relief of pain and suffering of palliative care patients. As to reproductive health, he supported the work undertaken at an international level to help Member States to strengthen and increase access to their respective national reproductive health services, particularly in the light of the recent Zika virus outbreak. In respect of research on health, he called for WHO to prioritize the translation of research into practical actions, establish the necessary research standards, manage research in areas of unmet needs and promote essential research in low- and middle-income countries.

The representative of MALAWI, speaking on behalf of the Member States of the African Region on progress report E, welcomed the steps taken to accelerate progress towards the attainment of Sustainable Development Goal 3, target 3.7, on universal access to reproductive health services. However, progress remained uneven across countries and regions. For example, reproductive health continued to represent a major public health challenge in the African Region, with sub-Saharan Africa accounting for 66% of the world's maternal deaths. He therefore urged the Secretariat and WHO's development partners to continue their efforts to overcome the logistic, economic, cultural and political barriers to sexual and reproductive health.

The representative of IRAQ said that a multisectoral approach was vital in combating iodine deficiency and other micronutrient deficiencies. In regard to improving health and health equity, special attention should be paid to combating social determinants of health as part of efforts to ensure sustainable action across sectors to improve health and health equity. Concerning palliative care, particular emphasis should be placed on family health as a component of providing comprehensive care throughout the life-course. In respect of reproductive health care, health services should consider the issue of gender, equity and equality more effectively and take into account technological advances in health care when moving towards universal health coverage. Access to, and the effective use of, essential medicines should form the cornerstone of any universal health care strategy. Importance should also be placed on the role of research in health.

The representative of CHAD said that, pending the results of operational research, steps had been taken to quarantine dogs in the light of the recent canine infections of dracunculiasis in the country. His Government remained fully committed to the monitoring, prevention and eradication of dracunculiasis and called for further multisectoral action to combat the disease.

The representative of INDONESIA, referring to reports G and H, said that her access to medicines and vaccines was a priority in Indonesia that was reflected in a national medicine policy that was implemented according to good governance principles. Decisions had been taken about which biotherapeutic products could be used within the national health insurance scheme, and a national regulatory framework for biopharmaceuticals had been established. He urged WHO to continue its work in ensuring the accessibility of global essential medicines and vaccines for the Expanded Programme on Immunization and its trilateral collaboration with WTO and WIPO, through which it could provide further information to Member States on how policies on trade, health and intellectual property interacted with each other.

The representative of TIMOR-LESTE, referring to progress report G, said that, in his country, expenditure on pharmaceuticals was already the largest health care cost, at a time when adequate funding remained a challenge. The Government had established a body to procure and supply medicines and a national medicines regulatory authority. Despite progress in improving access to medicines, health ministry still required significant technical and expert support from the Regional Office for South-East Asia and the WHO country office.

The representative of MALDIVES, referring to progress report B, welcomed the commissioning of an updated review on the effects of iodine supplementation on women during the preconception, pregnancy and postpartum periods. Despite progress, continued efforts were needed to eliminate iodine deficiency disorders, especially among vulnerable groups. He stressed the need to establish a population-level baseline for dietary salt intake, educate the public, and promote behavioural change both to reduce salt intake and to use iodized salt. Useful approaches included reducing salt intake in processed foods, and establishing national committees to ensure that dietary salt reduction and salt iodization policies were compatible.

The representative of CAMEROON, speaking on behalf of the Member States of the African Region on access to essential medicines, welcomed progress report G but said that it should have dealt with the challenge of implementing a plan to develop the pharmaceutical industry in Africa. Efforts to secure access to high-quality essential medicines must continue.

The representative of TOGO, speaking on behalf of the Member States of the African Region on progress report F, acknowledged WHO's contribution to improving access to prevention and treatment services by bringing together mobile telephone operators and the health and development community, and urged continuation of that work. Countries needed information about the situation of e-health in the Region in order to take evidence-based decisions. Major challenges that remained in the Region included ensuring that universal health coverage applied to the informal sector and establishing regional- and national-level health-care databases. Levels of technical support and financing varied greatly throughout the Region. Member States in the Region would benefit if partners took a more harmonized approach under the leadership of WHO. Universal health coverage was an important part of achieving Sustainable Development Goal 3.

The representative of MONACO, referring to progress report J, said that more should be done to ensure a better linguistic balance in the Secretariat. Less than a third of the material available in English on the WHO website was also available in French, with an even smaller proportion available in the other official languages. It was particularly regrettable that tools for the prevention of noncommunicable diseases were almost exclusively in English, despite the stated intention to make those tools the primary reference for national focal points on such diseases. Translating documents, particularly technical ones, as soon as possible into all the official languages would contribute to sustainable development on health-related matters.

The observer of CHINESE TAIPEI, referring to progress report C, said that provisions relating to palliative care were included in the health insurance system of Chinese Taipei. Legislation had been enacted in 2016 to safeguard palliative care provision and patient autonomy.

The observer of the INTERNATIONAL FEDERATION OF RED CROSS AND RED CRESCENT SOCIETIES, referring to progress report C, deprecated the lack of access globally and in particular in Africa to palliative care. Her organization ran community- and home-based palliative care programmes, but much more was needed.

The representative of the UNION FOR INTERNATIONAL CANCER CONTROL, speaking at the invitation of the CHAIRMAN and referring to progress report C, welcomed the efforts to create new guidance, tools and training. Under a joint global programme UNODC, WHO and her organization on improving access to controlled medicines for pain and palliative care, work to implement the provisions of resolution WHA67.19 had begun in Ghana, Timor-Leste and the Democratic Republic of Congo. She called for other countries besides existing donors to provide funds to that end. Palliative care should be included as part of national plans for universal health coverage. All countries should adopt national strategies for palliative care that include the training of health professionals and access to essential palliative care medicines. The next progress report should be submitted to the Seventy-first World Health Assembly in 2018.

The representative of the WORLDWIDE HOSPICE PALLIATIVE CARE ALLIANCE, speaking at the invitation of the CHAIRMAN and referring to progress report C, said that, despite the provisions of resolution WHA67.19, most governments did not include palliative care in health care policies and legislation. Although progress had been made since that resolution passed, there was still a lack of political will and public financing, and much work remained to be done on educating the health workforce. To make further progress, donor countries should make funds available for full

implementation of the resolution. All countries should adopt national strategies on palliative care as part of universal health coverage. The next progress report on the subject should be presented to the Seventy-first World Health Assembly.

The representative of the INTERNATIONAL FEDERATION FOR MEDICAL AND BIOLOGICAL ENGINEERING, speaking at the invitation of the CHAIRMAN and on behalf of the International Federation of Hospital Engineering, referred to progress report F. Health technology assessment objectives could be successfully achieved if government policies were based on the knowledge of experts such as biomedical engineers and medical physicists.

The representative of HEALTH TECHNOLOGY ASSESSMENT INTERNATIONAL, speaking at the invitation of the CHAIRMAN and referring to progress report F, said that success of health technology assessment depended on strategies that were based on the expertise of multidisciplinary teams and that took account of the views of stakeholders. Health technology assessment agencies should be established to inform and harmonize the processes of market access, reimbursement, provision and prescription of health technologies.

The representative of the GLOBAL HEALTH COUNCIL, speaking at the invitation of the CHAIRMAN and referring to progress report G, said that there was rarely a single reason behind the lack of access to innovative and life-saving technologies, especially those relevant to poverty-related and neglected diseases. The issue should be viewed in parallel with factors that could facilitate greater access, such as enabling regulatory and policy environments, well-functioning markets, engagement of local communities and affordable pricing.

The ASSISTANT DIRECTOR-GENERAL (HIV/AIDS, Tuberculosis, Malaria and Neglected Tropical Diseases), referring to comments on progress report A, reaffirmed the good progress towards eradicating dracunculiasis, with only two confirmed cases reported between January and April 2016, compared to four cases for the same period during the previous year. The target of eradicating transmission by the end of 2015 had not been met, but it was within reach, as no case had been reported in Ethiopia, Mali or South Sudan in the first four months of 2016. Following the finding of *Dracunculus medinensis* infection in dogs in African countries, appropriate research was being conducted. The Secretariat continued to be committed to the implementation of resolution WHA64.16.

Referring to progress report E, the ASSISTANT DIRECTOR-GENERAL (Family, Women's and Children's Health) said that comments from Member States were consistent with those in the discussions of the resolutions adopted during the current Health Assembly pertaining to women's, children's and adolescents' health; the global health sector strategy on sexually transmitted infections; and the plan of action to strengthen the role of the health system to address interpersonal violence, in particular against women and girls, and against children.

Regarding progress report B, the DIRECTOR (Nutrition for Health and Development) reaffirmed the progress in reducing iodine deficiency throughout the world but he recalled the caveat in the report about the limitations of the data; , it was not possible to assess the iodine status of other sections of the population than school-aged children. The preferred strategy for controlling iodine deficiency disorders remained universal salt iodization. To ensure that that strategy was compatible with strategies to reduce sodium intake, adequate monitoring of sodium and iodine consumption at country level was required. Iodine concentrations in salt should be adjusted by individual countries according to local data on salt intake.

The representative of INDIA, referring to progress report H, recalled that in resolution WHA69.21 (2014) the Health Assembly had requested the Director-General to convene the Expert Committee on Biological Standardization in order to update the 2009 guidelines on evaluation of biotherapeutic products, taking into account technological advances and considering national regulatory needs and capacities, and to report on the update to the Executive Board. He sought clarification, as there was no reference to that request in the progress report.

The DIRECTOR (Essential Medicines and Health Products) said that a new document had been developed for consideration by the Expert Committee on Biological Standardization later in 2016.

The Committee noted the progress reports.

Dr Phusit Prakongsai resumed the Chair.

4. HEALTH SYSTEMS (resumed)

Addressing the global shortages of medicines, and the safety and accessibility of children's medication: Item 16.4 of the agenda (document A69/42) (continued from the fifth meeting)

The CHAIRMAN introduced the following revised version of draft resolution introduced in the fifth meeting:

The Sixty-ninth World Health Assembly,

PP1 Having considered the report on global shortages of medicines and the safety and accessibility of children's medicines;

PP2 Recommends to the Sixty-ninth World Health Assembly the adoption of the following resolution:

PP3 Recalling the World Health Assembly resolutions WHA67.22 on access to essential medicines, WHA60.20 on better medicines for children, WHA67.20 on Regulatory system strengthening, WHA67.21 access to biotherapeutic products, including similar biotherapeutic products, and ensuring their quality, safety and efficacy, WHA61.21 on global strategy and plan of action on public health, innovation and intellectual property, WHA65.19 on substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products, WHA65.17 **on the global vaccines action plan**, WHA68.7 **on the global action plan on antimicrobial resistance**, and WHA67.25 on antimicrobial resistance, ~~as well as resolutions WHA64.9 on sustainable health financing structures and universal coverage, and also, recalling the Resolution A/HRC/RES/12/24 from the Human Rights Council on access to medicines;~~

PP4 Noting with particular concern that for millions of people, the right to the enjoyment of the highest attainable standard of physical and mental health, including access to medicines, remains a distant goal, that especially for children and those living in poverty, the likelihood of achieving this goal is becoming increasingly remote [reference (A67/81)];

PP5 Recognizing that the continuous supply of quality, safe, effective medicines is one of the building blocks of every well-functioning health system, which requires a reliable supply

chain: and noting reports of global medicines shortages¹ and stockouts² that also infringe on patients right to **the enjoyment of the highest attainable standard of health**; undermine **the attainment of** public health prevention and treatment goals; and threaten governments' ability to scale up services towards achieving universal health coverage;

PP6 Recalling the Agenda 2030 for Sustainable Development, which includes, inter alia, the commitment to achieve universal health coverage, financial risk protection, access to primary health-care services and access to safe, effective, quality and affordable medicines and vaccines for all by 2030;

PP7 Acknowledging that Agenda 2030, supports the research and development of vaccines and medicines for the communicable and noncommunicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, (A/RES/70/1 target 3.b);

PP8 Noting that the challenges related to medicine shortages and stockouts are widespread, affecting medicine manufacturers, procurement agencies and countries at every economic level, and they appear to be escalating in severity, and the factors that affect the non-availability of medicines **include problems with the manufacture of the medicine (including inability to source the active pharmaceutical ingredient), regulatory processes, challenges can be categorised into three areas: problems with the manufacture of the medicine, challenges with the procurement of medicines, selective marketing strategies** and problems with the supply chain which result in medicines being unavailable when patients access care; therefore interventions to address weaknesses in all ~~three~~ areas are critical to ensure that medicines are available at the point of care;

PP9 Aware that ~~the~~ shortages of medicines ~~is~~ **are** a global problem; **and** the causes and implications ~~of which~~ vary from one country to another and that there is insufficient information to determine the magnitude and specific characteristics of the problem;

PP10 Noting also that the implications of these shortages in the case of infectious diseases goes beyond the individual patient and impacts public health as a shortage/stockout of antibiotics, antituberculosis drugs, antiretrovirals, **antimalarials** or vaccines may result in the spread of infection beyond the individual patient;

PP11 Considering that there is a need for improved international collaboration on the management of shortages of medicines given that medicines shortages may increase risks of SSFFC medical products entering the supply chain;

PP12 Concerned about the challenges that shortages of medicines pose to Member States, in relation to **progress towards ensuring** universal access to healthcare, ~~research and development~~, rational use of medicines, and that the financial sustainability of health systems can be affected by technological pressures **arising from new** ~~caused by~~ high-cost medicines; **and noting that investment in research and development for new products may help develop alternative treatments, and** aware that urgent patient-centred action is needed by the international community, Member States and relevant actors in health systems,

¹ A medicine shortage refers to a situation where there is insufficient quantity of a particular medicine relative to usual need at any point/s in the supply chain (from manufacturer to facility where patient receives treatment). Stockouts that occur at manufacturer or wholesaler level are serious since they are more likely to lead to many patients receiving no treatment if not urgently addressed.

² A medicine stockout refers to a situation where there is no stock of a particular medicine at any point/s in the supply chain (from manufacturer to facility where patient receives treatment). Stockouts can also occur at any point in the supply chain however those stockouts that occur at manufacturer or wholesaler level are serious since they are more likely over time to lead to many patients receiving no treatment.

1. URGES Member States;¹
(OP1) to develop strategies that may be used to forecast, avert or reduce shortages/~~stockouts~~, adapted to national priorities and contexts, including:
 - (1) to implement effective notification systems that allow remedial intervention to ~~avoid circumvent~~ **avoid** medicine shortages;
 - (2) to ensure that best practices for medicines procurement, distribution and contract management processes are in place to mitigate the risk of shortages;
 - (3) to develop **and/or strengthen** systems that are capable of monitoring medicine supply, demand, availability and alerting procurement departments to possible medicine availability problems;
 - (4) to strengthen institutional capacity to ensure sound financial management of procurement systems, to prevent funding shortfalls for medicines;
 - (5) to promote, review and strengthen programmes, ~~public~~ policies, **and develop responsive** regulatory frameworks, **and systems and authorities that provide timely and efficient registration of new medicines, new age-appropriate formulations, generics, and post-approval supplements, thereby promoting access to medicines and furthermore** to align policy frameworks to be responsive to medicines that are at risk of being unavailable at the point of care; ~~through the appropriate regulatory strategies;~~
 - (6) ~~to urge Member States, when confronted with shortages, to prioritize the health needs of to focus on health rights of everyone especially~~ **to prioritize the health needs of** vulnerable groups and to ensure these groups have timely access to medicines in shortage;
 - (7) to ~~seek~~ **consider measures** to make medicines more affordable through the implementation of various strategies to manage prices such as **addressing excessive supply chain mark-ups, elimination of taxes and import tariffs**, price negotiations/regulation, voluntary/compulsory licences, **consistent with the Global Strategy and Plan of Action for Public Health Innovation and Intellectual Property**, in order to decrease prices of medicines in shortage;
 - (8) **to support reliable and sustainable supply of quality, off-patent medicines through adequate pricing and through effective enforcement of drug regulatory and supply chain security standards.**
(OP32) to advance gradually regional and international integration of national notification systems including but not limited to sharing of best practices, training for human capacity building **through regional and subregional structures** where necessary ~~with a view of establishing an international notification system for essential medicine shortages and stockouts;~~
(OP23) calls upon manufacturers (active pharmaceutical ingredient and formulation), wholesalers, global, and regional procurement agencies and other relevant stakeholders to contribute to global efforts to address the challenges of medicines shortages, including through participation in notification systems;
2. REQUESTS the Director-General:
 - (1) to support Member States in addressing the global challenges of medicines shortages by developing a global medicine shortage notification system; which **would** ~~may~~ include information to better detect and understand the causes of medicines shortages;

¹ And, regional economic integration organizations, as appropriate.

- (2) to propose global best practices for the notification ~~and management~~ of shortages, (including data standards, database management), ~~and management of shortages and regulatory/legislative strategies~~ **(including measures to address mark-ups, taxes, tariffs, voluntary licenses and the full use of TRIPS flexibilities in accordance with the WHO Global Strategy and Plan of Action on Public Health Innovation and Intellectual Property) to avoid and to minimize the impact of shortages where appropriate;**
- (3) to develop an assessment of the magnitude and nature of the problem of shortages of medicines, including **the relative contributions of** factors such as: market supply system failures, **obstacles to access and availability, and pressures,** manufacturing and distribution challenges, and recommended solutions, to address the most important factors identified;
- (4) to identify medicines that are at particular risk of being in short supply and develop strategies to **facilitate ensure** their availability at an affordable price in collaboration with global partners;
- (5) to prioritize, the development of new or updated procurement and supply chain guidelines **for health products**, to support the effective functioning of health systems and minimize the risk of shortages;
- (6) to work with global partners to strengthen systems for supply chain management **for health products;**
- (7) to support Member States in the implementation of surveillance systems that will monitor and report supply and demand of medicines, using standardized formats throughout the supply chain, to predict needs and shortages, and that also reduce the risk of SSFFC **medical products** entering the supply chain;
- ~~(8) to continue to support the Member State mechanism on SSFFC medical products;~~
- (98) to report on progress and outcome of the implementation of this resolution to the Seventy-first session of the World Health Assembly.**

The CHAIRMAN announced that a further revision of the draft resolution on addressing the global problem of medicines shortages had just been distributed to the Committee.

The representative of SOUTH AFRICA explained that the informal working group had further revised the above text. The revision read:

The Sixty-ninth World Health Assembly,

PP1 Having considered the report on global shortages of medicines and the safety and accessibility of children's medicines;

PP2 Recommends to the Sixty-ninth World Health Assembly the adoption of the following resolution:

PP3 Recalling the World Health Assembly resolutions WHA67.22 on access to essential medicines, WHA60.20 on better medicines for children, WHA67.20 on Regulatory system strengthening, WHA67.21 access to biotherapeutic products, including similar biotherapeutic products, and ensuring their quality, safety and efficacy, WHA61.21 on global strategy and plan of action on public health, innovation and intellectual property, WHA65.19 on substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products, WHA65.17 on the global vaccines action plan, WHA68.7 on the global action plan on antimicrobial resistance, ~~and~~ WHA67.25 on antimicrobial resistance, WHA64.9 on sustainable health financing structures and universal coverage, and Resolution A/HRC/RES/12/24 from the Human Rights Council on access to medicines;

PP4 Noting with particular concern that for millions of people, the right to the enjoyment of the highest attainable standard of physical and mental health, including access to

medicines, remains a distant goal, that especially for children and those living in poverty, the likelihood of achieving this goal is becoming increasingly remote;

PP5 Recognizing that the continuous supply of quality, safe, effective and affordable medicines is one of the building blocks of every well-functioning health system, which requires a reliable supply chain; and noting reports of global medicines shortages and stockouts that also infringe upon the right to the enjoyment of the highest attainable standard of health as envisaged by the WHO Constitution; undermine the attainment of public health prevention and treatment goals; and threaten governments' ability to scale up services towards achieving universal health coverage as well as their ability to adequately respond to outbreaks and health emergencies;

PP6 Recalling Goal 3, Target 8 of the Agenda 2030 for Sustainable Development, which includes the commitment to achieve universal health coverage, financial risk protection, access to quality essential health care services and access to safe, effective, quality and affordable medicines and vaccines for all;

PP7 Acknowledging that Agenda 2030, supports the research and development of vaccines and medicines for the communicable and noncommunicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the agreement on Trade-Related Aspects on Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all (A/RES/70/1 target 3.b);

PP8 Noting that the challenges related to medicines shortages affect access to medicines, are complex and widespread, increasing in frequency, and affect citizens, procurement agencies and countries at every level of development and that there is insufficient information to determine the magnitude and specific characteristics of the problem;

PP9 Noting also that the implications of these shortages in the case of infectious diseases impacts public health as a shortage/stockout of antibiotics, antituberculosis drugs, antiretrovirals, antimalarials and vaccines may result in the spread of infection beyond the individual patient;

PP10 Considering that there is a need for improved international collaboration on the management of shortages of medicines;

1. URGES Member States;¹

(OP1) to develop strategies that may be used to forecast, avert or reduce shortages/stockouts, in accordance with national priorities and contexts, including:

- (a) to implement effective notification systems that allow remedial measures to avoid medicine shortages;
- (b) to ensure that best practices for medicines procurement, distribution and contract management processes are in place to mitigate the risk of shortages;
- (c) to develop and/or strengthen systems that are capable of monitoring medicine supply, demand, availability and alerting procurement departments to possible medicine availability problems;
- (d) to strengthen institutional capacity to ensure sound financial management of procurement systems, to prevent funding shortfalls for medicines;
- (e) to prioritize, in the case of shortages, the health needs of the most affected groups and to ensure these groups have timely access to medicines;

¹ And, regional economic integration organizations, as appropriate.

(OP1.2) to advance gradually regional and international cooperation in support of national notification systems including but not limited to sharing of best practices, training for human capacity building through regional and subregional structures where necessary;

(OP2) CALLS upon manufacturers, wholesalers, global, and regional procurement agencies and other relevant stakeholders to contribute to global efforts to address the challenges of medicines shortages, including through participation in notification systems;

OP3 2. REQUESTS the Director-General:

- (1) to develop technical definitions as needed for medicines shortages and stock outs, taking due account of access and affordability in consultation with Member State experts in keeping with WHO established processes and to submit a report on the definitions to the Seventieth World Health Assembly through the Executive Board;
- (2) to develop an assessment of the magnitude and nature of the problem of shortages of medicines;
- (3) to support Member States in addressing the global challenges of medicines shortages by developing a global medicine shortage notification system; which would include information to better detect and understand the causes of medicines shortages;
- (4) to report on progress and outcome of the implementation of this resolution to the Seventy-first session of the World Health Assembly.

The representative of the UNITED STATES OF AMERICA welcomed the draft resolution. It was important to distinguish the issue of shortages of medicines from the broader challenges of access, pertaining to affordability and general availability. Shortages most frequently affected products that were old, off-patent or difficult to formulate and had a tightly-defined shelf life, few or one sole manufacturer, for example in the case of sterile injectables. There was poor availability and quality of data on actual demand; inadequate management practices in procurement and the supply chain, combined with large tender contracts that did not sufficiently define quality standards but whose sole emphasis was on obtaining the lowest prices; and inadequate incentives for manufacturers. The revised text provided an excellent basis for focused WHO action, and he was pleased to support it.

The representative of COLOMBIA supported the revised draft resolution. He proposed amending the ninth preambular paragraph to include a reference to antiparasitic medicines.

The representative of THAILAND endorsed the revised draft resolution and wished to be included on the list of cosponsors.

The representative of IRAQ proposed a series of further amendments to the text. Throughout the document, he proposed adding “and vaccines” to all mentions of medicines, with the title including the phrase “shortages of medicines and vaccines”. In the ninth preambular paragraph, he proposed adding the phrase “, medicines to treat neglected tropical diseases” after the word “antimalarials”. He proposed adding, in the tenth preambular paragraph, the words “and responsibility” after “collaboration” as that was a delicate issue. In the first operative paragraph, he proposed amending subparagraph (a) by replacing “remedial” by “pharmaceutical”; amending subparagraph (b) by the addition of “and vaccines” after “medicines”; amending subparagraph (c) to read “to develop and/or strengthen systems that are capable of monitoring and evaluating medicines and vaccines supply, demand and availability and alerting procurement departments to possible medicine and vaccine availability and utilization problems”; amending subparagraph (d) to read “to strengthen personnel with institutional capacity-building to ensure sound financial management of procurement and management systems, to prevent funding shortfalls for medicines and vaccines”; and amending the

second half of subparagraph (e) to read "...the health needs of vulnerable groups ensuring that these groups have timely access to medicines and vaccines". In operative paragraph 2 he proposed amending the text to read "to upgrade gradually regional and international cooperation in support of national notification systems including (but not limited to) sharing of best practices and buys, training for human capacity building through regional and subregional structures where necessary". In the second operative paragraph, he proposed adding the words "and vaccines" after "medicines". He proposed amending the first request to the Director-General to read "to develop technical definitions as needed for medicines and vaccines shortages and stock-outs ...", and amending request (3) to read "to support Member States in addressing the global challenges of medicines and vaccine shortages by developing a global medicine shortage notification system; which would include effective information systems to better detect and understand the causes of medicines shortages, to effectively support their collective work plans".

The representative of ZIMBABWE expressed support for the revised draft resolution. His Government was willing to cosponsor the resolution in its current form.

The representative of SOUTH AFRICA said that it would be difficult to make changes to the text at such a late stage, given the time constraints. However, he understood that the issue of vaccines was relevant, and that the intent of the draft resolution was to cover both medicines and vaccines. He agreed that the title could be amended to "medical products". It would also be possible to add a reference in the ninth preambular paragraph to "antiparasitics" and "medicines for neglected tropical diseases", as those amendments were not substantive. Other proposed amendments would require further consultation.

The meeting was suspended at 17:10 and resumed at 17:25.

The representative of SOUTH AFRICA said that the informal working group had agreed that the title of the resolution would be amended to read "Addressing the global shortages of medicines and vaccines, and the safety and accessibility of children's medication" and that the text of the ninth preambular paragraph would be amended to read "Noting also that the implication of these shortages in the case of infectious diseases impacts public health as a shortage/stockout of, antibiotics, antituberculosis drugs, antiretrovirals, antimalarials, antiparasitics and medicines for neglected diseases and vaccines may contribute to the spread of infection beyond the individual patient".

The representative of the UNITED STATES OF AMERICA, remarked that the informal working group had agreed that the ninth preambular paragraph should refer to neglected *tropical* diseases. He welcomed the engagement of representatives with the issues at hand, but advised that amendments should preferably be submitted in advance, rather than during the Committee's meeting.

The representative of SOUTH AFRICA confirmed that the text should indeed refer to "neglected tropical diseases".

The draft resolution, as amended, was approved.¹

¹ Transmitted to the Health Assembly in the Committee's fourth report and adopted as resolution WHA69.25.

5. FOURTH REPORT OF COMMITTEE B (document A69/75)

The SECRETARY of Committee B read out the draft fourth report of Committee B.

The report was adopted.

6. CLOSURE OF THE MEETING

After the customary exchange of courtesies, the CHAIRMAN declared the work of Committee B completed.

The meeting rose at 17:35.

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