Access to treatment

Adaptive licensing pathways
A recent publication takes a look at the environmental changes that may make adaptive licensing pathways the approach of the future.

The concept of adaptive licensing foresees an early approval of a medicine for a restricted patient population, based on small initial clinical studies. The initial marketing authorization is then progressively adapted to make the medicine accessible to broader patient populations, based on data gathered from its use and from additional studies.

Key drivers that could make adaptive pathways the preferred approach in future include: growing patient demand for timely access to promising therapies in particular where there are unmet medical needs; identification of subgroups of patients who are likely to respond to certain medicines better than others; rising payer influence with calls for a more targeted use of medicines to increase their therapeutic value; and pressure on industry and investors to make drug development sustainable by targeting smaller, better defined patient populations to bring medicines forward at a lower initial cost.


Appraisal of expensive medicines
An editorial in the Bulletin of the World Health Organization presents the case for a global forum to discuss objectivity and equity in access to high-priced drugs.

Increasingly, patients are asking for early access to new drugs, for example to treat cancer. Often these drugs are very expensive. Price-setting is largely a function of the market, and the prices of some recently introduced drugs – for example sofosbuvir – have been questioned.

The authors argue that it is time for a global forum for the development of methods to evaluate available data for early market entry, determine an appropriate initial price, optimize the collection of data from clinical practice, enable independent trials and manage the exit of products that, in practice, are found to be insufficiently effective.


BRICS Ministers tackle priority diseases
Brasília – At their Meeting held on 4-5 December 2014, Ministers of Health from Brazil, Russia, India, China and South Africa (BRICS) reaffirmed their commitment to fight priority diseases.

They committed to ambitious tuberculosis targets and approved the development of a plan to achieve universal access to first line
anti-tuberculosis medicines in BRICS and low- and middle-income countries. The plan will include common approaches to promote research and innovations on tuberculosis diagnostics and treatment, share technologies, and identify manufacturing capacities and means of financing.

The Ministers also committed to ambitious HIV treatment targets to end the AIDS epidemic as a global threat by 2030, and they reaffirmed their support to initiatives to overcome barriers in access to medicines.

They further expressed their support for WHO global action plans to stop the Ebola outbreak, to fight neglected tropical diseases, to reduce antimicrobial resistance, and to fight non-communicable diseases.

► IV Meeting of the BRICS. Joint Communiqué. 5 December 2014.

LDCs request extension of intellectual property rights waiver for medicines

Geneva – At the World Trade Organization (WTO) intellectual property committee meeting held on 24-25 February 2015 a group of least-developed countries (LDCs) have proposed to extend the current waiver to intellectual property rights enforcement for pharmaceutical products past the deadline of 2016, until they are no longer considered LDCs.

LDCs are disproportionately exposed to the health risks associated with poverty. In its statement the group notes that “patent protection contributes to high costs, placing many critical treatments outside the reach of LDCs”.


Medicines Patent Pool signs licensing agreements for paediatric antiretrovirals

Geneva – The Medicines Patent Pool (MPP) has signed two new licensing agreements for HIV paediatric formulations, enabling pharmaceutical companies to develop, manufacture and sell low-cost product versions in countries with high disease burdens.

An agreement has been signed with AbbVie for lopinavir and ritonavir, covering 102 countries of which more than 65 are classified as middle-income nations. Moreover, provisions in the agreement permit manufacture and distribution in countries where AbbVie does not hold patents, such as in India where the company has withdrawn its patent applications for both lopinavir and ritonavir. (1)

An agreement has also been signed with MSD, known as Merck in the United States and Canada. The agreement is for paediatric formulations of raltegravir and covers 92 low- and middle-income countries. Raltegravir fills an important gap in the care of children who fail on their first-line HIV regimens. (2)

The licenses will support the work of the recently launched Paediatric HIV Treatment Initiative (PHTI) to develop better adapted medicines for children living with the virus.

The MPP cooperates with the WHO Prequalification of Medicines Programme to ensure that medicines made with MPP licences meet international quality and safety standards and are acceptable for UN procurement.

► (1) MPP Press release, 1 December 2014.
► (2) MPP Press release, 24 February 2015.
Anti-TB drug donation agreed
Geneva – The United States Agency for International Development (USAID) and the Johnson & Johnson affiliate Janssen Therapeutics have signed a memorandum of understanding to provide 30,000 treatment courses of the newly developed medicine bedaquiline worth US$ 30 million for free through USAID’s programmes. The medicine will be distributed to nearly 100 eligible low- and middle-income countries over four years. Eligibility criteria will be developed over the coming months.

Bedaquiline is the first new anti-tuberculosis drug developed in four decades. It is effective against strains of tuberculosis that are resistant to two or more antibiotics.

The Executive Secretary of the Stop TB Partnership, Dr Ditiu, noted that the community should use this opportunity wisely to save lives, and that the deal sets a precedent for collaboration between pharmaceutical companies and international organizations to tackle drug-resistant tuberculosis.


Product development

New anti-tuberculosis medicine starts clinical testing
New York – The Global Alliance for TB Drug Development (TB Alliance) has announced the start of the first human trial of a new tuberculosis drug candidate, a next-generation nitroimidazole designated TBA-354. It is the first new TB drug candidate to begin a Phase I clinical trial since 2009.

TBA-354 was identified in studies conducted by TB Alliance in collaboration with the University of Auckland and University of Illinois-Chicago. In preclinical studies, TBA-354 demonstrated more potent anti-bactericidal and sterilizing activity than pretomanid, another nitroimidazole drug that is currently being tested as a component of other novel regimens in multiple clinical trials.

The TB Alliance is a not-for-profit organization dedicated to finding faster-acting and affordable drug regimens to fight tuberculosis through innovative science with support from partners around the globe.

► TB Alliance News release, 18 February 2015.

Disease updates

Ebola: an unforgiving virus
Geneva – One year after the first Ebola cases emerged in Guinea, WHO has released a series of 14 papers that take an in-depth look at different aspects of the epidemic (1).

Vaccines

As the epidemic begins to ebb, efforts to develop, test, and approve Ebola vaccines are followed through as they will have a significant impact on the further evolution. Two vaccines are at an advanced stage of development; large volumes of vaccine doses could become available from early 2015 although deployment and further evaluation in the aftermath of the outbreak will be demanding (2). The first Phase III trial was launched in Guinea in March 2015 (3). A third vaccine candidate is in Phase I trials and a number of others are under development (4).

Treatments

Convalescent blood therapies and medicines have been further evaluated.
Two medicines approved for other uses – favipiravir and brincidofovir – warrant further investigation in clinical trials in affected countries (2). The EMA has reviewed seven medicine candidates to treat Ebola, and has found that available evidence is not sufficient to draw conclusions on their safety and efficacy (5).

**Diagnostics**

WHO has established an emergency quality assessment mechanism for in vitro diagnostics (IVDs) for Ebola Virus Disease. The mechanism aims to identify products that are acceptable for procurement by UN organizations and other partners while further data are being developed. In November 2014 WHO accepted the first Ebola in vitro diagnostic product under this mechanism; the first rapid test followed in February 2015. Other products are under assessment.

WHO is working with the Foundation for Innovative New Diagnostics (FIND), Médecins Sans Frontières (MSF), manufacturers and regulators to guide the development of new tests. (6)

**The way forward**

Four main lessons have been learned from this largest and longest Ebola outbreak in history: Firstly, resilient health systems must be built in all countries to absorb the shocks of future epidemics and climate changes. Secondly, vigilance and preparedness make a huge difference. Thirdly, a host of control measures must be coordinated to fight disease outbreaks, and lastly, community engagement is essential for an effective response. (7)

At a special session held in January 2015 the WHO Executive Board unanimously adopted a comprehensive resolution on next steps to end the Ebola outbreak and on what is needed in the longer term for the world to respond to health emergencies under WHO’s leadership. (8)

**Non-communicable diseases: preventable early deaths**

Geneva – WHO has launched its global status report on noncommunicable diseases (NCDs) for 2014. The report calls for government action to reduce the annual toll of 16 million premature deaths – before the age of 70 – from heart and lung diseases, stroke, cancer and diabetes. 82% of these deaths occur in low- and middle-income countries.

The report outlines a plan with nine voluntary global targets to address key NCD risk factors. It identifies “best buy” cost-effective preventive interventions to reduce tobacco use, salt intake, physical inactivity, high blood pressure...
and harmful use of alcohol. Targets are also set for access to drug therapy and counselling – including glycaemic control – to prevent heart attacks and strokes, and for availability of affordable basic technologies and essential medicines – including generics – to treat major NCDs in both public and private facilities.


Tuberculosis: further to go

Geneva – Improved data show that there are almost half a million more tuberculosis cases worldwide than previously estimated. According to the WHO Global Tuberculosis Report 2014 (1) nine million people developed tuberculosis in 2013, and 1.5 million died. Encouragingly, incidence and mortality rates are still falling, and an estimated 37 million lives have been saved through effective diagnosis and treatment since 2000.

Nevertheless a staggering number of lives continue to be lost to this curable disease. Around three million tuberculosis cases are still being missed by health systems each year because they are either not diagnosed or not reported.

The multidrug-resistant tuberculosis (MDR-TB) crisis continues, with severe epidemics in some regions and low treatment success rates in many settings around the world. Extensively drug-resistant tuberculosis (XDR-TB), which is even more expensive and difficult to treat than MDR-TB, has now been reported in 100 countries. The report includes a supplement that marks 20 years of anti-TB drug-resistance surveillance and outlines the MDR-TB response and priority actions.

The authors of a comment in The Lancet (2) have called on all governments and donors to increase their funding for urgent, swift, and visionary action to reach the target defined in the WHO Global TB strategy, which is to eliminate tuberculosis as a public threat by 2035.

 ► (1) WHO. Global Tuberculosis Report 2014.


Malaria: fragile gains

London – The World Malaria Report 2014, launched in the United Kingdom Houses of Parliament in December 2014, shows some encouraging results. The number of people dying from malaria has fallen dramatically since 2000, and malaria cases are also steadily declining. Between 2000 and 2013, the malaria mortality rate decreased by 47% worldwide and by 54% in the WHO African Region, where about 90% of malaria deaths occur.

While biological and technical challenges remain, a strong pipeline of innovative new products has the potential to transform malaria control and elimination. However, despite a threefold increase since 2005, funding to combat malaria is still only around half of the US$ 5.1 billion needed to achieve global targets. (1)

Adequate resourcing is particularly important to contain the parasite resistance to antimalarials that now affects five Asian countries. A recent study found that resistant strains have spread throughout Myanmar and have reached the border with India. If resistant malaria spreads to Africa, millions of lives could be at risk. (2)

 ► (1) WHO News release, 9 December 2014.

(2) Tun KM et al. Spread of artemisinin-resistant Plasmodium falciparum in Myanmar: a cross-sectional survey of the K13 molecular marker. Lancet Infect
HIV: fast track targets

Geneva/Los Angeles – A UNAIDS flagship report launched during an event at the University of California, Los Angeles (UCLA) in November 2014 shows how the world can now build on past achievements to end the AIDS epidemic as a global health threat.

By the end of 2013, 35 million people were living with HIV worldwide. New HIV infections in 2013 were estimated at 2.1 million, which was 38% lower than in 2001. The number of AIDS-related deaths also continues to decline, with 1.5 million people dying of AIDS-related causes in 2013, down 35% from the peak in 2005.

There is a global consensus to aim for 90% of people living with HIV knowing their HIV status, 90% of people who know their status receiving treatment and 90% of people on HIV treatment having a suppressed viral load thus reducing the risk of transmission. Other targets include reducing the annual number of new HIV infections by more than 75%, to 500 000 in 2020, and achieving zero discrimination. Investments will be critical in achieving these targets. Particular efforts are needed in the 30 countries that together account for 89% of new HIV infections worldwide, requiring significant commitments from both national and international sources.

Neglected tropical diseases: domestic investments needed

Geneva – WHO has released its report Investing to overcome the impact of neglected tropical diseases. The Organization urges affected countries to scale up their investment in tackling 17 neglected tropical diseases in order to improve the health and well-being of more than 1.5 billion people. This investment would represent as little as 0.1% of current domestic expenditure on health in affected low- and middle-income countries for the period 2015-2030.

Neglected tropical diseases cause blindness, disfigurement, permanent disability and death. While good progress has been made towards eliminating some of them, others are gaining ground because of rapid and unplanned urbanization, population movement and environmental change. Dengue is one of them: it is now present in more than 150 countries. The report outlines an investment case and essential package of interventions for each of the 17 neglected tropical diseases targeted by WHO.

WHO matters

MQAS procurement guidelines now available in French

Geneva – The 2014 revisions of two procurement-related WHO guidelines are now also available in French: The Model quality assurance system for procurement agencies (1) and the Assessment tool based on the model quality assurance system for procurement agencies: aide-memoire for inspection (2).

These guidelines are widely used by international organizations to assure the quality of the health products that they purchase or finance globally.


Note: To complement the two WHO guidelines a self-assessment tool on compliance with MQAS principles has been published in WHO Drug Information, Vol. 28, No. 4). An Excel version is available from druginfo@who.int.

Do you manufacture these APIs? We are interested in you
The World Health Organization’s prequalification scheme gives free help to manufacturers of selected active pharmaceutical ingredients (APIs), medicines and vaccines who want to boost their standards and access international markets.
Read this article for more details:

Note: The 7th Invitation for API manufacturers to submit an Expression of Interest (EOI) for evaluation of their API by the WHO Prequalification Team - Medicines is available at: http://apps.who.int/prequal/info_applicants/eqaas/EOI-API-EOI_V7_1.pdf.

New phase of WHO’s external quality control laboratory scheme

The important role of QC laboratories
Quality of medicines is a major public health challenge, particularly in light of the cross-border health-related issues and the international dimensions of trade.

Within the wide range of quality assurance measures that are needed to help ensure that quality medicines reach the patient, quality control has traditionally been one of the key elements. Pharmaceutical quality control laboratories play a major role in protecting patients from harm.

Quality control (QC) testing is complex. Errors are not only costly but may jeopardize patient safety. Patients may receive ineffective or even harmful medicines if true quality deficiencies are not identified. Conversely, if non-conforming results are falsely interpreted as quality failures, expensive medicines may be returned or destroyed, potentially leaving patients without life-saving treatment until the products are replaced at sometimes enormous additional costs.

Given these high stakes, trust in a QC laboratory’s capabilities is essential for all stakeholders who request its services.

New phase of EQAAS
WHO is pleased to announce Phase 6 of its External Quality Assurance Assessment Scheme (EQAAS) at preferential fees far below cost for participants from lower- and middle-income countries. In order to enhance the efficiency and save costs, two studies will be carried out for each shipment. Fees are based on the World Bank classification of income and are as follows:

• Laboratories in low-income countries: US$ 1000
• Laboratories in middle-income countries: US$ 2000
• Laboratories in high-income countries: US$ 4000
The above fees cover shipment of test samples for two studies, together with the study protocols and the subsequent statistical evaluation of the submitted results. WHO informs the laboratories
about their performance and provides additional guidance for improving their capabilities. The scheme is set out in close cooperation with related WHO programmes, including the programme dealing with the prequalification of QC laboratories.

**Funding**

*International donors may be approached for funding of participation in the EQAAS.* The Global Fund to Fight AIDS, Tuberculosis and Malaria encourages grant applicants to include this item in their applications for funding. The Global Fund requires grant recipients to arrange systematic random QC testing of products throughout the in-country supply chain for medicines worth about US$ 600 million delivered to grant-funded programmes every year. It also funds large quantities of laboratory equipment and reagents. Other donors have similar policies.

**WHO invites laboratories to participate in EQAAS Phase 6 studies.** To ensure continued assistance to laboratories in Member States, WHO will offer advice on possible funding sources through WHO country projects for laboratories in developing countries that have no means to recuperate the fee, and for whom the fee represents an obstacle for participation.

**More about EQAAS**

*WHO at present offers the only global, independent scheme to measure laboratories’ QC testing capabilities.* The EQAAS was established by WHO in 2000 at the request of the Global Fund as a mechanism to maximize health benefits achieved with grant investments in pharmaceuticals and laboratory supplies. The EQAAS has proven to be a major asset to WHO Member States. More than 60 laboratories across WHO’s six regions, many of them in Africa, have participated in its past comparative external assessment studies. Participation in such studies is mandatory according to WHO good practices for pharmaceutical quality control laboratories and for ISO 17025 accreditation.

► For more information and expression of interest to participate in this new phase of WHO’s QC laboratory scheme, please contact WHO at: EQAAS@who.int.

**WHA resolutions now on official record**

*Geneva – The Sixty-seventh World Health Assembly (WHA), held in May 2014, adopted a total of 25 resolutions, including two with particular relevance to medicines regulation. Resolution WHA67.20 urges Member States and WHO to work together to strengthen national regulatory systems around the world, while Resolution WHA67.21 emphasizes the need for updated norms and regulations for biotherapeutic and biosimilar products. This new generation of medicines holds great promise if they can be put within the reach of all who need them.*

The final wording of the Sixty-seventh World Health Assembly’s resolutions is now available in WHO’s official online records of resolutions and decisions ([http://apps.who.int/gb/or/](http://apps.who.int/gb/or/)). The two above-mentioned resolutions are reproduced on the following pages for easy reference.

► **World Health Assembly. Resolution WHA67.20. Regulatory system strengthening for medical products. 24 May 2014.**

► **World Health Assembly. Resolution WHA67.21. Access to biotherapeutic products including similar biotherapeutic products and ensuring their quality, safety and efficacy. 24 May 2014.**
WHA67.20: Regulatory system strengthening for medical products

The Sixty-seventh World Health Assembly,

Having considered the report on regulatory system strengthening;  

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, 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, efficacy and affordability of medicines, including blood products;

Reaffirming resolution WHA65.19 on substandard/spurious/falsely-labelled/falsified/counterfeit medical products, 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 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;

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1 See Annex 6 for the financial and administrative implications for the Secretariat of this resolution.
2 Document A67/32.
3 For the purpose of this resolution, medical products include medicines, vaccines, diagnostics and medical devices.
Aware of the regulatory challenges presented by the ever-increasing complexities of medical product supply chains and welcoming the work plan of the Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products;

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 the WHO 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 levels;

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 the strengthening of regulatory systems should complement the efforts of the Secretariat and Member 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) to strengthen national regulatory systems, including – as appropriate and voluntarily – by:

   (a) undergoing self-evaluations, including with WHO’s support, to identify the strengths and opportunities for improvement in regulatory system functions, as a first step towards formulating plans for regulatory system strengthening, including through WHO-coordinated institutional development plans;

   And, where applicable, regional economic integration organizations.
(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 of the development or expansion of local or regional production of quality, safe and efficacious medical products;

(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 programme, including exploring modalities in consultation with Member States 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:

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5 And, where applicable, regional economic integration organizations.
(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;
(e) provide technical support to national regulatory authorities and governments;

(2) to continue to develop appropriate norms, standards and guidelines, 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;

(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 programme, including its 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 State 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.

(Ninth plenary meeting, 24 May 2014 – Committee B, fourth report)
WHA Resolutions

**WHA67.21: Access to biotherapeutic products, including similar biotherapeutic products,¹ and ensuring their quality, safety and efficacy²**

The Sixty-seventh World Health Assembly,

Having considered the report on regulatory system strengthening;³

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;

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 further that an update of the norms and standards applicable to medicines is required in the 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;

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, the high cost of such medicines affects the sustainability of health systems and could in many cases affect access to them;

Noting the importance of, and using as appropriate, WHO’s Expert Committee on Biological Standardization’s guidelines on evaluation of similar biotherapeutic products (2009), 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.

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

² See Annex 6 for the financial and administrative implications for the Secretariat of this resolution.

³ Document A67/32.
perspective that ensure the efficacy, quality and safety of these products at the national and regional levels;

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

   (2) to develop the necessary scientific expertise to facilitate development of solid, scientifically-based regulatory frameworks that promote access to products that are affordable, safe, efficacious and of quality, taking note of the relevant WHO guidelines that 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 biotherapeutic products, including similar biotherapeutic products;

2. **REQUESTS** the Director-General:

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

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

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

   (4) to convene WHO’s Expert Committee on Biological Standardization to update the 2009 guidelines, taking into account the technological advances for the characterization of biotherapeutic 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 progress in the implementation of this resolution.

(Ninth plenary meeting, 24 May 2014 – Committee B, fourth report)

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4 And, where applicable, regional economic integration organizations.