Report prepared by Brenda Chizana and Alexandre Gajardo

Day 5 of the EB was one many watchers had been waiting for; finally there was going to be some discussion on the UN HLP report on access to medicines! As those who have been following the Skype channel or reading our **daily reports** may already know, day 1 of the EB saw India fervently requesting the UNHLP report be introduced as an agenda item, but received no support from the EB Members so this was not included as a separate agenda item. The concession given by the Chair was that he would allow it to be discussed under item 8.5 CEWG.

With warning from the Chair that there was a packed agenda and that it would be a long day, the EB was underway.

Continuing the theme Preparedness, surveillance and response, the first item on the agenda was 7.3 Poliomyelitis.

Preparedness, surveillance and response (continued): 7.3. Poliomyelitis

The Executive Board considered report EB140/13 on the status of the Polio Eradication Programme and human resources update EB140/46 and together agreed on decision paper EB140(4). Both the report and decision were sponsored by Congo, Colombia and Norway.

Despite great successes in the eradication of polio, 26 cases of wild type 1 Polio virus had been detected in Pakistan, Afghanistan and Nigeria. This was taken by most member states as a reason to continue the programme.

Three main problems were highlighted by Member states: IPV vaccine shortages, vaccine costs and the funding gaps some countries would experience as the programme winds down. India and Panama had responded to the high vaccine costs and by using fractionated vaccine doses. Canada, the Netherlands, Mexico and Sweden supported a transition phase and joined the sponsors in calling for the DG to publish an impact analysis of the vaccine programme on health systems in developing countries. They also recommended the reassignment of staff who worked in the polio programme. Instability in some countries was identified as not only impeding vaccination programmes but also hampering epidemiological surveillance efforts.

UNICEF, IFRC, Global Initiative and Path all supported the global action plan.

The ADG for Polio reiterated the global vaccine shortage, commended country efforts and acknowledged successes in cross country collaboration. The secretariat was working together with partners to ensure adequate IPV stocks especially for priority countries. Following the success of fractionated doses in India, the Secretariat would also assist other countries who wanted to implement the fractionated dosing. He confirmed the AFRO and SERO regions are implementing post eradication programmes.

The DG rounded off this agenda item by thanking all the partners involved. She acknowledged the work of scientists and called on everyone to redouble their efforts.

There were no further comments from Member States, so the Chair invited the board to note the report and adopt the decision requesting the Secretariat compiles a report to be presented at WHA 70 which outlines 'the programmatic, financial, and human-resource-related risks resulting from the

current winding-down and eventual discontinuation of the Global Polio Eradication Initiative, as well as an update on actions taken and planned to mitigate those risks while ensuring that essential polio-related functions are maintained' and 'to continue reporting regularly to the Health Assembly, through the Executive Board, on the planning and implementation of the transition process'

In response to the request by the EB and MS to show how much this extra work would cost, the Secretariat produced a conference paper which estimated that they would require US\$0.6 million for the independent review.

Item 7.5- review of the Pandemic Influenza Preparedness Framework was considered together with sub-item 7.4 Public Health Implications of the implementation of the Nagoya Protocol EB140/15

Sub item 7.4 had been postponed until Friday while we awaited the arrival of Professor Ampofo, the WHO expert on the Nagoya Protocol. He started off the agenda item describing how the PIP framework has been innovative and worked extremely well, despite the decline in virus sharing. He suggested that genetic sequence data (GSD) should also be included within the framework and in order to encourage more virus sharing; PIP should be declared a special international instrument under the Nagoya Protocol. He said industry requested more predictability and a revision of the partnership formula could result in more predictability. He felt that PIP could be a tool in the successful implementation of the IHR's.

Malta represented the EU and proposed some amendments; these were also supported by EU countries and Mexico. Whilst acknowledging the successes of the PIP framework, there was a call by the AFRO region for capacity building. Some EB members were disappointed by the decline in virus sharing and felt implementation of the Nagoya Protocol would have implications on public health. Along with Liberia, Thailand requested that PIP become a special instrument under the Nagoya Protocol. Canada and Thailand both welcomed the inclusion of GSD within the PIP framework. Russia questioned whether seasonal flu should be included under the PIP framework and felt a working group to review this would be essential and volunteered its services. The US agreed with Russia in questioning the need for inclusion of seasonal flu and also stated this needed further investigation before they could make a decision. They encouraged benefit sharing within the Nagoya protocol and unsurprisingly the need to work with private partners. China encouraged the adoption of national laws to implement the sharing mechanisms within the Nagoya Protocol. Concerns raised by MS were similar to those of EB members: with further calls for review of seasonal flu and GSD before their inclusion in the PIP framework.

Medicus Mundi International on behalf of PHM and Third World Network (TWN) agreed that the PIP framework was an innovative tool for pandemic preparedness especially as it places virus sharing and benefit sharing on equal footing. It requested a revision of the amount paid into the Partnership contributions by manufacturers given the running costs of the WHO GISRS were estimated at US\$ 122 million. In order not to negate the positive contribution of the PIP framework, PHM also called for a new framework to be developed for seasonal flu.

The secretariat agreed to review MS comments and raised these areas as ones that require further investigation: the decline in virus sharing, partnership contributions and how the PIP framework will work within IHR and R&D blueprint as well as GSD and seasonal flu.

The report was noted by the EB and with the adoption of recommended amendments, decision paper EB/140(5) was adopted by the board.

This concluded the Morning Session with a break for lunch.

The afternoon session commenced with the first hot topic of the day for those who advocate for access to medicines: The follow up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination. The Chair made the concession that Countries could comment on the UN HLP report but not on the report's content.

Item 8.5 Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination

Most of the States delegations who took the floor commended the progress made in the implementation of the work plan. More precisely, several Member States reiterated their support to a voluntary pooled fund. However, all delegations raised the problem of the underfunding of both the Global Observatory and of the demonstration projects. In this regard, Germany announced a voluntary contribution of 2million Euros for the Observatory. But the funding gap remains huge and it is of particular concern that only few Member States are providing funds. Colombia, India and Brazil called on the WHO to seriously consider the negotiation of a binding R&D Convention that would delink the costs of R&D from the end prices of drugs. That recommendation has already been put forth by the CIPH, GSPOA, the CEWG and now by the UNHLP. Those delegations called to look into new R&D models. They consider this recommendation as an opportunity for WHO and the new DG to show leadership into moving forward into this area of work, as some other organizations have done so (such as UNAIDS, WTO and the WIPO Standing Patent Committee). Marie Paul Kieny, Assistant to the Director General, stated that it has been hard to keep this topic alive due to underfunding. She said that the first observations of the Observatory are available in the website of the Observatory. She also insisted on the major funding gap. The Board noted the report.

Sub Item: Report of the UN Secretary General High level panel on access to medicines (UNHLP)

Some developed countries expressed concern about the report (especially Japan, USA, Switzerland and Malta, on behalf of EU). They considered that the report was not comprehensive enough and did not address access to medicines in its whole complexity. USA did not appreciate the numerous examples and the criticism of their national measures contained in the report, such as the example on the Bayh-Dole Act. Meanwhile, EU recognized that there was a need to find new solutions in order to address market failures. They took note that the UNHLP report was a new element in this area of work and ensured that they would engage in a constructive manner, especially within the context of GSPOA and the new expert working group. A particularly interesting position came from the Netherlands. They expressed their will to discuss the follow-up of this report and complained about the proliferation of high cost medicines, which constitutes an increased pressure on public spending, even for developed countries. Netherlands also urged to look at the huge profit margins of pharmaceutical companies and insisted on the need to assess exactly how much money is invested in R&D. Developing countries, such as India, Colombia, Algeria, South Africa, Venezuela, Thailand, Iran and Brazil welcomed the findings of the report and urged WHO to seriously consider the possibility to analyse this report in a separate agenda item during the WHA70.

Medicus Mundi International, on behalf of Universities Allied for Essential Medicines and Peoples' Health Movement welcomed the report and urged Member States, inter alia, to include a separate agenda on the UNHLP report during the WHA70 and to convene an Open-ended meeting in 2017

that would address the so called remaining issues, especially the possibility to negotiate a binding R&D Convention.

Item 8.4 Evaluation and Review of the Global Strategy and Plan of Action of Public Health, Innovation and Intellectual Property (GSPOA)

All developing countries who took the floor reaffirmed the importance of GSPOA but most of them expressed concern that the majority of the achievements was not due to GSPOA. They express deep concern about the lack of awareness of GSPOA. Some developed countries questioned the extension of GSPOA and considered that its implementation was a waste of resource, and that those resources could be reallocated to other projects. Some developing countries, such as India, Colombia, South Africa and Brazil considered that the Evaluation should have considered the UNHLP findings as an area for further work. Most of the States who took the floor, astonishingly welcomed the Evaluation report. However Brazil criticized the Evaluation and asked the Secretariat how the external evaluator was nominated and how much it has cost. Brazil pointed out that the Evaluator failed to address most of the main issues. Brazil criticized the use in the Evaluation of the World Bank group of countries. Brazil considered the Evaluation as totally incomplete and due to these reasons, declared that the Evaluation should not inform the Overall Programme Review. Some States, such as USA, Thailand and Fiji proposed some amendments to the terms of references of the Overall Programme Review. Medicus Mundi International, on behalf of the Third World Network and Peoples' Health Movement, raised huge gaps in the Evaluation and stated that the Evaluator had clearly failed to fulfil its mandate.

The response from the ADG (responsible for the Evaluation), recalled that the details on the nomination of the Evaluator was provided in Document EB138/38. He said that the exclusion of the UNHLP report from the evaluation was due to the fact that the report was outside the temporal scope of the Evaluation. He argued that the use of World Bank groups of countries was a compromise as it was difficult to draw a line between developed and developing countries. The Board suspended this item to take action on this issue on Saturday 28th, in order to let some times for MS to address the amendments proposed.

Item 8.6 Member State mechanism on substandard / spurious / falsely-labelled / falsified / counterfeit medical products

All States recognized the threat posed by substandard and falsified medical products and reiterated their support to the MSM. The debate on this agenda item mainly focused on the proposed new working definition. Most of the States who took the floor called on the adoption of the new working definition, which would avoid the conflation between the issue of quality of medicines with IP issues. More specifically, India asked to rename the MSM, taking into account the proposed new working definition. All NGOs commended the proposed new working definitions. Marie Paul Kieny stated that she will take into account the comments and that if the decision is adopted, she would modify the website of the MSM. The draft decision has been adopted.

This concluded the afternoon session. There was a quick break and the evening session began with agenda item 9.1 Global Vaccine Action Plan.

Item 9.1 Global Vaccine Action Plan (GVAP)

The Chair announced that Colombia, Brazil and Australia proposed a draft resolution. Most of Member States who participated to the debate welcomed the SAGE report, but noted with concern the slow pace of implementation of the GVAP. Most of developed countries (such as UK, USA, Canada) who took the floor raised concern about the fact that all countries were currently offtrack

with regard to the GVAP, insisted on the importance of immunization and of the involvement of all stakeholders, such as GAVI and its partners, in order to achieve the GVAP goals. Gambia (on behalf of AFRO), but also the Russian Federation underlined the importance of Research and Development for the supply and innovation of vaccines. The latter however stated that the report contains incorrect data. Some developing countries (especially Thailand and Pakistan) stressed the importance to ensure a smooth GAVI transition. Colombia insisted on the need to take into account the issues of the prices of vaccines. Malta (on behalf of EU and other States) proposed several substantial amendments to the draft resolution. Morocco also proposed some amendments. The Director FWC took note of the slow progress and insisted on the need to enhance accountability and monitoring. He insisted on the importance of GAVI and its partners, such as the Bill and Melinda Gates foundation and promoted routine immunization. With regard to the several amendments proposed, especially by EU, the core group decided to postpone the adoption of the resolution.

IFPSA: International Pharmaceutical Students' Federation (IPSF)

FIP: International Pharmaceutical Federation (FIP) MSF:Médecins Sans Frontières International (MSF)

Save the children Fund: The Save the Children Fund (Save the Children)

Global Health Council: Global Health Council, Inc.(GHC)

Item 9.2 - Global Vector Control Response

The board was invited to consider and provide guidance on the draft report on the Global Vector Control Response

Fiji began by articulating the risk of Pacific nations to vector borne diseases which has been increasing because of climate change. They wished the momentum to be maintained and requested the Secretariat prepare a draft resolution in consultation with Member States on the global vector control response in advance of WHA 70. EB and MS supported Fiji's request. EB members agreed there was a need for more expertise particularly entomologists. In addition to capacity building some MS also required as system strengthening. EB members called for an integrated approach with should be coordinated by WHO. Thailand reiterated the need to consider the effect of climate change and how adequate vector control without the consideration of the effects of climate change.

The ADG thanked MS for their comments and looked forward to working with them in drafting the resolution for the WHA 70.

The EB took note of the report and agreed that a Resolution should be drafted for WHA 70.

On completion of item 9.2 the Chair decided to go back to item 8.4 in an attempt to close it, but as there was no consensus amongst board members it was postponed until Saturday or Monday.