

Fourth report of Committee B

Committee B held its sixth and seventh meetings on 24 May 2014 under the chairmanship of Dr Ruhakana Rugunda (Uganda) and Dr Mohsen Asadi-Lari (Islamic Republic of Iran).

It was decided to recommend to the Sixty-seventh World Health Assembly the adoption of the attached resolutions and decision relating to the following agenda items:

15. Health systems

15.2 Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination

One decision

15.4 Access to essential medicines

One resolution, as amended

15.6 Regulatory system strengthening

One resolution, as amended, entitled:

- Regulatory system strengthening for medical products,

One resolution, as amended, entitled:

- Access to biotherapeutic products including similar biotherapeutic products and ensuring their quality, safety and efficacy

15.7 Health intervention and technology assessment in support of universal health coverage

One resolution, as amended

15.8 Follow-up of the Recife Political Declaration on Human Resources for Health: renewed commitments towards universal health coverage

One resolution, as amended

16. Preparedness, surveillance and response

16.5 Antimicrobial drug resistance

One resolution, as amended, entitled:

- Antimicrobial resistance

Agenda item 15.2**Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination**

The Sixty-seventh World Health Assembly, having considered the follow-up of the report of the Consultative Expert Working Group on Research and Development Financing and Coordination,¹

- (1) noted the progress made in implementation of resolution WHA66.22 and decision EB134(5);
- (2) recognized the indicators to measure success in implementing the health research and development demonstration projects, and requested the addition of an analysis of the extent of innovative components being implemented by the projects, including financing, the use of open access models, multisectoral research platforms, and delinkage, among other criteria;
- (3) requested the Director-General to expedite the process of the remaining four projects, in addition to the four already agreed, and to report on progress to the 136th session of the Executive Board;
- (4) noted, without prejudice to future discussions in the context of recommendations of the Consultative Expert Working Group on Research and Development Financing and Coordination and actions on other sustainable mechanisms for financing health research and development, the assessment made by the Secretariat and the possibility of using an existing mechanism to host a pooled fund for voluntary contributions towards research and development for type III and type II diseases and the specific research and development needs of developing countries in relation to type I diseases;
- (5) requested the Director-General to further explore this option with the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR), including the following elements:
 - recognizing that the scope of the diseases should not be limited to type III diseases but should be in line with the GSPA-PHI mandate;
 - recognizing the need for a sustainable financial mechanism for health research and development;
 - recognizing the role of Member States in the governance of the coordination mechanism;
- (6) requested the Director-General to report to the Sixty-eighth World Health Assembly through the 136th session of the Executive Board with reference to this decision.

¹ Documents A67/27, A67/28 and A67/28 Add.1.

Agenda item 15.4

Access to essential medicines

The Sixty-seventh World Health Assembly,

Having considered the report on access to essential medicines;¹

Noting that WHO's definition of an essential medicine² contains the following elements: "Essential medicines are those that satisfy the priority health care needs of the population" and "Essential medicines are selected with due regard to their public health relevance, evidence of efficacy and safety, and comparative cost-effectiveness";

Recalling resolution WHA28.66 on prophylactic and therapeutic substances that relates to the formulation and implementation of medicines policies and pharmaceutical strategies; the Declaration of Alma-Ata in 1978 that recognized the provision of essential medicines as one of the pillars of primary health care, and subsequent resolutions in relation to essential medicines, such as resolution WHA54.11 on the WHO medicines strategy, WHA58.27 on improving the containment of antimicrobial resistance, WHA60.16 on progress in the rational use of medicines, WHA60.20 on better medicines for children, WHA60.29 on health technologies, WHA61.21 on the global strategy and plan of action on public health, innovation and intellectual property, and WHA64.9 on sustainable health financing structures and universal coverage, as well as WHA66.10 in which the Health Assembly endorsed the WHO global action plan for the prevention and control of noncommunicable diseases 2013–2020, and which includes Target (9) on the availability of essential medicines required to treat noncommunicable diseases;

Bearing in mind that the WHO medicines strategy, as set out in the Twelfth General Programme of Work 2014–2019, is based on the principles of evidence-based selection of a limited range of medicines, efficient procurement and distribution systems, affordable prices, and the rational use of medicines in order to promote better management and greater availability of medicines, more cost-effective use of health resources, and higher quality health care;

Considering that the effective implementation of the above principles is of critical importance to improving people's health, progressing towards universal health coverage and achieving the health-related Millennium Development Goals;

Welcoming WHO's regional actions in support of greater access to – and availability, affordability and rational use of – safe, effective and quality-assured essential medicines, including development of the Regional Office for the Western Pacific Regional Framework for Action on Access to Essential Medicines (2011–2016);

¹ Document A67/30.

² WHO Expert Committee on the Selection and Use of Essential Medicines. Geneva: World Health Organization; in press (WHO Technical Report Series, No 985).

Acknowledging the complexity of the medicines supply chain and the challenges that countries encounter in this regard, the importance of good governance for medicines programmes,¹ and the consequences of the high costs of medicines, which are among the factors that make accessing care and treatment unaffordable;

Aware that shortages of essential medicines are a global problem that has an impact on the care of patients, 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;

Realizing the role of evidence-based clinical treatment guidelines to guide cost-effective treatment practices, the need for reliable and unbiased information to support rational prescribing, and the importance of increased health literacy to support patients and consumers to use medicines wisely;

Noting with concern that despite sustained efforts over a number of decades by Member States, the Secretariat and partners, most low-income countries are still facing a multitude of challenges in improving the availability, affordability and rational use of essential medicines;

Noting that the goal of Member States is to increase access to affordable, safe, effective and quality-assured essential medicines, including as appropriate, through the full use of the flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights in line with the Global Strategy and Plan of Action on Public Health Innovation and Intellectual Property;

Noting that support for research and development is important for the sustainable supply of future essential medicines, to address public health needs,

1. URGES Member States:²

(1) to provide adequate resources, as required, for the development and implementation of comprehensive national medicine policies, as appropriate, to strengthen good governance of pharmaceutical systems including regulatory, procurement and distributions systems and to coordinate responses to address the complex and interrelated activities that affect access to essential medicines, in order to improve their availability, affordability, quality and rational use;

(2) to improve national policies for selection of essential medicines which should include medicines critical to their priority public health needs particularly by using transparent, rigorous, evidence-based processes based on the methods of health technology assessment in selecting medicines for inclusion in the national essential medicines lists according to each country's health needs and priorities;

(3) to encourage and support research on health systems regarding the procurement, supply and rational use of essential medicines;

¹ In WHO's assessment instrument for measuring transparency in the public pharmaceutical sector (document WHO/EMP/MAR/2009.4), "good governance" refers to the formulation and implementation of appropriate policies and procedures that ensure the effective, efficient and ethical management of pharmaceutical systems, in particular medicines regulatory systems and medicine supply systems, in a manner that is transparent, accountable, follows the rule of law and minimizes corruption.

² And, where applicable, regional economic integration organizations.

- (4) to promote collaboration and strengthen the exchange of information on best practices in the development, implementation and evaluation of medicine policies and strategies, that enhance access to affordable, safe, effective and quality-assured essential medicines;
- (5) to place greater emphasis on medicines for children and to promote the availability, affordability, quality and safety of essential medicines for children through the development and manufacture of appropriate paediatric formulations and to facilitate market access to these medicines;
- (6) to improve the education and training of health care professionals in order to support the implementation of national policies and strategies in relation to essential medicines, and to develop and implement evidence-based clinical practice guidelines and other interventions for the rational use of essential medicines;
- (7) to strengthen the engagement with the general public and civil society to increase awareness and knowledge of essential medicines and public involvement, as appropriate, and through transparent mechanisms and structures, in enhancing access to and the rational use of these medicines;
- (8) to identify key barriers to access to essential medicines and to develop strategies to address these barriers, making use of WHO's tools¹ and guidance as appropriate;
- (9) to establish or strengthen, as appropriate, systems to monitor the availability using effective inventory management systems, affordability and utilization of safe, effective and quality-assured essential medicines in public and private health facilities;
- (10) to systematize information collection and strengthen monitoring mechanisms, in order to better detect and understand the causes of essential medicines shortages, and to develop strategies to prevent and mitigate the associated problems and risk caused by shortages;
- (11) to consider, as appropriate, adapting national legislation in order to make full use of the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to that agreement, in order to promote access to essential medicines, in line with the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property;

2. REQUESTS the Director-General:

- (1) to urge Member States to recognize the importance of effective national medicines policies, and their implementation under good governance, in order to ensure equity of access to affordable, safe, effective and quality-assured essential medicines and their rational use in practice;

¹ Including but not limited to: pharmaceutical sector country profiles, the assessment instrument for measuring transparency in the public pharmaceutical sector, the WHO/Health Action International tool for measuring medicine prices, availability, affordability and price components, and guidance on how to investigate drug use in health facilities.

- (2) to facilitate and support the exchange of information and collaboration among Member States on best practices in the development and implementation of medicines policies;
- (3) to support Member States in sharing best practices in the selection of essential medicines, and facilitating collaboration between the Secretariat and Member States in developing processes for the selection of medicines for national essential medicines lists consistent with the evidence-based methods used for updating the WHO Model List of Essential Medicines;
- (4) to support Member States in building capacity for the evidence-based selection of essential medicines, the development and dissemination of, and adherence to, clinical practice guidelines and the promotion of other strategies for the rational use of affordable, safe, effective and quality-assured essential medicines by health care professionals and the public;
- (5) to support Member States in developing and implementing their national medicines policies and supply systems especially with regard to regulation, financing, selection, procurement, distribution, pricing, reimbursement and use, in order to increase their efficiency and ensure the access to safe, effective and quality-assured essential medicines, including high price essential medicines;
- (6) to support Member States in systematizing information collection and strengthening monitoring mechanisms, in order to better detect and understand the causes of essential medicines shortages, and in developing strategies to prevent and mitigate the associated problems and risk caused by shortages;
- (7) to urge Member States to expedite progress towards the achievement of the Millennium Development Goals and universal health coverage by, inter alia, implementing national medicines policies for improving access to affordable, safe, effective, and quality-assured essential medicines;
- (8) to provide, as appropriate, upon request, in collaboration with other competent international organizations, technical support, including, where appropriate, to policy processes to Member States that intend to make use of the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to that Agreement, in order to promote access to essential medicines, in accordance with the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property;
- (9) to report to the Sixty-ninth World Health Assembly on the implementation of this resolution.

Agenda item 15.6

Regulatory system strengthening for medical products

The Sixty-seventh World Health Assembly,

Having considered the report on regulatory system strengthening;¹

Welcoming the efforts of the Director-General, and recognizing the pivotal role that WHO plays in supporting countries in strengthening their regulatory systems of medical products for human use,² and in promoting equitable access to quality, safe, efficacious, and affordable medical products;

Recalling the Constitution of the World Health Organization, which affirms that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition;

Recalling also United Nations General Assembly resolution 67/81 on global health and foreign policy, which, inter alia, recognized the importance of universal coverage in national health systems, especially through primary health care and social protection mechanisms, in the provision of access to health services for all, in particular for the poorest segments of the population;

Recalling further resolutions WHA45.17, WHA47.17, WHA52.19, WHA54.11, WHA59.24, WHA63.12, and WHA65.19, all of which encompass aspects of the need to promote the quality, safety, efficaciousness and affordability of medicines, including blood products;

Reaffirming resolution WHA65.19, which establishes a new Member State mechanism for international collaboration, from a public health perspective, excluding trade and intellectual property considerations, to prevent and control substandard/spurious/falsely-labelled/falsified/counterfeit medical products and to promote access to affordable, safe and quality medical products;

Recognizing that effective regulatory systems are an essential component of health system strengthening and contribute to better public health outcomes, that regulators are an essential part of the health workforce, and that inefficient regulatory systems themselves can be a barrier to access to safe, effective and quality medical products;

Recognizing also that effective regulatory systems are necessary for implementing universal health coverage, responding to the dual burden of infectious and noncommunicable diseases, and achieving Millennium Development Goal 4 (Reduce child mortality) Goal 5 (Improve maternal health) and Goal 6 (Combat HIV/AIDS, malaria and other diseases);

Aware that health systems need to promote access to essential medical products and that, in order to ensure universal access to health care, rational use of medicines and the sustainability of

¹ Document A67/32.

² For the purpose of this resolution, medical products include medicines, vaccines, diagnostics and medical devices.

health systems, urgent action is needed by the international community, Member States and relevant actors in health systems;

Very concerned by the impact on patients of medical products of compromised quality, safety and efficacy, in terms of poisoning, inadequate or no treatment, contributions to drug resistance, the related economic burden, and erosion of public trust in the health system;

Aware of the regulatory challenges presented by ever-increasing complexities of medical product supply chains and welcoming the SSFFC Member State mechanism work plan;

Emphasizing WHO's role in strengthening regulatory systems for medical products from a public health perspective, and in supporting national drug regulatory authorities and relevant regional bodies in this area, and in particular in developing countries;

Recalling WHO's global strategy and plan of action on public health, innovation and intellectual property, in particular element three, which calls for establishing and strengthening regulatory capacity in developing countries as one effective policy for building and improving innovative capacity, and element six, which promotes establishing and strengthening mechanisms to improve ethical review and regulate the quality, safety and efficacy of health products and medical devices;

Noting with appreciation the many existing national and regional efforts to strengthen regulatory capacity (including through a variety of models), improve regulatory coherence and convergence among regulatory authorities, and enhance good governance, including transparency in decision-making, leading to the improved availability of quality, safe, efficacious and affordable medical products, such as the European Union regulatory framework for medical products, work under way in PAHO following the adoption by its Directing Council in 2010 of resolution CD50.R9 on strengthening national regulatory authorities for medicines and biologicals, the African Medicines Regulatory Harmonization Initiative, and the regulatory harmonization and cooperation work in ASEAN;

Noting the ongoing collaboration between national and regional regulatory authorities in promoting cooperation among regulatory authorities at the regional and global level;

Recognizing the significant investments made in the procurement of medicines through national health budgets, and global health initiatives;

Also recognizing the essential role of WHO's prequalification programme in facilitating procurement of medical products with assured quality, safety and efficacy;

Stressing that strengthening of regulatory systems should complement the efforts of WHO and Members States to promote access to affordable medical products with assured quality, safety and efficacy;

Recalling the WHO good clinical practices that focus on the protection of human research subjects;

Recalling also WHO's ongoing reform agenda and welcoming in this regard the establishment in November 2012 of the Health Systems and Innovation cluster,

1. URGES Member States:¹

- (1) to strengthen national regulatory systems, including through as appropriate and voluntarily, by:
 - (a) undergoing self-evaluations, including with WHO support, to identify the strengths and opportunities for improvement in regulatory system functions, as a first step towards formulating plans for regulatory systems strengthening, including through WHO-coordinated institutional development plans;
 - (b) collecting data on regulatory system performance to enable analysis and benchmarking for improved systems in the future;
 - (c) developing strong legal foundations and political leadership to underpin a regulatory system with a clear focus on patient safety and transparency in decision-making;
 - (d) identifying and developing a core set of regulatory functions to meet country and/or regional needs, such as market control and postmarket surveillance;
 - (e) developing needed competencies as an integral part of, although not limited to, the health workforce, and encouraging the development of the regulatory field as a profession;
 - (f) facilitating the use of relevant guidance and science-based outputs of WHO expert committees and good regulatory practices at the national, regional and international levels;
 - (g) devising and implementing strategies to address the increasing complexities of supply chains;
- (2) to engage in global, regional and subregional networks of national regulatory authorities, as appropriate, recognizing the importance of collaboration to pool regulatory capacities to promote greater access to quality, safe, efficacious and affordable medical products;
- (3) to promote international cooperation, as appropriate, for collaboration and information sharing, including through electronic platforms;
- (4) to support regulatory systems for medical products with appropriate funding as an essential component of the health system;
- (5) to support regulatory system strengthening as an essential component to the development or expansion of local or regional production of quality, safe and efficacious medical products;

¹ And, where applicable, regional economic integration organizations.

(6) to achieve access to and rational use of quality, safe, efficacious and affordable essential medicines, noting the growing emergence of resistance, and as a foundation for achieving broader access to quality, safe, efficacious and affordable medical products;

(7) to support WHO's institutional capacity relating to promoting access to and rational use of quality, safe, efficacious and affordable medical products in the context of universal health coverage;

(8) to strengthen the national and regional initiatives of regulatory authorities to improve regulatory capacities for review of medical products, promoting WHO's long-term objective of supporting the strengthening of national regulatory authority capacity among Member States;

(9) to support WHO's prequalification programmes including exploring modalities in consultation with Member States¹ for improved sustainability of this critical programme;

(10) to identify the need to strengthen regulatory system capacity, collaboration and cooperation in the technically complex areas where substantial gaps may still exist, such as the regulation of biotherapeutic products, blood products, and in vitro diagnostics;

2. REQUESTS the Director-General:

(1) to continue to support Member States upon their request in the area of regulatory system strengthening, including, as appropriate, by continuing to:

(a) evaluate national regulatory systems;

(b) apply WHO evaluation tools;

(c) generate and analyse evidence of regulatory system performance;

(d) facilitate the formulation and implementation of institutional development plans; and

(e) provide technical support to national regulatory authorities and governments;

(2) to continue to develop appropriate norms, standards and guidelines, including taking into account national, regional and international needs and initiatives, in accordance with WHO principles;

(3) to ensure that all relevant parts of the Organization, at all levels, are actively engaged and coordinated in the carrying out of WHO's mandate pertaining to regulatory system strengthening as an integrated part of health system development, recognizing that WHO's support in this critical area, particularly for developing countries, may be required, as appropriate, well into the future;

¹ And, where applicable, regional economic integration organizations.

- (4) to prioritize support for establishing and strengthening regional and subregional networks of regulatory authorities, as appropriate, including strengthening areas of regulation of health products that are the least developed, such as regulation of medical devices, including diagnostics;
- (5) to promote the greater participation of Member States in existing international and regional initiatives for collaboration, and cooperation in accordance with WHO principles and guidelines;
- (6) to strengthen WHO's prequalification programmes, including their integration and coherence, taking into account the needs and capacities of national and regional regulatory systems to assist in ensuring a supply of quality, safe, efficacious and affordable medical products;
- (7) to support the building-up of effective national and regional regulatory bodies and networks;
- (8) to increase support for and recognition of the significant role of the International Conference of Drug Regulatory Authorities in promoting the exchange of information and collaborative approaches among drug regulatory authorities, and as a resource to facilitate further development of regulatory cooperation and coherence;
- (9) to raise awareness of the importance of effective regulatory systems within the health system context;
- (10) to increase support and guidance for strengthening the capacity to regulate increasingly complex biological products with the focus on biotherapeutic products, blood products and associated in vitro diagnostics, and, where appropriate, on new medicines for human use based on gene therapy, somatic-cell therapy and tissue engineering;
- (11) to ensure that any activity carried out under this resolution does not duplicate or circumvent the work plan and mandate of the Member States mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products;
- (12) to report to the Seventieth and Seventy-second World Health Assemblies on progress in the implementation of this resolution.

Agenda item 15.6**Access to biotherapeutic products including similar biotherapeutic products¹ and ensuring their quality, safety and efficacy**

The Sixty-seventh World Health Assembly,

Having considered the report on regulatory system strengthening;²

Recalling the WHO Constitution, which affirms that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition;

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, that millions of people are driven below the poverty line each year because of catastrophic out-of-pocket payments for health care, and that excessive out-of-pocket payments can discourage the impoverished from seeking or continuing care;

Recalling resolution WHA55.14 on ensuring accessibility of essential medicines, which recognizes “the responsibility of Member States to support solid scientific evidence, excluding any biased information or external pressures that may be detrimental to public health”;

Further recalling that in resolution WHA55.14 the Health Assembly urged Member States, inter alia, “to reaffirm their commitment to increasing access to medicines, and to translate such commitment into specific regulation within countries, especially enactment of national drug policies and establishment of lists of essential medicines based on evidence and with reference to WHO’s Model List, and into actions designed to promote policy for, access to, and quality and rational use of, medicines within national health systems”;

Considering that one of the objectives of pharmaceutical regulation is the assurance of the quality, safety and efficacy of pharmaceutical products through the regulatory processes of authorization, vigilance and monitoring;

Considering also that national pharmaceutical regulation should contribute to the performance and sustainability of health systems and the general welfare of society;

Considering that an update of the norms and standards applicable to medicines is required in light of advances made in biotechnology, and the new generation of medicines introduced as a result, in order to ensure the entry into the market of medicines that are affordable, safe, efficacious, of quality and accessible in a timely and adequate fashion;

¹ Acknowledging that national authorities may use different terminologies when referring to similar biotherapeutic products.

² Document A67/32.

Recognizing that the use of such medicines has a positive impact on morbidity and mortality rates and that, while there are multiple barriers to access, their high cost affects the sustainability of health systems and could in many cases affect access to them;

Noting the importance of, and using as appropriate, WHO Guidelines on evaluation of similar bioterapeutic products (2009) by the Expert Committee on Biological Standardization, and recognizing the need to update them, particularly in terms of technological advances and characterization, in order to promote more efficient regulatory frameworks from a public health perspective that ensure the efficacy, quality and safety of these products at the national and regional levels;

Conscious that similar bioterapeutic products could be more affordable and offer better access to treatments of biological origin, while ensuring quality, safety and efficacy,

1. URGES Member States:¹

(1) to develop or strengthen, as appropriate, national regulatory assessment and authorization frameworks, with a view to meeting the public health needs for bioterapeutic products, including similar bioterapeutic products;

(2) to develop the necessary scientific expertise to facilitate development of solid, scientifically-based regulatory frameworks that would promote access to products that are affordable, safe, efficacious and of quality, taking note of the relevant WHO guidelines which may be adapted to the national context and capacity;

(3) to work to ensure that the introduction of new national regulations, where appropriate, does not constitute a barrier to access to quality, safe, efficacious and affordable bioterapeutic products, including similar bioterapeutic products;

2. REQUESTS the Director-General:

(1) to support Member States in strengthening their capacity in the area of the health regulation of bioterapeutic products, including similar bioterapeutic products;

(2) to support, as appropriate, the development of national regulatory frameworks that promote access to quality, safe, efficacious and affordable bioterapeutic products, including similar bioterapeutic products;

(3) to encourage and promote cooperation and exchange of information, as appropriate, among Member States in relation to bioterapeutic products, including similar bioterapeutic products;

(4) to convene the WHO Expert Committee on Biological Standardization to update the 2009 guidelines, taking into account the technological advances for the characterization of bioterapeutic products and considering national regulatory needs and capacities and to report on the update to the Executive Board;

(5) to report to the Sixty-ninth World Health Assembly on the progress with the implementation of this resolution.

¹ And, where applicable, regional economic integration organizations.

Agenda item 15.7**Health intervention and technology assessment in support of universal health coverage**

The Sixty-seventh World Health Assembly,

Having considered the report on health intervention and technology assessment in support of universal health coverage;¹

Recalling resolutions WHA52.19 on the revised drug strategy, WHA58.33 on sustainable health financing, universal coverage and social health insurance, WHA60.16 on progress in the rational use of medicines, WHA60.29 on health technologies, WHA63.21 on WHO's role and responsibilities in health research, and WHA64.9 on sustainable health financing structures and universal coverage;

Recognizing the importance of evidence-based policy development and decision-making in health systems, including decisions on resource allocation, service system designs and translation of policies into practice, as well as reaffirming WHO's roles and responsibilities in provision of support to strengthen information systems and health research capacity, and their utilization in Member States;

Noting that the efficient use of resources is a crucial factor in the sustainability of health systems' performance, especially when significant increases in access to essential medicines, including generic medicines, to medical devices and procedures, and to other health care interventions for promotion, prevention, diagnosis and treatment, rehabilitation and palliative care are pursued by Member States, as they move towards universal health coverage;

Noting that *The world health report 2010*² indicates that as much as 40% of spending on health is being wasted and that there is, therefore, an urgent need for systematic, effective solutions to reduce such inefficiencies and to enhance the rational use of health technology;

Acknowledging the critical role of independent health intervention and technology assessment, as multidisciplinary policy research, in generating evidence to inform prioritization, selection, introduction, distribution, and management of interventions for health promotion, disease prevention, diagnosis and treatment, and rehabilitation and palliation;

Emphasizing that with rigorous and structured research methodology and transparent and inclusive processes, assessment of medicines, vaccines, medical devices and equipment, and health procedures, including preventive intervention, could help to address the demand for reliable information on the safety, efficacy, quality, appropriateness, cost-effectiveness and efficiency dimensions of such technologies to determine if and when they are integrated into particular health interventions and systems;

¹ Document A67/33.

² The world health report 2010. Health systems financing: the path to universal coverage. Geneva: World Health Organization; 2010.

Concerned that the capacity to assess, research and document the public health, economic, organizational, social, legal and ethical implications of health interventions and technologies is inadequate in most developing countries, resulting in inadequate information to guide rational policy, and professional decisions and practices;

Recognizing the importance of strengthened national capacity, regional and international networking, and collaboration on health intervention and technology assessment to promote evidence-based health policy,

1. URGES Member States:¹

(1) to consider establishing national systems of health intervention and technology assessment and to encourage the systematic utilization of independent health intervention and technology assessment in support of universal health coverage to inform policy decisions, including priority-setting, selection, procurement supply system management and use of health interventions and/or technologies, as well as the formulation of sustainable financing benefit packages, medicines, benefits management including pharmaceutical formularies, clinical practice guidelines and protocols for public health programmes;

(2) to strengthen the link between health technology assessment (HTA) and regulation and management, as appropriate;

(3) to consider, in addition to the use of established and widely agreed methods, developing as appropriate national methodological and process guidelines and monitoring systems for health intervention and technology assessment in order to ensure the transparency, quality and policy relevance of related assessments and research;

(4) to further consolidate and promote health intervention and technology assessment within national frameworks, such as those for health system research, health professional education, health system strengthening and universal health coverage;

(5) to consider strengthening national capacity for regional and international networking, developing national know-how, avoiding duplication of efforts and achieving better use of resources;

(6) to consider also collaborating with other Member States' health organizations, academic institutions, professional associations and other key stakeholders in the country or region in order to collect and share information and lessons learnt so as to formulate and implement national strategic plans concerning capacity-building for and introduction of health intervention and technology assessment, and summarizing best practices in transparent, evidence-informed health policy and decision-making;

(7) to identify gaps with regard to promoting and implementing evidence-based health policy, as well as improving related information systems and research capacity, and considering seeking technical support and exchanging information and sharing experiences with other Member States, regional networks and international entities, including WHO;

¹ And, where applicable, regional economic integration organizations.

(8) to develop and improve the collection of data on health intervention and technology assessment, training relevant professionals, as appropriate, so as to improve assessment capacity;

2. REQUESTS the Director-General:

(1) to assess the status of health intervention and technology assessment in Member States in terms of methodology, human resources and institutional capacity, governance, linkage between health intervention and technology assessment units and/or networks with policy authorities, utilization of assessment results, and interest in and impediments to strengthening capacity;

(2) to raise awareness of, and to foster knowledge and encourage the practice of health intervention and technology assessment and its uses in evidence-based decision-making among national policy-makers and other stakeholders, by drawing best practices from the operation, performance and contribution of competent research institutes and health intervention and technology assessment agencies and programmes, and sharing such experiences with Member States through appropriate channels and activities, including global and regional networks and academic institutions;

(3) to integrate health intervention and technology assessment concepts and principles into the relevant strategies and areas of work of WHO, including, but not limited to, those on universal health coverage, including health financing, access to and rational use of quality-assured medicines, vaccines and other health technologies, the prevention and management of noncommunicable and communicable diseases, mother and child care, and the formulation of evidence-based health policy;

(4) to provide technical support to Member States, especially low-income countries, relevant intergovernmental organizations and global health partners, in order to strengthen capacity for health intervention and technology assessment, including, when appropriate, the development and use of global guidance on methods and processes based on internationally agreed practices;

(5) to ensure adequate capacity at all levels of WHO, utilizing its networks of experts and collaborating centres, as well as other regional and international networks, in order to address the demand for support to facilitate evidence-based policy decisions in Member States;

(6) to support exchange of information, sharing of experiences and capacity-building in health intervention and technology assessment through collaborative mechanisms and networks at global, regional and country levels, as well as ensuring that these partnerships are active, effective and sustainable;

(7) to report on progress in the implementation of this resolution to the Sixty-ninth World Health Assembly.

Agenda item 15.8

Follow-up of the Recife Political Declaration on Human Resources for Health: renewed commitments towards universal health coverage

The Sixty-seventh World Health Assembly,

Having considered the outcome document of the Third Global Forum on Human Resources for Health (Recife, Brazil, 10–13 November 2013);¹

Recognizing the leadership role of WHO in human resources for health, and the mandate given in this regard by resolution WHA63.16 on the WHO Global Code of Practice on the International Recruitment of Health Personnel, WHA66.23 on Transformative Health Workforce Education in Support of Universal Health Coverage, WHO Global Policy Recommendations on Increasing Access to Health Workers in Remote and Rural Areas through improved retention in 2010, WHO Guideline on Transforming and Scaling up Health Professional Education and Training in 2013;

Recalling the commitment to attain universal health coverage and the need for an improved health workforce to achieve it;

Reaffirming the importance of the Kampala Declaration and Agenda for Global Action, as well as the WHO Global Code of Practice on the International Recruitment of Health Personnel, and recognizing the need to renew these commitments and take them forward in light of new developments with a view to progressing towards universal health coverage,

1. ENDORSES the call to action in the Recife Political Declaration on Human Resources for Health: renewed commitments towards universal health coverage;
2. WELCOMES the commitments made by Member States in the Recife Political Declaration on Human Resources for Health: renewed commitments towards universal health coverage;
3. URGES Member States to implement, as appropriate, and in accordance with national and subnational responsibilities, the commitments made in the Recife Political Declaration on Human Resources for Health: renewed commitments towards universal health coverage;
4. REQUESTS the Director-General to take into consideration the Recife Political Declaration on Human Resources for Health: renewed commitments towards universal health coverage in the future work of WHO;
5. REQUESTS the Director General to develop and submit a new global strategy for human resources for health for consideration of the sixty-ninth World Health Assembly.

¹ Document A67/34, Annex

Agenda item 16.5**Antimicrobial resistance**

The Sixty-seventh World Health Assembly,

Having considered the report on antimicrobial drug resistance;¹

Recognizing WHO's leadership role in the containment of antimicrobial resistance;

Recalling resolutions WHA39.27 and WHA47.13 on the rational use of drugs, WHA51.17 on emerging and other communicable diseases: antimicrobial resistance, WHA54.14 on global health security, WHA58.27 on improving the containment of antimicrobial resistance, WHA60.16 on progress in the rational use of medicines and WHA66.22 on follow up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination;

Aware that access to effective antimicrobial agents constitutes a prerequisite for most of modern medicine, that hard-won gains in health and development, in particular those brought about through the health-related Millennium Development Goals, are at risk due to increasing resistance to antimicrobials, and that antimicrobial resistance threatens the sustainability of the public health response to many communicable diseases, including tuberculosis, malaria and HIV/AIDS;

Aware that the health and economic consequences of antimicrobial resistance constitute a heavy and growing burden on high-, middle- and low-income countries, requiring urgent action at national, regional and global levels, particularly in view of the limited development of new antimicrobial agents;

Recognizing that the main impact of antimicrobial resistance is on human health, but that the contributing factors and consequences, including economic and others, go beyond health and therefore there is a need for a coherent, comprehensive and integrated approach at global, regional and national levels, in a "One Health" approach and beyond, involving different actors and sectors such as human and veterinary medicine, agriculture, environment and consumers;

Noting that awareness of the broad scope and urgency of the threat posed has been limited and that previous resolutions of the Health Assembly and WHO's strategies for the containment of antimicrobial resistance have not yet been widely implemented;

Recognizing that antimicrobial resistance involves a wide range of pathogens including bacteria, viruses and parasites but that the development of resistance among some pathogens, particularly antibiotic-resistant bacteria, is of particular urgency and most in need of immediate attention;

Welcoming the establishment of the WHO Global Task Force on Antimicrobial Resistance and the tripartite collaboration between FAO, OIE and WHO,

¹ Document A67/39.

1. URGES Member States:

- (1) to increase political awareness, engagement and leadership in order to accelerate efforts to secure access to effective antimicrobials and to use them responsibly;
- (2) to take urgent action at national, regional and local levels to strengthen infection prevention and control, by means that include application of basic hygiene measures;
- (3) to develop or strengthen national plans and strategies and international collaboration for the containment of antimicrobial resistance;
- (4) to mobilize human and financial resources in order to implement plans and strategies to strengthen the containment of antimicrobial resistance;
- (5) to strengthen overall pharmaceutical management systems, including regulatory systems and supply chain mechanisms, and, where appropriate, laboratory infrastructure, with a view to ensuring access to and availability of effective antimicrobial agents, taking into account financial and other incentives that might have a negative impact on policies for prescribing and dispensing;
- (6) to monitor the extent of antimicrobial resistance and monitor regularly the use of antibiotics in all relevant sectors, in particular health and agriculture, including animal husbandry, and to share such information so national, regional and global trends can be detected and monitored;
- (7) to improve, among all relevant care providers, the public and other sectors and stakeholders, awareness of (i) the threat posed by antimicrobial resistance, (ii) the need for responsible use of antibiotics and (iii) the importance of infection prevention and control measures;
- (8) to encourage and support research and development, including by academia and through new collaborative and financial models, to combat antimicrobial resistance and promote responsible use of antimicrobials, develop practical and feasible approaches for extending the lifespan of antimicrobial medicines and encourage the development of novel diagnostics and antimicrobial medicines;
- (9) to collaborate with the Secretariat in developing and implementing a draft global action plan to combat antimicrobial resistance including antibiotic resistance, which is based on all available evidence and best practices;
- (10) to develop antimicrobial resistance surveillance systems in three separate sectors: (i) inpatients in hospitals; (ii) outpatients in all other health care settings and the community; and (iii) animals and non-human usage of antimicrobials;

2. REQUESTS the Director-General:

- (1) to ensure that all relevant parts of the Organization, at headquarters, regional and country levels, are actively engaged and coordinated in promoting work on containing antimicrobial resistance, including through the tracking of resource flows for research and development on antimicrobial resistance in the new global health research and development observatory;

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- (2) to set aside adequate resources for the work in the Secretariat, in line with the Programme budget 2014–2015 and the Twelfth General Programme of Work, 2014–2019;
- (3) to strengthen the tripartite collaboration between FAO, OIE and WHO for combating antimicrobial resistance in the spirit of the “One Health” approach;
- (4) to explore with the United Nations Secretary-General options for a high-level initiative, including a high-level meeting, to increase political awareness, engagement and leadership on antimicrobial resistance;
- (5) to develop a draft global action plan to combat antimicrobial resistance, including antibiotic resistance, which addresses the need to ensure that all countries, especially low- and middle-income countries, have the capacity to combat antimicrobial resistance and which takes into account existing action plans and all available evidence and best practice as well as the recommendations of WHO’s Strategic Technical Advisory Group on antimicrobial resistance and the WHO policy package to combat antimicrobial resistance, which asks Member States:
- (a) to commit to a comprehensive, financed national plan with accountability and civil society engagement;
 - (b) to strengthen surveillance and laboratory capacity;
 - (c) to ensure uninterrupted access to essential medicines of assured quality;
 - (d) to regulate and promote rational use of medicines, including in animal husbandry, and ensure proper patient care;
 - (e) to enhance infection prevention and control;
 - (f) to foster innovation and research and development for new tools;
- (6) to apply a multisectoral approach to inform the drafting of the global action plan, by consulting Member States as well as other relevant stakeholders, especially other multilateral stakeholders, such as FAO and OIE, taking into account the need to manage potential conflicts of interest;
- (7) to submit to the Sixty-eighth World Health Assembly, through the Executive Board at its 136th session, a draft global action plan to combat antimicrobial resistance, including antibiotic resistance, together with a summary report on progress made in implementing the other aspects of this resolution.

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