REPORT OF THE AFRO REGIONAL CONSULTATION MEETING ON THE WORK OF THE CONSULTATIVE EXPERT WORKING GROUP ON R&D FINANCING AND COORDINATION
Cote d'Ivoire, Abidjan 27.08.2011

INTRODUCTION

1. A one-day regional consultation meeting was held on 27 August 2011, Cote d'Ivoire, Abidjan, to examine the appropriateness of the different research and development (R&D) financing approaches under review by the Consultative Expert Working Group on R&D Financing and Coordination (CEWG) and to examine the feasibility of the implementation of these approaches in the WHO AFRO region.

2. The meeting was attended by representatives from the following Member States: Angola, Burundi, Cape Verde, Cameroon, Gabon, Senegal and Zimbabwe. It was also attended by two members from the CEWG from the WHO African region, three further regional experts and by staff from the WHO country and regional offices in Cote d'Ivoire and Congo and from WHO Headquarters. It was noted with regret that the invited representative from the African Network for Drugs and Diagnostics Innovation (ANDI) was unable to join the meeting.

3. The Assistant Regional Director to the WHO AFRO region Dr Moeti opened the regional consultation meeting by welcoming participants. She also emphasized the importance of the regional consultations by stressing that the results of these consultations would help the CEWG provide better answers to some of the important questions frequently raised by Member States. These questions pertained to both, the possibility of attracting funds to carry out necessary and sustainable R&D on diseases that disproportionally affected countries in the African region and to the question of how best to coordinate research initiatives and relevant actors in the area of global health R&D.

AGENDA

4. Five presentations were held in the morning of the consultations meeting in order to set the context of the meeting, to introduce and embed the work undertaken by the CEWG and to link the group's work with the WHO African region.

5. Dr Mirza, Coordinator of the Department of Public Health, Innovation and Intellectual Property Rights introduced the work of the CEWG by delivering a presentation on the mandate of the CEWG

6. Dr Ndumbe, Programme Manager for Research, Publications and Library Services in AFRO, further highlighted the important role of R&D in the African region by giving a presentation on R&D financing and coordination efforts in the WHO African Region in the context of the WHO Research Strategy.

7. Ms Clados, Technical Officer WHO, gave a presentation on the methodology used by the CEWG to evaluate different financing and coordination approaches.

8. Prof Bongani, CEWG member from South Africa, gave a presentation that outlined the content and the CEWG's preliminary assessment of various R&D financing and coordination proposals currently under review by the CEWG.

9. Dr. Loua, CEWG member from Guinea, gave a presentation which discussed in more detail the CEWG's analysis of two R&D financing and coordination mechanisms. Mechanisms discussed in Dr Loua's presentation referred to the "Reduction of Patent Duration" and the "Removal of Data Exclusivity".

10. All R&D financing and coordination mechanisms presented were then individually discussed and assessed by the attendees of the meeting. The conclusions of these discussions can be found below.

OUTCOMES OF THE MEETING

11. General outcomes of the meeting¹:

• There was a general feeling among participants that further investments needed to be made in the development of innovative capacity in countries in Africa.

• Participants stressed that the regional consultations on the work of the CEWG were nowhere else as important as in the African region as stakes for Africa were particularly high in these discussions, more so than in other regions. There was therefore a general feeling that the regional consultative process could have been even broader and more systematic.

• Participants stressed the need to properly address the issue of potential sources of funding of R&D and of the sustainability of R&D on many occasions and also during the discussions on individual proposals.

• While discussing individual proposals it was mentioned that there are conceptual overlaps and interconnectedness among many proposals. The Biomedical R&D Treaty was felt to constitute

¹ In order of importance or priority.
one such overarching proposal that could benefit from many good and viable ideas available in other proposals.

- Participants were surprised to note that there was hardly any proposal for strengthening and supporting the research institutions in developing countries.
- There was recognition that Africa is very resourceful in terms of R&D financing and coordination capacity and in terms of monitoring and evaluation of relevant activities, but the challenge remains to harness this resourcefulness by setting priorities right and through the leadership of governments. The public sector needed to spend appropriately on needs driven research and development.
- There was an agreement among the participants that they want to continue the engagement within themselves on the topics of R&D financing and coordination in Africa with the facilitation of WHO from this point onwards and there was some planning during the meeting to this end.
- ANDI’s absence from the meeting was conspicuous and disappointment was repeatedly expressed by the participants. However, this was also a reflection of the perceived importance and relevance of ANDI in these discussions in Africa. On the other hand the caliber of African experts invited in this consultation was high and their inputs in the discussion were valuable.
- There was criticism on not making available all the documentation from the CEWG in all the official languages which limited a meaningful engagement with the regions and countries for whom English is not their first language.

SUMMARY OF OUTCOMES WITH REGARD TO INDIVIDUAL R&D FINANCING AND COORDINATION PROPOSALS DISCUSSED

12. Tax Breaks to Companies:

- The proposal seemed to focus on and hence mostly benefit pharmaceutical companies from developed countries. In order for this or a related proposal to gain relevance in the context of African countries it would have to be adapted to this region’s needs. In particular, universities and other public research institutions which undertake most of the relevant R&D in developing countries, should benefit from this scheme. Moreover, because much of the research in developing countries is taking place in public institutions these countries would much benefit from a proposal that aimed at strengthening these institutions.
- An example from Nigeria was provided by one participant, where the government is taxing the import of raw materials and uses the monies collected that way to support the national research institutions in undertaking scientific and technological research. It was agreed that the CEWG should further explore this.
- A suggestion was also made that governments should consider taxing the import of those products the equivalents of which are already being produced locally. Monies collected this way should be used to support national research organizations. An example provided by one
participant was a tax on imported anti-malaria drugs the equivalents of which are also produced locally.

- Although an interesting idea, a delegate wondered how the effect of these taxes on innovation could be shown.
- Conclusion: It was felt that more evidence should be collected that showed the benefit of this proposal for developing countries.

13. **Removal of Data Exclusivity**

- Most of the discussion on this proposal was clarifying in nature.
- Conclusion: There was a general agreement with the analysis and conclusion of the CEWG on this proposal.

14. **Green IPP**

- It was felt that the proposal could result in an even stronger intellectual property protection in African countries which would result in continuing high prices of medicines.
- It was further felt that the capacity of patent offices in Africa is already weak and they would generally not be able to administer such a scheme. Moreover, while some countries had the capacity to track funds that could be collected as a result of this proposal, other countries would still have to significantly build up this capacity.
- Several attendees also voiced concerns regarding the guarantee of that funds sourced through this proposal would really go into R&D financing.
- Conclusion: There was no support for this proposal.

15. **Health Impact Fund**

- There was a discussion about having such a fund at country level first, then at regional level and then at the global level. It was felt that if such a fund was set up at country level it would be easier to track expenditures.
- It was not clear from this proposal that it would bring down the prices of drugs, and if so, how much closer to the production prices. It was also not clear how the production price was calculated.
- It was thought that some countries do have the capacity to assess the impact of medicines and health technologies. An example was given for the assessment of the health impact of anti-malarial medicine in Zimbabwe. Other countries, however, lacked such a capacity.
- It was not clear where the money for this fund would come from and how the fund would ensure that drugs developed by relying on this fund would be of high quality.
- The governance and management of this fund was not clear.
• If such a fund was to be set up at country level it was not clear how it could be ensured that neighboring countries that did not have such a fund did not import the drugs at the lower prices from their neighboring country and hence distort the effect of the Health Impact Fund.

• Conclusion: It was generally felt that the Health Impact Fund was an interesting idea but that it would be difficult to implement the proposal and that there would be a need to strengthen the surveillance capacity in developing countries.

16. Orphan Drug Legislation

• After clarifying that this legislation only exists in and for the jurisdictions of developed countries participants agreed with the analysis and conclusion of the CEWG. In its present form Orphan Drug Legislation was thought to have little relevance to developing countries.

17. Priority Review Voucher

• In principle the mechanism of a Priority Review Voucher was considered to constitute a good idea provided the medicine developed by the companies in the developed countries does actually benefit the people in developing countries. A precondition for this is that such medicines are affordable for the governments and the people in developing countries.

• Conclusion: Participants agreed with the analysis and conclusion of the CEWG.

18. Transferable Intellectual Property Protection Rights

• There was some discussion on whether the drug in relation to which the benefit in terms of prolonged intellectual property protection would be reaped would actually be beneficial to developing countries.

• It was also not clear how long the product to which the patent protection was transferred would be protected and whether the transfer of such patent rights would not result in the drug becoming prohibitively expensive.

• Conclusions: Participants agreed with the analysis and conclusion of the CEWG.

19. Patent Pool

• Participants agreed with the analysis and conclusions of the CEWG.
20. **Open Source**

- Participants agreed with the analysis and conclusions of the CEWG.

21. **Pooled Funds**

- In principle the mechanism of "pooled fund" was thought be a good idea, yet the sustainability of funding was considered to be an issue.
- It was mentioned that development banks in developing countries e.g. the African Development Bank, had the capacity to manage such funds.
- A point was made about linking up such initiatives with the existing schemes at the regional and sub-regional level. For example, some initiatives were mentioned in the SADC region, i.e. pooled procurement; local manufacturing plan, etc.
- Existing international funds or planned projects in the region should also be explored, e.g. the Global Fund to Fight AIDS, Tuberculosis and Malaria is already including a non-disease specific agenda in its project portfolio by now supporting health system strengthening.

22. **Grants**

- Grants were considered to be a proposal worthy of further support, yet it was felt that capacity needed to be built up in order for organizations in developing countries to be the receiver of funds.
- The production of Active Pharmaceutical Ingredients (APIs) and its support through grants was proposed since it is very much needed in the region. It would also lead to innovation.
- In South Africa the Technology Innovation Agency (TIA) could already be considered as a model for how grants are administered. It was agreed that the CEWG should further investigate this scheme.

23. **Prizes**

- Participants considered the idea of prizes to be good and agreed with the analysis of CEWG.

24. **Procurement Agreements**

- The Advanced Market Commitment was seen as having improved access to new vaccines. This mechanism can also be considered for medicines.
- The question of sustainability was raised as it was not clear whether procurement agreements could help to keep prices of drugs consistently low.
• Conclusion: Participants considered procurement agreements to be of high priority to the region.

25. Regulatory Harmonization

• Regional and sub-regional regulatory harmonization was considered very important and the proposal a much needed mechanism for Africa as it can improve access and can bring more investment.
• Regulatory harmonization was seen as being more than standards and specifications. It was about procedures which often are unnecessarily cumbersome and differ in detail between regulatory authorities, resulting in long and avoidable delays in market authorization.
• Conclusion: The proposal was supported as long as it would not only consider global harmonization.

26. Biomedical R&D Treaty

• There was an unequivocal and strong support for the idea.
• It was thought that R&D treaty was an "umbrella mechanism" that had the potential to bring together elements from many other proposals.

27. Coordination

• All the participants agreed on the need for having better coordination mechanisms in place.
• Conclusion: The issue of coordination needs to be addressed by WHO and partners as suggested by the CEWG.

28. Patent Duration

• The proposal dealing with patent duration was considered to be a proposal that sought to address "an old question" with no real satisfying answer to date.
• It was felt that it might overall be more satisfying to pay attention to the existing exceptions and possibilities in patent laws.
• It was felt that the reduction of costs for the application for patents might be more beneficial than reducing the duration of patents as applying for patents can be costly and time-consuming. South Africa could be considered a model in this as it already had an agency and funds to help those applying for a patent.
CONCLUSIONS

- Solid discussions on all proposals currently under review by the CEWG took place and substantive value was added to these by the examination of their feasibility and implementability from an African perspective. The important input received through the AFRO regional consultations will help inform the future work of the CEWG.

- Agreement was reached among participants to continue the engagement within themselves on the topics of R&D financing and coordination in Africa with the facilitation by WHO from this point onwards. Some planning took place during the meeting to this end.

- The report on the AFRO regional consultation meeting will be presented to the CEWG for its consideration during its 3rd meeting in November 2011. The CEWG will take the outcome of this meeting and the points raised into consideration when further assessing the R&D financing and coordination proposals before it.

ANNEX 1: LIST OF PARTICIPANTS, AFRO REGIONAL CONSULTATION MEETING ON THE WORK OF THE CONSULTATIVE EXPERT WORKING GROUP ON R&D FINANCING AND COORDINATION, ABIDJAN, COTE D’IVOIRE, 27 August 2011

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