



## **Highlights of the WHO Executive Board: 140th Session**

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### **Introduction**

The 140th session of the Executive Board (EB) of the World Health Organization (WHO) tackled an extensive agenda of issues, including the short list and interview of candidates for Director General that will be presented at the World Health Assembly (WHA) in May 2017. This Policy Brief reports on highlights of the EB deliberations on selected agenda items.

### **The WHO Executive Board, 140th session**

The 140th session of the Executive Board of the WHO took place in Geneva from 23 January to 1 February 2017. The session was chaired by Dr. Ray Busuttil from Malta.

The EB is comprised of 34 members designated by their respective countries. A certain number of WHO member states from the six WHO regions nominate the respective members of the EB. Other WHO member states can participate in the EB as observers. The EB meets twice a year – in January and May respectively. The January meetings of the EB discuss important substantive matters on which the EB makes recommendations to the World Health Assembly (WHA) for approval. This session of the EB also draws up the agenda for the WHA. The May 2017 session of the EB, which is held immediately after the WHA, predominantly discusses administrative matters.

### **The agenda**

The draft agenda for the EB is prepared by the EB bureau and made available in advance. Accordingly, the adoption of the agenda at the EB is generally a formality. This was not the case at the 140th session of the EB.

The agenda of the 140th session of the EB included 45 items and sub-items. Most of the items involved interim reporting by the WHA Secretariat. Others required discussion among member states, including on the implementation of resolutions and decisions of the WHA.

There was controversy over the non-inclusion of the report of the United Nations Secretary-General's High-Level Panel on Access to Medicines (UNHLP report) in

the draft agenda. The 11 member states of the South East Asia Region – Bangladesh, Bhutan, South Korea, India, Indonesia, Maldives, Myanmar, Nepal, Sri Lanka, Thailand, and Timor-Leste – as well as Brazil, Iran, and South Africa had requested the item to be included in the agenda. During the EB discussion on the approval of the agenda, India, Brazil, Venezuela and Iran raised serious concern and disappointment on the non-inclusion of the agenda item by the EB without any explanation. India stressed that it would be inconceivable and inexcusable that the WHO, being the main UN agency that should be at the forefront of the access to medicines agenda, does not discuss and take appropriate follow-up action on the UNHLP report. India further stressed that if the EB does not discuss the report, the WHO will risk losing its leadership on such a vital global health issue, and this would be a serious setback to its credibility and integrity. Brazil reiterated that it is inadmissible that the WHO does not discuss a report on access to medicines convened by the United Nations Secretary-General.

The Chair explained that the EB bureau had felt that there were sufficient items on the agenda relating to medicines within which the report of the UNHLP could be discussed. The opposition of the US to the proposal also appeared to influence the decision.

The Chair invited formal proposals for inclusion of a discussion on the UNHLP report in the agenda from any standing EB member. As none of the EB members came forward with the request, the draft agenda was adopted without this item.

At the request of Thailand, the EB agreed to include a new sub-item on the agenda concerning physical activities for health, under the agenda item on non-communicable diseases. An understanding was reached that there would be no discussion on the topic and the WHO Secretariat will be requested to submit a global action plan on this issue for further discussion at the 142nd session of the Executive Board in January 2018.

## Shortlisting and selection of candidates for the post of Director-General

The term of the current Director-General (DG), Margaret Chan expires on 30 June 2017. The Executive Board is responsible for the short list and interview of candidates before the final election by the Members of the WHA in May 2017.

The 140th session of the EB undertook two rounds of shortlisting and selection of candidates for the post of the Director-General of the WHO, to recommend three candidates. Six candidates were nominated for the post of DG by their respective governments - Dr. Tedros Adhanom Ghebreyesus (Ethiopia), Dr. Flavia Bustreo (Italy), Prof. Philippe Douste-Blazy (France), Dr. David Nabarro (UK), Dr. Sania Nishtar (Pakistan) and Dr. Miklos Szocska (Hungary). The EB drew a shortlist of 5 candidates from Ethiopia, Italy, France, UK and Pakistan. The EB conducted interviews with the shortlisted candidates and finally recommended Dr. Tedros Adhanom Ghebreyesus, Dr. David Nabarro and Dr. Sania Nishtar.

This is the first time in the history of the WHO that the EB has recommended a list of three candidates, from which the 194 member States in the WHA are invited to elect the DG. This marks a departure from the past practice where the 34 member States in the EB would recommend a single candidate for the approval of the WHA.

## R&D for potentially epidemic diseases preparedness, surveillance and response

The 140th session of the EB discussed a progress report by the WHO Secretariat in regard to a blueprint for research and development (R&D blueprint) preparedness and response for potentially epidemic diseases. The progress report covered activities undertaken in the period from May 2016 to January 2017. The EB took note of the report.

The WHO Secretariat started work on developing the R&D blueprint in June 2015. The overall goal of the R&D blueprint is to reduce delays between the identification of an outbreak and the deployment of effective medical interventions.

The progress report referred to specific activities in relation to the Middle East respiratory syndrome coronavirus (MERS-CoV) and the Zika virus; activities to support potential platforms for rapid development of vaccines, diagnostics and other medical technologies; revision of epidemic threats and list of pathogens prioritized by the WHO; activities to increase coordination in R&D during epidemics including a global coordination framework and principles for such collaboration, which include the development of global norms and agreements for sharing of data and samples.

The EB members generally expressed support for the R&D blueprint. Canada sought more information about the norms and mechanisms for sharing data and results during health emergencies and whether these norms and mechanisms will be reviewed and endorsed by member States. The UK sought more information on how the WHO is looking for additional funders for the WHO blueprint. It also noted that the WHO blueprint is not the only coordination mechanism for global R&D, and therefore sought information about what steps the WHO is taking to seek collaboration, effective competition and no unnecessary duplication with these mechanisms. The US opinion is that the focus of the blueprint should remain on reducing delays between identifying potential outbreaks and deploying effective medical interventions and that WHO should coordinate and provide information that facilitates research agenda setting by stakeholders and work with member states in the design of clinical trials and stressed that WHO should not define the R&D agenda itself. Switzerland also took note of parallel discussions on R&D related to antimicrobial resistance, neglected tropical diseases and other potential epidemics, and stressed on the need to ensure effective coordination between these mechanisms.

India sought more clarity on the proposed public health financial model for supporting R&D on emerging pathogens prioritized in the WHO blueprint process. India also expressed concern that the report by the Secretariat did not recognize the principle of delinking the price of products from the cost of the research and stressed that health R&D should be needs-driven and evidence-based and should be guided by the core principles of affordability, effectiveness, efficiency and equity. India further pointed out that there should be policy coherence between the blueprint and the broader WHO R&D agenda. India also stated that the WHO Secretariat should organize more frequent public consultations regarding the activities of the R&D blueprint, and the composition of scientific and other advisory expert groups should ensure adequate representation from low and middle-income countries. Brazil supported India and advanced that the blueprint should be addressed from the broader perspective of intellectual property, pricing, de-linkage and access. It noted that the recommendations of the UNHLP on access to medicines will be very relevant in the discussion and further elaboration of the blueprint.

## Antimicrobial resistance

A progress report on the implementation of the Global Action Plan on Antimicrobial Resistance was considered at the Executive Board. According to this report, 32 countries have submitted National Action Plans and 59 are in the process of drafting plans. A more detailed progress report will be presented at the 70th session of the WHA in May.

The 68th session of the WHA adopted the Global Action Plan (GAP) on Antimicrobial Resistance (AMR) by

resolution WHA68.7 in May 2015 and as part of the GAP all countries should have National Action Plans in place by the 70th Assembly in May 2017. The United Nations General Assembly (UNGA) adopted a political declaration on AMR under resolution A/RES/71/3 following a High Level Meeting on AMR on 21 September 2016.

The UNGA political declaration clearly specifies the need for WHO to finalize the Global Development and Stewardship Framework and requested the Secretary-General to establish, in consultation with WHO, the Food and Agriculture Organization (FAO) and World Organization for Animal Health (OIE), an *ad hoc* inter-agency coordination group, co-chaired by the Executive Office of the Secretary-General and the WHO.

Developing countries, during their interventions at the Executive Board evening session on 25 January, highlighted the urgency of ensuring financial and technical assistance, as well as the need for transparency in the appointment of the interagency group. Countries also expressed their support for advancing the negotiations on the Stewardship and Development Framework, reaffirming the principles (affordability, effectiveness, efficiency, equity and the principle of delinkage) of the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG). They also called for ensuring that during the process of the development of the Stewardship and Development Framework there should be consultations with experts but also with Member States.

Developing countries also stressed the important role governments will need to play in the regulation aspect for tackling antimicrobial resistance and the need to ensure affordable access to medicines, vaccines and diagnostics. Member States further highlighted the importance of looking at the animal health and agricultural aspects as key challenge areas.

The Member States' statements were accompanied by important calls made by several NGOs referring to the necessity to guarantee health system strengthening, policy coherence, and civil society's involvement in the process taking place not only at the headquarters level of WHO but at the regional and national levels too. Civil society groups also emphasized the importance of ensuring a transparent and free of conflict of interest process around the UNGA's call for an *ad hoc* inter-agency coordination group and the critical need for affordable access to vaccines, diagnostics and drugs.

### **Review of the Pandemic Influenza Preparedness Framework and public health implications of the Nagoya Protocol**

The EB took note of a report by an independent expert group reviewing the WHO Pandemic Influenza Framework (PIP Framework) established by the member

States in 2011 to provide a framework to facilitate sharing of influenza viruses of pandemic potential and also facilitate benefit sharing. The PIP Framework calls for a review of the PIP Framework by 2016 with a view to proposing to the 2017 World Health Assembly revisions to the framework to reflect appropriate developments. The EB also took note of a study by the Secretariat on how the implementation of the Nagoya Protocol might affect the sharing of pathogens and its potential public health implications.

The PIP Review Group pointed out before the EB that a key concern was that the sharing of virus within the Global Influenza Surveillance and Response System (GISRS) network had declined and there is a need to identify and remedy the causes of this. Technological changes such as the ability to use genetic sequence data (GSD) to substitute the need for physical viruses have important implications on how the viruses are shared. Resolving the handling of genetic sequence data within the PIP framework is a critical issue to ensure the relevance of the framework going forward. The review group had identified two areas where member States could consider amending the framework. First, the definition of PIP biological materials could be expanded to include genetic sequence data. Second, specific points in the text of the framework could be altered to emphasize member States' choice of database.

With regard to the public health implications of the Nagoya Protocol, the review group recommended that the PIP framework be recognized as a specialized international instrument under the Nagoya Protocol. The review group also discussed whether the PIP framework should be expanded to include seasonal influenza viruses. The review group recommended that the Director General undertake a study to determine whether such an expansion will be practical and desirable.

During the discussions on the report of the PIP Review Group and the study on the public health implications of the Nagoya Protocol, developed countries such as the US, Finland and Germany expressed concern about inclusion of GSD in the definition of PIP biological material and supported the need to recognize the PIP Framework as a specialized international instrument under the Nagoya Protocol. The US stressed that a distinction should be maintained between PIP biological materials and GSD. The US also did not consider the Nagoya Protocol to be applicable to influenza viruses. Finland also stated that the GISRS should be a specialized instrument under the Nagoya Protocol. Russia proposed the establishment of a working group to address the issues identified in the PIP review.

Developing countries expressed support for inclusion of genetic sequence data within the scope of the PIP Framework and the need for further analysis led by the CBD on whether the PIP Framework can be a specialized instrument under the Nagoya Protocol. The African Group enquired about the implications of the PIP frame-

work becoming a legal instrument independent of the Nagoya Protocol. Brazil stated that the study on the public health implications of the Nagoya Protocol is a first take within the WHO on the possible correlation between the PIP system and ABS obligations. Brazil considered that discussions on whether the PIP framework is a specialized instrument within the Nagoya Protocol must be led in the CBD which will determine the criteria of what constitutes a specialized instrument. PIP should evolve to incorporate GSD establishing a workable system of tracking and tracing access and use. The implications of large databases and biobanks outside the GISRS should also be studied further. Though inclusion of seasonal influenza viruses within the scope of PIP would enhance complexities, it would also enhance opportunities for better public health response to needs and emergencies. Further, consultations on the same would be welcome. Indonesia supported further work on the optimum handling of GSD under the PIP framework and stressed that the Nagoya Protocol supports public health objectives. Discussions on these issues will continue in the Assembly in May 2017.

The EB adopted a decision – EB140(5) – to extend the allocation of the PIP partnership contributions between pandemic preparedness measures and pandemic response activities, as decided by the EB in 2012, until 28 February 2018. In 2012, the EB decision 131(2) allocated 70 per cent of the PIP partnership contributions to pandemic preparedness activities and 30 per cent to pandemic response activities from 2012 to 2016. The PIP partnership contributions are annual cash contributions received by WHO from influenza vaccine, diagnostic and pharmaceutical manufacturers who use the WHO Global Influenza Surveillance and Response System (GISRS) which monitors the evolution of influenza viruses and provides recommendations in areas including laboratory diagnostics, vaccines, antiviral susceptibility and risk assessment. The decision by the EB to extend the current allocation formula for the PIP partnership contributions will allow the member States to decide on the new allocation methodology based on the outcome of the discussions on the review of the PIP Framework in the WHA in May 2017.

The EB decision also requested the WHO DG to continue consultations with the Secretariat of the Convention on Biological Diversity (CBD) and other relevant international organizations as appropriate, on access to pathogens and fair and equitable sharing of benefits, in the interest of public health and report to the 2017 Assembly. This request was included pursuant to the request from Malta on behalf of the European Union.

## Addressing the Global Shortage of Medicines and Vaccines

In 2016, the WHA adopted resolution 69.25 on the global shortage of medicines and vaccines. The resolution requested the WHO DG to develop, in consultation with member States, technical definitions for medicines and vaccines shortages and stock outs, taking due account of access and affordability, and report to the 2017 Assembly through the EB. The 140th session of the EB took note of a report from the Secretariat setting out proposed technical definitions for medicines and vaccines shortages and stock outs.

While some countries welcomed the proposed definition in the report, other countries pointed to the need for further improvement in the definitions. Eritrea on behalf of the African Group noted that the report fell short of conducting any assessment of the nature and magnitude of the problem of shortage, and stressed the need to prepare a comprehensive report in this respect. India stated that the definition excluded price barriers to procurement, IP barriers, unreasonably stringent regulatory standards and lack of competition.

India viewed the recommendation of the UNHLP report that governments should require manufacturers and distributors of health technologies to disclose to drug regulatory and procurement authorities information pertaining to: (1) the costs of R&D, production, marketing and distribution of health technology; and (2) any public funding received in the development of the health technology including tax credits, subsidies and grants; as highly relevant to the development of the report on shortages and stock outs. India suggested that WHO should establish and maintain a database of patented and generic medicines and biosimilars registered in all countries. India called upon the WHO Secretariat to develop a report taking a broader view of shortages rather than limit its focus on supply chain malfunctions.

Bangladesh also stated that the definitions failed to cover all situations and all regions. It observed that stock outs may be triggered by reasons beyond the supply chain, such as lack of API manufacturing, and stressed the need broader definitions to reflect ground realities in developing countries. Brazil also stated that discussions on fair pricing should be brought in and made more visible.

Kazakhstan pointed out that shortages may be caused by market monopolies or patent policies by transnational corporations, keeping prices high and supplies low for profit motives.

## Evaluation and review of the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property

The EB discussed a report by the Secretariat containing the executive summary of a comprehensive evaluation of

the implementation of the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA) and approved the terms of reference for the overall programme review after considering amendments to the same proposed by three EB members.

In 2008, the WHA adopted the GSPOA which provides a medium-term framework for securing an enhanced and sustainable basis for needs driven essential health research and development relevant to diseases which disproportionately affect developing countries, proposing clear objectives and priorities for R&D, and estimating funding needs in this area. The time frame for the GSPOA was 2008-2015. This time frame was extended from 2015 till 2022 by the Assembly in 2015.

In 2009, the WHA requested the DG to conduct an overall programme review of the GSPOA on its achievements, remaining challenges and recommendations on the way forward to the Health Assembly. The 2015 WHA extended the time frame for the overall programme review to 2018. It also requested the DG to initiate a comprehensive evaluation of the implementation of the GSPOA, to be undertaken by an independent expert evaluator and to be overseen by an ad-hoc evaluation management group.

During the discussions on the comprehensive evaluation report, New Zealand questioned the need for continuing with the GSPOA or undertaking a full and final evaluation. New Zealand observed that the report concludes that while member States have made progress in coordinating research and development over the last eight years, little, if any, of these gains, can be directly attributed to the GSPOA. It stated that the evaluation suggests that the GSPOA implementation is not effective and increasing compliance costs for members seems unjustified. New Zealand finally questioned whether continuation of the GSPOA represents the best use of scarce resources in the context of funding challenges of the WHO, and whether spending on a final evaluation can be justified. This view was also endorsed by the US.

The US suggested amendments to the terms of reference of the overall programme review, so that it be based on an assessment of the costs and benefits of the GSPOA and whether it should be continued beyond 2022. The US wanted to ensure that the programme review is conducted based on consensus decisions, and that the review should involve consultations with stakeholders from the public and private sectors involved in biomedical R&D, as well as inputs from WTO, WIPO and UNCTAD.

Many developing countries expressed support for the continuation of the GSPOA, and for the overall GSPOA programme review to consider the UNHLP report. Colombia, an EB member, stressed that the UN-

HLP report should be one of the technical inputs for the GSPOA evaluation. Colombia also called to start a debate followed by negotiations for an international agreement on global coordination and financing of R&D. This process would be informed by the Global Strategy. India was of the view that the terms of reference of the GSPOA review require the reviewers to consider the UNHLP report, and advise on how the GSPOA can help implement the recommendations of the UNHLP. India stated that the finding in the evaluation report about the widespread lack of awareness about the GSPOA and lack of evaluation and monitoring of the system calls for a stronger promotion of the GSPOA. India recalled WHA Resolution 56.23 of 2003 which requested the DG to monitor trade agreements, but observed that the evaluation report is silent on the many barriers to the full use of TRIPS flexibilities in many bilateral and regional free trade agreements. The terms of reference should also refer to the 2003 resolution on monitoring and analyzing trade agreements.

Brazil requested information on the selection process of the external firm that was commissioned to do the evaluation and the cost incurred by the WHO. New Zealand similarly raised concerns about the spending on the GSPOA external evaluation. Brazil also pointed out that the classification of developing countries into tiers of low and middle income countries in the report is not in keeping with the practice of the WHO. Brazil further stated that the methodology of the report is unclear and points to a lack of specialization of the evaluators on issues of application and management of IP. There is no mention of the UNHLP report. There is an assumption that R&D is mainly performed by the private sector though several studies have underlined the magnitude and importance of the public sector. Brazil said that the terms of reference cannot be guided by the comprehensive evaluation because of these shortcomings. No answers were given to the queries posed by New Zealand and Brazil.

The EB approved the terms of reference for the overall programme review after considering revisions to the draft, as proposed by Thailand, Vietnam and the United States. The approved terms of reference did not depart significantly from the original draft. The revised terms of reference did not include the suggestion made by some developed countries for the overall review to assess the need to continue the GSPOA beyond 2022; neither do they require the panel to arrive at a conclusion by consensus or to specifically consult private or public sector firms involved in biomedical R&D. Nevertheless, the terms of reference allow for consultation with non-state actors in accordance with the WHO Framework of Engagement with Non-State Actors (FENSA). The terms of reference also mandates the programme review to assess the continued relevance of the aims and objectives and the eight elements of the GSPOA.

The final report of the programme review will be submitted to the WHA in 2018 through the EB.

## **Follow up of the Report of the WHO Consultative Expert Working Group on Research and Development: Financing and Coordination and the Report of the UN Secretary-General's High-Level Panel on Access to Medicines**

The EB discussed a report presented by the Secretariat on the implementation of the recommendations of the WHO Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG). The report included the terms of reference and a costed work plan for a Global Observatory on R&D and a WHO Expert Committee on Health R&D. It also developed further the proposal and operational plan for a voluntary pooled fund. The report also presented an updated status of the implementation of R&D demonstration projects. The EB took note of the report.

Thailand, Congo, India, Colombia and Brazil were among the members that welcomed the launch of the proposal for the observatory, expert committee and the voluntary pooled fund. Some expressed concern over the funding challenges of these initiatives and of the demonstration projects. Congo on behalf of the African Group supported the establishment of the observatory, the expert committee and the pooled fund. Congo raised concerns about the major funding gaps in the R&D demonstration projects as well as in the budget plan for the observatory. India supported the proposal for the observatory, expert committee and the pooled fund, but noted the huge gap in the financial resources required for these mechanisms and the financial contributions made or pledged, and sought more details from the Secretariat on how this critical impediment can be overcome. India also pointed out that the report by the Secretariat did not explain how the proposed new mechanisms will adhere to the core CEWG principles. India also noted that the issue of establishing an open-ended meeting of member States to address the outstanding CEWG issues is directly related to the issue of kick-starting negotiations for a binding R&D treaty.

Similarly, Colombia supported the observatory, expert committee and the pooled fund and stated that the negotiation of a binding R&D treaty is the best way for implementing the CEWG recommendations.

Brazil stated that the terms of reference for the observatory should refer to it as a tool for identifying gaps in R&D and to facilitate coordination, and not limit its scope to generation of reports. Challenges remain regarding the sustainability of the three mechanisms, noting that the 6 demonstration projects and the observatory have raised 12 million USD while the operational cost of the pooled fund alone will amount to 7.6 million USD. WHO should not shy away from discus-

sions on alternative models for needed innovations in public health, including serious consideration of an R&D convention as recommended in the CEWG report and mandated by the GSPOA and the contributions of the UNHLP. This is a new opportunity for WHO, its new Director General and member States to show leadership and commitment for moving forward on this crucial topic as other intergovernmental organizations like UNITAID, UNAIDS, WTO and WIPO have started to do.

The US said that the experts in the expert committee should have extensive and substantial experience in managing research portfolios and taking products through the development process from research to the market, and should not have any conflict of interest. The US expressed disappointment at the low level of funding received for the demonstration projects from non-traditional donors. The US noted that the operational plans for the projects envisaged an annual funding of 100 million USD over a ten year period and a diversified portfolio of 35-40 R&D projects. The US stated that if a viable path to these goals does not appear in the near future there may be a need to consider terminating this line of work in the WHO. In the absence of raising additional funds, these projects may distract from other viable work in the WHO. The expert committee should limit its approval to short term projects to support late stage research until this initiative establishes a record of successfully attracting financing and bringing products through the development process.

Germany stated that it had made an additional contribution of 2 million euros to the WHO in support of the demonstration projects.

Switzerland supported the mandate for the observatory and the expert committee. As the demonstration phase will end at the end of 2017 there will be very little time to earmark the necessary funding for financing the demonstration projects and the observatory. Switzerland committed to make resources that are still available from its counterparty fund to the tune of 1.3 million USD till the end of 2017. Switzerland had established the counterparty fund to finance the demonstration projects pledging to increase the contribution of each low and middle-income country by 50 per cent up to the tune of 2 million USD. So far 700,000 USD have been disbursed. Switzerland also stated that a decision to establish the voluntary pooled fund must be made soon or the initiative should be scrapped, noting a number of external initiatives on R&D such as the Global Antibiotic Research and Development Partnership (GARDP) and the Coalition for Epidemic Preparedness Innovations (CEPI).

The Secretariat stated the difficulties to keep this agenda item "alive and funded" and highlighted the launch of the Observatory and also the contributions of several countries for the demonstration projects but also warned that the current lack of funding will mean that some of those projects will have to end before being completed.

## The UN High Level Panel on Access to Medicines

Under the agenda item of the follow up of the CEWG, the Chair also invited discussion on the High Level Panel Report on Access to Medicines, which several member States had requested to be placed as a separate the agenda item of the EB.

Developing countries and some developed countries made statements supporting discussion of the UNHLP report.

Malta on behalf of the European Union noted that the UNHLP Report is a new element in global discussions of a complex issue. It further remarked that the EU is ready to engage in a constructive manner within the context of GSPOA and the new expert group, but also recommended WHO to continue the useful the trilateral cooperation with WTO and WIPO on these issues.

The Netherlands aligned with the EU position and expressed that it was ready to discuss the follow up of the report of the UNHLP. It also noted that the proliferation of high cost medicines are increasing pressure on public spending of all countries and that it would continue efforts to prevent TRIPS plus provisions in free trade agreements that are negotiated and to provide for safeguards against the abuse of intellectual property (IP) measures and procedures for enforcing IP rights. The Netherlands mentioned their support for a fair price initiative that has being undertaking by the WHO.

Colombia noted the need for consistency in approaching public health challenges and that the recommendations of the UNHLP provide viable alternatives to promote access to medicines. Colombia also stressed that TRIPS flexibilities have helped countries to provide access to medicines that otherwise would not be possible, and suggested that further discussion is undertaken on the UNHLP recommendations.

Thailand emphasized that there were two UN High Level reports before the Executive Board and the need to treat them fairly. This was a reference to the UN High-Level Commission on Health Employment and Economic Growth, which was added to the agenda of the Board, and the UNHLP report that was not. Thailand further noted that the majority of the report is acceptable, and the Board should consider both with the same treatment.

Algeria said that access to medicines is a problem that affects developed nations as well as developing ones and which puts intolerable pressures on governments due to budgetary pressures. It further stressed the difficulties experienced by doctors and patients due to lack of access to medicines that are readily available

but too expensive. The High Level Panel report gives an opportunity to address this issue and the conclusions of the report are very important and need to be considered as soon as possible.

India highlighted a number of the UNHLP recommendations that merited immediate consideration, such as:

- countries making full use of TRIPS flexibilities
- using licensing agreements that ensure public health returns for publicly-funded research
- creating new incentives for R&D beyond patent monopolies; coordinating and sustainably financing R&D through innovative models
- de-linking the costs of R&D from the price of medicines; negotiating a binding R&D Convention or Agreement based on de-linkage and other principles promoting public health, and ensuring transparency, accountability and governance in the R&D process
- governments should require manufacturers and distributors of health technologies to disclose to drug regulatory and procurement authorities information pertaining to the costs of R&D, production, marketing and distribution of health technology being procured or given marketing approval with each expense category separated, and
- public funding received in the development of the health technology including tax credits, subsidies and grants.

The UNHLP report also recommends building on the current discussions at the WHO, the UN Secretary-General should initiate a process for governments to negotiate global agreements on the coordination, financing and development of health technologies, including a binding R&D convention that delinks costs of R&D from end prices to promote access to good health for all.

India emphasized that without comprehensively addressing the issue of access to medicines and vaccines guided by the principles of affordability and equity, it will not be possible to achieve the Sustainable Development Goals and Universal Health Coverage.

India proposed a web-based consultation with member States before the 70th WHA, on the UNHLP recommendations and the convening of an open-ended meeting of member States by the 70th WHA to discuss the recommendations and other relevant recommendations in the CEWG report.

Brazil stressed that the UNHLP report was convened by the Secretary-General of the UN and has a broad constituency and the report related to several agenda items of the WHO that had to be discussed, such as GSPOA, Sustainable Development Goal alignment process with health targets, and shortage of medicines. It pointed out that the development of the report included an advisory group of experts, which was enlarged to appease some member

States. Brazil further said that the aim was to allow for a discussion on the UNHLP report to take place within WHO. There was no attempt to seek consensus to endorse neither the content of the report nor for the report to become an official document of the WHO.

The US was of the view that the report has a narrow mandate and does not address critical parts of the complex problem of promoting innovation and access to medicines. It added that the panel was unable to find consensus on key recommendations with two of the panellists which had the most extensive experience in managing R&D portfolio warning that the report's recommendations could result in serious negative unintended consequences for R&D.

The US stated that the UNHLP was not a Member State-driven process and had no mandate from the UN General Assembly, adding that the report's criticism of US policy on management of IP for research in the public sector was "misguided".

Switzerland stated that the areas of analysis of the UNHLP are priorities for Switzerland and they took note of the report but that it was without Member State mandate and the issue of access to medicines is very complex matter. It further observed that the SDGs suggest an integrated approach and that the scope of the report is not comprehensive. However, it noted that some recommendations are interesting for example the creation of a data basis to assess patents but in the recommendations on intellectual property rights the report doesn't recognize the central role of IP in R&D and said that weakening IP rules will undermine innovation.

The discussion on the High Level Panel report was taken up once again, as the EB session was about to close, on the last day since no decision had been reached on whether to hold further discussions on the report or to include it as an item in the agenda of the WHA. The Director-General then suggested that the secretariat would prepare a new document on shortage of medicines that will include access to medicines and that it would take into consideration the comments that had been made during the session and look at the work that has been done in the context of the GSPOA. This report would provide an overview of what has been done and what has not be done because of lack of resources or lack of consensus.

### **Member State Mechanism on Substandard/ Spurious/Falsely labelled/Falsified/ Counterfeit medical products**

The Member State Mechanism (MSM) during its fifth meeting on 23-25 November, 2016 had agreed to recommend to the World Health Assembly to drop the term "counterfeit" in referring to quality-compromised medical products, acknowledging the definition of

"trademark counterfeit goods" included in the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

At the Executive Board meeting member States reiterated their support to the Member State Mechanism. The debate on this agenda item mainly focused on the proposed new working definition. Most of the member States who took the floor called on the adoption of the new working definition, which would avoid the conflation between the issues of quality of medicines with IP issues.

India asked that the MSM be renamed, taking into account the proposed new working definitions.

The WHO Secretariat agreed to take into account the comments and to modify the website of the MSM if such a decision is adopted. The draft decision was approved and will be presented at the WHA for its adoption.

### **Framework of Engagement with non-State Actors**

The 2015 World Health Assembly had adopted a WHO Framework of Engagement with non-State Actors (FENSA), replaced two former policies governing WHO engagements with NGOs and the private sector and requested the Director General to start the implementation immediately.

Prior to the EB the first report of the implementation of FENSA was presented to the Program Budget and Administration Committee (PBAC), which has the function to oversee the implementation of FENSA. The report had summary information on the engagements that had been examined. The EB took note of the report from the Secretariat and endorsed the agreements reached at the PBAC including accepting 5 new organizations into official relations, including the Bill and Melinda Gates Foundation.

Over 30 civil society organizations had written a letter to the EB members pointing out the conflict of interest arising from accepting the Bill and Melinda Gates Foundation into official relations with the WHO and requested the EB to defer the decision. The letter claimed: "According to the United States Government's Securities and Exchange Commission, the Bill and Melinda Gates Foundation Trust endowment – the source of revenue for the Foundation – is heavily invested in many of the food, alcohol, and physical inactivity-related consumer products that cause or treat the current crisis of preventable heart disease, stroke, cancer, and diabetes" The letter also provided a list of investments that includes McDonald's biggest franchise, Coca Cola and Walmart among others.

Mexico stated that there were many changes in the cooperation between WHO and non-state actors (NSA) and that there is now public access of information on NSAs and the classification of types of engagement. It also



pointed out that the process was not fully implemented and there will be a need to assess the implementation.

Thailand welcomed the decision and the criteria and principles for secondments and wanted to hear more on the progress of the register including information on the evaluation of the framework

India observed that the focus of the report was on the implementation plan but there was no information on engagement since adoption of the FENSA. India also pointed out the need for more details on the types of engagement, risk assessments, steps taken to ensure management of risk. It also voiced its concern about the implementation, joint action work program; clarity and transparency. FENSA should clearly inform and there is a need for more information on conflicts of interests and risk management. India also highlighted that the Secretariat should ensure implementation of guidelines and keep in mind the provision in FENSA that refers directly to exercising particular caution with certain industries.

Panama mentioned that FENSA excludes the arms and tobacco industry from engagements and WHA70 will be able to review the progress made in implementation. It also noted that the register of NSAs and the manual and guidance have not been concluded entirely.

The Secretariat stated that the information about a handbook for NSA and the guide for staff will be ready for the 70th WHA. The registry of NSAs will be finalized in April and be operational in May, and there will be a demonstration for the WHA and all new engagements will be added to the register.

## WHO Reform implementation

The EB considered and took note of a report of the Secretariat on the status of the implementation of WHO reform. There are three broad areas of WHO reform: programmes and priority-setting; governance; and management. The report notes that inadequate financing of the programme budget and donor dependence remains a challenge. There is a current funding shortfall of the base budget of USD 471 million.

This matter was discussed in the PBAC meeting prior to this session of the EB and the PBAC had recommended the EB to take note of the report.

The PBAC had expressed concern about the funding shortfalls in certain programmes and noted the need to ensure alignment and predictability of funding across all levels of the WHO. Several PBAC member States noted that governance reforms were still lagging behind other areas of reform, and expressed concerns about the number of agenda items in meetings of the governing bodies, and the volume of the associated

documentation, which can be burdensome, especially for small delegations. Member States stressed on the need for continuing reform efforts, ensuring that reform has an impact on WHO's work at country level; and achieving a realistic budget and sustainable funding. Particular concerns were raised about the WHO Health Emergencies Programme and its funding gap, and the potential impact on other WHO programmes.

The African Group endorsed the bottom up approach of identifying priorities in the programme and budget and expressed concern about the problems encountered in funding the programme and budget. The group also expressed support for a multidimensional approach to funding the programme and budget, including increase in the assessed contributions, increasing the base of donors, increasing efficiency and greater flexibility in the voluntary funds and deepen thinking on ways to increase voluntary contributions.

The EU noted that further efforts are needed to improve the efficiency and effectiveness of the governing body sessions. The EU called for a discussion about WHO presence in countries, noting that half of WHO overall staff and financial resources are currently allocated to the WHO country offices. The EU also welcomed the proposals on a set of criteria and principles for secondments to the WHO from Non-State Actors (NSAs), as a result of electronic consultation of Member States, and underline that any secondment must be fully in line with FENSA. The EU sought reassurance that FENSA is being implemented in a harmonized way throughout WHO.

China stated that the working methods of the governing bodies should be more efficient, transparent and of better quality. The agenda-setting should be more precise and forward looking and the discussions should be more efficient. China also stressed on the need for capacity building of the country offices and reflection on the needs of regional offices as well as improvement of coordination between the country offices, regional offices and the Headquarters.

Thailand expressed concern about the slow progress of the WHO reform process which could prevent WHO from taking a lead role on global health issues in the SDG era, and urged the Secretariat to fully implement the reform in the coming year. Thailand hoped that the evaluation of the reforms to be reported to member States in May will enhance the reform implementation process.

## Conclusion

All issues mentioned in this Brief will be further discussed by Members in the WHA in May 2017, with the exception of the overall programme review of the GSPOA.

Most importantly, the forthcoming WHA, composed of the 194 member States of the WHO, will for the first time elect a new Director-General, to be chosen among the

three shortlisted candidates that were recommended by the 140th EB. The new Director-General will assume office on 1 July 2017.

Members during the WHA should reassert their aspirations and expectations to the new leadership of the WHO on priority global public health issues and stand ready to provide guidance and direction to the new Director-General.

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