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- **The Independent Oversight and Advisory Committee for the WHO Health Emergencies Programme**

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Document not available on 27 April 2017.

- **WHO response in severe, large-scale emergencies**

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The report provides information on all Public Health Emergencies of International Concern, WHO Grade 3 emergencies and United Nations Inter-Agency Standing Committee Level 3 emergencies in which WHO took action between 1 January and 1 October 2016. In addition, it provides an update on WHO's action in Grade 2 emergencies. An earlier version of this report was considered by the Executive Board as its 140th session in January 2017.

During the period under review, WHO responded to major emergencies in 47 countries, areas and territories, including 31 acute emergencies and 19 protracted emergencies. Five acute graded emergencies were classified Grade 3: the complex humanitarian crises in Iraq (graded in August 2014), South Sudan (revised grading in February 2015), Syrian Arab Republic (including Jordan, Lebanon and Turkey, graded in January 2013) and Yemen (revised grading in July 2015); and the Ebola virus disease outbreak in West Africa (graded in 2014, deactivated June 2016).

WHO declared one new Grade 3 emergency between January and October 2016: the escalating humanitarian crisis in Nigeria (initially graded 2 in April 2015 and upgraded in August 2016). On 1 February 2016, the Director-General declared the recent cluster of microcephaly cases and other neurological disorders reported in Brazil, associated with the outbreak of Zika virus infection a Public Health Emergency of International Concern and WHO classified it as a Grade 2 emergency.

WHO also responded to the health needs of affected populations in 16 other low-graded emergencies including the Grade 2 humanitarian crisis in Ukraine. All new emergencies have been managed through WHO's Incident Management System (IMS), supported by funds released within 24 hours from the WHO Contingency Fund for Emergencies.

Of particular relevance for the European Member States is the humanitarian crisis in the Syrian Arab Republic, through the Whole of Syria Approach:

- 13.5 million people are in need of humanitarian assistance, including 6.6 million internally displaced people and a further 4.8 million have fled to surrounding countries.
- More than half the country's health facilities are either closed or are only partially functioning and childhood immunization programmes are almost at a standstill.
- Almost 1.2 million people have been injured since the conflict began.
- In Syria, WHO has a main office in Damascus with 90 staff members and suboffices in Homs, Aleppo, Lattakia and Al-Hasakeh.
- Cross-border operations are managed from operational bases in Gaziantep in southern Turkey and from Amman in Jordan.
- The Whole-of-Syria response for the health sector is coordinated by a team in Amman.
- The WHO field presence in Gaziantep has been supporting the Syrian areas that are accessible only from Turkey. All supplies procured by WHO/EURO were prepositioned in northern Syria and delivered to Aleppo to support health services in eight hospitals.
- WHO and its partners have increased their condemnations of attacks on health care workers, health facilities, delays in medical evacuations and removal of medicines and other medical supplies from convoys. In Gaziantep, the Health Cluster has established a mechanism for reporting regularly on attacks on health care workers and health facilities in the Syrian Arab Republic.

In the Annex, a summary of WHO's actions in Grade 2 emergencies is provided (Cholera in the African Region, Central African Republic, Ecuador, Ethiopia, Libya, Niger, Ukraine, Yellow fever outbreak in Angola and the Democratic Republic of the Congo)

Of particular relevance for the European Member States is the humanitarian crisis in Ukraine:

- The conflict affected 3.1 million people and displaced almost 3 million, with 10 000 deaths to date directly related to the conflict.
- WHO has organized a large-scale response, delivering medical supplies to support facilities that have treated close to 2 million people.
- WHO supports disease surveillance and response activities and a comprehensive network of mobile medical units to provide health services to internally displaced people.
- WHO is linking the response activities with rehabilitation and "building back better".

The World Health Assembly is invited to note this report.

Implication for the European Region

In line with the reform of WHO's work in health emergencies the European Region is strengthening its capacities at both regional and country levels, providing overall leadership and support to the two ongoing protracted emergencies. WHO Europe is currently

responding to two large scale protracted emergencies, the Syria Crisis (Grade 3) through WHO Country Office in Turkey and its Field Office in Gaziantep, and the humanitarian crisis in Ukraine (Grade 2), through the WHO Country Office and its 3 Field Offices in east Ukraine (2 in the Non-government Controlled Areas). All actions are taken within the WHO Health Emergencies Programme. Two Health Cluster Coordinators have been recruited and recruitment for priority positions in vulnerable countries is ongoing.

The WHO Field Office in Gaziantep, Turkey, has been operational since October 2013. The team coordinates the Health Cluster and enables cross-border activities to and from Syria under the UN Security Council Resolutions 2139, 2165 and 2191. This includes shipments of medicines, training of health workers in Syria, and evacuation of patients to Turkey.

Turkey currently hosts almost 3 million refugees, accounting for around 3.5 per cent of the population of Turkey. The number is increasing due to the increased fighting in Syria. Turkey is the host of the highest number of refugees in the world, enabling them to have access to health services. For this, WHO, from his Office in Ankara, chairs the health sector jointly with the Turkish Ministry of Health, coordinating more than 20 NGOs, some are active implementing partners. The Health Emergencies team is working closely with the WHO European Region Migration team to ensure policy adjustment and sustainable development.

WHO activities under the Whole of Syria Approach in Turkey included:

WHO has been working with the Turkish Ministry of Health to ensure Syrian refugees access to health services, addressing barriers and deterrents to seeking health care, including mental health services. Some of the activities are:

- Syrian health workers have been trained and integrated into the Turkish health system. In total 225 Syrian doctors, 101 Syrian nurses and 125 translators were trained, using a revised curriculum, in collaboration with the Turkish MOH and Gaziantep University.
- Knowledgeable medical translators have been recruited to help guide the Arabic speaking patients through the health care system.
- Medical equipment has been provided to a field hospital providing services in a refugee camp and supported trainings on Communicable Disease Surveillance, and the establishment of Refugees Health Centers by the MOH of Turkey.

WHO activities under the Whole of Syria Approach in Northern Syria by WHO Turkey Office/ Gaziantep Field Presence included:

- For the past two years, the Health Cluster for northern Syria has been chaired by WHO jointly with Save the Children, to coordinate the activities of more than 60 NGOs active in northern Syria.

- More than 19,388 health workers inside Syria were trained on immunization procedures and more than 3.8 million immunizations were provided.
- WHO established 535 Early Warning sentinel sites, trained 835 surveillance officers and health professionals.
- More than 3 tons of lab supplies & equipment were prepositioned and 450 000 leaflets and 18000 posters on prevention of acute watery diarrhoea were disseminated.
- WHO in partnership with its 23 implementing partners in Syria and their representatives in Gaziantep, delivered 270 tons of essential medicines and medical supplies in value of 2.9 million USD, supporting more than 1.5 million treatments provided in over 200 health facilities in northern Syria.
- The delivery of emergency medical services was strengthened through equipping 75 ambulances, 6 emergency facilities and 1 hospital with drugs, supplies, equipment and operational costs coverage.
- WHO, with partners in Gaziantep, is maintaining a real-time-database on attacks against health care facilities and health care workers to provide feedback for advocacy actions to stop such attacks and protect health workers.
- Assessments of 48 hospitals and 30 primary health facilities in the areas of surgery and trauma management were conducted.
- A technical working group on noncommunicable diseases was established, 11 training sessions were held training 118 doctors and 200 community health workers and 45 primary care physicians in Syria, including in mental health.
- Between 14 December and 23 December 2017, medical evacuation of people residing in eastern Aleppo was carried out successfully through the Health Cluster in Gaziantep. In total, 36.086 people were evacuated to rural western Aleppo. 811 patients were admitted to 17 referral hospitals in western rural Aleppo and Idleb, that were prepared and supported with essential medicines and supplies to receive critically ill patients and provide proper care and 156 ambulances were mobilized for patients' transportation. 26 mobile clinics were serving area along the evacuation route, providing essential primary health care services, mental health screening, nutrition screening and referral of cases to specialized services as needed.
- On 4th of April 2017, WHO was informed of 607 cases with 91 deaths of cholinergic syndrome consistent with toxic chemicals exposure in Khan Shaykhun, southern rural Idlib, Idlib Governorate, Syria.

  WHO and partners have been working towards increasing the level of preparedness and response to the threat posed by highly toxic chemicals in Syria since 2012. Prior to the incident, the WHO office in Gaziantep trained 65 northern Syrian doctors on management of exposures to toxic chemicals. In 2016 and 2017 134,000 ampules of Atropine sulfate were distributed to 77 locations, including hard to reach areas in 9 governorates of northern Syria. Currently WHO is implementing with Health Cluster Partners a comprehensive operational plan for preparedness and response to possible similar incidents in the future.

- The total financial requirements for the health sector in Turkey for 2017 are 48 Million USD.

In Ukraine, 4.4 million people continue to be affected by the conflict and more than 10,000 people were killed, including 2,000 civilians. 1.78 million are registered as internally displaced persons in Ukraine and 1.1 million are registered as refugees from Ukraine in neighbouring countries. The need for health services and medical supplies for the population in the conflict areas remain high – 2.2 million people are in need for health and nutrition. The situation for the 800.000 people living along both sides of the contact line (200 000 in government controlled areas, and 600.000 in non-government controlled areas), is particularly difficult.

WHO has been leading the international humanitarian health response in Ukraine since the beginning of the crisis in 2014, through its Country office in Kiev and field offices in Donetsk, Luhansk and Severodonetsk, targeting the hard-to-reach populations and supporting the provision of life-saving care for the most vulnerable IDPs living in the hosting areas where existing health facilities are not able to cope with the high demand for care.

WHO is linking the emergency response and operations with the health system and universal access to people-centered quality health services through actions directed at recovery and sustainable development.

Key activities of WHO in Ukraine include:

- In 2016, 35 Mobile Emergency Primary Care Units (MEPUs) were operating in the government controlled areas (GCA) locations along the contact line where the provision of health services has been cut or severely disrupted due to the conflict. MEPUs personnel provided 232,287 consultations and referrals (25%) to higher-level health facilities, 74% of beneficiaries were IDPs. Mental Health and Psychosocial Support (MHPSS) consultations were provided by multidisciplinary MEPUs teams as part of WHO project “Developing a model of community-based mental health care in Ukraine”.
- Partners under WHO coordination delivered essential medicines, consumables, medical supplies and equipment to the cluster partners and health facilities of GCA and non-government controlled areas (NGCA) of Donetsk and Luhansk oblasts to cover needs of 2,078,219 people (90.4% of targeted population) and to scale-up the availability of critical health interventions.
- WHO procured and delivered Emergency Trauma Kits for health facilities of GCA and NGCA to cover needs of 6,800 patients requiring surgical care. Support to trauma care through treatment and capacity building was provided by health cluster partners to 33,162 beneficiaries.
- 70 sentinel sites were established and started actively reporting on infectious diseases at regular intervals during 2016.

- 662 Interagency Emergency Health Kits (basic and supplementary) designed for health facilities without a doctor and health centres with a doctor were procured and delivered by WHO to 350,000 beneficiaries in GCA and NGCA during for a period of 12 months in 2016.
- 13 health facilities in GCA and NGCA were supported and eight rehabilitated through basic provision of medical supplies and equipment, and training/capacity building activities organized for health care providers.

In December 2016, the Federal Foreign Office of Germany donated €2.5 million to WHO to deliver emergency health services, including the provision of life saving medical supplies, trauma and injury care, mental health, critical disease surveillance and Health and Nutrition cluster coordination to crisis-affected people in Ukraine over a 12 month period.

The Health and Nutrition Cluster is appealing for US$ 23.3 million for 2017.

Zika

WHO responded to the cluster of microcephaly cases and other neurological disorders reported in Brazil, associated with the outbreak of Zika virus infection and declared a Public Health Emergency of International Concern and classified as a Grade 2 emergency. The WHO Regional Office for Europe undertook a country-level assessment of the risk for a Zika virus outbreak in the European Region, and subsequently made recommendations for targeting preparedness work and guiding prioritization of activities.

The assessment concluded that the overall risk for a Zika virus outbreak across the region is low to moderate during the spring and summer months and higher in those areas with the mosquito species Aedes aegypti. However there is good capacity in the Region to contain Zika virus transmission at an early stage.

WHO Europe also convened a regional consultation in Portugal on 22–24 June 2016 to examine the conclusions of the risk assessment and identify countries' needs, strengths and gaps in relation to preventing and responding to Zika virus disease.

At the end of the 2016 transmission season, there was no mosquito-borne Zika virus transmission in the region, although imported cases continue to be reported. Detection and notification of imported cases to Europe, particularly from areas with previously unknown transmission, highlight the importance of reporting under the International Health Regulations (2005) to inform the global epidemiological picture, and to implement necessary response measures.

- **Research and development for potentially epidemic diseases**

Document A70/10

In January 2017, the Executive Board, as its 140 session, considered an earlier version of this report. In response to resolution EBSS3.R1 on Ebola, the Secretariat developed a blueprint for research and development preparedness and response (the R&D Blueprint) for potentially epidemic diseases to reduce delays between the identification of an outbreak and the deployment of effective medical interventions. In addition, it aims to complement the Secretariat's efforts to foster research and development related to Type II and Type III diseases, and the specific research and development needs of developing countries in relation to Type I diseases, in line with the global strategy and plan of action on public health, innovation and intellectual property and the recommendations of the Consultative Expert Working Group on Research and Development: Financing and Coordination.

It was prepared with global experts from all relevant disciplines and under the guidance of an independent advisory group. The current document provides with an update on progress since May 2016.

R&D road maps for research and development to address potential outbreaks of disease due to priority pathogens: The Secretariat started elaborating research and development road maps for 11 pathogens prioritized in an expert consultation (Geneva, December 2015) as likely to cause public health emergencies in the near future. The list will be reviewed periodically. By defining the needed medical products, delineating actions and assigning roles, these road maps will save time and facilitate the activation and coordination research and development.

The Secretariat issued an R&D road map for the *Middle East respiratory syndrome coronavirus*[1] (MERS-CoV) based on four strategic goals: establishment of a surveillance network of coronavirus laboratories ; better understanding of the pathogenesis MERS-CoV infection ; development, manufacture, testing, licensure and use of improved diagnostics, preventive and therapeutics ; establishment of a direct path for manufacturers from preclinical proof-of-concept studies to post-licensing procurement of MERS-CoV products.

R&D blueprint activities on Zika virus: Following the declaration of Public Health Emergency of International Concern in February 2016, the Blueprint framework was used to trigger rapidly a series of research and development actions. Initial activities included the *mapping* of existing research and product development. After consultation on regulatory considerations of Zika virus vaccines, a *target product profile* for vaccines aimed at protecting against Zika virus infection and associated congenital syndrome vaccines for emergency use as an outbreak response was issued in July 2016. In October 2016, WHO and

[1] Available at http://www.who.int/csr/research-and-development/mers-roadmap-may-2016.pdf?ua=1 (accessed 11 October 2016).

the Welcome Trust discussed on how best to *capitalize* on the commonalities of mosquito-borne viral diseases so as to define common research approaches for the development of products. The latest information on Zika vaccine development was reviewed at a consultation co-organized by WHO and the United States National Institutes of Health (, January 2017).

Platform technologies: In October 2015, a public consultation on health technologies platforms outlined that the main requirements were; flexibility to enable expedited development and manufacture of candidate products for clinical trials; affordability of candidate products and significant participation by entities in developing countries. Out of the 35 proposals received 6 were presented to potential funders and interested Member states during a technical workshop in July 2016.

Revision of epidemic threats and the list of pathogens prioritized by WHO: Consultations were held in December 2016 to fine-tune the prioritization methodology. The WHO's list of pathogens for priority research and development, which only includes pathogens for which there are no medical countermeasures available, and excludes pandemic influenza, was reviewed and updated on in January 2017 and now contains the infectious agents for the following diseases: Lassa fever and other severe arenaviral haemorrhagic fevers; Crimean-Congo haemorrhagic fever; filoviral diseases (including Ebola virus disease and Marburg haemorrhagic fever); Middle East respiratory syndrome (MERS); other highly pathogenic coronaviral diseases (such as severe acute respiratory syndrome (SARS)); Nipah and related henipaviral diseases; Rift Valley Fever; severe fever with thrombocytopenia syndrome; Zika virus disease; and any new disease "X" identified by the decision instrument.

Stakeholder coordination: The Secretariat is leading efforts to better coordinate research and development activities during epidemics by establishing frameworks for research oversight and management at the national level and global mechanisms for fruitful collaboration. To that end, it has completed the mapping of all relevant global stakeholders by their areas or diseases of interest and current participation in collaborative networks. A database of research preparedness resources has been created and will be integrated into WHO's Global Observatory on Health Research and Development. A guidance document on good participatory practices in a research context as related to prioritized diseases is being finalized.

In addition, a set of principles for a global collaboration framework were discussed at a high-level meeting in November 2016 and a template for a coordination framework to streamline global stakeholder collaboration will be discussed during the first meeting of the Blueprint Global Coordination Mechanism in London on March 2017.

In September 2016, WHO signed a memorandum of understanding with the Coalition for Epidemic Preparedness Innovations, a new public–private partnership that aims to finance

and coordinate the proactive and expedited development of new vaccines to prevent and contain infectious disease epidemics. The memorandum of understanding provides the basis for collaborative and mutually strengthening efforts within the broad scope of the R&D Blueprint foster such sharing, include scientists from countries at risk and facilitate governance of multiparty collaborations are effective tools.

Sharing of data and samples: Sharing of data and samples is crucial for informed research and development efforts and for ensuring equitable access to potential new products, especially during epidemics. Agreements that foster such sharing, include scientists from countries at risk and facilitate governance of multiparty collaborations are effective tools.

The Secretariat is developing *global norms* for sharing data and results and elaborating *mechanisms* for collaboration and data sharing during public health emergencies. It has initiated *a process to reach consensus on principles for open-access repositories of biological samples* (bio-banks), including the development of a virtual resource linking national bio-banks through an information sharing platform. Principles for a *shared system of governance and decision-making* are being elaborated. A *Material Transfer Agreement capacity-building tool* has been prepared in order to inform negotiations at country level on sharing biological samples. WHO aims at finalizing such a capacity-building tool during the second quarter of 2017 through consultations with various stakeholders, with subsequent conversion into a web-based application to support partners engaging in negotiations of such agreements.

Regulatory capacity: Building capacity to design and conduct clinical trials for vaccines and therapeutics for emerging disease threats in developing countries is part of the Blueprint's plans to create enabling environments for research and development during emergencies and to ensure that national actors and scientists in countries at risk can function as equal partners in international efforts. The Secretariat has outlined a clear set of steps to inform exchanges on trial designs for prioritized diseases, and the assessment of those designs. The next step will be the development of generic protocols for the prioritized diseases to ensure consistent approaches among all stakeholders in a given research and development effort.

The World Health Assembly is invited to note this report.

Implication for the European Region

The report provides a summary of major activities and achievements over past year on global health research and development.

The processes and methodologies for prioritisation of emerging or neglected infectious diseases have been modified based on measures of disease burden, as well as on other important factors to drive investment in the research and development of vaccines, new diagnostics and novel treatments. Many of public and private actors are responding to the

R&D priorities, accomplishing this with the support of WHO European Region based funding agencies.

Selection of most promising platforms to support development and production of health technologies for priority infectious diseases with epidemic potential, has shown significance in R&D conducted in the European Region. Of 35 applications, four of six finalists are based in the Region and comprise variety of public-private partnerships. The selection process confirmed European based R&D importance and a signal to funding agencies to continue support for European based technologies development in the context of increasing global public health security.

WHO published recently the ethical guidance[2] based on well-established principles, with the focus and further modification to outbreak situations including deployment of experimental or novel outbreak management strategies and products. Outbreak situations tend to be affected by urgency, scientific uncertainties and health system disruptions. These guidelines form a prerequisite for any future technical or humanitarian assistance provided by member states, international or nongovernmental organizations, either by emergency medical teams, deployment of experimental therapies, diagnostics or vaccines, or otherwise.

- **Health workforce coordination in emergencies with health consequences**

Document A70/11

Strong coordination of all health actors in emergencies and collaboration with actors in other sectors is vital to ensuring the predictability, coherence and effectiveness of emergency operations as demonstrated by recent history[3]. The present report describes the steps taken by WHO to strengthen internal coordination for emergency response across the three levels of the Organization (global, regional and country level) and external coordination with partners working on emergencies with health consequences. An earlier version of the Document A70/11 was considered by the Executive Board at its 140th session in January 2017.

Central to improved coordination is the concept of the Global Health Emergency Workforce, comprising national responders and international responders from networks and partnerships. These networks and partnerships include the Global Outbreak Alert and Response Network, the Global Health Cluster, emergency medical teams, standby partners and other members of the Inter-Agency Standing Committee.

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[2] http://apps.who.int/iris/bitstream/10665/250580/1/9789241549837-eng.pdf

[3] WHO monitors over 160 public health events annually, and between January and October 2016 it responded to emergencies in 47 countries (see the complementary report by the Secretariat on the WHO response in severe, large-scale emergencies, Document EB140/7).The past two decades have witnessed important major outbreaks due to emerging diseases as well as "traditional" outbreak-prone diseases. Worldwide, an estimated 130 million people are in need of humanitarian assistance, with over 200 million also affected annually by natural and technological disasters.

Coordination across three levels of WHO : WHO has undertaken substantive reform of its work in emergencies with health consequences4 through its new Health Emergencies Programme. It is aimed at managing WHO's work in the prevention of, preparedness for, response to and early recovery from emergencies, regardless of the hazard, including infectious diseases, natural disasters and societal conflicts. Aligned across the three levels of WHO, the Programme now follows a common structure reflecting the major functions of WHO in emergency risk management: infectious hazard management; country preparedness (pursuant to the International Health regulations (2005)) ; health emergency information and risk assessment; emergency operations; and management and administration. Over the next 12 to 18 months, all aspects of the Programme will be operationalized.

Standard operating procedures are being developed to ensure coherent approaches to emergency health information, risk assessment, grading and emergency response across the Programme. An incident management system is being institutionalized to strengthen the management of WHO emergency operations through the adoption and institutionalization of an incident management system. Critical emergency management functions are established at country level, with support teams at regional and headquarters levels providing technical and operational backstopping and oversight.

Effective application of this new approach to multicountry, multiregional events was demonstrated in the response to the outbreak of Zika virus disease. Together with a proactive approach to communications, this has strengthened the operational response, improved the support provided to countries, and advanced WHO's global leadership role.

A biennial results framework for the Programme has been developed to better align and integrate work planning, budgeting and implementation across the three levels of the Organisation, to establish clear lines of accountability and to monitor progress towards specific coordination objectives. Furthermore, the Programme's human resource capacity is being strengthened with additional personnel across offices, and emergency response rosters of staff from within and outside the Programme, to address skills gaps and enhance interoperability.

Coordination at global level

Inter-Agency Standing Committee: The IASC is the primary mechanism for interagency coordination of humanitarian assistance, a forum for key UN and non-UN humanitarian partners. WHO participates actively in the main bodies under the Committee:

- the Principals group, overseeing global priorities and strategies for collective

[4] Further to the request of the EB during its special session on the Ebola emergency in January 2015 and reflecting many of the recommendations from the series of evaluations carried out during and after the Ebola crisis in West Africa.

humanitarian action and on which the Director-General represents the Organization;
- the Emergency Directors Group, addressing operational priorities and issues at country level;
- and the Working Group, overseeing the development of interagency policy and guidance.

The IASC already has clear protocols and processes for a collective response to and coordination of large-scale natural disasters or conflicts that require system-wide mobilization (so-called "Level 3 (L3)" emergencies) but not for large-scale outbreaks. It has been encouraged through the Health Assembly decision WHA69(9).

Based on existing Committee mechanisms and endorsed by the IASC Principals in December 2016, new protocols (known as "IASC+") were developed for leadership and coordination in large-scale events due to infectious hazards. It allows for interagency Level 3 activation and temporary expansion of the IASC, on an as-needed basis, to include the Global Outbreak Alert and Response Network and major public health institutions involved in the response.

The newly defined procedures include a time-bound situation assessment by WHO and OCHA; consultation and decision-making with the Emergency Directors Group (and other non-IASC stakeholders as appropriate, including the Global Outbreak Alert and Response Network for infectious disease risks and events); recommendations to the Principals of the Standing Committee; and explicit activation and deactivation triggers. The immediate communication of joint strategic response priorities and allocation from the United Nations' Central Emergency Response Fund to support these priorities will be initiated and a review of the coordination and leadership arrangements within 7−10 days. These IASC+ activation procedures were endorsed by the IASC Principals in December 2016

Global Health Cluster: The IASC's cluster approach is a vital mechanism for coordinating sectoral action in humanitarian emergencies[5]. The health cluster is currently activated in 24 countries to support national authorities in meeting the health needs of 72.2 million crisis-affected people. The Global Health Cluster comprises 48 partners, including international organizations and United Nations agencies, non-State actors, national authorities, academic and training institutes and donor agencies. There are more than 300 partners at country level.

WHO is recruiting 24 health cluster coordinators on longer-term contracts to ensure more predictable, dedicated and skilled leadership at country level. To support countries with coordination of in-country operational partners and to build operational and technical capacity, additional surge roster capacity is being identified through mapping and gap

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analysis. A new multiyear development plan is being rolled out to build and sustain capacity within the cluster.

Strengthened collaboration and coordination are being sought with other clusters (for example, those for nutrition, water and sanitation, food aid and logistics) to improve the overall response to emergencies with health consequences. WHO plays an important role in the Inter-Cluster Coordination Group at global level and is working more closely with other clusters. Inter-cluster collaboration is also a key element of the IASC's IASC+ protocol.

Global Outbreak Alert and Response Network: The Global Outbreak Alert and Response Network is a system of over 200 multidisciplinary technical partners. Priority for the Health Emergencies Programme, its enhancement and expansion is being accomplished by strengthening the Network's oversight, policies and secretariat functions; identifying and engaging new partners and consolidating existing commitments; strengthening its ability to leverage functional experts of the health emergency workforce and provide operational support, specifically for staff health and safety; and implementing joint training with partners to improve field-level coordination. In line with the above, the Network's 21-member Steering Committee[6] has agreed on priorities for the development and operations of "GOARN 2.0".

Since the beginning of 2016, Network partners have been more involved in alert, risk assessment, preparedness and response activities (notably through regular consultations by teleconference). The first European regional meeting of Network partners was held in St Petersburg, Russian Federation, in October 2016. WHO is exploring how to strengthen Network involvement in and support for national alert and response capacity through the Joint External Evaluation initiative (in the context of the International Health Regulations (2005)), including capability to deploy and receive international experts.

Emergency medical teams: The WHO emergency medical teams secretariat manages the training, capacity-building, standard-setting and quality assurance processes for this global initiative. The overall goals are to strengthen national capacity to respond to emergencies with health consequences, as part of the global health emergency workforce, and to create mechanisms for that capacity to be effectively leveraged and coordinated by national health emergency operations centers, including through calling on neighbour, regional and global teams to provide temporary surge capacity in times of need, consistent with the principles of the International Health Regulations (2005).

Over 75 organizations have started the process of mentorship, training and quality improvement, with 30 visited in 2015, and seven teams verified as reaching the agreed international standard.

In coordination with the OCHA, the WHO emergency medical teams secretariat has created

[6] It meets every six months to provide strategic direction to the development and operations of the Network.

a coordination platform for work with other forms of rapid response teams, particularly those engaged in search and rescue[7]. This system, active within minutes of a disaster, uses the agreed virtual on-site operations coordination centre, recording team arrivals and referring them to the affected country's coordination mechanisms within the ministry of emergency management and ministry of health, with support from OCHA and WHO. The system, trialed for the first time in the Nepal earthquake in 2015, was shown to be fit for the purpose of coordinating the 149 teams responding to that disaster, with an estimated 3500 medical responders in the first seven days. That finding was confirmed in Ecuador in 2016.

A minimum data set has been agreed for emergency medical teams to report on to the affected MS when working there, enabling the affected health system to respond.

The emergency medical teams initiative has become more active in complex and protracted emergencies, with involvement in coordination and operational planning in Iraq, Nigeria and Yemen. In 2017, the WHO emergency medical teams secretariat is continuing to work on defining rapid, field-focused working groups to strengthen other aspects of team deployment, continuing to build the capacity of rapid response clinical and public health teams, and to strengthen coordination systems for national and international or bilateral response operations by bolstering health emergency operating centres in affected MS.

Standby partners: Launched in 2013, the WHO standby partners initiative is an increasingly central element of WHO's coordination in response to humanitarian emergencies. WHO holds global agreements with seven partners[8] to rapidly deploy highly skilled personnel of the global health emergency workforce to support field emergency work. Through the International Humanitarian Partnership, two further partnerships are under negotiation with government agencies to support individual deployments, as well as highly specialized service packages.

Operational support and logistics: The Health Emergencies Programme provides guidance and technical support to the Global Supply Chain initiative for pandemic preparedness and response. The goal is to identify public–private supply chain options or preparedness solutions, to estimate needs and monitor global supply resources, and to develop better mechanisms to access supplies in times of public health emergencies of international concern and pandemics. The (informal) network is developing an information platform with support from the University of Minnesota (United States of America), to provide upstream and downstream supply chain visibility and coordination in operations.

Regional coordination: Targeted human resource capacity-building has been undertaken in priority regions to ensure that the Programme is better able to support vulnerable

[7] This system, active within minutes of a disaster, uses the agreed virtual on-site operations coordination centre, recording team arrivals and referring them to the affected country's coordination mechanisms within the ministry of emergency management and ministry of health, with support from OCHA and WHO.

[8] International Civilian Response Corps (CANADEM), the Information Management and Mine Action Program (iMMAP), the Netherlands Enterprise Agency, the NGO Consortium for the Global Health Cluster, the Norwegian Refugee Council, RedR Australia and the United Kingdom Department for International Development.

countries. One country in which this approach has had a significant impact is the Syrian Arab Republic. In line with the reform of WHO's work in health emergency management, additional human resources have been deployed at regional and country levels to support the "whole of Syria" humanitarian health response.

Coordination at country level: Coordination structures and mechanisms at country level vary according to the capacities of national and local authorities and the scale and type of emergency. As far as possible, national leadership of health sector coordination is promoted and supported.

- In acute public health events, rapid engagement of the appropriate partners of the global health emergency workforce with technical and operational capacities may be sufficient to stop an outbreak. Global Outbreak Alert and Response Network partners are often key to this.
- When an outbreak amplifies, additional coordination mechanisms may be required to draw on capacities from technical and intersectoral partners.
- For events and outbreaks due to zoonoses, coordination with the animal health sector is vital.
- For conflict-related and sudden onset disasters, many responders from the global health emergency workforce may be present, including non-State actors, emergency medical teams and technical agencies. One overarching coordination mechanism for the health sector is needed, often with related task teams to address specific issues, such as surgical care or reproductive health, in more detail. There may also be a need for a specific coordination cell for emergency medical teams.

Depending on the circumstances of the emergency, a health cluster might be formally activated. A health cluster is the main coordination mechanism in 24 of the 47 countries where WHO is currently responding. Established practices of good coordination, clear commitment by partners, accountability to affected populations and transparent communication must be followed, and close linkages and active collaboration with other sectors (such as nutrition or water and sanitation) must be ensured.

Budget and resource mobilization: To implement the core activities of the Programme, WHO must raise US$485 million in 2016-2017: a gap of 445 still remains. Appeals linked to humanitarian response plans have a funding gap of 66% (the total requirement for funding from appeals is US$ 656 million).The WHO Contingency Fund for Emergencies has raised US$ 31.5 million of its US$100 million target capitalisation. Allocations to date total US$ 18.16 million in support of WHO activities in response to humanitarian crisis, disease outbreaks and the impact of natural disasters.

The Health Assembly is invited to note this report.

Implication for the European Region

GOARN: GOARN is a central part of the Emergency Programme also at the Regional Office with critical roles in both alert and response. WHO European Region has the largest number of GOARN partners of all WHO Regions. Out of 55 GOARN partners in the European Region, some 40 have contributed to GOARN missions around the world during the past 15 years. The effective functioning of GOARN for outbreak response requires the active support of all the Departments of the WHO Health Emergency Programme.

WHO Regional Office for Europe organized the 1st European GOARN Partners Meeting in St. Petersburg in October 2016, in cooperation with the Russian Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing, and with support from the Government of the Russian Federation. An important objective of the meeting was identification of new GOARN partners from Europe, especially from the Russian-speaking countries. Potential partner institutions from most Russian-speaking Member States and from the Central and South-eastern Europe had the opportunity to learn about GOARN during the meeting. A workplan for regional activities for the development and operations of GOARN in European Region was developed during the meeting.

In March 2017, the German Robert Koch Institute and WHO cohosted a workshop of GOARN Rapid Response Capacities Partners in Berlin. The Workshop took place against the background that Member States and institutions are developing both national and international rapid response capacity, including infectious disease outbreak response teams and for other emergencies. The rapid response approach provides for rapid deployment of pre-defined, scaleable, and well-coordinated teams of experts, that will be deployed both bilaterally and/or via GOARN or other mechanisms, including the Global Health Cluster, and Emergency Medical Teams.

Health Cluster: WHO Europe is currently responding to two large scale emergencies, in which the Cluster System is activated, the Syria Crisis and the humanitarian crisis in Ukraine.

In Turkey, the WHO Office in Gaziantep co-chairs the Health Cluster for northern Syria under the Whole of Syria Approach jointly with Save the Children, coordinating more than 60 NGOs active in northern Syria. Through the Country Office in Ankara, WHO chairs the health sector jointly with the Turkish MoH to coordinate more than 20 NGOs in their response to health needs of Syrian refugees in Turkey.

In Ukraine, WHO is coordinating the Health and Nutrition cluster through its Country office in Kiev and field offices in Donetsk, Luhansk and Severodonetsk, closely working with the Ministry of Health in Ukraine at national and sub-national level, coordinating 45 partners.

EMT: mentorship and verification activities of WHO EMT minimum standards are ongoing in the WHO European Region. There are currently 30 EMTs from Europe that have applied for verification, of which 43% are government teams, 53% are NGOs and 4% are military teams.

In 2016, four teams have achieved classification status after a peer view verification visit. Three are government teams (The United Kingdom Emergency Medical Team, EMERCON of Russian Federation and All Russian Centre for Disaster Medicine) and have achieved status of type 2 classified EMT and one is a military team from Israel (Israel Defence Force Medical Corps), which was classified as a type 3 EMT provider. Two EMTs from Germany (Arbeiter Samariter Bund and Jonhanniter International) will receive verification visits in June 2017. During 2016 the first EMT training and regional workshops were conducted, respectively in Italy Kazakhstan. WHO also provided input as part of the Core Group in the preparations for the EU Module Exercises (Modex) and as Exercise Control staff for the Field exercise for EMTs and Mobile Labs. WHO collaborates with the European Medical Corps (EMC) as part of the voluntary pool of assets of the EU Civil Protection Mechanism in February 2016.

In September 2016 WHO European Region team participated in the Triplex Exercise in Norway, one of the largest full scale civilian led humanitarian field exercises with more than 200 participants. In May 2017 WHO Europe participated in the Regional Insarag Earthquake Response Exercise in Istanbul. The establishment of a joint EMT Coordination Cell by WHO and the Turkish Ministry of Health was exercised. 8 EMTs participated in this exercise all from Europe.

12.2 Antimicrobial resistance

Documents A70/12, A70/13 and EB 140/2017/REC/1, resolution EB140.R5

The Executive Board at its 140th session in January 2017 noted an earlier version of document A70/12.

This report provides an update on implementation of resolution WHA68.7 (2015) on the global action plan on antimicrobial resistance and the United Nations General Assembly resolution 71/3, “Political declaration of the high-level meeting of the General Assembly on antimicrobial resistance”, which was the outcome of the high-level meeting on antimicrobial resistance at the United Nations headquarters in New York in September 2016 and adopted in October 2016.

The political declaration includes commitments by Heads of State and Government and representatives of States and Governments to develop their multisectoral national action plans in line with the One Health approach; to mobilize funding for, inter alia, the implementation of these plans and for research and development; to ensure that national plans cover the development of surveillance, monitoring and regulatory frameworks on the preservation, use and sale of antimicrobial medicines; and to increase and sustain

awareness of and knowledge about antimicrobial resistance among the public and health professionals.

The political declaration includes three major requests to WHO, FAO and OIE: 1) to finalize a global development and stewardship framework on antimicrobial medicines and resistance, 2) to support development and implementation of national action plans and other activities to counter antimicrobial resistance at national, regional and global levels in collaboration with development banks, other United Nations agencies and intergovernmental organizations, civil society and multisectoral stakeholders, and 3) to establish an ad hoc interagency coordination group, in consultation with the Secretary-General, to provide practical advice on approaches to ensure effective action to address antimicrobial resistance.

WHO is working with the Secretary-General, FAO and OIE on these requests and a progress report will be prepared for the UN Secretary General to submit to the General Assembly at its seventy-third session. The Secretary-General announced the establishment of the ad hoc interagency coordination group, chaired by UN Deputy Secretary General and WHO Director General.

In resolution WHA68.7 (2015), the Health Assembly urged Member States to have national action plans on antimicrobial resistance in place by the Seventieth World Health Assembly. To date, 67 Member States have completed their national plans on antimicrobic resistance, and a further 62 are in process of doing so. These represent the largest and most populous countries (in total 6500 million people) and include all regions. Many remaining countries are either small, fragile or affected by conflict. Almost all national action plans reflect the One Health approach, with a multisectoral coordination group and actions planned across health, agriculture and other sectors. The challenge is now to implement plans, sustain action and ensure that essential priority actions are appropriately budgeted.

Awareness of antimicrobial resistance is increasing through targeted media outreach and multiyear campaigns. Activities during World Antibiotic Awareness Week (November, 2016) included the development and dissemination of a comprehensive campaign toolkit for countries, specific messages and materials for different types of health workers, and a series of personal stories from people around the world affected by antibiotic resistance. Engagement with a broad range of partners, opinion-leading media and the public through social media around the United Nations General Assembly high-level meeting on antimicrobial resistance (New York, September 2016) was highly effective.

The Global Antimicrobial Surveillance System has been established with 43 countries enrolling. The System will focus on bacterial pathogens in humans and collect information on countries' progress in strengthening national surveillance systems. A methodology to

measure antibiotic consumption at national levels has been developed with participants in 35 countries being trained.

Prevention of infection is critical to reduce the need for antibiotics. In addition to ongoing work on immunization, new recommendations on infection prevention and control were recently published, including global guidelines on the prevention of surgical site infection and guidelines on core components of infection prevention and control programmes. Assessment tools and practical manuals for implementation of core components of infection prevention and control, in particular in low-resource settings are being developed.

The antibiotic chapter of the WHO Model List of Essential Medicines, which will be published in May 2017, will offer guidance on management of major infective syndromes. Guidelines on the management of the five most common paediatric infections have also been revised.

WHO has also issued a list of priority antibiotic-resistant bacterial pathogens where new medicines are most urgently needed. WHO restates the importance of research and development into interventions for tuberculosis as a major global priority. The Global Antibiotic Research and Development Partnership, to which WHO is providing technical support , is a new facility for antibiotic development focusing on new products with global application for gonorrhea and neonatal sepsis; and opportunities for new combinations of medicines and adjustments of current formulations for greater efficacy.

Provision of support for the development of national action plans and their implementation, monitoring and evaluation is a high priority for WHO. WHO/FAO/OIE have developed a monitoring questionnaire to review each country's progress. Results will be released on line for the 70th Health Assembly. Self-reporting will be periodically verified through the Joint External Evaluation of The International Health Regulations process. Finally, the Secretariat is developing a broader monitoring framework for implementation of the global action plan which will be consulted with Member States and with FAP and OIE.

Since the adoption of the global action plan on antimicrobial resistance, the Secretariat has expanded efforts to prevent and control drug resistance in HIV, tuberculosis and malaria. In 2016, WHO has issued new guidelines on programmatic management of multidrug-resistant tuberculosis, approved a rapid test that enables the triage of patients with multidrug-resistant tuberculosis, and revised the composition of antibiotic combinations for patients who need longer treatment regimens, including children. The Secretariat is leading the development of a global action plan on HIV drug resistance (2017-2021) and guidance on global and national responses to increasing HIV drug resistance is being prepared and is due to be disseminated in the second quarter of 2017. The Secretariat is also preparing a global report on HIV drug resistance, based on data for the period 2014–2016 Antimalarial

resistance is being monitored globally and resistance management strategies are being implemented.

In resolution WHA68.7 (2015), the Health Assembly also requested the Director-General to develop options for establishing a global development and stewardship framework to support the development, control, distribution and appropriate use of new antimicrobic medicines, diagnostic tools, taking into account the need of all countries and in line with the global action plan on antimicrobic resistance. The Secretariat continues working to meet this request, by consulting Member States and FAO and OIE. A draft road map providing options for finalization a global development and stewardship framework will make available on the WHO website, in order to inform the discussion at the Seventieth World Health Assembly.

The Health Assembly is invited to note this report.

Document A70/13: Improving the prevention, diagnosis and clinical management of sepsis

The Executive Board at its 140th session considered an earlier version of the Document A70/13.

An international consensus has recently recommended that sepsis should be defined as "life-threatening organ dysfunction caused by a dysregulated host response to infection" and septic shock as "a subset of sepsis in which particularly profound circulatory, cellular, and metabolic abnormalities are associated with a greater risk of mortality than with sepsis alone"[9]. Both definitions are accompanied by clinical criteria to translate them into practice to support diagnosis and clinical management during patient care.

The occurrence and frequency of sepsis are determined by a complex interplay of many host, pathogen and health system response factors. Several chronic diseases, demographic and social factors as well as access to health care systems, in particular intensive care, and the timeliness and quality of care are also associated with the occurrence of sepsis and its fatality rate.

It is impossible to estimate precisely the global epidemiological burden of sepsis. The estimates were based exclusively on data from high-income countries; the epidemiological burden of sepsis is likely to be much higher in low- and middle-income countries.

In the community, sepsis often presents as the clinical deterioration of common and preventable infections such as those of the respiratory, gastrointestinal and urinary tract, or of wounds and skin. Sepsis is frequently under-diagnosed at an early stage when it is still

[9] Singer M et al. The third international consensus definitions for sepsis and septic shock (Sepsis-3). JAMA. 2016;315(8):801-10. doi: 10.1001/jama.2016.0287.

potentially reversible. It may also result from infections acquired in health care settings caused by resistant to antibiotics bacteria and therefore the clinical condition of the patient can rapidly deteriorate.

In 2015, infectious diseases accounted for more than 50% of all deaths in neonates and children aged under 5 years, especially in southern Asia and sub-Saharan Africa. Among these, pneumonia (920 000 deaths/year), diarrhoea (526 000 deaths/year), neonatal sepsis (401 000 deaths/year) and malaria (306 000 deaths/year) were the most frequent causes of death.

Antimicrobial resistance is a major factor determining clinical unresponsiveness to treatment and rapid evolution to sepsis and septic shock. Approximately 214 000 neonatal deaths due to sepsis worldwide each year could be attributable to resistant pathogens. Sepsis patients with resistant pathogens have been found to have a higher risk of hospital mortality.

International Context – recent efforts on sepsis: Recognition of sepsis as a major cause of preventable morbidity and mortality globally has grown in recent years, due to efforts of a wide range of public and private actors. One such actor, the Global Sepsis Alliance, a non-profit organization, was launched in 2010 to understand and combat sepsis better. The main initiatives to date include the promotion of World Sepsis Day (on 13 September) and the World Sepsis Congress (the first congress was held in 2016).

In order to mitigate sepsis-associated mortality, the Surviving Sepsis Campaign developed guidelines that recommend administration of empirical antimicrobial therapy within one hour of recognition of severe sepsis or septic shock in adult and paediatric patients. Observational studies have demonstrated that adherence to these guidelines improves processes of care and survival in high-income countries. Implementation in low- and middle-income countries, however, is proving very challenging.

A Lancet Infectious Diseases Commission recently discussed the global burden of sepsis, its determinants, clinical management and most importantly a new road map for future research[10].

WHO's response to sepsis: Preventing and reducing harm from sepsis is relevant to achieving SDGs (Goal 3 and 6), the United Nations Global Strategy for Women's, Children's and Adolescents' Health, the WHO global action plan on antimicrobial resistance, implementation of the International Health Regulations (2005) and of the WHO framework on integrated, people-centred health services.

[10] Cohen J et al. Sepsis: a roadmap for future research. Lancet Infect Dis. 2015;15(5):581-614. doi: 10.1016/S1473-3099(15)70112-X.

WHO and other key stakeholders are in the process of launching a global quality of care network for maternal, newborn and children's health to accelerate reduction of preventable maternal and neonatal deaths, which includes prevention, early detection and prompt management of sepsis, in particular through implementation of essential newborn care packages and care at home.

Regarding the prevention of sepsis in children and the reduction of its contribution to the global burden of child mortality, the Health Assembly has adopted the following resolutions over the past few years: on working towards the reduction of perinatal and neonatal mortality (WHA64.13 (2011)); global vaccine action plan (WHA65.17 (2012)); and newborn health action plan (WHA67.10 (2014)).

WHO with key partners developed the global action plan on antimicrobial resistance. All five principles of the global action plan are relevant to reducing the burden of sepsis worldwide, as they aim to increase awareness of the problem, strengthen surveillance capacity and data dissemination, prevent antimicrobial resistance through infection prevention and control, improve water quality and sanitation, and promote a more appropriate use of antibiotics, as well as research to develop new medicines to overcome the problem of antimicrobial resistance. New evidence-based guidelines outlining the core components for effective infection prevention and control programmes at national and health care facility levels were issued in November 2016 to provide support to capacity-building efforts in countries, including national action plans on antimicrobial resistance.

To provide relevant guidance on clinical management during outbreak responses, WHO developed the IMAI district clinician manual: hospital care for adolescents and adults: guidelines for the management of common illnesses with limited-resources in 2011, which includes guidance on sepsis and severe respiratory infections. During the 2013–2016 outbreak of Ebola virus disease in West Africa, WHO incorporated these WHO adult sepsis guidelines into guidance on management of patients (Clinical management of patients with viral haemorrhagic fever: a pocket guide for front-line health workers. Interim emergency guidance for country adaptation, first issued in March 2014, updated February 2016). Support for training on sepsis management tailored to settings with limited resources has also been provided through development of a learning programme, the WHO IMAI Quick Check+/Clinician's role in disease surveillance and response training curriculum (QC+).

WHO will update the Model List of Essential Medicines in March 2017 and will review the information on antibiotics by reviewing treatment of 20 of the most prevalent and severe syndromes globally. A specific guidance document on neonatal sepsis will be included in the revised list in 2017 to provide support to countries in implementing evidence-based recommendations.

WHO and the Drugs for Neglected Diseases Initiative have collaborated in recent years to create the Global Antibiotic Research and Development Partnership, which aims to develop new antibiotic treatments for global health needs and promote sustainable and equitable access to them, including optimal conservation of antimicrobials.

Future priorities: The following priorities were identified by the Secretariat:

- To work together to improve understanding an monitoring of the burden of sepsis;
- To eliminate health systems factors that contribute to sepsis occurrence and inappropriate diagnosis and clinical management;
- To increase access to and use of available vaccines that prevent the most common infections that can lead to sepsis;
- To prioritize actions that increase awareness of the clinical manifestations of sepsis among the public and community health care practitioners;
- To support the use of appropriate diagnostic tools;
- To ensure that the basics of care are reliably delivered as part of global efforts to achieve high-quality universal health coverage;
- To increase access to management of neonatal and infant sepsis when referral is not possible;
- To coordinate, support and undertake high-quality research to identify new medicines and treatments, for prevention and management of infections that most frequently lead to sepsis.

Resolution EB140/R5: Improving the prevention, diagnosis and management of sepsis

The Executive Board at its 140th session, recommended to the 70th Health Assembly to adopt a resolution acknowledging that the inappropriate and excessive use of antimicrobials contributes a threat to antimicrobial resistance. The resolution urges Member States to include prevention, diagnosis and treatment of sepsis in their national plans, to promote appropriate use of antimicrobials and research in new antimicrobials and alternative medicines, to increase public awareness and develop training for health professional including on infection prevention and patient safety. It further urges Member States to apply the use of the International Classification of Disease system to establish the prevalence and profile of sepsis and antimicrobial resistance.

The resolution requests the Director-General to draw attention to the public health impact of sepsis by publishing a report by the end of 2018; to support Member States and collaborate with other UN organizations and partners; to define standards and guidelines, infrastructures, strategies and tools to reduce incidence of sepsis and to report to the 73th Health Assembly on the implementation of this resolution.

Implication for the European Region

Many Member States of the European region have played a critical part in escalating the challenges posed by antimicrobial resistance to the level of the United Nations General Assembly. This led to the political declaration (resolution 71/3) which reinforces the ongoing efforts in the European region for the development and implementation of national antimicrobial resistance action plans. Countries of the WHO European Region will hopefully be as engaged and supportive of discussions on options for a global development and stewardship framework. The experience gained in a number of European countries provides guidance and inspiration to other countries in region and elsewhere.

Despite this high level of awareness and activity in the European region, much work still needs to be done throughout the region. Country responses of the self-assessment questionnaire indicate that 25 countries do not have or are still developing a multisectoral AMR action plan. Collaboration across sectors remains a challenge and many countries indicate that they have no formal or functional multi-sectoral governance or coordination mechanism. The training of healthcare workers and the veterinary workforce in AMR-related subjects also still need to be institutionalized in many countries. Policies for infection prevention and control and antimicrobial stewardship need to be strengthened and enforced.

WHO/Europe and partners are supporting countries in the region with the implementation of the European strategic action plan on antibiotic resistance (2011) and the global action plan on antimicrobial resistance (2015). Activities include: supporting the development of National Action Plans through organization of national and multinational stakeholder meetings, providing templates, tools and expert support; setting up or strengthening national surveillance of antimicrobial medicines consumption and resistance through organizing workshops for national and regional surveillance networks, providing national laboratory training and expert support on quality management and standardized antimicrobial susceptibility testing, performing External Quality Assessment to assess and improve laboratory performance, organizing antimicrobial stewardship training courses, and supporting national awareness and behavior change campaigns.

The regional overview of the situation of antimicrobial consumption and resistance obtained through the surveillance networks hosted by the European Centre for Disease Prevention and Control (ECDC) for the European Union continues to be expanded throughout the region through the efforts of the Antimicrobial Medicines Consumption network (AMC) and the Central Asian and Eastern European Surveillance of Antimicrobial Resistance network (CAESAR) of WHO/Europe. ECDC and WHO/Europe work closely together with the newly established Global Antimicrobial Surveillance System (GLASS), hosted at WHO headquarters, to avoid the additional burden of double-reporting for Member States of the European region that wish to enroll in GLASS.

In close collaboration with ECDC, awareness raising activities have been supported across 47 countries of the region, providing a major contribution to the World Antibiotic Awareness Week. In 2017, the World Antibiotic Awareness Week will take place from 13 to 19 November.

In September 2013, the Strategic and Technical Advisory Group on Antimicrobial Resistance (STAG-AMR) was established as the principal technical advisory group to WHO on antimicrobial resistance (AMR). The group advises the Director-General on WHO's strategic plan and priority activities, major challenges, the engagement of relevant partners and the implementation of the global AMR action plan. According to the terms of reference, each year one third of all members will be replaced. In the process of selecting new members, consideration will be given to achieving an adequate technical distribution of expertise, geographical representation and gender balance. The AMR Secretariat is now actively looking for candidates, from whom the Director-General will select and appoint new members for the period of three years starting from September 2017.

12.3 Poliomyelitis
Documents A70/14 and A70/14 Add.1 (

A70/14 Add.1 Document not available on 27 April 2017.

INTERRUPTION OF POLIOVIRUS TRANSMISSION: In 2016, 37 cases of paralytic poliomyelitis due to wild poliovirus were reported globally, compared to 74 in 2015. All the cases were report from Pakistan, Afghanistan, and Nigeria were all cause by wild poliovirus type 1. Also in 2016, three cases of circulating vaccine-derived poliovirus type 1 reported from Lao People's Democratic Republic and two cases of type reported from Nigeria, compared to 32 cases reported from seven countries in 2015.

Countries with continued endemic transmission of wild poliovirus: Pakistan, Afghanistan and Nigeria: Afghanistan and Pakistan continue to be treated as a single epidemiological block. In 2016, 20 cases of paralytic poliomyelitis were reported in Pakistan, compared to 54 in 2015. In Afghanistan, 13 cases were reported in 2016, compared to 20 in 2015. Coordination between the two programmes has significantly improved at the national and subnational levels in 2016. In Nigeria four new cases of poliomyelitis due to wild poliovirus type 1 were confirmed in July – August 2016 from Borno State, the first reported since July 2014. With limited access to conduct high-quality vaccination and surveillance activities, this strain likely circulated undetected for two years.

Public Health Emergency of International Concern – minimizing the risk of international spread of poliovirus: Episodes of international spread of poliovirus continued in 2016 with the polio circulating across the shared border of Afghanistan and Pakistan. Minimizing the risk and consequences of new international spread of polioviruses requires. During its

teleconference (7 February 2017), the Emergency Committee under the International Health Regulation (2005) extended the Temporary Recommendations for a further three months.

PHASED REMOVAL OF ORAL POLIO VACCINES: The successful switch from trivalent to bivalent oral polio vaccine was accomplished; it was the largest-ever withdrawal of one vaccine and introduction of another. By end-September, all Member States had confirmed completion of the switch. Cessation of the use of oral polio vaccine is necessary to eliminate the rare long-term risks of the emergence of vaccine-derived polioviruses. It is a key strategy of the Polio Endgame Plan, which has been endorsed by the Strategic Advisory Group of Experts on Immunization and the Health Assembly.

CONTAINMENT: Efforts to contain poliovirus type have progressed in 2016, following the publication of the WHO global action plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use (GAPIII). [11] WHO has published the Containment Certification Scheme to support the WHO Global Action Plan for Poliovirus Containment. [12] With WHO support, concerned Member States are expected to complete Phase I and progress with Phase II of GAPIII, formally engaging concerned facilities in the certification process.

TRANSITION PLANNING: Polio transition planning (previously referred to as legacy planning) has intensified in 2016 and in 2017. The transition planning efforts within the Global Polio Eradication Initiative have three goal: 1) to ensure that those functions essential to maintaining a polio-free world after eradication are mainstreamed into continuing public health programmes; 2) to ensure that the lessons learned from polio eradication activities are captured and then shared with other health initiatives and all Member States; and 3) to plan the transfer of capabilities, assets and processes in order to support other health priorities. An Organization-wide Global Polio Transition Human Resources Working Group has also been established to full identify and manage the human resource risks and associated liabilities (see annex summary below).

FINANCE AND MANGEMENT OF THE GLOBAL POLIO ERADICATION INITIATIVE: Thanks to the generous support of Member States and the international develop community; the budge for planned activities in 2016 was fully funded. Effort are under way to mobilize, by mid-2017, the additional US$ 1.3 billion[13] required to fully fund the implementation of the Polio Eradication and Endgame Strategic Plan and to secure a lasting polio-free world and global certification in 2020.

[11] 2 Document WHO/POLIO/15.05 (http://polioeradication.org/wp-content/uploads/2016/09/GAPIII_2014.pdf, accessed 7 March October 2017).

[12] The Containment certification scheme to support the WHO global action plan for poliovirus containment (GAPIII-CCS) (available at http://polioeradication.org/wp-content/uploads/2017/02/CCS_2016EN.pdf, accessed

[13] The most up-to-date budget and financial information is available at http://polioeradication.org/financing/ (accessed 7 March 2017).

ANNEX: WHO'S HUMAN RESOURCES FUNDED BY THE GLOBAL POLIO ERADICATION INITATIVE: The Secretariat is working at all levels to address the strategic challenge of decreasing staffing levels that will occur in line with the Global Polio Eradication Initiative's declining budgets for 2017 – 2019. The Polio Eradication Department at headquarter in coordination with regional offices and the Department of Planning, Resources Coordination and Performance Monitoring have ensured that lower budget targets are reflected in the proposed 2018 – 2019 programme budgets. The Secretariat will continue to provide reports to Member States every six months.

The Health Assembly is invited to note this report.

Implication for the European Region

National emergency action plan to interrupt circulation of endemic poliovirus transmission: As part of the annual progress report required by the European Regional Certification Commission for Polio Eradication (RCCPE), all Member States were requested to submit an updated National Polio Outbreak Preparedness Plan in April 2016. Almost all Member States included a preparedness plan with their annual progress reports; about half were updated in 2015. Only five Member States have actively tested their plans. New GPEI polio outbreak response Standard Operating Procedures has changed the requirements for national outbreak response plans. *In light of the new recommendations, all Member States are requested to update their preparedness plans as soon as possible.*

Preventive activities in the Region: In March 2017, a wild poliovirus type 1 was report in northern Afghanistan – Kunduz province, which is less than 2km from the densely populated Khatlon province in Tajikistan. Immunization activities in northern Afghanistan have been limited over the last year due to security concerns – further circulation is expected with possible cross-border transmission. The Regional Office has been in contact with Global Polio Eradication partners, as well as the Regional Office for Eastern Mediterranean and UNICEF to coordinate and synchronize activities with the Afghanistan team. The Regional Office continues to monitor the situation with GPEI partners.

The Regional office recommended that Tajikistan conduct two preventive subnational immunization rounds in the 9 districts of the Khatlon province for children 0 – 5 years of age using bOPV. Rapid technical and financial support allowed the first immunization round to take place 17 – 19 April and the second round is scheduled for 3 – 5 May (synchronized with the immunization activities in Afghanistan). More than 160,000 children were immunized during the first round. Tajikistan, Turkmenistan and Uzbekistan were also advised to enhance poliovirus surveillance, expand sample collection, and conduct refresher training for staff.

Measures to limit international spread of polio under the auspices of the Public Health Emergency of International Concern (PHEIC): In April 2016, an external outbreak response assessment team concluded that cVDPV1 transmission in Ukraine had stopped. However, significant risks remain due to gaps in surveillance and immunity. In November 2016, the 11th meeting of the International Health Regulation (IHR) Emergency Committee recommended that Ukraine remain in the following category: *no longer infected but vulnerable* to emergence or international spread of polioviruses.

Phased removal of oral polio vaccines and global containment activities: By the end of April 2016, all Member States in the European Region continuing to use OPV (20) had successfully switched from tOPV to bOPV, and National Validation Reports have been received from all of them.[14] Six Member States successfully introduced IPV into their routine schedules.[15] In Armenia, introduction of standalone IPV was completed in July 2016, introduction in other 5 countries[16] was delayed due to IPV global supply constraints. IPV supplies remain uncertain beyond 2018. *The introduction of bOPV in the absence of available IPV will leave a sizable cohort of children in at least five countries in the Region without protection against polio type 2. Once IPV is available, catch-up activities will need to be conducted.*

In 2016, the Region has made substantial progress in implementing GAPIII. The process has been enhanced by collaborating with global and European partners, particularly with the European Commission (EC) and the European Centre for Disease Prevention and Control (ECDC). Due to the large number of global-level polio/enterovirus laboratories and Europe-based polio vaccine manufacturers, there will likely be a large number of polio essential facilities (PEFs) in the Region, and will require a considerable amount of work to fully implement all of the polio containment requirements. *Member States considering establishing PEFs should be fully aware of all of the requirements of GAPIII.*

Transition planning for Global Polio Eradication Initiative and financial implications: The WHO European Region was certified polio-free in 2002 after the last case of indigenous wild poliovirus was detected in 1998. Since certification, the Region has transitioned its polio-specific assets to support routine immunization and other vaccine preventable diseases. The Region receives minimal financial support from global partners for polio eradication. *Current funding is directed at maintaining polio surveillance and risk mitigation activities in anticipation of global eradication.*

[14] 2 Document WHO/POLIO/15.05 (http://polioeradication.org/wp-content/uploads/2016/09/GAPIII_2014.pdf, accessed 7 March October 2017).

[15] Eight countries are procuring bOPV through UNICEF tenders (Albania, Armenia, Azerbaijan, Georgia, Kyrgyzstan, Tajikistan, Turkmenistan and Uzbekistan), 11 are self-procuring (Belarus, Bosnia and Herzegovina, Israel, Kazakhstan, Montenegro, Republic of Moldova, Poland, the former Yugoslav Republic of Macedonia, Serbia, Turkey and Ukraine), and one is self-producing (Russian Federation)

[16] Albania and Azerbaijan introduced standalone IPV, Georgia, Kazakhstan, Serbia and the Former Yugoslav Republic of Macedonia introduced IPV-containing combination vaccines

12.4 Implementation of the International Health Regulations (2005)

Documents A70/15 and A70/16

Documents not available on 27 April 2017.

12.5 Review of the Pandemic Influenza Preparedness Framework

Document A70/17

Through this document, the Director-General transmits the report of the 2016 Pandemic Influenza Preparedness (PIP) Framework Review Group. An earlier version of the Director-General's report was considered by the Executive Board at its 140th session in January.

The Board also adopted decision EB140(5) in which, inter alia, it decided to extend until 28 February 2018 the application of decision EB131(2) (2012) on the PIP Framework for the sharing of influenza viruses and access to vaccines and other benefits. The Board's decision was consistent with the Advisory Group's recommendation to the Director-General, and will allow the Director-General and the Advisory Group to benefit from the discussions of the Seventieth World Health Assembly in developing the next proposal for the proportional division of funds between pandemic preparedness measures and response activities, to be submitted for consideration by the Executive Board at its 142nd session in January 2018.

This is the first review of the PIP Framework, conducted by an independent group of experts appointed by the Director General, with a wide-range of expertise and from across all WHO regions. The findings are based on a systematic analysis of the PIP Framework, highlighting areas considered not to be functioning effectively and possible reasons for this, reviewed key documents, including reports relating to the work of the Advisory Group, and a study on the implementation of the Nagoya Protocol. Using a transparent and inclusive approach, the Review Group actively sought input from Member States and representatives of the Global Influenza Surveillance and Response System (GISRS), WHO staff, industry, civil society organizations (s), and relevant databases, through both interviews and an electronic open consultation process that included questions for response.

The report discusses 1) achievements; 2) whether implementation of the PIP Framework improved global pandemic influenza preparedness, including inter-pandemic surveillance, and capacity to respond, and 3) possible challenges and ways of addressing them. Part I of this briefing summarizes the achievements and challenges and Part II describes the implications for the Member States.

Overarching: The PIP Framework is a bold and innovative tool for pandemic influenza preparedness, is being well implemented, and the principle of placing virus sharing and benefit sharing on an equal footing remains relevant today. The implementation of the PIP Framework has led to greater confidence and predictability in the global capacity to respond

to an influenza pandemic. This is based on the expanded scope and capacity of the GISRS, the improved capacities in countries supported through the Partnership Contribution, significant improvement in access to pandemic vaccine, antivirals and diagnostics through SMTA2, effective governance by the AG and the regular, committed engagement by WHO and Member States with key stakeholders including industry, civil society, and others, and progress by the AG in the handling of GSD (see Figure 3.1, Annex 1; p31 of the Review report).

Virus sharing: In general, virus sharing is working well. GISRS has expanded in scope and been strengthened since the PIP Framework was adopted in 2011, and provides significant benefits to Member States, including risk assessment, candidate vaccine viruses (CVVs), diagnostic kits, reagents, training, capacity building and other expertise. However, despite a prompt and comprehensive response to the emergence of the H7N9 strain in 2013, there has since been a reduced sharing of influenza viruses of pandemic potential (IVPP) from some countries. A study by the PIP Framework Secretariat identified a need for technical operational guidance and training for National Influenza Centres (NIC) to ensure that they are fully aware of their roles as agreed in the Standard Material Transfer Agreement 1, the effective use of the Influenza Virus Traceability Mechanism, and the importance of appropriate sharing of all PIP biological materials and genetic sequence data (GSD).

Genetic Sequence Data (GSD): Due to the complexities of its handling under the PIP Framework, GSD was not included in the definition of PIP biological materials (BM) when the PIP Framework was set up. Thus, while the sharing of viruses is tracked via the influenza virus tracking mechanism (IVTM), the sharing of GSD is not, and therefore does not trigger specific benefit sharing under the PIP Framework. GSD is becoming increasingly critical in influenza research, and can in some cases substitute for physical samples for pandemic risk assessment and the development of commercial products. The Advisory Group has made good progress in examining possible approaches to handling GSD under the PIP Framework. A key challenge has been the lack of agreement among a range of players on what should be traced, whether to track access to GSD or the commercial products developed using such data. Transparency in both the sharing and traceability of GSD is crucial in order to identify any resulting benefit that should be shared. There also remains some confusion among stakeholders as to the potential options for future sharing of GSD. Clarity is urgently required on the handling of GSD under the PIP Framework.

Benefit sharing

Standard Material Transfer Agreement 2 (SMTA2): There has been good progress made in signing SMTA2s with access secured to approximately 350 million doses of pandemic vaccine to be delivered in real time during an influenza pandemic. However, PIP Framework options for SMTA2 commitments from manufacturers of other pandemic products (such as

diagnostics, syringes, etc.) are too narrow, and need to include a wider choice of commitments. Prequalified vaccines and antivirals have also been secured.

Partnership Contribution (PC) collection and implementation: There is strong buy-in of industry with 96% of overall funds collected for 2013 and 2014. Not all companies pay by the expected deadline, which is of concern since the PC mechanism relies on all stakeholders fulfilling their obligations. The fluctuation in the amount of PC industry is asked to pay each year poses budgetary challenges, and they would prefer to pay a set amount - a consultative process to review the PC formula is ongoing. A survey of GISRS running costs indicated that total running costs are likely to have increased from the 2010 estimate of USD 56 million.

Implementation of the PC mechanism since 2014 has allowed countries to develop multi-year plans and has fostered sustained and meaningful capacity building in priority countries in each of the five Areas of Work for Preparedness (Laboratory and Surveillance; Burden of Disease; Regulatory Capacity building; Planning for Deployment; and Risk Communication). A Response fund has also been established for use by WHO at the time of a pandemic outbreak. However, expenditure does not always keep pace with collection, leading to a mistaken perception among some stakeholders that either additional Preparedness funds are not needed or that work plans are failing to be implemented according to planned timeframes. Stakeholders regularly raise specific issues with WHO regarding the rationale for the response funds (in reserve as contingency funds), the basis on which recipient priority countries are selected and how PC funds are building capacity in countries to increase preparedness for pandemic influenza.

Governance: The PIP Framework has a well-functioning governance structure that oversees how the PIP Framework is operationalized, with strong commitment at each of WHO's three levels: Headquarters; Regional Offices; and Country Offices. The Advisory Group continues to play a key role in effective governance by providing impartial, committed, and pragmatic oversight and guidance, representing its independent deliberations. However, the engagement with civil society needs to be broadened, and some GISRS members, notably WHO CCs, feel there should be greater interaction between themselves, the Advisory Group, and the PIP Framework Secretariat, including in the setting up of technical working groups and the subsequent selection of experts. The regular, direct contact that occurs between the Advisory Group and industry/civil society groups might also be helpful if it included GISRS representatives.

Linkages with WHO programmes and other legal instruments

Global Action Plan for Influenza Vaccines: There are important synergies between the PIP Framework and the GAP programme, which closed in November 2016, including the encouragement of technology transfers and capacity building for burden of disease studies,

regulatory authorities and risk communications. However, technology transfer agreements are currently not being obtained through SMTA2s. The report recommends that the Advisory Group identify any aspects of the GAP that would support implementation of the PIP Framework.

International Health Regulations (2005): Activities under the PIP Framework are undertaken in close synergy with implementation of the IHR, although data describing the relationship are not yet available (and should be collected for the next review of the PIP Framework).

Nagoya Protocol to the Convention on Biological Diversity: The PIP Framework is a multilateral access and benefit sharing instrument that appears to be consistent with the objectives of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity. The intergovernmental negotiation of the PIP Framework established rules for access to IVPP and sharing of benefits; by contrast, the implementation of the Nagoya Protocol may introduce uncertainty in relation to the sharing of influenza viruses, since numerous bilateral transactions could be required to be negotiated, which could delay the access to viruses. As more countries put in place domestic legislation to implement the Nagoya Protocol, the urgency increases to resolve this uncertainty and reduce the risk to global health security.

Implication for the European Region

WHO/Europe supports the implementation of the PIP Framework through participation in the PIP Advisory Group meetings and by conducting a broad range of activities at the country and intercountry (regional, subregional) levels that cover all aspects of prevention and control of seasonal, zoonotic and pandemic influenza. The activities are funded by the PIP Framework Partnership Contribution funds, by other Voluntary Donations and by corporate funds. Coordination with technical partners and donors ensures there is no duplication but rather synergy in implementation. In particular, there is close coordination and collaboration with the ECDC and with the US CDC, which has bilateral cooperative agreements with 11 countries in the European Region. All activities conducted in the area of influenza are also supported by in-kind contributions from the Member States, through their support of National Influenza Centres and WHO Collaborating Centres, provision of influenza surveillance data to WHO for publication in Flu News Europe (the joint WHO/Europe-ECDC influenza bulletin), as well as data on seasonal influenza vaccine uptake to WHO through the WHO-UNICEF Joint Reporting Form on vaccine preventable diseases programs, contribution of experts to regional and global technical meetings and normative work, and to the Global Outbreak Alert and Response Network, GOARN.

The current PIP Partnership Contribution implementation plan in the Region targets 6 Member States in establishing and enhancing their capacities for surveillance and response for influenza, developing national guidelines for the surveillance of influenza, outbreak investigation and response, and clinical management of severe respiratory infections. WHO/Europe contributes to the development of global guidelines on national regulatory capacities for pandemic response and strengthening national regulatory capacities for the market authorization and pharmacovigilance of pandemic vaccines and medicines, and assessments in two countries.

WHO/Europe provides support to National Influenza Centres, through training in laboratory techniques, shipment of infectious substances, and through external quality assessment programs. These activities ensure that the Regional influenza network is in a constant state of readiness to respond to emerging influenza viruses as well as other respiratory viruses with pandemic potential (eg. MERS-Coronavirus). The majority of Member States in the WHO European regularly share seasonal influenza viruses with WHO (33 Member States shared seasonal influenza viruses in time for the February 2016 Vaccine Composition Meeting). The WHO European Region coordinates a substantial number of laboratories participating in the GISRS: 49/143 National Influenza Centres, 1/6 WHO Collaborating Centres for Reference and Research on Influenza (WHO CCs), 1/4 WHO Essential Regulatory Laboratories (WHO ERLs) and 2/13 WHO H5 Reference Laboratories (WHO H5RLs). These laboratories are supported by in-kind contributions from the countries, and NICs are also supported by PIP PC funds.

WHO/Europe is supporting the development of estimates of disease and economic burden due to influenza at the country (Romania), regional (euroMOMO, literature review) and global level, providing methodologies and experts.

WHO/Europe also implements in other four areas of work, namely Burden of Disease, Regulatory Capacity Building, Planning for Deployment and Risk Communication. WHO/Europe provides training in risk communication in 9 Member States of eastern and south-eastern Europe and central Asia, focusing on improving decision making, response time and the quality of the response. Furthermore, risk communication capacities of countries are being strengthened through increased capacity in WHO Country Offices and the global Emergency Communications Network.

In addition, funds for Laboratory and Surveillance are used to support intercountry activities which benefit all Member States that participate in regional and global surveillance, through the WHO European Region Influenza Network and the GISRS. The Regional influenza network coordinated jointly with ECDC, and the joint WHO/Europe-ECDC Flu News Europe bulletin, contributed to the regional and global influenza surveillance and risk assessment. In 2016, WHO/Europe held the fifth joint annual influenza meeting with ECDC for 53 Member

States in Budapest. WHO/Europe supports countries to increase the uptake of seasonal influenza vaccine through the fourth Flu Awareness Campaign in 2016.

Moreover, the capacities built under the PIP Framework contribute to the implementation of IHR core capacities and thus preparedness and response to other high threat pathogens, such as Ebola, Crimean-Congo Haemorrhagic Fever, cholera etc. WHO/Europe is currently mapping the number of outbreaks due to high threat pathogens in the Region in order to prioritise the work of the Infectious Hazard Management Program Area of Work under the new WHO Emergency Program. The findings will be shared with the Member States in 2017 and published and will be used as the basis for development of pathogen specific preparedness plans within the country context.

A new PC implementation plan for 2018-2022 is under development with input from Member States and a wide range of stakeholders and will be discussed at the next AG meeting in March 2017.

13. Health systems

13.1 Human resources for health and implementation of the outcomes of the United Nations' High Level Commission on Health Employment and Economic Growth

Document A70/18

Document not available on 27 April 2017.

13.2 Principles on the donation and management of blood, blood components and other medical products of human origin

Document A70/19

The Executive Board at its 140th session considered an earlier version of this report.
Medical products of human origin encompass all biological materials that are derived wholly or in part from the human body and intended for clinical application. They are anatomical component, secretion of excretion retrieved from living or deceased persons and used as raw or processed materials for beneficial and cost effective treatment of several life threatening conditions.

Depending on the donation of biological materials from living or deceased persons, they raise concern for the *dignity and human rights of donors,* in particular their own right to health and security and then require high ethical standards in the procurement of biological materials for use as medical products of human origin. Particular care must be taken to ensure that donors are not subject to exploitation, coercion or abuse. The human origin of

these medical products also entails risks to *public health*. The recurrent emergence of diseases requires systems of production of medical products of human origin that can predict and mitigate transmission of pathogens and swiftly be adapted to new threats. Essential safety measures need to be taken allowing promptly investigation of events of disease transmission and development of risk containment and mitigation strategies, including rapid recall. Also, considerable inequalities remain in access to medical products of human origin between and within countries and regions[17].

The demand for medical products of human origin is growing[18] and outpacing the increase in their availability. The Health Assembly has endorsed ethical principles and governance mechanisms[19] and the Secretariat, WHO collaborating centres and nongovernmental organizations have issued further guidance to facilite their implementation. Nevertheless, the available guidance is fragmented and generally oriented towards a number of specific products (e.g. blood and organs/tissues/cells).

In decision EB136(2) (2015), the Board "requested that the Director-General convene consultations with Member States and international partners, to support the development of global consensus on guiding ethical principles for the donation and management of [...] medical products of human origin; good governance mechanisms; and common tools to ensure quality, safety and traceability, as well as equitable access and availability, as applicable, to result in a document to be submitted to the Seventieth World Health Assembly for its consideration."

Process for building global consensus: Pursuant to the request in decision EB136(2), the Secretariat elaborated a framework of principles on donation and management of medical products of human origin, in collaboration and consultation with a large and broad group of independent experts and scientific societies. The document was based on previous guidance and proposed a globally harmonized approach to governance using shared tools. The goal was to foster consistency of ethical practices in order to strengthen the overall safety, quality and availability of medical products of human origin.

That draft framework of principles and policy options was opened on a dedicated web page on the WHO extranet for a public consultation between 22 September and 15 October 2016. All Member States, WHO collaborating centres, non-State actors in official relations with WHO, other institutions and stakeholders, such as scientific and professional societies,

[17] For instance, of the 112.5 million whole blood donations collected globally, about half are collected in high-income countries, home to just 19% of the world's population.

[18] Causes are the emergence of new therapeutic applications, improved access to health care in some regions, changing demographics of potential donor and recipient populations (such as ageing and increased burdens of chronic diseases) as well as the failure to prevent the progression of many of the diseases that lead to the need for medical products of human origin, such as trachoma causing corneal blindness and diabetes resulting in kidney failure.

[19] Resolutions WHA28.72 (1975), Utilization and supply of human blood and blood products; WHA58.13 (2005), Blood safety: proposal to establish World Blood Donor Day; WHA63.12 (2010), Availability, safety and quality of blood products; and WHA63.22 (2010) Human organ and tissue transplantation, in which the Health Assembly endorsed the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation.

patients' associations and civil society members active in the field were invited to provide comments. A full report of the consultative process and the results is available on the WHO website[20]. All the input provided through the consultative process has been analysed and taken into consideration in drafting the latest version of the framework of principles, which follows.

Principles: The following 10 principles for promoting ethical practices in the donation and management of medical products of human origin are proposed.

Principle 1: Governments are responsible for ensuring the ethical and effective procurement, distribution and use of medical products of human origin. This responsibility includes the obligation to develop and enforce regulations to ensure the maximum possible level of safety, quality and efficacy, both within and across national borders. This responsibility stems from not only governments' core duty to protect and promote public health, but also their role in protecting the fundamental rights and freedoms of individuals, which may be endangered by unethical practices of procurement or distribution. Fulfilling this responsibility depends on the effective functioning of health care services and systems, together with good cooperation between professional organizations, scientific societies and other stakeholders, as well as the creation and enforcement of regulations to ensure a high level of safety, quality and efficacy within and across national borders.

Principle 2. Equity in donation should be promoted by engaging all segments of society in efforts to meet the need for medical products of human origin. Health authorities have a responsibility to establish systems and organizations that reduce or eliminate barriers to donation of and access to medical products of human origin, thereby promoting equity. Individuals and groups should be neither denied the opportunity of donating biological materials for use in medical products of human origin where this exists, nor encouraged to donate where the opportunity does not exist, except where clearly justifiable reasons apply. Where a prospective donation may be unnecessary, for example if there is a surplus of a particular medical product of human origin or it is unduly harmful for the prospective donor or intended recipients, health care providers should not accept the offer to donate (in the case of a surplus) or should not proceed with the procurement (in case of risk to the donor).

Principle 3. Outside clinical research and for the advancement of science, medical products of human origin should be used only in situations of clinical utility and in the absence of alternative and affordable therapies with a comparable or more favourable balance of risks and benefits. The efficient use of medical products of human origin requires good clinical practice and management within the broader health care system. Human biological materials should be procured only when necessary to meet the prospective needs of recipients or, with the consent of donors, for other purposes such as research or training

[20] See http://www.who.int/servicedeliverysafety/en/ (accessed 28 April 2017)

that may serve to accomplish donors' overarching goals of contributing to improving human health.

Principle 4. Biological materials from living persons for use as medical products of human origin should be taken only with the donor's prior informed and voluntary consent. When biological material from a deceased person is to be used as medical product of human origin, it is imperative to verify that the individual has provided his or her prior consent or has not expressed objections to be a donor, as mandated by national laws. The requirement for consent protects potential donors against violation of their bodily integrity and respects their interests in making important life choices in accordance with their values and personal goals. In the absence of effective processes for informing potential donors and obtaining their consent, individuals may be vulnerable to coercion or exploitation, such that they feel forced to donate or agree to donate against their personal preferences and values. On the other hand, providing clear and adequate information to prospective donors may increase their will to donate and therefore often expand the pool of potential donors.

Regulation on requirements to obtain explicit consent to retrieve biological materials from deceased persons depends upon each country's social, medical and cultural traditions. In any case, no biological materials should be removed from a deceased person if the person, while alive, expressed an objection to donation. Countries that do not require explicit consent for the retrieval of biological materials from deceased persons should ensure that the public is fully informed of this policy, and that individuals who do not want their biological materials retrieved upon death have an easy way to express this objection.

Principle 5: Policies governing payment to persons who provide biological materials for use as medical products of human origin should seek to guard against the exploitation of vulnerable individuals and promote equity in donation. The best way to achieve these goals is to adhere to a policy of financial neutrality, in which persons who donate their biological materials for use as medical products of human origin should neither benefit nor lose financially as a result of the donation. Countries that choose not to apply the principle of financial neutrality for specific biological materials should ensure that the burden of donating these materials does not fall primarily on economically disadvantaged groups.

Financial gain from the human body is ethically problematic. According to the principle of financial neutrality, donors should not benefit financially as a result of donation, neither should they suffer financial injury as consequence of donation. This principle is consistent with payments, reimbursement or coverage of reasonable costs associated with donation, such as transportation expenses and documented lost wages. Governments in countries in which the principle of financial neutrality is not currently being applied for specific products are encouraged to explore the possibility of a future transition, while ensuring that systems are in place to minimize the risk that the burdens of donation do not fall primarily on economically disadvantaged populations. These safeguards could include tracking systems

to limit how frequently an individual can serve as a donor, and adequate insurance coverage for donors, irrespective of any payments made to them.

Principle 6. Prospective and actual donors of human biological materials for use in medical products should be protected against physical and psychosocial risks to the fullest extent possible.

Principle 7. Depending on the product, and in addition to other information routinely provided when offering medical products of human origin to prospective recipients, the human origin of the product should be disclosed without compromising the confidentiality of the donor's identity. In addition to information about the potential risks and benefits of using specific medical products of human origin, which should be provided to prospective recipients as part of routine consent procedures, prospective recipients should also be explicitly informed that the clinical product they are to receive is derived wholly or in part from human biological materials. This procedure constitutes an acknowledgement of the donors and promotes societal awareness of the necessity of donation.

Principle 8. Equity in access to the benefits of medical products of human origin should be promoted by sustained efforts to remove barriers to access. Any waiting lists and allocation systems that are developed for medical products of human origin should be based on clinical criteria and ethical norms, not considerations of financial or social status.

Although directed donation of biological materials has the potential to undermine equity in access to the benefits of donation, some directed-donation programmes may actually reduce the societal burdens of unmet needs for medical products of human origin.

Principle 9. In order to minimize the risk of harm to donors and recipients and to protect the stability and sustainability of services for medical products of human origin, all steps in the development and use of medical products of human origin should be fully traceable and subject to effective quality-management systems and vigilance and surveillance programmes. Quality-management systems and vigilance and surveillance programmes promote timely responses to new or recurrent threats and enable the application of new knowledge to improve the safety and quality of products, thereby protecting donors, recipients and public health.

Principle 10. The organization and delivery of activities related to medical products of human origin, as well as their clinical results, must be transparent and open to scrutiny, while ensuring that the confidentiality of donors and recipients is always protected and adheres to national laws.

The provision of adequate information and data enables the public to make informed choices about donation and use of medical products of human origin. Such transparency and mechanisms to ensure the traceability of medical products of human origin are not

incompatible with the protection of confidential information concerning individual donors and recipients of such medical products.

Key considerations for implementation: Different types of medical products of human origin may require different operational systems and regulatory oversight adapted to their specificities. The manner in which countries implement these principles may differ depending on the type of product in question.

Consolidation of regulatory oversight and national coordination of services providing different types of medical products of human origin may be beneficial through economies of scale, optimal use of professional expertise or consistent communication with the public. Services related to the procurement, manufacture and provision of medical products of human origin and their coordination and regulatory oversight should be integrated in the health system to ensure smooth and efficient communication with users of those products and regulators of other types of health products.

Some medical products of human origin, specifically those that undergo an extensive manufacturing process such as plasma-derived medicinal products, may be regulated as pharmaceuticals, whereas others, such as tissue-derived products used in orthopedics, could be regulated independently or as medical devices. Regardless of how particular medical products of human origin are classified, all forms of regulation should explicitly address requirements specific to those medical products, such as donor protection.

In practice, close collaboration among regulators internationally and among regulatory bodies within countries, and oversight of the various steps from procurement of the human biological material through to clinical application of the final product will be necessary to ensure efficiency and maintenance of standards across the whole process of preparing and using medical products of human origin.

Each principle should be further elaborated with strategic approaches and potential policy options and interventions for its attainment. The appropriate mix of policies and interventions to be used at the country level will need to be designed and developed according to the local context, values and priorities. Governance mechanisms are generally valid for all medical products of human origin, including: legislation and regulation; policy and strategic planning; financial sustainability; traceability; vigilance and surveillance; transparency; public engagement; and crisis response plans. The Secretariat is able to provide support to Member States in the implementation procedure through guidance on the basis of input from technical consultations, literature reviews and expert opinion.

The Health Assembly is invited to note this report and provide further guidance on the draft framework of guiding principles.

13.3 Addressing the global shortage of, and access to, medicines and vaccines

Document A70/20

The Executive Board at its 140th session noted an earlier version of this report which is revised extensively to capture developments in implementation of WHA67.22 (2014) on access to essential medicines.

Access to medicine: In 2016, the Sixty-ninth World Health Assembly noted a progress report on implementation of the resolution WHA67.22 (2014), requesting the Director-General: to urge Member States to recognize the importance of effective national medicines policies, and their implementation under good governance; to facilitate collaboration among Member States on how to implement medicines policies most effectively; to support Member States in the selection of essential medicines and in ensuring a supply of affordable and effective essential medicines; to support Member States in monitoring essential medicines shortages; to urge Member States to expedite progress towards the achievement of the MDGs; and to provide, on request, in collaboration with other international organizations, technical support on issues relating to intellectual property and access.

A comprehensive health systems approach is needed, that cover all the stages involved, from manufacturing to selection, pricing and reimbursement, efficient procurement and supply and responsible use. The UN Sustainable Development Goal 3.8 recognizes the importance of ensuring access to safe, effective, quality and affordable essential medicines for all in order to achieve universal health coverage. Access to medicines is central in the implementation of public health programs as antimicrobial resistance, noncommunicable diseases, maternal and child health, HIV, tuberculosis and malaria.

The High-Level Panel on Access to Medicines convened by the United Nations Secretary-General reported in September 2016 and recommended WHO to work more closely with other relevant international agencies, as UNCTAD, WIPO and WTO on issues related to the balance between “the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies”.

Progress has been made by the Secretariat in several areas:

- **Needs-based research, development and innovation.** The Global Observatory on Health R&D went live in January 2017 and provides information on research and development for products for neglected diseases. The Global Antibiotic Research and Development Partnership, a joint activity of WHO and the Drugs for Neglected Diseases initiative, has been established for developing and delivering new or improved antibiotic treatments, while endeavoring to ensure sustainable access. WHO has published a priority pathogens list to highlight neglected areas of research and development. Under the

strategy and plan of the R&D Blueprint, WHO is maintaining a list of priority emerging infectious diseases with epidemic potential. This list is updated annually. It is expected that WHO's new Expert Committee on Health Research and Development will provide oversight to the above prioritization exercises.

- **National regulatory capacity and local production**. In line with resolution WHA61.21 (2008) on the global strategy and plan of action on public health, innovation and intellectual property, preparatory work was carried out to look at the interplay of health and industrial policies.
- **Quality, safety and efficacy.** The Secretariat continues to provide support to countries in building national regulatory capacity for regulation and pharmacovigilance of health products, with support by Member States through Health Assembly resolutions including WHA67.20 (2014) on regulatory system strengthening for medical products.
- **Substandard and falsified medicines.** Examination of reports received by the WHO Global Surveillance and Monitoring System for substandard and falsified medical products indicates that shortages and stock outs of medicines and vaccines contribute to the appearance of substandard and falsified medical products in the supply chains.
- **Public health-oriented intellectual property and trade policies.** Based on the organizations' (WHO, WIPO and WTO) joint study on promoting access to medical technologies and innovation[21] the aim of collaboration is that: each agency can fulfil its own mandate more effectively; respective initiatives support each other; efforts are not duplicated; and resources are used efficiently. Collaboration covers various areas, including training activities, joint symposia and joint publications.[22] In December 2016 WHO called for an "all-agency meeting" with UNAIDS, UNCTAD, UNDP, UNITAID, WTO, WIPO and the High Commissioner for Human Rights to discuss the different activities and plan for the future, including how to best follow up on the High-Level Panel's report. WHO has engaged in various training activities and published updated patent information on the new treatments for hepatitis C and those for cancer and diabetes.
- **Selection of medicines.** Additional medicines for cancer and new medicines for hepatitis C and tuberculosis were included in the 19th WHO Model List of Essential Medicines and the 5th WHO Model List of Essential Medicines for Children. Antibiotics for infectious diseases, sexually transmitted infections and paediatric indications were reviewed by the Expert Committee on the Selection and Use of Essential Medicines at its 21st meeting (Geneva, March 2017), which evaluated medicines for noncommunicable diseases including cancer, palliative care and diabetes. WHO is preparing treatment guidelines for the management of pain in cancer patients. In 2015, some 140 countries had established national lists of essential medicines.

[21] WHO, WIPO, WTO. Promoting access to medical technologies and innovation: intersections between public health, intellectual property and trade. Geneva: World Health Organization, World Intellectual Property Organization, World Trade Organization; 2012 (http://www.who.int/phi/promoting_access_medical_innovation/en/, accessed 25 April 2017).

[22] http://www.who.int/phi/implementation/trilateral_cooperation/en/ (accessed 25 April 2017).

- **Pricing, reimbursement and affordability**. In 2016, WHO published the first global report on access to treatment for hepatitis C, which provides detailed information on the patent and regulatory status of the new hepatitis C treatments and pricing information for all new treatments, and describes ways to access these treatments at affordable prices. Expert consultations took place in November 2015 and in November 2016 for the review of the 10 key policy areas to ensure access to affordable medicines. The consultations prepared the way for the Fair Pricing Forum due to be held in the Netherlands, May 2017 to explore options to ensure a sustainable supply of affordable, quality medicines, including assessment of the production costs of essential medicines.
- **Efficient procurement and supply-chain management.** Support has been provided to Member States for the establishment of policies and good practices, capacity-building for improving governance, efficiency and quality of procurement and supply-chain management, both in ordinary and emergency situations, including normative guidance and support to countries to improve coordination and quality of donations and the development of pre-packaged medical kits.
- **Appropriate prescribing and rational use.** Guidelines on the use of antimalarials, contraceptives, medicines for the treatment of maternal infections and other medicines have been published[23]. An expert consultation (Geneva, March–April 2016) contributed to the development of a WHO methodology for surveillance of antimicrobial consumption. The Secretariat developed a protocol for WHO's hospital point prevalence survey on antimicrobial use on the basis of that issued by the ECDC. Implementation of surveys of use of antimicrobials in hospitals is planned for later in 2017.
- **Access to controlled medicines.** WHO has played a leading role in the promotion of balanced public policies, including a published guidance document.[24] It has also responded to the challenges in forecasting and quantification of controlled medicines by issuing a joint WHO/International Narcotics Control Board guide on estimating requirements for substances under international control[25]. WHO works in close collaboration with the UNODC and the International Narcotics Control Board to promote access to controlled medicines, providing training and support to countries. WHO is part of the Joint Global Programme on access to controlled medicines for medical purposes, in particular for the management of pain. The Secretariat provides support to countries for identifying potential regulatory or procurement barriers that limit access to controlled substances and for identifying potential interventions to improve access.
- **Transparency.** WHO's Global Price Reporting Mechanism provides pricing and procurement data for HIV, tuberculosis and malaria treatments and has recently been

[23] Available through the information portal: http://apps.who.int/medicinedocs/en/ (accessed 16 April 2017).

[24] Ensuring balance in national policies on controlled substances: guidance for availability and accessibility of controlled medicines. Geneva: World Health Organization; 2011 (http://apps.who.int/iris/bitstream/10665/44519/1/9789241564175_eng.pdf , accessed 27 April 2017)

[25] Available at: http://www.who.int/medicines/areas/quality_safety/guide_estimating_requirements/en/ (accessed 3 March 2017)

expanded to include the new hepatitis C treatments.[26] The Secretariat has set up a comprehensive web platform providing data on vaccine product, price and procurement with the goal of increasing price transparency and informing decisions on vaccine introduction and implementation. WHO is assessing the production costs of essential medicines, which will allow procurement agencies to evaluate better their performance and will contribute to the overall objective of transparency.

- **Monitoring.** WHO has developed a data collection tool for gathering information on the prices and availability of medicines using a smartphone application. In early 2016, pilot tests in 19 low- and middle-income countries proved the application to be a simple and cost-effective way to collect national data on access to medicines. The use of the tool is now being extended to more countries and being used for programme-specific purposes such as gathering price and availability data on medicines for NCDs.

  More effort is required to improve access to quality medicines, including measures in national policies and plans, through regional activities and by committing resources, as recommended in resolution WHA60.16 (2007) on progress in the rational use of medicines.

Shortages: WHO commissioned a systematic review of the available definitions used in the management of medicines and vaccines shortages and stockouts. The preliminary results notably revealed that functional definitions vary broadly depending on the context of use, underscoring the need to harmonize and develop well-understood definitions. The review also showed that terms are used interchangeably to refer to different aspects of shortages. Based on the preliminary results of the systematic review and the informal expert consultations, the Secretariat has developed an overarching draft technical definition of medicines and vaccines shortages and stock outs. It is divided into supply-side and demand-side definitions[27], in accordance with the outcome of the systematic review and informal expert consultations. In addition, a framework is under development to articulate more detailed considerations, such as variables for implementation and indicators for measurement. All definitions must have a clear purpose and guidance on the appropriate context is needed in order for them to be useful and avoid unintended consequences.

The Secretariat will conduct a broader Member State consultation in 2017 to expand the involvement of stakeholders in the development of these definitions and to provide

[26] http://www.who.int/hiv/amds/gprm/en/ (accessed 27 April 2017).

[27] The overarching draft definition, which refers to shortages on the supply side and shortages and stock outs on the demand side, reads as follows:

- On the supply side: A "shortage" occurs when the supply of medicines, health products and vaccines identified as essential by the health system is considered to be insufficient to meet public health and patient needs. This definition refers only to products that have already been approved and marketed, in order to avoid conflicts with research and development agendas.
- On the demand side: A "shortage" will occur when demand exceeds supply at any point in the supply chain and may ultimately create a "stock out" at the point of appropriate service delivery to the patient if the cause of the shortage cannot be resolved in a timely manner relative to the clinical needs of the patient.

appropriate guidance. It will also work further on strategic efforts to develop a medicine and vaccine shortage notification system for medicines and vaccines at risk of shortage.

Pursuant to the other provisions of resolution WHA69.25, WHO has embarked on collaborative work on health data management, notably as part of the Health Data Collaborative, to promote the availability of reliable data on shortages and stock outs and data for improved planning and management. In addition, WHO's programme on the prequalification of medicines and vaccines aims to include medicines at risk of shortage and stock outs in order to provide efficient regulatory pathways and contribute to improved market stability. In this regard, the programme's fee structures have been revised to ensure its sustainability. WHO is also supporting collaboration at high levels across supply chain programmes and will serve as the secretariat for the Interagency Supply Chain Group in 2017.

The Health Assembly is invited to note this report

Implication for the European Region

In 2015-2016, countries across WHO Regions and income groups reported shortages of vaccines and medicines, in some instances causing critical disruptions of services and interruption of treatments. Multiple vaccines were affected, including yellow fever, BCG, DTP (diphtheria-tetanus-pertussis vaccine), acellular pertussis containing vaccines and IPV (inactivated polio vaccine).

WHO is requested to take an active role in facilitating country collaboration, in generating evidence and in developing l policy dialogue to further access to medicines and to act as a forum to debate good practices. The Regional office is providing support and technical guidance in medicines selection, regulation, manufacturing, procuring and distributing quality pharmaceuticals.

The Regional Committee in 2017 will have a session on "Towards improving access to medicines in the WHO European Region: a proposal for member state co-operation" This builds on Technical Briefing at RC66 (2016) on Access to new high-priced medicines: challenges and opportunities.

WHO/Europe conducted a survey to map the current procurement processes for pharmaceuticals in place in the region with a focus on tendering and a Strategic Procurement consultation with Member States (42 countries participated) was held in September 2016 in Copenhagen to review national procurement experiences and explore opportunities for collaboration between countries.

The WHO Regional Office for Europe contributed at the Minsk meeting (2-3 November 2016), where Ministries of Health of Eastern Europe and Central Asia reaffirmed the urgent

need for full coverage of patients and the importance of expand access to HIV and TB treatment. They committed to work together to ensure sustainable access to quality and affordable pharmaceuticals to all patients in needed.

The Regional Office contributed during technical workshops organized by the Maltese presidency of the EU to discuss opportunities for structured cooperation between Member States in the area of strategic procurement of pharmaceuticals. The outcomes of the workshops fed into a ministerial meeting on 20 March 2017. This in turn will set out the political direction for drafting Council conclusions on this topic.

Several trainings and workshops are being organized in 2017 by the Regional Office for national experts on different topics, of which some are developed specifically for Russian speaking participants. Below are some examples of ongoing and planned events;

Quality and regulation: First WHO Pre-qualification training for Russian Speaking inspectors to provide a high level training in the practical aspects of quality and bioequivalence assessment (19-20 May, Copenhagen); implementation of WHO guidelines for bio therapeutics including biosimilars in Russian speaking countries (5 to 7 July 2017); 3rd WHO Global Medical Devices Forum in WHO Geneva (10 to 12 May 2017), including pre-meeting on regulation of medical devices (9th May); self-assessment of the National Regulatory Authority (NRA) in Kyrgyzstan (July 2017).

Responsible use and antimicrobial consumption: -First antimicrobial medicines consumption (AMC) report will be published 1st May presenting consumption data 2011-2014 for 12 non-EU Member States; annual meeting of the antimicrobial consumption (AMC) network, in July, which will involve 17 countries and Kosovo.

Pricing and reimbursement: The document on Medicines procurement strategies, sharing and minimising risk: impact on prices and availability) will be presented during the Fair pricing forum in Netherlands in May 2017; first meeting of the Pharmaceutical Pricing and Reimbursement Information (PPRI) network for CIS countries will be held in Moldova in June 2017and the report on pricing and reimbursement policies in Kyrgyzstan (in collaboration with our WHO CC) which was published in November 2016.

Strategic procurement of pharmaceuticals: WHO Regional Office for Europe hosted several country consultations to explore collaboration opportunities amongst MS on procurement. Following recommendations from previous consultations, collaboration in the area of Horizon Scanning (HS) could be considered. It will focus on estimating budget impact related to the introduction of new medicines.

The vaccine supply shortage survey initiated by WHO/EURO in September 2015 revealed that at least 28 out of 53 WHO European Region Member States faced vaccine supply shortages (i.e. lack of tender offers, disruptions of the supply schedule and volume).

WHO vaccine product price and procurement (V3P) platform: A global web based platform to share and access vaccine price and procurement information has been established by WHO in 2014. Over 3 years, participation has consistently increased, driven by participation in all WHO regions, and particularly Europe. Of the 40 countries that contributed data to V3P in 2015 at global level, 30 are from the WHO European Region. In the period since data has been collected through this project, large discrepancies between vaccine prices paid by individual countries have begun to decrease, and an overall trend of declining vaccine prices is observed. Revisiting in-country procurement confidentiality clauses and practices represents an important opportunity to expanding benefits from sharing vaccine price data to strengthen country procurement power and improve procurement decision making.

WHO Regional Office for Europe works with a broad range of partners (including the UN agencies, the EU Commission and other international agencies) to support Member States in addressing vaccine supply shortages and stock outs through various platforms, focusing , in particular, on the need for concerted actions across various sectors and technical areas such as:

- adoption of proactive long term approaches in aligning “demand” and “supply”, including through multi-year immunization policy and strategic planning;
- development of contingency plans and preparedness for supply interruptions,
- revisiting national procurement systems objectives, procedures and requirements to balance long versus short term benefits and risks in regard to procurement effectiveness (continuous supply) and efficiency (at best price); to share experiences of best practices with countries.
- expanding the supplier base and competition by reviewing country regulatory and programmatic requirements to vaccine products and exploring alternative product and supply options (including through joint procurement mechanisms);
- building effective medicine national regulation systems to ensure that standards of quality, safety and efficacy are met at every stage of pharmaceutical manufacture, supply and use. Providing specific technical assistance and training to manufacturers and regulators to help them achieve internationally recognized quality standards.
- WHO prequalification: in 2016, 3 finished pharmaceutical products and 3 active pharmaceutical ingredients were produced by European manufacturers.
- strengthening supply management through improved forecasting, reducing wastage, establishing safety stocks, monitoring demand and availability and notifying shortages and stock outs; voluntary collaboration on procurement within and across countries could improve availability of affordable medicines for patients in the region.
- advocating for exercising Member States power in generating (where possible and available) vaccine market evidence by using common platforms (such as WHO Vaccine Product price and procurement – V3P online database) for sharing vaccine supply information and using it to inform procurement and programmatic decisions;

- planning for assessing and addressing impact of shortages with involvement of national technical advisory bodies to prevent future immunity gaps due to reactive changes in the immunization schedules.

Member States' commitment to sharing data and information to support developing a global medicine and vaccine shortage notification system would allow detect shortages, understand their causes and assess the risks. Adoption of technical definitions of medicines and vaccines shortages and stock outs by Member Stated would allow further harmonization of shortage and stock out data and information collection, sharing and use.

13.4 Evaluation and review of the global strategy and plan of action on public health, innovation and intellectual property

Document A70/21

The Executive Board at its 140 session considered and noted the report of the comprehensive evaluation of the implementation of the global strategy and plan of action on public health, innovation and intellectual property and adopted in decision EB 140(8) the terms of reference of the overall programme review.

Through document A70/21, the secretariat submits the executive summary of the final comprehensive evaluation report to the Health Assembly.

The Health Assembly is invited to note the report

The overall purpose of the comprehensive evaluation is to assess the status of implementation of the following eight elements of the global strategy: (a) prioritizing research and development needs, (b) promoting research and development, (c) building and improving innovative capacity, (d) transfer of technology, (e) application and management of intellectual property to contribute to innovation and promote public health, (f) improving delivery and access, (g) promoting sustainable financing mechanisms, and (h) establishing monitoring and reporting systems, and to document achievements, gaps and remaining challenges and generate recommendation on the way forward.

The goals of this evaluation include: assessing the implementation of GSPOA; informing the overall programme review planned for 2017; identifying achievements, gaps and remaining challenges; and providing a forward-looking view of improvements and their implementation with an assessment of the possible and existing constraints involved.

In aligning the terminology of GSPOA with the four income groups of the World Bank, whenever, GSPOA refers to developing countries, these countries are referred to in this evaluation as lower-middle-income and low-income countries, especially when evaluation findings are being reported and recommendations made.

The comprehensive evaluation was conducted between January and November 2016 and the final report was presented by the external evaluation team to the WHO evaluation office in early December 2016.

The evaluation resulted in the following key overall findings:

• Awareness and engagement of stakeholders. The observed findings may be better than the reality, as a result of excluding countries that have not even named a Focal Point, and may not have made as much progress or are not aware of GSPOA. It was also noted that many local stakeholders in the countries visited were not aware of or engaged in the implementation of GSPOA.

• Variance across income groups. Finding is quite similar: stakeholders may be aware of GSPOA, but progress in implementation varies and it seems to be smaller in lower-middle-income and low-income countries with less resources. The way in which each element was implemented therefore depended on the priorities and capacity of each country.

• Attribution. Findings show countries doing related activities, but not considered a result of GSPOA, which must be taken into account in the interpretation of this report. GSPOA does not occur in a vacuum and the challenge here is to see what effects can be attributed to GSPOA. It may not be possible to separate the effect as a result of GSPOA from the internal dynamics of the countries in some cases.

The comprehensive list of recommendations and the areas identified for further work are intended to guide the overall programme review

Element 1: Prioritizing research and development needs

GSPOA suggests that health R&D policies of developed countries need to reflect adequately the health needs of developing countries. Mapping global R&D for identifying gaps in R&D is needed and R&D in traditional medicine needs to be encouraged.

Recommendations

Member States should ensure that their health R&D at national and sub-national level is prioritized, including for traditional medicine, through multistakeholder consultation, using national focal points or units for effective intersectoral coordination.

WHO Secretariat should support Member States to monitor progress in R&D prioritization; promote coordination of health R&D at national, regional and global levels, in collaboration with partners across all sectors; promote publicly accessible repositories for health research in order to improve access to knowledge; support Member States in carrying out national assessments and analyse and compare data gained at national and regional level and

identify further steps for improved assessment; and conduct periodical re-evaluations of the coordination of health research.

Element 2: Promoting research and development

GSPOA recognizes the need for political, economic and social institutions in each country to participate in the development of health research policy.

Recommendations

Member States should promote upstream research in lower-middle-income and low-income countries with strengthened international cooperation and joint work between the public and private sector in areas that address their health needs, as well as at the international level and between high-income and lower-middle-income countries; and enhance national capacity for analysing and managing clinical trial data; to promote broader multisectoral participation in the development of health research policy.

WHO Secretariat should strengthen its work with partners for creating and renewing strategic research networks to support governments to develop their national health programmes, including the necessary communication tools.

It is recommended that all stakeholders to improve access to scientific and technological knowledge, including wider availability of libraries and databases; to strengthen the efforts towards improving cooperation, participation and coordination of health and biomedical R&D with and between lower-middle-income and low-income countries.

Element 3: Building and improving innovative capacity

GSPOA acknowledges the need for framing, developing and supporting policies which promote health innovation capacity improvement in developing countries. The key areas for capacity development are science and technology, regulation, clinical trials, IP, production of pharmaceuticals and evidence-based traditional medicine.

Recommendations

Member States, with the support of WHO and other international organizations, should strengthen their efforts for tapping the unrealized potential of traditional medicinal knowledge, by boosting local R&D and manufacturing capacity, enhancing educational and training efforts to safeguard the locally available knowledge base on traditional herbal medicine and traditional medical treatment methods; and negotiate partnerships with high-income and upper-middle-income countries for mutual advantage; and align their R&D objectives with the public health needs of their populations.

WHO Secretariat should explore options to support the development of health products in accordance with the demonstrated R&D needs of lower-middle-income and low-income countries, focusing on Type II and Type III diseases and the specific needs of these countries in relation to Type I diseases; and increase their support to lower-middle-income and low-income countries in the area of better safeguarding and exploiting the existing traditional medicinal knowledge in terms of development of new products and treatments; promote, organize and support more actions in teaching and training, including building R&D capacity, with a focus on Type II and Type III diseases and the specific needs of lower-middle-income and low-income countries in relation to Type I diseases.

It is recommended that all stakeholders should contribute to the development of possible new incentive schemes for health-related innovation, in line with the recommendations of the Consultative Expert Working Group on Research and Development and improve innovative capacity in lower-middle-income and low-income countries by providing more funding and infrastructure for research, including translational research.

Element 4: Transfer of technology

GSPOA supports development cooperation, partnerships and networks for building and improving transfer of technology related to health innovation. The aim of Element 4 is the promotion of technological innovation and transfer of technology to the mutual advantage of producers and users of health technologies.

Recommendations

Member States should work with other stakeholders to improve the enabling environment for technology transfer for the production of health products.

WHO Secretariat and other stakeholders should encourage further work in needs assessment of lower-middle-income and low-income countries to continuing to provide support for technology transfer; encourage relevant studies and analyses to better understand local needs to improve local capacity for providing essential medicines and health technologies and creating a business-friendly environment for these efforts.

Element 5: Application and management of intellectual property to contribute to innovation and promote public health

GSPOA acknowledges the need for strengthening innovation capacity and the capacity to manage and apply IP in developing countries. This includes the use of flexibilities provided in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to take measures to protect public health.

Recommendations

Member States, WHO Secretariat, other international organizations and nongovernmental organizations should strengthen awareness of the flexibilities provided in the TRIPS Agreement, IP rights and the need for equitable and affordable access to essential health products in lower-middle-income and low-income countries; strengthen capacity and create incentives related to IP management, continue efforts to better integrate existing and new initiatives and schemes in this area in the implementation of GSPOA; and focus more on creating the required baseline data, indicators and evidence base needed to properly evaluate the outcome of GSPOA initiatives under this element; support ongoing non-profit drug development models, by exploring and promoting possible incentive schemes to overcome IP barriers and promote public health.

Element 6: Improving delivery and access

Access to medicines is directly related to income and, despite progress made during the last decade, this access is still a major problem for most lower-middle-income and low-income countries.

Recommendations

It is recommended for consideration by Member States in collaboration with other stakeholders, to join efforts for increasing funding to improve delivery of, and access to, health products; to strengthen their national regulatory agencies to facilitate rapid access to health products for their citizens; in collaboration with other stakeholders, to explore regional partnerships to share expertise between countries and strengthen policies and regulations for health products.

It is recommended for consideration by the WHO Secretariat to continue and strengthen its efforts under the Prequalification of Medicines Programme; in collaboration with WHO partners, to expand its efforts at conducting and coordinating joint reviews of clinical trials of medicines and vaccines; in collaboration with WHO partners and relevant stakeholders, to further strengthen national drug regulatory capacity, improve ethical review of clinical trials, and help to develop capacity to address barriers to access to affordable health products and medical devices.

Element 7: Promoting sustainable financing mechanisms

GSPOA aims to make health products available in developing countries through new and innovative mechanisms.

Recommendations

Member States should secure adequate funding and facilitate R&D efforts for development of health products and medical devices; encourage public–private partnerships and product

development partnerships; support new, innovative schemes for identifying new sources of funding for health R&D and operationalize their use, such as those recommended by the Consultative Expert Working Group on Research and Development.

WHO Secretariat should work with other stakeholders to implement the recommendations of the Consultative Expert Working Group on Research and Development.

Element 8: Establishing monitoring and reporting systems

GSPOA supports the establishment of systems to monitor performance and progress towards the objectives contained in the strategy and the plan of action.

Recommendations

Member States should plan for a final evaluation of GSPOA implementation in 2023; and strengthen their monitoring and evaluation systems to monitor progress and evaluate the performance of the implementation of GSPOA in their countries.

WHO Secretariat should complete the development of a web-based platform for monitoring and information-sharing regarding Member States' progress and experience in implementing GSPOA; revise the National Assessment Tool appropriately to capture better the existing capacity of Member States.

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

Document A70/22

In January 2017, an earlier version of this report was considered and noted by the Executive Board and its 140th session.

In resolution WHA69.23 (2016), the Health Assembly requested the Director-General to expedite the full implementation of the strategic work plan endorsed in resolution WHA66.22 (2013). Resolution WHA69.23 includes the following elements:

A. Development of WHO's Global Observatory on Health Research and Development;
B. Full implementation of the strategic work plan;
C. Establishment of an Expert Committee on Health Research and Development to provide technical advice on the prioritization of health research and development; and
D. Exploration of the feasibility of a voluntary pooled fund to support research and development for Type III and Type II diseases and specific research and development needs of developing countries in relation to Type I diseases.

This document describes in annex:

1. Terms of reference and a costed work plan of the Global Observatory on Health Research and Development;
2. Proposal for a voluntary pooled fund
3. Terms of reference for the Expert Committee on Health Research and Development

(1) TERMS OF REFERENCE AND A COSTED WORKPLAN OF THE GLOBAL OBSERVATORY ON HEALTH RESEARCH AND DEVELOPMENT

In January 2016, a demonstration version of the Global Observatory was published online which incorporated data on: funding for health research and development (from Policy Cures Research's Grant Finder survey); health products that are under development (from four data sources); clinical trials (from the WHO International Clinical Trials Registry Platform); research publications (from PubMed); gross domestic expenditures on health research and development by country (from UNESCO, OECD, La Red de Indicadores de Ciencia y Tecnología – Iberoamericana e Interamericana and Eurostat) and other relevant country-level macroeconomic data such as total health expenditures (from WHO's global health expenditures database) and burden of disease (from the Global Health Observatory). Following consideration of feedback from users, the Global Observatory on Health Research and Development was released in early January 2017. It includes new elements, such as indicators for monitoring activities in and resources for health research and development, comprehensive analyses of data on health research and development by disease, comparative analyses of health research and development activities between countries and across diseases, and a section on classifications and standards, as a first step towards harmonization of future data collection efforts.

Annex 1 describes the following terms of reference for the WHO's Global Observatory on Health Research and Development :

(a) to produce comprehensive analyses and syntheses of existing data and information on health research and development for specific health conditions (for example, tuberculosis, malaria and leishmaniasis) in order to identify gaps and opportunities for health research and development and inform the setting of priorities;

(b) to monitor and report on global trends related to health research and development, including investments in health research and development and capacity for health research at national level; registered clinical trials and health technologies that are under development (the research and development pipeline); as well as approved medicines;

(c) to benchmark and compare health research and development activities across countries and health conditions; for example, comparing investments in health research and

development across countries and health conditions with indicators such as burden of disease, gross domestic product, gross domestic expenditures on health, and expenditures on other types of research;

(d) to contribute to improving data collection and sharing standards by making available classifications and terminologies it uses as a step towards consensus building and better harmonization of future data-collection efforts;

(e) to make all data and analyses available to the general public in a web portal; and

(f) to conduct comprehensive analysis and syntheses of data based on the advice of the Expert Committee on Health Research and Development.

In 2015, the Ad-hoc Committee for the Demonstration Projects/Global Health R&D Observatory reviewed the workplans and budget proposals for five demonstration projects as well as those of the Global Observatory on Health Research and Development, and recommended allocation of funding for the first year of implementation of those five demonstration projects and the Observatory. Letters of agreement were signed and funds were disbursed for demonstration projects three projects in 2015 and for an additional demonstration project in September 2016, using all available funds. The fifth demonstration project was approved for funding by the Ad-hoc Committee and the letter of agreement was signed with funds disbursed in March 2017. The Global Observatory on Health Research and Development has not received any funding so far. A sixth demonstration project was only recognized as a demonstration project in April 2016 and will receive funding subject to approval by the Ad-hoc Committee. A meeting of stakeholders for this demonstration project was held on 27 February 2017 in Geneva.

The estimated total net cost for 2016–2019 is US$ 6.3 million. The total net earmarked funds received or pledged (as of January 2017) are US$ 1.77 million (net of programme support costs) for 2016–2017. Taking into account the allocated WHO programme budget funds from assessed contributions, the total gross funding gap for 2016–2017 is US$ 0.32 million. Without additional financial contributions, the total funding gap is estimated at US$ 2.05 million for 2018–2019.

The estimated total financial requirement over the period 2014–2017 for the implementation of the demonstration projects and establishment of the Global Observatory is US$ 85 million. As at 20 January 2017, a total of US$ 2.52 million over the four years had been contributed or pledged by France, Germany, Switzerland, the United States of America and the European Commission to the Global Observatory. A total of US$ 10.49 million had been contributed by Brazil, Germany, India, Norway, South Africa and Switzerland to the voluntary fund designated for demonstration projects. This includes US$ 1.20 million that has been contributed or pledged by Norway and Switzerland as matching grants for

contributions from developing countries on the basis of half a dollar for each dollar contributed, and US$ 1.40 million of Swiss matching funds are still available, pending developing country contributions. US$ 70.59 million is still required.

(2) PROPOSAL FOR A VOLUNTARY POOLED FUND AND PROMOTING AND ADVOCATING FOR SUSTAINABLE AND INNOVATIVE FINANCING

The success of a voluntary pooled fund will depend on its ability to attract sufficient amounts of funding, with a minimum size of US$ 100 million per year. As highlighted by the Expert Working Group on Research and Development Financing3 and the subsequent Consultative Expert Working Group on Research and Development: Financing and Coordination, there are very many possible ways available for reference by Member States to finance such a fund. To come up with some realistic options, the Secretariat is currently undertaking a study into financing options that could be used to feed the voluntary pooled fund and the results will be made available on the WHO website before the 140th session of the Board. Member States are invited to consider the options presented in the study, focusing on a mixed model that combines different instruments and involves different sources of funding.

For example, Member States could commit themselves to contribute a certain amount through voluntary contributions. These extra voluntary contributions by Member States could be combined with matching funds contributed by the private sector. The remaining funds needed to reach an annual budget of US$ 100 million could be financed through a financial instrument such as a social impact bond guaranteed by Member States or philanthropic research and development investors.

Where there are buyers for future products, advance market commitments could be another option to generate funds. Where eligible products are being developed, revenues from selling priority review vouchers could be another source of income of the fund. The last two options can, however, only be used with respect to specific products and projects and would still require a loan to finance the initial research and development cost and to bear the risk of failure.

Member States could also consider setting up a fund that would invest its revenues in health research and development, following the example of the Australian Medical Research Future Fund. A fund amounting to US$ 2000 million could guarantee an annual 5% investment, namely US$ 100 million, into research and development.

In addition, Member States could opt to use a replenishment model, in which each donor independently fixes its contribution in the form of a pledge. This model is less sustainable

than creating a mechanism that creates revenue. An example of the latter is the introduction of a fee or levy on marketing activities of pharmaceutical companies, following the Italian model. The Italian Government introduced a 5% levy on the promotional expenditures of pharmaceutical companies. The resulting revenue has been used to fund an independent research and development programme on pharmaceuticals; this represented about €78 million between 2005 and 2007.

These options will be further described in the study that is currently undertaken by the Secretariat. In any case, the pooled fund should also be able to accept voluntary, preferably unspecified, funding from non-State actors, such as philanthropic foundations, following WHO's rules on acceptance of donations. The Special Programme for Research and Training in Tropical Diseases would ensure appropriate management of conflicts of interest in subsequent decisions on the allocation of funds, in other words ensuring that such contributions have no impact on the process of selection of projects.

The proposal for a voluntary pooled fund is contained in Annex 2. The UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases has developed an operational plan for a voluntary pooled fund to support health research and development.

(3) TERMS OF REFERENCE FOR THE EXPERT COMMITTEE ON HEALTH RESEARCH AND DEVELOPMENT

In resolution WHA69.23, the Health Assembly requested a description of how the Global Observatory on Health Research and Development, the proposed Expert Committee on Health Research and Development and the Scientific Working Group of a voluntary pooled fund would work together in terms of specific disease examples.
The analyses produced by Global Observatory on Health Research and Development will be used by the Expert Committee on Health Research and Development to recommend priority areas for research and development of specific health products and technologies; for example, the need for an innovative vaccine against pulmonary tuberculosis in adults, a condition that accounts for most cases of tuberculosis worldwide, or an accurate and specific, easy-to-use diagnostic tool that can be used in rural health settings. The Scientific Working Group of the proposed pooled fund would then operationalize the priorities established by the Expert Committee by defining the detailed product characteristics. The interaction of this system is illustrated in the recent report on Health product research and development fund: a proposal for financing and operation.

The Executive Board at its 140th session also noted the terms of reference for the Expert Committee on Health Research and Development as set out in document EB140/22.

POLICY COHERENCE WITH OTHER RELEVANT RESEARCH AND DEVELOPMENT-RELATED ACTIVITIES

The Health Assembly in resolution WHA69.23 additionally requested the Director-General to promote policy coherence within the Organization. The Secretariat thus ensures that key principles agreed with respect to research and development as a follow up to the report of the Consultative Expert Working Group are also applied in its other areas of engagement, namely in new initiatives such as the Research and Development Blueprint to foster research and development preparedness for infectious diseases with epidemic potential, or the Global Antibiotic Research and Development Partnership, a joint venture by WHO and the Drugs for Neglected Diseases initiative.

The Health Assembly is invited to note the report and to provide guidance on future strategic directions.

Implication for the European Region

In 2013, WHO Europe received 18 submissions for demonstration projects of which 17 proposals met the submission inclusion criteria. After expert review, four projects where shortlisted[28] which were submitted to WHO HQ by the EURO Secretariat. Subsequently, the project "Exploiting the Pathogen Box: an international open source collaboration to accelerate drug development in addressing diseases of poverty" submitted by the Medicines for Malaria Venture (MMV) was selected as of one of the 6 demonstration projects.

As of 6 April 2016, France and Switzerland have contributed financially to the establishment of the Observatory, and Norway and Switzerland have pledged voluntary fund designated for demonstration projects and the Observatory. For demonstration projects, US$ 1.02 million was contributed by Switzerland and Norway as matching grants for contributions from developing countries on the basis of half a dollar for each dollar contributed, and US$ 1.56 million more matching fund was pledged, pending developing country contributions. During the open-ended meeting of Member States, Germany has pledged funding for the Observatory.

Ms. Tania Dussey-Cavassini, Vice-Director General, Ambassador for Global Health, Federal Office of Public Health, Switzerland was elected as Vice-Chair for the Open-Ended Meeting of Member States.

13.6 Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products

[28] See also: http://www.who.int/phi/implementation/EURO_procedure_for_selection_of_demo_projects.pdf

Document A70/23 and EB140/2017/REC/1, decision EB140(6)

The Director-General transmits to the Executive Board at its 140th session the report of the fifth meeting of the Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products, which met in Geneva in November 2016.

The Executive Board as its 140th session considered an earlier version of the Director-General's report.

Annex 1 includes the report of the fifth meeting of the Member States mechanism to which the Secretariat provided an update on activities to implement the work plan, including on the WHO Global Surveillance and Monitoring System, the smartphone application pilot study, regulatory strengthening and capacity building activities, and the circulation of a survey from the International Coalition of Medicines Regulatory Authorities. Member States were encouraged to comment on the WHO Draft Guidance on Testing of "Suspect" Spurious/Falsely-Labelled/Falsified/Counterfeit Medicines by January 2017.

The working group meeting revised and agreed by consensus a document entitled "Guidance on developing a national plan for preventing, detecting responding to actions, activities and behaviors that result in substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products," which was agreed by consensus by the fifth Meeting of the Member State mechanism and is attached at Appendix 1.

The working group meeting revised and agreed by consensus a document entitled "Available authentication technologies for the prevention and detection of SSFFC medical products," which was agreed by consensus by the fifth Meeting of the Member State mechanism and is attached (Appendix 2).

The Secretariat provided an update on the study on the public health and socioeconomic impact of SSFFC medical products, as outlined in document A/MSM/4/6.

The Member State mechanism agreed by consensus to recommend that the WHO governing bodies endorse the definitions as set out in Appendix 3. The Member State mechanism further agreed by consensus to ***recommend the WHO to replace the use of "substandard/spurious/falsely-labelled/falsified/counterfeit medical products" with "substandard and falsified medical products"*** as the term to be used in the name of the mechanism and in all future documentation on the subject of medical products of this type.

Draft decision

The Health Assembly is invited to adopt a draft decision endorsing the definitions set out in appendix 3 and requesting the Director-General to use the term substandard and falsified medical products in all future documentation.

13.7 Promoting the health of refugees and migrants

Document A70/24

Document not available on 27 April 2017.

14. Communicable diseases

14.1 Global vaccine action plan

Document A70/25

In May 2012, the 65th World Health Assembly adopted resolution WHA65.17, in which it endorsed the global vaccine action plan and requested the Director General to monitor progress and report annually on progress towards achievement of global immunization targets, through the EB, to the Health Assembly, until the 71st World Health Assembly.

At its 140th session in January 2017, the Executive Board considered an earlier version of this report, together with a draft resolution.

The Strategic Advisory Group of Experts on Immunization (SAGE) in October 2016 reviewed the progress against each of the indicators for the goals and strategic objectives of the global vaccine action plan at the mid-point[29], based on data from 2015, and prepared the 2016 Assessment Report of the Global Vaccine Action Plan. A summary of the latter is included in the Annex of document A70/25.

The report re-affirms immunization as one of the world's most effective and cost-effective tools against the threat of emerging diseases and has a powerful impact on social and economic development. However, SAGE is gravely concerned that progress toward the goals to eradicate polio, eliminate measles and rubella, eliminate maternal and neonatal tetanus, and increase equitable access to life saving vaccines is too slow.

- Global average immunization coverage has increased by only 1% since 2010.
- In 2015, 68 countries fell short of the target to achieve at least 90% national coverage with the 3rd dose of diphtheria-tetanus-pertussis vaccine.
- 26 countries reported no change in coverage levels and 25 countries reported a net decrease in coverage since 2010.

SAGE considers the next four years as presenting an unprecedented opportunity for countries to leverage the attention and support that immunization receives and apply it with the support of stronger leadership and governance of national immunization systems.

[29] http://www.who.int/entity/immunization/global_vaccine_action_plan/SAGE_GVAP_Assessment_Report_2016_EN.pdf?ua=1

Strident efforts on the part of all countries and immunization stakeholders are required to catch up and achieve GVAP goals by 2020. Alongside specific leadership recommendations, SAGE (the report) recommends that Member States and immunization partners: prioritize immunization system strengthening, secure necessary investments to sustain immunization during polio and Gavi transitions, improve surveillance capacity and data quality, enhance accountability mechanisms to monitor implementation of Global and Regional Vaccine Action Plans, support vaccine R&D capacity in low- and middle-income countries, and accelerate the development and introduction of new vaccines and technologies.

The Health Assembly is invited to take note of this report and consider the recommendations for actions to be taken by the stakeholders (especially Member States) of the Global Vaccine Action Plan.

The Executive Board agreed to postpone the adoption of a draft resolution in order to allow for further consultations among Member States during the intersessional period before the Seventieth World Health Assembly in order to reach consensus.

Implication for the European Region

WHO Regional Office for Europe is committed to contribute to the achievement of GVAP goals by 2020. The European Vaccine Action Plan 2015–2020 (EVAP) has been developed and endorsed by the Regional Committee to complement, regionally interpret and adapt the Global Vaccine Action Plan in harmony with Health 2020 and other key regional health strategies and polices. (WHO/Europe was the first Region to develop such a Plan).

Regional progress against the EVAP indicators is steady and action to achieve EVAP and GVAP goals should be accelerated:

Progress of measles and rubella elimination is slow but evident – with fewer cases in 2016 than in any previous year on record - and 37 countries having interrupted endemic transmission of one or both diseases. The countries of the European Region have successfully introduced new and under-utilized vaccines consistently over the past three years, with more countries than ever having established National Immunization Technical Advisory Groups (NITAGS) and having achieved financial sustainability. The Region's Member States also proudly endorsed an Action Plan on Viral Hepatitis in September 2016.

Evidence indicates that countries are challenged by a lack of adequate financial resource commitment to immunization due to competing priorities, have difficulty in accessing vaccines at affordable and optimum prices, are affected by global supply shortages for vaccines and face difficulties in sustaining programme performance in part due to poorly researched access and hesitancy issues, and a growing anti-vaccine agenda and visibility.

These issues are particularly acute in middle-income countries (MICs), many of whom self-procure vaccines and rely solely on their domestic financial resources, continue to face significant challenges in expanding their immunization programmes through introduction of new vaccines and sustaining performance of their programmes.

The WHO Regional Office has significantly scaled-up its support to Member States in tackling these challenges – including prominent price transparency projects, vaccine safety management and communications capacity building, resource mobilization tool development, dissemination and training for securing domestic financing of immunization programmes, delivery of capacity building on specific elements of vaccine demand and in building awareness and advocating measurement of vaccine hesitancy – with proposed solutions.

Whilst EVAP highlights these challenges and proposes solutions and priority activities to overcome, the Region is dedicated to move forward with development of a more cohesive strategy that addresses the challenges that Middle Income Countries (MICs) are facing. The Secretariat is exploring the interest of Member States to develop a strategy and action plan for Middle Income Countries in the Region in 2017, in consultation with Member States - with a potential for replication and adaptation by other Regions.

14.2 Global vector control response

Document A70/26

At its 140th session, the Executive Board noted an earlier version of this report and requested the Secretariat, in consultation with Member States, to prepare a draft resolution for consideration by the Seventieth World Health Assembly.

Vector-borne diseases pose a major threat to the health of societies around the world. They are caused by parasites, viruses and bacteria transmitted to human beings by mosquitoes, sandflies, triatomine bugs, blackflies, ticks, tsetse flies, mites, snails and lice. Major global vector-borne diseases of humans include malaria, dengue, lymphatic filariasis, Chagas disease, onchocerciasis, leishmaniasis, chikungunya, Zika virus disease, yellow fever, Japanese encephalitis and schistosomiasis. Other vector-borne diseases are of local importance in specific areas or populations.

Impressive gains have been made against malaria, onchocerciasis, lymphatic filariasis and Chagas disease but the burden of many other vector-borne diseases has increased in recent years. Social, demographic and environmental factors have altered pathogen transmission patterns, resulting in intensification, geographical spread, re-emergence, or extension of transmission seasons. Vector control has not yet been used to its full potential or had

maximal impact because interventions are inadequately delivered[30]; this situation arises because of meagre investments, collapse and dire lack of public health entomology capacity, poor coordination within and between sectors, weak or non-existent monitoring systems and limited sustainable and proven tools for certain vectors and situations.

The recent upsurge in vector-borne diseases reiterates the need for a comprehensive approach to vector control. Achievement of SDG 3[31] relies on effective vector control, and work towards other targets under the 2030 Agenda for Sustainable Development. Additional opportunities for better vector control will also become available through the development of novel tools, technologies and approaches. Advantage can be taken of advances that enable an evidence-based approach.

Document development process: *T*he draft global vector control response 2017-2030 was developed through an extensive consultation process that began in June 2016. Development of the document was led by the WHO Global Malaria Programme, Department for Control of Neglected Tropical Diseases and Special Programme for Research and Training in Tropical Diseases and coordinated by a Steering Committee. Representative from the European Region was invited to participate at the first WHO meeting to lay the foundation of a new Global Vector Control Response which was held in Geneva in August 2016 and provided contribution reflecting specificities of the Region. The document was discussed during several international meetings and web-based consultation for Member States and other stakeholders organized by WHO between June 2016 and April 2017.

Rationale: Major vector-borne diseases account for an estimated 17% of the global burden of all infectious diseases, and disproportionately affect poor populations. Every year insects and other vectors transmit infectious pathogens to more than one billion people, resulting in over 700,000 deaths worldwide. More than 80% of the global population lives in areas at risk from at least one major vector-borne disease, with more than half at risk from two or more. Vector-borne diseases impede economic development through direct medical costs and indirect costs such as loss of productivity and affecting negatively the tourism industry.

Climate change, increasing movement of people and goods, and unplanned urbanization have caused increases in vector-borne diseases, with major outbreaks of dengue, chikungunya, yellow fever and Zika virus disease in the recent years. Vector-borne diseases are preventable by well-implemented vector control. Strong political commitment and significant investments have led to major reductions in malaria, onchocerciasis and Chagas disease.

[30] This situation arises not only because of meagre investments, but the collapse and dire lack of public health entomology capacity, poor coordination within and between sectors, weak or non-existent monitoring systems and limited availability of proven tools for certain vectors and situations.

[31] Ensure healthy lives and promote well-being for all at all ages.

The full impact of vector control can be achieved by (re)building public health entomology capacity, good coordination within and between sectors, good monitoring systems and implementation of proven and innovative interventions.

The draft global vector control response 2017-2030 in brief

It aims to support the implementation of a comprehensive approach to vector control that will enable the setting and achievement of disease-specific national and global goals and contribute to attainment of the SDGs. It also aims to support countries in mounting coherent and coordinating their efforts to counter the increasing burden and threat of vector-borne diseases.

The document provides strategic guidance to countries and development partners for urgent strengthening of vector control and calls for significant enhancement of vector control programming, supported by increased numbers of technical staff, stronger monitoring and surveillance systems, and improved infrastructure.

The vision of this response is a world free of human suffering from vector-borne diseases, with the goal of reducing the burden and threat of vector-borne diseases through effective locally adapted and sustainable vector control.

The response sets an ambitious target of at least 75% reduction in global mortality and 60% reduction in morbidity due to vector-borne diseases by 2030 relative to 2016, with interim milestones of at least 30% reduction in mortality by 2020 and at least 50% reduction in mortality by 2025, and reductions in morbidity of at least 25% and 40% over the same time periods

The response framework is built on the following two foundations and four pillars of action and the two core elements are:

(1) enhanced human, infrastructural and health systems capacity for vector control and vector surveillance within all locally relevant sectors,:

(2) increased basic and applied research to underpin optimized vector control, and innovation for development of new tools and approaches.

Action is required in four key areas (pillars) to attain effective locally adapted and sustainable vector control.

Pillar 1. Strengthen inter- and intra-sectoral action and collaboration.

Pillar 2. Engage and mobilize communities

Pillar 3. Enhance entomological surveillance and monitoring and evaluation of interventions.

Pillar 4. Scale up and integrate tools and approaches.

Implementation of the draft global vector control response will require strengthening of three determining factors: (1) country leadership; (2) advocacy, resource mobilization and partner coordination, and (3) regulatory, policy and normative support.

Role of the secretariat: The Secretariat will continue to set and disseminate normative guidelines, policy advice and implementation guidance to support regional and country actions. It will ensure that its policy-setting process responds to changing vector control needs and that its global technical guidance is regularly updated. It will strengthen its own capacities and capabilities at the global, regional and country levels and provide support to initiatives on advocacy, resource mobilization and partner coordination. The Secretariat will promote the generation of research and knowledge to progress towards a world free of vector-borne diseases, monitor implementation of the response and regularly evaluate progress towards the interim milestones and the targets for 2030.

The Health Assembly is invited to note the report and adopt the draft resolution will be presented to the Assembly

Implication for the European Region

Although the burden of vector-borne diseases in the European region is not high, it should not be neglected and underestimated.

Recently, significant achievement has been reached in the WHO European region in controlling vector-borne diseases. The European Region is the first in the world to have achieved interruption of indigenous malaria transmission. Vector control was one of the key components of the strategy for controlling and then, eliminating malaria. The gained experience is being used to adapt and strengthen the systems that have been put in place in order to prevent and/or contain other vector-borne diseases as early as possible.

It is noteworthy that a number of vector-borne diseases such as leishmaniasis, West Nile fever, Crimean-Congo haemorrhagic fever, Lyme borreliosis, tick-borne encephalitis among others are still reported in the European region.

The introduction and establishment of Aedes mosquito species into the WHO European Region is a growing problem. Possible factors driving this problem are globalization, the increasing volume and pace of trade and travel, continuing urbanization and environmental challenges which include climate change. *Aedes albopictus* and *Aedes aegypti* mosquitoes are effective vectors of potentially severe diseases such as dengue and chikungunya and

Zika. In areas where these invasive mosquitoes have been established or re-established, there is a genuine risk of local transmission of these diseases.

To support countries in their efforts to prevent reintroduction of malaria the Regional framework for prevention of malaria reintroduction and certification of malaria elimination 2014-2020 outlining the key approaches and measures to prevent malaria reintroduction was developed to support countries. Vector surveillance and control remains one of the key interventions.

A Regional framework for surveillance and control of invasive mosquito vectors and re-emerging vector-borne diseases in the WHO European Region 2014-2020 was adopted by the 63rd session of the WHO Regional Committee for Europe in response to the introduction, establishment and spread of Aedes mosquito species (*Aedes albopictus* and *Aedes aegypti*) into the WHO European Region and increasing number of dengue and chikungunya outbreaks reported in the Region.

In 2014, the "Strategic framework for leishmaniasis control in the WHO European Region, 2014–2020" outlining the regional goal and objectives to be achieved by 2020, and the recommended strategic approaches and priority interventions was developed and published to help countries in their efforts to control the disease. Integrated vector control is one of the proposed priority interventions.

In the context of malaria elimination, particular emphasis is given to situations in which there is a risk of the spread of malaria between countries and regions. In order to tackle the issue of malaria elimination in border areas, the Regional Office has initiated and supported cross-border collaboration within the Region and across regions, notably with the Eastern Mediterranean Region. Joint statements on cross-border collaboration have been signed between several countries.

To address the threat of vector-borne diseases, the Regional office is providing technical guidance to Member States. During the WHO Regional Technical Consultation on Zika virus which was held in Portugal in June 2016, vector control was explicitly discussed. Several promising potential new vector control tools have been reviewed by WHO in the context of the response to Zika virus. While some tools are supported by strong evidence of entomological effect, there is a lack of comprehensive data on epidemiological impact for any Aedes-borne viruses.

15. Noncommunicable diseases

15.1 Preparation for the third High-level Meeting of the general Assembly on the Prevention and Control of Non-communicable Diseases, to be held in 2018

Document A70/27 and EB140/2017/REC/1, resolution EB140.R7

Document not available on 27 April 2017.

15.2 Draft global action plan on the public health response to dementia

Document A70/28 and EB140/2017/REC/1, decision EB140

In June 2016, the Executive Board adopted decision EB139(1), requested the Director-General to develop a Draft Global Action Plan on public health response to Dementia, for consideration by the Seventieth World Health Assembly, through the 140th session of the Executive Board. In January 2017, the Executive Board, as its 140th session, noted this report and adopted decision EB140(7).

The document includes in annex a draft Global Action Plan prepared by the secretariat which builds upon the work of WHO's report, Dementia: A Public Health Priority10 (2012) and the conclusions of the First Ministerial Conference on the Global Action against Dementia hosted by WHO in Geneva in March 2015.

The Plan has been offered for consultation to all stakeholders through a combination of seminars, meetings and WebEx consultations. In the European Region, a meeting was offered to Member States, but web based consultation was preferred.

The draft action plan sets out clear actions for Member States, Secretariat and partners and proposes key indicators and global targets. It is designed to provide guidance for the development and implementation of policies on dementia aligned with universal health coverage.

The goal of the draft action plan on public health responses to dementia is to improve the lives of people with dementia, their carers and families, while decreasing the impact of dementia on them as well as on communities and countries. It is grounded on 7 cross cutting principles: human rights of people with dementia, empowerment and engagement of people with dementia and their carers, evidence based practice for dementia risk reduction and care, multisectoral collaboration, universal health and social care coverage for dementia, equity and appropriate attention to prevention, cure and care.

The Action Plan comprises 7 action areas, each proposing activities for Member States, Partners and the Secretariat and specifying global targets:

1. Dementia as a public health priority.

2. Dementia awareness and friendliness.

3. Dementia risk reduction.

4. Dementia diagnosis, treatment and care.

5. Support for dementia carers.

6. Information systems for dementia.

7. Dementia research and innovation.

In an Appendix, indicators for measuring progress are proposed.

Draft decision

The Health Assembly is invited to consider a draft decision which endorses the draft global action plan on the public health response to dementia 2017-2025, urges Member States to develop ambitious national responses to the implementation of the global action plan and request the DG to submit progress reports on the implementation of the decision to the WHA in 2020,2023 and 2026.

Implication for the European Region

Dementia is a very high priority for European countries. In many European countries dementia has become a leading cause of morbidity and mortality, associated with the aging of the population. It is estimated that between 5-7% of people over 60 years of age in countries in the European Region suffer from dementia. Probable risk factors of dementia are shared with risk factors of other NCDs and mental health such high blood pressure, alcohol, smoking, lack of exercise and poor nutrition. Science is progressing fast in this field and new evidence is emerging. Ability to diagnose early is improving, but developments of new treatments are disappointing.

The burden on the health and social care systems are large and growing, and new models of care, evidence of preventative measures and effective treatments are under development. European countries are very active addressing this issue in partnership with several intergovernmental agencies such as the WHO, European Commission and OECD. Large and growing amounts of funding are invested in research, treatment and care.

European Member States are also actively involved in the development of the WHO Global Dementia Observatory which will serve as the monitoring mechanism to track the

implementation and progress of the global action plan. Continued development of the Global Dementia Observatory is being carried out in collaboration with relevant stakeholders including OECD, the EU, Alzheimer's Europe and Alzheimer's Disease International (ADI).

15.3 Public health dimension of the world drug problem

Document A70/29

The Executive Board at its 140th session in January 2017 considered and noted an earlier version of this report. The Secretariat had previously reported on the subject to the Sixty-ninth World Health Assembly.

The General Assembly adopted the outcome document of its special session on the world drug problem (April 2016). Heads of State and Government, ministers and representatives of Member States reiterated their commitment to promote the health, welfare and well-being of all individuals, families, communities and society as a whole. In December 2016, the General Assembly adopted resolution 71/211, which supported strengthened international cooperation to address and counter the world drug problem and which, inter alia, encouraged all relevant United Nations bodies and specialized agencies to commence implementing recommendations made in the outcome document mentioned above within their existing mandates.

Drug use and its related health conditions are major public health concerns and constitute a significant but preventable health and social burden. The public health strategies and the health sector have an important role in mitigating drug related harm at all levels but face many challenges especially in less-resourced countries. To prevent a significant global public health problem, technical support and strengthening of country capacity have to be ensured by WHO in implementing the recommendations made at the special session of the UN General Assembly.

The present report takes into account the recent discussions at WHO's governing bodies' sessions, the drug-related health targets of Sustainable Development Goal 3 (Ensure healthy lives and promote well-being for all at all ages), and the relevant outcomes of thematic discussions held at international forums to promote the implementation of operational recommendations on health-related issues agreed at the General Assembly's special session. It also presents an update on the Secretariat's activities on the public health dimensions of the world drug problem, including collaboration with United Nations Office on Drugs and Crime (UNODC) and International Narcotics Control Board.

WHO's role in the follow-up to the special session of the United Nations General Assembly on the world drug problem: WHO will have to ensure the coherence of public health-

oriented drug-related policies and provide especial support (including technical support) to national public health entities for strengthening public health response. International cooperation will have to be intensified – among Member States, United Nations entities and other relevant partners. Cooperation needs to be strengthened between WHO, UNODC, the International Narcotics Control Board and other competent United Nations bodies, within their respective mandates and with acknowledgement of the primacy of the Commission on Narcotic Drugs as the policy-making body of the United Nations with overall responsibility for drug control matters.

In February 2017, WHO and UNODC signed a memorandum of understanding to strengthen and expand existing cooperation on the public health dimension of the world drug problem, with special emphasis on the implementation of the health-related operational recommendations included in the outcome document of the General Assembly's special session on the world drug problem. The memorandum of understanding builds on the ongoing collaboration between WHO and UNODC and is focused on seven main areas of current and planned collaborative activities: (a) prevention of drug use; (b) prevention and treatment of drug use disorders; (c) access to medicines under international control; (d) new psychoactive substances; (e) prevention, diagnosis, treatment, care and support for HIV, viral hepatitis and tuberculosis among people who use drugs and among people who are in prisons; (f) prevention of violence and violence-related deaths; and (g) monitoring drug use and its health and social consequences.

Demand reduction and related measures: *WHO* will develop, promote, implement and evaluate guidelines, norms, information products and standards, and, on request, provide technical support to support the implementation of public health-oriented drug policies and programmes in health systems. It will also provide support to Member States for ensuring universal availability, accessibility, acceptability, coverage and quality of the health workforce for effective prevention and management of drug use, drug use disorders and associated health conditions.

The *collaborative programme of WHO with UNODC* on drug dependence treatment and care will be strengthened and expanded to other health-related areas. Recent examples of collaboration with UNODC on demand reduction include the development of standards for treatment of drug use disorders, promotion of the international standards on drug use prevention and of cooperation within the framework of UNODC's "Listen First" initiative, collecting information on good practices of public health-oriented interaction between health and law enforcement sectors, development of drug dependence treatment services for people living in rural areas, and identification and management of disorders due to use of new psychoactive substances.

WHO and UNODC will continue to organize jointly information sessions for Member States, technical expert meetings and scientific consultations, to collaborate on the preparation of

joint information products and technical tools and to provide support to Member States in development of their drug treatment systems. Special efforts will be invested in promoting and implementing the standards on the treatment of drug use disorders, developed jointly by UNODC and WHO.

Within *the framework of the global health sector strategies on HIV and viral hepatitis*, and of the End TB Strategy, WHO will promote and support the implementation of interventions outlined in the WHO, UNODC, UNAIDS technical guide with the aim of reaching the 2020 and 2030 fast-track targets in line with the SDGs.

Access to controlled medicines: WHO will keep developing and disseminating normative guidance and providing technical support to countries to improve adequate access to controlled substances for medical and scientific purposes. It regularly updates the WHO Model Lists of Essential Medicines. The Secretariat is reviewing medicines for pain and mental and behavioral disorders which will be considered for addition to the Model Lists by WHO's Expert Committee of Selection and Use of Essential Medicines at its 21st meeting in March 2017. In addition, the Secretariat is drafting guidelines for the management of cancer pain. It will collaborate with UNODC and the International Narcotics Control Board in providing training and support to countries to maximize access to controlled medicines and through its participation in the latter's Learning Project. WHO is also a part of the Joint Global Programme supporting countries in identifying and addressing barriers to access.

Cross-cutting issues: There is a clear need for a comprehensive package of drug control measures for the entire public health continuum. In its work, WHO will take into account the specific health needs of children, young people and women, focus on improving coverage and effectiveness of appropriate prevention, treatment, care and harm reduction interventions and also ensure access to controlled medicines for medical use.

WHO is responsible for determining whether substances should be controlled under the Single Convention on Narcotic Drugs and the Convention on Psychotropic Substances. Those data are then delivered to the WHO's Expert Committee on Drug dependence which will provide advice to the Commission on narcotic Drugs to facilitate its informed decision-making on the international scheduling of psychoactive substance. When data are insufficient to justify a review by the Expert Committee, WHO will itself proceed to surveillance of the substances which demonstrate a potential for abuse, dependence and harm to health, including new psychoactive substances and for which there is not enough data to justify a review by the Expert Committee.

WHO (together with UNODC notably) will provide technical support and guidance to Member States to improve their national monitoring systems with an emphasis on treatment coverage for drug and other substance use disorders and coverage of people using drugs along the HIV prevention, testing and treatment cascade. New projects will

develop appropriate sets of indicators and strengthen the research capacity of Member states with special efforts needed in the field of psychoactive substances.

Following a consultation between WHO and UNODC, an interagency technical working group on drug epidemiology has been established to improve coordination and cooperation between intergovernmental organizations in this area[32] and produce joint estimates related to drug use and its consequences.

The Health Assembly is invited to note this report.

Implication for the European Region

The Regional Office will continue to work closely with CND, UNODC, EMCDDA and the Pompidou Group of the Council of Europe to tackle the world drug problem.

15.4 Outcome of the Second International Conference on Nutrition

Document A70/30

Document not available at 27 April

15.5 Report of the Commission on Ending Childhood Obesity: implementation plan

Document A70/31

Among the noncommunicable disease risk factors, childhood obesity is particularly concerning. Childhood obesity prevalence is increasing in all countries with the most rapid rises in in low- and middle-income countries and poses a very important challenge. The Sustainable Development Goals, set by the United Nations in 2015 identify prevention and control of noncommunicable diseases as one of the core priorities.

The Commission on Ending Childhood Obesity was established by the DG and produced a report in order to prevent infants, children and adolescents from developing obesity. Having reviewed the scientific evidence, consulted with over 100 WHO Member States and considered nearly 180 online comments, the Commission developed a report containing a package of recommendations to address childhood obesity. The Report calls for governments to take leadership and for all stakeholders to recognize their moral responsibility in acting on behalf of the child to reduce the risk of obesity.

The Sixty-ninth World Health Assembly, having considered the Report, adopted a decision requesting WHO to develop, in consultation with Member States and relevant stakeholders, an implementation plan guiding further action on the recommendations included in the

[32] Including regional intergovernmental entities and institutions such as the African Union and the European Monitoring Centre for Drugs and Drug Addiction.

Report of the Commission on Ending Childhood Obesity to be submitted through the Executive Board a sits 140th session, for consideration by the Seventieth World Health Assembly.

In January 2017 the Executive Board, at its 140th session, considered and earlier version of this report and broad support was expressed for the draft implementation plan.

The Draft Implementation Plan to guide further action on the recommendations included in the report of the commission on ending childhood obesity builds on the recommendations and accompanying rationales in the report of the Commission on Ending Childhood Obesity and aims to advise Member States and international partners on the necessary actions to implement the recommendations of the Commission to address childhood obesity. It recognizes that Member States face different challenges with respect to all forms of malnutrition. The implementation Plan strongly suggests that the goals of ending childhood obesity should be align with the global development agenda If Member States take prompt and comprehensive action to prevent and treat childhood obesity, then other health initiatives, including those to improve maternal, child and adolescent health, nutrition and physical activity, will be further strengthened, thus contributing to broader targets for health and well-being.

The Draft Implementation Plan aims to guide Member States and international partners on the necessary actions to implement the recommendations of the Commission to address childhood obesity. It recognises that actions to end childhood obesity should be integrated in existing strategies, policies and programmes across a number of diverse domains at both global and regional levels.

The draft plan comprises two sections. The first sets out the aim, scope and guiding principles of the implementation plan. The second defines the actions needed to end childhood obesity in the specific areas of (I) leadership; (II) the set of six recommendations of the Commission; (III) monitoring and accountability; (IV) key elements for successful implementation; and (V) roles and responsibilities of stakeholders.

Guiding principles: The Commission on Ending Childhood Obesity identified the following key guiding principles: the child's right to health, government commitment and leadership, a whole-of-government approach, a whole-of-society approach, equity, aligning with the global development agenda, integration into a life course approach, accountability, universal health coverage.

Actions needed to end childhood obesity: The Commission proposed six sets of recommendations to tackle the obesogenic environment and interventions at critical time points in the life course for the prevention of obesity and the treatment of children who are already obese, such as promote healthy diet, promote physical activity, preconception and

pregnancy care, early childhood diet and physical activity, health, nutrition and physical activity for school-age children, weight management. Two groups of outcomes we identified, namely intermediate (healthier environment, healthier behavior and reduced biological risk factors) and long term outcome (reduced prevalence of children with obesity).

Effective implementation of the recommendations will require political commitment and leadership as well as capacities to deliver the required interventions and effective monitoring of accountabilities of different stakeholders.

In implementing actions for ending childhood obesity, consideration should be given to certain elements, as highlighted by the Commission in its report, such as prioritization; awareness, communication and education; mobilization of resources; capacity-building.

The Health Assembly is invited to consider and endorse the draft implementation plan.

Implication for the European Region

European Region Member States could benefit from the proposals of the Implementation Plan in order to streamline and scale-up actions around the prevention of childhood overweight and obesity. The recommended comprehensive sets of actions do incorporate many of the success stories and good practices from the European Region could support the reduction of the problem. The adoption of the initiatives suggested in the Implementation Plan will help member states in the Region to halt the rise of childhood obesity.

The development of this Implementation Plan is based on important guiding principles notably the child's right to health, Government commitment and leadership, a whole-of-government and whole-of-society approach, Equity, Accountability, a life course approach, and Universal Health Coverage and treatment of obesity; the same principles that have been already incorporated by the European Member States in Health 2020, as well as the European Food and Nutrition Action Plan 2015-2020 and the Physical Activity Strategy for the WHO European Region 2016-2025. Examples of countries where childhood obesity is decreasing or levelling off are mainly from the Region and they can be used as inspiration for other Regions.

European Member States may also consider the several sets of proposed actions in the Implementation Plan namely for academic institutions and medical professional associations, philanthropic foundations, the private sector, nongovernmental organizations, WHO and other International Organizations.

15.6 Cancer prevention and control in the context of an integrated approach

Document A70/32

In January 2017, the Executive Board, at its 140th session, considered an earlier version of this report that contained a draft resolution. Discussion on a draft resolution for the Health Assembly is continuing in the inter-sessional period.

The document reports on the current global cancer situation, covering burden, trends and progress in cancer and control (prevention, early diagnosis and screening, treatment, palliative care and surveillance) and provides a description of WHO's response to cancer control, including development of technical materials, provision of data, collaborative country missions, workshops and training.

Burden and trends: In 2012, there were 14.1 million new cases and 8.2 million cancer-related deaths worldwide including 4.3 premature deaths of which 75% in low- and middle income countries. The number of new cases is projected to increase to 21.6 million annually by 2030. The greatest impact is in low- and middle-income countries, many of which are ill-equipped to cope with the escalating burden of disease, and where 65% of cancer deaths occur.

Progress in cancer control has been uneven. While there have been moderate improvements in cancer mortality rates in high-income countries, overall declines in mortality from cancer have not been achieved globally. Certain population groups (women, children, indigenous groups, ethnic minorities and socioeconomically disadvantaged groups) are often inequitably exposed to cancer risk factors and have limited access to diagnosis and care services, which result in poorer outcomes.

The economic impact of cancer is significant and is increasing. In 2010, the total annual economic cost of cancer was estimated at approximately US$ 1.16 trillion. As recognized in the Addis Ababa Action Agenda resources for financing national cancer responses increasingly need to come from domestic budgets. According to some estimates, only 5% of global resources for cancer prevention and control are spent in low- and middle-income countries, despite the majority of preventable deaths occurring in these countries. Innovative financing is needed, including through increased taxes on tobacco and alcohol.

Orienting funding through domestic, bilateral and multilateral channels towards evidence-based cost-effective interventions can reduce expenditure on high-cost interventions, medicines and technologies. Cost-effective strategies for cancer prevention include vaccination against human papilloma virus and hepatitis B virus, higher taxes on tobacco and alcohol, elimination of exposure to tobacco smoke and tobacco marketing tactics,

restriction on marketing of foods and non-alcoholic beverages to children, reduced air pollution and quality public open space and adequate infrastructure for physical activity.

Developing and implementing national cancer control plans: In the 2015 WHO country capacity survey for NCDs, 68% of the 177 responding Member States reported having an operational policy, strategy or action plan for all or some cancers. Implementing national cancer control plans require adequate resources, monitoring and accountability together with an effective health system, founded on the principles of universal health coverage and strong primary health care to provide high-quality, resource-appropriate cancer prevention and control services.

Prevention, early diagnosis, screening and treatment: Cancer is caused by a wide range of risk factors, including the four shared noncommunicable disease risk factors (tobacco use; unhealthy diet; physical inactivity; and harmful use of alcohol), obesity, infections, indoor and outdoor air pollution, radiation, environmental chemicals and occupational exposures.

One third to one half of all cancers are potentially preventable. Orienting funding towards primary prevention interventions can reduce expenditure on high-cost interventions, medicines and technologies. Cost-effective strategies for cancer prevention include vaccination against human papilloma virus and hepatitis B virus, higher taxes on tobacco and alcohol, elimination of exposure to tobacco smoke and tobacco marketing tactics, restriction on marketing of foods and non-alcoholic beverages to children, reduced air pollution and quality public open space and adequate infrastructure for physical activity.

Early diagnosis and prompt and appropriate treatment improve the outcomes and quality of life of cancer patients. Cancer screening has had a limited impact in many low- and middle-income countries due to low participation, inadequate quality assurance measures and insufficient health infrastructure to deliver organized services. In the 2015 WHO country capacity survey, only 20% of the countries having a screening programme achieved greater than 70% participation for cervical or breast cancer screening. Member States should increase efforts to strengthen health systems at the national and local levels to ensure diagnosis of cancers at early stage and secure accessible, affordable and high-quality care for all patients.

Of the estimated 20 million people who need palliative care each year, 6.6 million (33%) are cancer patients, yet 83% of the global population live in countries with low or non-existent access to adequate pain management. In resolution WHA67.19 (2014) on the strengthening of palliative care, the Sixty-seventh World Health Assembly urged Member States to integrate palliative care services in the continuum of care, with emphasis on primary care, community and home-based care, and universal coverage schemes.

WHO's response: WHO and it's specialized cancer research agency (IARC) have developed extended technical material to guide Member states in all aspects of cancer control (prevention, early detection & screening, diagnosis, treatment, palliative care, cancer advocacy and cancer registration) All WHO regional offices and many country offices have provided direct support to Member States by organizing regional workshops and training courses, convening meetings and passing resolutions.

Recommended actions for Member States: Countries should develop and implement national cancer control plans with focus on equity and access and with adequate resources and accountability to provide high-quality, resource-appropriate cancer prevention and control services. They should implement cost effectivepolicies and programmes in line with global strategies to reduce the risk factors for noncommunicable diseases and the WHO Framework Convention on Tobacco Control, improve access to timely diagnosis and treatment, optimize use of human resources and anticipate future requirements for cancer prevention and control, improve data collection to inform decision making.

Actions for the Secretariat: The Secretariat will develop technical tools for and provide support to Member States in planning, implementation , monitoring and evaluation of cancer prevention and control strategies, including costing of national cancer plans, the implementation of cost-effective interventions including "best buys" in the context of the global action plan for the prevention and control of noncommunicable diseases 2013–2020, strengthening the workforce, promoting access to essential medicines and technology and integrating cancer prevention and control into national health systems, support Member States to the strengthening of scaling up tobacco control, reduction of harmful use of alcohol, addressing environmental and occupational carcinogens, promote healthy diet and physical activities and increase vaccination coverage.

The Health Assembly is invited to note the report

Implications for the European Region

Cancer is a high priority for the European countries and a leading cause of mortality in the region. It is estimated that each year 3.7 million new cancer cases are diagnosed in the European region (WHO Globocan 2012 estimates). Between 2005 and 2015, cancer mortality has decreased in the European region from 166 to 155 deaths per year per 100,000; however in ¼ of the countries, mortality rates have remained stable or have even increased (WHO Health for all database).

In the past 10 years, some European countries, but not all, have registered progresses regarding the two major and most preventable risk factor of cancer: Tobacco and alcohol, however more can be done. In almost all European countries coverage for hepatitis B and HPV vaccinations have increased and air pollution has decreased however too slowly.

Obesity a major risk factor for cancer is increasing rapidly in almost all European countries (WHO Health for all database).

Early diagnosis and timely treatment of symptomatic cancer is highly relevant to many European countries: a lot of resources are invested in launching screening programs which remain relatively ineffective at reducing mortality due to low participation, inadequate quality assurance measures and insufficient health infrastructure to deliver organized services. Furthermore in some countries non evidence-based screening activities are taking place such as screening for other cancer than cervix, breast and colorectal cancers or for people out of the recommended age ranges, resulting in wasting of resource and harms for healthy people (for example overtreatment of prostate cancer or of mild cervical dysplasia in young women).

Among WHO regions, the European region has the highest rate of adult in need of palliative care: 562/100,000, 25% of which attributable to cancer (WHO - WHPCA, Global Atlas of Palliative care at the end of life, 2014). But provision of palliative care remain under-developed in the Europe region with only 13 countries out of 53 where hospice-palliative services are at a stage of advanced integration into mainstream service provision.

15.7 Strengthening synergies between the World Health Assembly and the Conference of the Parties to the WHO Framework Convention on Tobacco Control

Document A70/33

Document not available on April 27

15.8 Prevention of deafness and hearing loss

Document A70/34 and EB139/2016/REC/1, resolution EB139.R1

Document not available on April 27

16. Promoting health through the life course

16.1 Progress in implementation of the 2010 Agenda for Sustainable Development

Document A70/35

Document not available on 27 April 2017.

16.2 The role of the health sector in the Strategic Approach to International Chemicals Management towards the 2020 goal and beyond

Document A70/36

Document not available on 27 April 2017.

16.3 Global Strategy for Women's, Children's and Adolescents' Health (2016-2030)

Document A70/37

Document not available on 27 April 2017.

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