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

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## In focus

The Assembly will consider two reports:

- Document <u>A68/34</u> deals with the proposed funding mechanism to fund de-linked R&D;
- Document <u>A68/34 Add.1</u> reports on progress made in implementing the selected health research and development demonstration projects.

At its meeting in January the Board noted earlier versions of both reports. See notes of discussion at the EB here.

# Proposed pooled funding mechanism and involvement of TDR

Document A68/34 proposes using the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR) to host a pooled fund towards research and development. The report describes the establishment of such a fund, under the management of the Special Programme, as well as its relationship with the Global Health Research and Development Observatory and the future coordination mechanism.

The Assembly is invited to note the report "and to consider the establishment of a pooled fund for voluntary contributions towards research and development for type III and type II diseases and the specific research and development needs of developing countries in relation to type I

diseases to be hosted by the Special Programme for Research and Training in Tropical Diseases".

# Review of demonstration projects

In line with resolution <u>WHA66.22</u> and decision <u>WHA67(15)</u>, the Assembly will consider a second report (<u>A68/34 Add.1</u>) detailing progress made in implementing the selected health research and development demonstration projects.

# **Background**

See below, under 'The pre-history of the CEWG' for the earlier background, leading up to WHA66.22 and WHA66(12).

# Funding coordination and hosting and resource mobilisation

Resolution <u>A66.22</u> commissioned further exploration of pooled funding and funding coordination.

A67/27 discussed 'Managed coordination' of R&D activities and their funding. It argued that the creation of any new funding mechanism would introduce strong, managed coordination of the research that a new fund would support. The priorities supported under such a financing mechanism would be those identified through the global advisory committee and could be endorsed at the annual stakeholder conference.

In Decision A67(15) the Assembly asked the Secretariat to explore this proposal in more detail and to report, through EB136 to WHA68 in May 2015 on the outcomes of this exploration.

A range of possible hosts for the pooled funding had been considered in <u>EB134/26</u> (Jan 2014) and the EB was advised that TDR had rated highly on most criteria. In early May 2014 WHO hosted a meeting of the proponents of the four projects selected in the initial round of demonstration projects (<u>A67/28 Add.1</u>). At this meeting TDR tabled a proposal (<u>9 May 2014</u>) outlining how it might take on the role of manager of the pooled funds (see also <u>TDR news release 9 May</u>). While the TDR proposal was not included in the papers published by the Secretariat for WHA67 it was clearly under consideration with several speakers referring to it in debate and its endorsement in <u>A67(15)</u> above.

The Joint Coordination Board (JCB), the top governing body of the Special Programme for Research and Training in Tropical Diseases (TDR) held its annual meeting in Geneva from 23 June 2014 to 25 June 2014. In its media note (<u>26 June, 2014</u>), TDR recorded the support of the JCB for taking on this role.

The TDR option was further discussed at EB136 and there was general support plus some specific suggestions which have been incorporated into A68/34.

# Implementation of demonstration projects

The emergence of the demonstration projects is documented <u>here</u>, from the original adoption of the Global Strategy and Plan of Action to the discussions at EB136.

<u>A68/34 Add.1</u> refers to this history but focuses on the more recent re-evaluation of one merged project and three resubmitted projects.

# Observatory

In resolution <u>WHA66.22</u> the Assembly requested the Director-General to establish a global R&D observatory and to review existing mechanisms which could be used to coordinate R&D under the CEWG process.

The Assembly (May 2014) considered the report A67/27 which *inter alia* reported on the work done to date in relation to the Observatory. It reported that the Secretariat has started the process of establishing the Global Health Research and Development Observatory. It proposed the establishment of a global research and development advisory body and the institutionalization of an annual research and development stakeholder conference.

The objectives of the Global Observatory are described in document A67/27. Further information is available at <a href="http://www.who.int/phi/implementation/phi\_rd\_observatory/en/">http://www.who.int/phi/implementation/phi\_rd\_observatory/en/</a>.

Document A68/34 discusses how the the relations between the Funding Mechanism, the Observatory, the Coordination Group and TDR are seen by the Secretariat.

# Pre-history of the CEWG

Since the TRIPS Agreement in 1994 the role of intellectual property (IP) protection in maintaining higher prices and constituting a barrier to access has been controversial within WHO. Particularly after the Treatment Action Campaign (1997-2001) in South Africa and the Doha Declaration on Public Health and Trade there were repeated debates about whether countries were (or should be) using the full range of flexibilities included in the TRIPS Agreement to promote access to medicines. (References and more detail <a href="here">here</a>.)

In June 2001 one of the Working Groups of the WHO Commission on Macroeconomics and Health published a paper (<u>Scherer and Watal</u>, 2001) exploring the use of compulsory licenses, parallel imports, and price controls, for ensuring affordable access to patented medicines in developing countries. It also reviewed the role of corporate charity (drug donations by research-based pharmaceutical companies) and the role of aid through intergovernmental and nongovernmental organizations.

The debate over access and pricing found its way onto the WHA56 Agenda (May 2003) with Secretariat report, <u>A56/17</u>. The WHA56 adopted resolution <u>WHA56.27</u> which urged member states (MSs) inter alia to: adapt national legislation to enable the full use of TRIPS flexibilities,

and requested the DG inter alia to: promote technology transfer; establish an expert inquiry into IPRs, Innovation and Public Health; and monitor and analyse trade agreements.

The Commission into IPRs, Innovation and Public Health was established 2004, at the end of Dr Brundtland's period as DG, and reported at the Assembly in 2006 which was the year Dr Lee died and so the Commission's report was inherited by Dr Chan. The terms of reference of the Commission were focused on how to reconcile the claims of the manufacturers that monopoly pricing was necessary to fund innovation and the claims of developing countries that high prices were an unconscionable barrier to access.

The final Report of the Commission was submitted to EB117 (in Jan 2006); was considered by WHA59 (in May 2006) which (in Resolution A59.24, p32) appointed an intergovernmental working group (IGWG) "to draw up a global strategy and plan of action in order to provide a framework based on the Commission's recommendations, with a focus on research and development relevant to diseases that disproportionately affect developing countries."

The final report of the IGWG was presented to the WHA61 in May 2008, see <u>Document A61/9</u>. A drafting committee was appointed to finalise the proposed global strategy and plan of action but it was not able to resolve all of the disagreements over the draft GSPA. In the end the Assembly adopted <u>WHA61.21 (p31)</u>: which endorsed "the global strategy and the agreed parts of the plan of action on public health, innovation and intellectual property...". These 'agreed parts' included a commitment "to establish urgently a results-oriented and time-limited *expert working group* to examine current financing and coordination of research and development".

The GSPA was considered again at WHA62 (May 2009) and after much debate an agreed GSPA was adopted (in Resolution <u>WHA62.16</u>); see <u>integrated version of finally agreed GSPA</u>.

Meanwhile the EWG was discussing financing and coordination of research and development as well as proposals for new and innovative sources of funding for R&D. A summary of the EWG report was considered by the EB126 (Jan 2010) but the full report had not been translated into all official languages. A member state consultation to consider the full report was arranged (for May 13, 2010).

Later in May 2010 WHA63 considered the EWG report (<u>A63/6 Add.1</u>) plus the Chair's summary of the member state consultation on 13 May, 2010 (<u>A63/6 Add.2</u>). The EWG report was poorly received, partly because it had not followed its terms of reference and partly because of allegations of poorly managed conflicts of interest (more <u>here</u>). In Resolution <u>WHA63.28</u> the Assembly established a new *Consultative Expert Working Group* to take forward the work of the EWG.

The final report of the CEWG (<u>Doc A65/24</u> and <u>A65/24 Corr.1</u>) was presented to WHA65 in May 2012 (<u>report of debate starts</u> and <u>continues</u> and <u>concludes</u>). The CEWG report set the scene, reviewed all of the proposals which had been considered by the EWG, reviewed options for funds mobilisation and coordination, and ended up proposing a binding instrument for health research and development. The Assembly had before it four resolutions. An informal drafting

group was set up which produced a draft resolution (mandating an open ended MS meeting) was presented which was adopted (<u>WHA65.22</u>).

The open ended Member State meeting to follow up the report of the CEWG was held 26-28 Nov, 2012 and reported to EB132 (Jan 2013) as <u>EB132/21</u> which comprised a brief report plus a draft resolution for submission to the WHA. The report and draft resolution were duly reported to the WHA66 (May 2013) as <u>A66/23</u>.

Dr Viroj Tangcharoensathien from Thailand who had chaired the OEMS meeting explained the substance of the proposed resolution:

"The outcome of the meeting held in November 2012 – the draft resolution contained in the Appendix to document A66/23 – provided for a complex, stepwise process of implementation and reporting thereon. Two reports would be drafted in time for the Sixty-seventh World Health Assembly, one on the review of existing coordination mechanisms, as proposed in subparagraph 4(5) of the draft resolution, and the other on the evaluation of existing mechanisms for contributions to health R&D, as proposed in subparagraph 4(6). A further report would be prepared for the Sixty-eighth World Health Assembly on the implementation of health research and development demonstration projects, as proposed in subparagraph 4(4). Another open-ended meeting of Member States would be held prior to the Sixty-ninth World Health Assembly and would report to that Health Assembly on its findings."

There was a long debate. In the <u>Sixth Meeting</u> of Committee B the Draft Resolution in <u>A66/23</u> was approved (as <u>WHA66.22</u>) and the draft decision (based on the US draft as amended, see pp2-3 of <u>record of 6th meeting</u>) was adopted as <u>WHA66(12)</u>.

Following WHA66 (May 2013) calls for demonstration project proposals were issued and 22 shortlisted for consideration by a technical consultative meeting of experts in early Dec 2013 which <u>identified 7+1 proposals</u> that were seen to have the potential to be demonstration projects.

EB134 (Jan 2014) considered <u>EB134/26</u> and adopted decision <u>EB134(5)</u>, identifying next steps – examination of the additional information and convening of stakeholder meetings. The decision also requested the Secretariat to identify indicators to measure success in this process.

In March 2014 four projects were identified as being ready for implementation.

WHA67 (May 2014) reviewed two Secretariat reports on action underway by way of follow up of the CEWG. <u>A67/27</u> presented a revised version of <u>EB134/26</u> dealing with the Observatory; options for coordination of R&D; and options for funding and management of funds. <u>A67/28</u> (a revised version of <u>EB134/27</u>) dealt with the selection of demonstration projects. WHA67 adopted decision <u>WHA67(15)</u>, which asks, among other things, the Secretariat to "expedite the process" of the other four projects (that were not selected).

EB136 (Jan 2015) reviewed report <u>EB136/30</u>, on the possibility of using the Special Programme for Research and Training in Tropical Diseases (TDR) to host a pooled fund towards research and development, and <u>EB136/30 Add.1</u>, detailing progress made in implementing the selected health research and development demonstration projects.

See the Secretariat Background page for more references.

# PHM Comment

### Overview

The scope of the proposed fund would be to finance R&D projects to address priority research gaps as identified by the Global Observatory and the future coordination mechanism (currently being explored by WHO).

The fund will be managed by the Special Programme, while the Global Observatory and the coordination mechanism will be managed by the WHO Secretariat.

The focus of the fund would be the development of effective and affordable health technologies related to type III and type II diseases and the specific research and development needs of developing countries in relation to type I diseases, taking into account the principles formulated by the Consultative Expert Working Group on Research and Development: Financing and Coordination, namely delinkage of the delivery price from research and development costs, the use of open knowledge innovation, and licensing for access.

The contractual arrangements for the funding of projects will ensure that any future health technologies financed through the fund will be accessible to those in need. Arrangements could include clauses on at-cost or preferential pricing, non-exclusive licensing agreements or licences to WHO or the Special Programme.

The priorities of the fund would be informed by the analysis of the research landscape provided by the Global Observatory.

The Health Assembly, on the recommendation of the Programme, Budget and Administration Committee of the Executive Board, would decide on the allocation of the research and development fund to be apportioned to support research and development projects and to support the Global Observatory and the coordination mechanism

A new scientific review group would be established within the Special Programme under the governance of its Joint Coordinating Board. The Joint Coordinating Board would approve the final selection of projects as submitted by the scientific review group.

There are weaknesses in the current proposals but they do represent a step towards public funding of R&D and delinking.

#### Funds mobilisation

PHM believes that voluntary funding of the system will prove to be unsustainable and that WHO will in due course need to return to a treaty with mandatory contributions.

# Broader scope of R&D

In the <u>KEI statement</u> to the 2014 Assembly, HAI and KEI argued that the purposes to be addressed by this CEWG initiative should be widened to include the development of new antibiotic drugs, better low cost diagnostics, basic research in areas of particular interest to all member states, and the funding of independent clinical trials to evaluate the efficacy of pharmaceutical drugs.

Other items on the EB138 agenda (see especially <u>9.2 STIs</u>) illustrate the need to broaden the range of medical products which will need to be included under this mechanism.

# Trade agreements

In the <u>KEI statement</u> to the 2014 Assembly, HAI and KEI argued for: need to confront more directly the barriers to access to treatment which arise from trade agreements. TRIP plus provisions are standard in contemporary plurilateral trade agreements.

Proceeding with the new system does not preclude WHO taking a more active stand in relation to the full use of TRIPS flexibilities and a moratorium on trade agreements which raise new barriers to affordability.

# Notes of discussion

#### **Documents:**

- • <u>A68/34</u> sect report
- A68/34 Add.1 sect report on demonstration projects

**Angola**: on behalf of AFRO, welcomes the report and progress made (a lot more that couldn't be documented)

**Turkey**: appreciates the work of WHO, creating fund sources and supporting research should be given importance, suport should be made in voluntarily bases, we are ready to support with our knowledge and experiences.

**Thailand**: we commend hard work of secretariat, main concern is adequacy and sustainability of pool fund, effective fund raising is vital, support by MS and donors is needed, government must be accountable and sufficient, regular reporting is part of accountability framework, A68/34 shows governance structure and effective fundraising is as important as governance. in conclusion we would like to see more country action

**Tanzania**: align to statement made by Angola on behalf of AFRO, congrats to sec on CEWG report, in addressing issues of pool funding, we are glad that there is special prog for tropical diseases in which to hold pool for type 2 and 3 diseases with relevance to affected countries, we note government structures and WHO TDR efforts, we continue to urge our colleges to consider investments, true change can only happen with committed funding process, lack of coordination continues to affect system of funding, we urge Sec to place observatory so that tool funds can indeed address priority issues, while we applaud partners in this project. we sincerely hope that these observations would be considered

**T&T**: committed to pursuit of knowledge related to health systems development, it is envisaged that pool funding is required to foster innovation in R&D in public health esp in relation to type 2 and 3 diseases this development will provide support for decision making in health and will place approp key health intervention in place.

**France**: Europe committed to pool fund with voluntary contributions to address LMIC health issues. coordination mechanism is important, need observatory to allocate according to right priorities. TDR and WHO coordination. urge WHO that mechanisms are as lean and cost effective as possible. support TDR to host pooled fund. region urges that funding comes through WHO budget. identifying R&D needs and gaps are core function of WHO. urge WHO to explore funding options. welcome money from India and call other to come on board.

Switzerland: Thanks for the report and progress made in designing financing mechanism globally esp on diseases affecting LMIC, we are committed to the process of follow up, and would like to support global system for fostering R&D we decided to make following contributions 4.2 m dollar, more than 2 million for designing R&D?; 40 thousand to set up global health R&D observatory, this report will fully depend on political will, for the last 15 years we have been talking about imp of providing medicine for neglected diseases, bring together as many stakeholders as possible, for each contribution of LMIC we will mate that by 50% to a maxmimum of 2m? we welcome brazil, india and South Africa contributions, its also functional to have broader coalition of countries, Swiss calls all MS to make their contributions so that we move fwd with this process

Monsieur le Président, - La Suisse s'associe à la déclaration de la France faite au nom de la région européenne de l'OMS. - La Suisse remercie le secrétariat pour ces rapports, ainsi que pour les progrès ré- alisés dans la conception d'un mécanisme global de financement pour la recherche-développement visant des maladies qui affectent de façon disproportionnée les populations des pays à faible et moyen revenu. - En accord avec son engagement dans le processus de suivi du rapport CEWG et afin de confirmer sa volonté d'appuyer la mise en place d'un système global de soutien à la recherche-développement, la Suisse a décidé de verser, comme elle l'a annoncé en janvier lors de la session du CE, les contributions suivantes : o Environ 4'200'000 USD comme contribution non-ciblée au financement des projets de démonstration. o Plus de 2'000'000 USD pour la conception d'un fonds global pour la recherche développement, y compris l'analyse continue des expériences du fonds commun dédié aux projets de démonstration. o Environ 40'000 USD pour démarrer l'Observatoire global de la

recherchedéveloppement. - Le succès de cette approche, et son potentiel à préfigurer un futur mécanisme global de financement, dépendra pleinement du soutien politique et financier des Etats membres de l'OMS. - Si vous me permettez une analogie, en moins de 10 ans, nous avons mis un homme sur la lune. Depuis 15 ans, nous parlons de l'importance de développer des médicaments contre les maladies tropicales négligées et aujourd'hui, le 3ème étage de notre fusée n'est toujours pas prêt. - Si nous voulons atteindre les ambitieux objectifs de développement durable après 2015, nous devrons assumer une responsabilité partagée et mettre en œuvre des initiatives qui réunissent un maximum d'acteurs et qui seront cofinancées par tous. - Ainsi, la Suisse a choisi un modèle de financement pour les projets de démonstration qui, outre une contribution directe et non-ciblée [que j'ai citée avant], prévoit un fonds de contrepartie où chaque contribution venant de pays à faible ou moyen 2/2 revenu, sera augmentée de 50% par la Suisse, jusqu'à un maximum de 2 mio USD. - En plus des annonces de la France et de la Norvège, nous tenons à saluer, dans le contexte du fonds de contrepartie, les contributions annoncées par le Brésil, l'Inde et l'Afrique du Sud. Néanmoins, afin d'assurer la mise en œuvre des projets de démonstration, il est indispensable d'avoir une coalition plus large de pays autour de notre responsabilité commune de financement de la R&D pour les maladies qui affectent de façon disproportionnée les populations dans les pays à faible et moyen revenu. La Suisse fait donc un appel aux autres Etats-Membres pour qu'ils apportent leur contribution de manière à faire avancer et prospérer ce processus. Je vous remercie

Indonesia: Chairperson, Excellencies, Distinguished Delegates, Indonesia would like to appreciate the Director General of the World Health Organization and WHO Secretariat for preparing the report under this agenda item. Indonesia believe that Research in health has a strategic role in accelerating health development.

In Indonesia, a number of players are conducting health research and development, inter alia, National Insitute of Health Research and Development (NIHRD) under Ministry of Health, universities under Ministry of Research, Technology and Higher Education, center and institutes under the Indonesia Institutes of Sciences, centers under the Ministry of Agriculture, Research and Development, agencies in local governments (province and districts) level, NGO and pharmaceutical companies.

Similarly with other developing countries, funding issue is still a challenge for research where the proportion for research funding compared to GDP is 0,05%. Other issues that affect the research development are research capacities and translating research into action in terms of research utilization.

Therefore, Indonesia support the Special Programme for Research and Training in Tropical Disease as reported on document A68/34. It is our believe that this particular program will be very important in addressing Tropical diseases, and at the same time sending a right signal to the international community that the issues are still need to be addressed in serious manner. Indonesia also encourage that the financial management will be managed by the Special

Programme. However, we request guarantee that there will be no conflict of interest in decisions and fund allocation.

Regarding to health research and development demonstration project, Indonesia appreciate the progress of demonstration projects and advise further monitoring and evaluation of the projects. Indonesia is waiting the knowledge sharing resulted from the projects.

In conclusion, Indonesia acknowledge that international collaboration and networking are crucial for improving health research capacity. Therefore, Indonesia sees the Joint Coordinating Board of The Special Programme for Research and Training in Tropical Disease as a strategic programme to improve health research and development in developing countries. Indonesia is seeking more opportunities to join this program to meet our strategies. Thank you, Chair.

**Uruguay:** On behalf of the south american country we thank the sec, we underscore the different contributions from brazil norway and swistzerland, we welcome the report on fund and possible financial mechanisms, specially in governance committee, the unfair loss of thousands of lives because of ebola so much relate to lack of research, it's possible to set new course to sustain health systems financially, we need to go back to discussions which was suspended, we ask the GD to convene an open ended working group to work on outcomes of R & D, [Uruguay also underscored the importance of delinkage in the context of the R&D Fund].

**Bolivia**: welcome the report of secretariat and support uruguay, they must adapt a mandate so that MS can be assured.

India: Mr. Chairman, We appreciate the Secretariat for presenting a comprehensive report on this agenda item. We support the demonstration projects finalized through the stakeholders' meeting in May 2014, as well as pursuant to the workshop organized in August 2014 and a subsequent follow up meeting in Geneva in November 2014. We also support the view that the project from Africa should be appraised and included in the scope of the R & D demonstration projects. As a mark of our commitment, we have already pledged our funding support of 1 million US dollars for this purpose.

Mr. Chairman, During Regional Consultations in July 2013 at Bangkok, the SEA Region Member States developed a grid for classification of norms and standards for health products R&D. This simplified classification has the potential to knit developed and developing countries on health products R&D mapping. We believe that this classification grid would be invaluable for the proposed R&D Observatory under consideration and may be considered for adoption.

Mr. Chairman, We strongly support the establishment of a pooled fund for voluntary contributions towards research and development for type III and type II diseases and the specific research and development needs of developing countries in relation to type I diseases, to be hosted by the Special Programme for Research and Training in Tropical Diseases. However, we also believe that a sustained funding mechanism with clarity and transparency is imperative to ensure success of the proposed mechanism and the R & D projects in global public health interest. The urgency of implementing the CEWG recommendations and taking

them forward is underscored by the recent Ebola virus outbreak and the growing threat of antimicrobial resistance. We, therefore, appreciate, in this context, the strong commitment expressed by many member states to contribute to the pooled fund.

We look forward to further discussions under the CEWG framework as mandated by WHA resolution WHA 66.22 to assess progress and continue discussions on issues relating to monitoring, coordination and financing for health. In this regard, we request the DG to convene an open ended meeting of the member states prior to the 69th session of the World Health Assembly in 2016 as mandated by WHA 66.22. Thank you Mr. Chairman.

**Bangladesh**: appreciates, we have also noticed that MS, the report by the secretariat lacks enough data

**USA**: we support the program and looking forward future updates.

<u>Brazil:</u> Mr. President, First of all, Brazil would like to inform that it aligns itself with the UNASUR statement. Brazil would like to congratulate the Secretariat for drafting the document, as well as for hosting, in august 2014, a seminar to assist the proponents of the demonstration projects to improve the innovative aspects of the original proposals.

We reiterate that such demonstration projects can be implemented, especially since they fill the requirements of innovative nature, technical and scientific merit and address public health needs.

In light of the need of its rapid implementation and, taking in consideration the matching funds models outlined in the last EB, Brazil would like to confirm it has made a contribution of one million dollars for the implementation of the demonstration projects. We congratulate other Member States especially those from developing countries, such as India an South Africa, that have also contributed.

Brazil emphasizes the importance of establishing the Pooled Fund, that the Fund could be administrated by TDR, as long as there is a clear methodology to select the projects, taking into consideration the aspects outlined in the CEWG report, and transparency mechanisms to ensure Member States participation. The Fund could work with a model similar as UNITAID's.

Mr. President, In order to avoid the establishment of multiple funds and pulverization of resources to finance R&D for different diseases, it is important to have in mind how to align those initiatives with CEWG principles.

Regarding the Observatory, Brazil reinforces the importance to establish a mechanism to identify gaps and opportunities of R&D in health, as well as to monitor and analyze information regarding global financing flows for R&D. The development of the Observatory should be transparent and aligned to guidance from Member States. Therefore, we would appreciate if the Secretariat could provide updated information about the current status of its development.

We acknowledge the paramount role of the CEWG activities, and call Member States to continue in the virtuous and daring purpose of investing in modern actions that promotes a new thinking regarding innovation and access to medicines, as established by the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property. Lastly, we request the Secretariat to convene the open ended working group to be held before the EB 138 to discuss the remaining issues of R&D, especially on the sustainability of it. Thank you,

**Argentina**: those models can not be linked to economic interest instead of public health. like to support open ended meeting of working group before EB 137 particularly in need to ensure availability of financial mechanism for these models.

**Togo**: supports Angola's statement. supports the formation of pool fund for projects for Type-2 and type-3. Our national health policy provides of swift availability of health information. Our national health strategy plan that supports R&D for health.

Malaysia: Mr Chair, Malaysia takes note of the report that clearly detailed the salient points for the establishment of a pooled fund towards better coordination for research and development. We take note of the governance and management of the pooled fund hosted by the Special Programme for Research and Training in Tropical Diseases with the focused funding for type III and type II diseases and for the specific research and development needs of developing countries in relation to type 1 diseases. We welcome the voluntary basis and unspecified funding from Member states and non-State members.

Thus, Malaysia agrees to the establishment of a pooled fund for voluntary contributions which is hosted by the Special Programme for Research and Training in Tropical Diseases. We suggest the pooled fund maintains its governance and management with the principle of equal but differentiated responsibilities. Thank you Chair.

**Morocco**: further attention required from civil society organisations. need of sustainable funding, quality of health in population is unvaluable element.

**China**: Thank you chair, support this pool fund and the fund should take into consideration principles of delinkage. 3 comments: we agree with establishment of neuroscientific WG. secretariat will establish criteria for membership of this WG to ensure inclusion of developing countries and ensure that their needs are taken care of. Each country need to strengthen R&D system. Also MS to support the Secretariat by collecting fees, they can also report regularly and ensure openness and transparency in the system.

**Canada**: thanks WHO for support in following up on recommendations of CEWG and supports pool fund as long as voluntary and managed by SPOTTD. recommends business plan demonstrating linkages to key disease.

**South Africa**: endorse Angola's statement. MS wish to reminded that this has come from CIPIH in 2003. We have made progress in terms of IPR. Particularly, Element 7 has been receiving focus. But we need to look at previous resolutions for review. we are encouraged countries that

have already made the contribution and urge other countries to contribute as well. Need to continue this journey to come out with ideas for innovation and research to take care problems such as Ebola, AMR.

**Sudan**: support establishment of pool fund with voluntary contributions. situation in Sudan with neglected tropical disease. ongoing demonstration projects along with Gov of sudan is greatly helping

<u>Maldives</u>: Thank You Chair, Maldives would like to commend the work of secretariat and acclaim the contribution of the CEWG and valuable contributions from WHO and member states in further developing CEWG recommendations including countries that volunteered to contribute voluntarily for this course.

Mr Chair, Maldives would like to note the report by Director General on the progress made in the implementation and further development of selected demonstration projects. Maldives would also like to welcome the proposed pooled fund and governance structure for managing CEWG voluntary funding by the special programme for Research and training in Tropical Diseases. We would also appreciate additional updates from WHO on the progress made in establishing the proposed global observatory.

Mr Chair, On a final note, although supporting the current voluntary mechanism for moving forward with CEWG recommendations, Maldives would like to emphasize on the importance of planning for a more concrete predictable financing mechanism to support the health Research &Development needs of developing countries to be in place. Thank you

**Chinese Taipei**: `ready to promote research capacity. eager to work with international community sharing our research capacity as well financial resources and trainings.

#### **NGOs**

- Drugs for Neglected Diseases initiative (DNDi)
- Médecins Sans Frontières International (MSF)
- Medicus Mundi International International Organisation for Cooperation in Health
  Care (MMI)
- Stichting Health Action International (HAI)

MMI/PHM: (video) Thank you Chair. I take the floor on behalf of MMI and PHM.

The CEWG was given the mandate to address structural issues related to R&D, including through the de-linkage of the costs of R&D and reducing prices.

The CEWG report recommended an instrument that would ensure funding and coordination of R&D to meet health needs of LMICs. Given this background, the open-ended meeting of MS to take place prior to the next WHA is the appropriate place to discuss in a comprehensive manner the proposals contained in document A68/34.

We urge MS to defer the decision on the proposed pooled fund to WHA69 and to task the open-ended meeting of MS to assess progress on the recommendations of the CEWG, including the fund.

The proposals in A68/34 do not fully reflect the recommendation of the CEWG, which specified a legally binding instrument with sustainable funding for R&D. The proposals in A68/34 foreshadow voluntary mechanisms of funding which would be unsustainable.

The voluntary nature of the proposed fund will make it vulnerable to undue influence from vested interest, including from donor countries, private entities and philanthropic organisations. Para 11 of the document states that the pooled fund should also be able to accept voluntary funding by NSA following WHO's rules on acceptance of donations. MS should note that the WHO does not have rules on acceptance of donations.

We urge Member States not to agree to the creation of a fund that relies on voluntary contributions; rather than a fund based on mandatory contributions governed by a binding mechanism, as envisaged by the CEWG.

The decisions to postpone the decision on a R&D Treaty was concluded late in the night without adequate translation. This greatly compromised the participation of LMICs; a binding R&D treaty remains on the agenda.

**Kayni?**: expect to launch observatory in January 2016, thanks for active participation for moving this forwards

Chair: report is noted; item is closed.