



PAN AMERICAN HEALTH ORGANIZATION
WORLD HEALTH ORGANIZATION

28th PAN AMERICAN SANITARY CONFERENCE

64th SESSION OF THE REGIONAL COMMITTEE

Washington, D.C., USA, 17-21 September 2012

Provisional Agenda Item 4.13

CSP28/18, Rev. 2 (Eng.)
20 September 2012
ORIGINAL: SPANISH

REGIONAL CONSULTATION ON THE REPORT OF THE CONSULTATIVE EXPERT WORKING GROUP ON RESEARCH AND DEVELOPMENT: FINANCING AND COORDINATION

Introduction

1. Within the framework of World Health Assembly Resolution WHA61.21 (2008), *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*, and Resolution WHA65.22 (2012), *Follow up of the Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination*, the 150th session of the Executive Committee of the Pan American Health Organization (PAHO) requested the Director to organize a regional consultation on the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) and other related analyses.

2. PAHO, in its capacity as secretariat, called on the Member States to participate in the regional consultation on the CEWG report and opened a parallel consultative process with interested sectors of civil society. This document provides background information on the consultation, the methodology used to carry it out, and a summary of the official contributions received from the Member States and civil society.

Background

3. The CEWG was established through World Health Assembly Resolution WHA63.28 (2010). The mandate of this special working group was to deepen the analysis conducted by the previous Expert Working Group on Research and Development: Coordination and Financing (EWG) and to take its work forward. The

report describes how the CEWG was established, its mandate, and the methodology adopted by the group of experts.¹

4. During the process in which the CEWG was established, a number of key milestones were highlighted reflecting the ongoing concern of Member States at the regional and international levels with regard to deficiencies in the mechanisms for funding and coordinating research and development activities to ensure access to needed health technologies and products in developing countries, especially for the most vulnerable sectors.

5. The Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH) was created in 2003 by Resolution WHA56.27. Its work led to the formation of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property in 2006 (Resolution WHA59.24) and culminated in the Member States' approval of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property in 2008 (Resolution WHA61.21).

6. The countries of the Region have played an active role in the negotiations leading to the approval of the global mandates and the establishment of the working groups. The commitment of the PAHO Member States is reflected in a series of complementary resolutions whose aim is to improve access to medicines in the Region. The resolutions on expanding treatment and improving access to medicines were key precursors to the adoption in 2008 of Resolution CD48.R15, *Public Health, Innovation, and Intellectual Property: A Regional Perspective*, which provides the framework for PAHO's cooperation activities as well as cooperation among stakeholders in the Member States in the implementation of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property. PAHO's 49th Directing Council complemented these actions through the adoption of Resolutions CD49.R10, *Policy on Research for Health*, and CD49.R19, *Elimination of Neglected Diseases and Other Poverty-Related Infections*. The Region has converted political willingness expressed in these resolutions into concrete action. Progress report CD51/INF/5, presented at the 51st Directing Council, summarizes the main achievements and progress in implementing the global strategy and regional plan of action.

7. Taking the findings of the previous Expert Working Group (EWG) and the analysis of research, financing and coordination as its starting point, the CEWG evaluated 109 proposals reviewed by the EWG and 22 new contributions, using clearly defined and transparent criteria. The proposals were divided into 15 groups and, based on the results of the evaluation, categorized as: (a) proposals that most closely met the criteria set, (b)

¹ Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination: Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination; WHO, 2012.

proposals that, notwithstanding their potential benefits and disadvantages, were not considered relevant to CEWG's mandate, and (c) proposals that in the judgment of the CEWG least met its criteria. The CEWG issued a series of key recommendations with regard to the implementation of the proposals as well as next steps they considered most appropriate.

8. Through Resolution WHA65.22, the 2012 World Health Assembly welcomed the CEWG report and, among other things, urged Member States to hold consultations involving stakeholders, and the regional committees to “discuss at their 2012 meetings the report of the CEWG in the context of the implementation of the global strategy and plan of action on public health, innovation and intellectual property in order to contribute to concrete proposals and actions.” The resolution also requests the Director-General to hold an open-ended meeting of the Member States to analyze the report and the feasibility of the recommendations proposed by the CEWG with a view to including follow-up of the CEWG report as a substantive item at the Sixty-sixth World Health Assembly. WHO is planning this meeting for November 2012.

Methodology

9. In order to respond rapidly and efficiently to the request from the Executive Committee to hold a regional consultation, the Pan American Sanitary Bureau (the Bureau), through the PAHO/WHO Representative Offices, requested the Member States to designate focal points to participate in the consultation on behalf of their countries.

10. PAHO opted to organize the consultation through the Regional Platform on Access and Innovation for Health Technologies (PRAIS). This platform provides tools to link virtual communities of practice, enabling people and institutions to work together. In order to facilitate the process, a community of practice was created exclusively for the focal points designated by the health authorities and the Bureau.

11. The consultation with the countries began with a virtual meeting held on 25 July 2012, in which the Bureau presented background information, explained the methodology for the consultation, and launched the community of practice, in which the main documents and key information were made available. The Bureau also posed four basic questions to guide country input (see Annex). On the basis of these four questions, countries were requested to upload their contributions to PRAIS so that all participants could readily have access to them.

12. In order to encourage all stakeholders to participate, PAHO organized a parallel open consultation that promoted the active participation of civil society, disseminated via listserv and a number of regional and global networks. The civil society consultation was conducted in a similar fashion to that of the Member States, but without the requirement that each stakeholder be represented. The consultation was held through a virtual meeting

with participants from different organizations. The community of practice for civil society is freely accessible and will facilitate ongoing interaction among the stakeholders involved.

13. The inclusion of additional questions by some Member States was a subject of discussion. Some countries wanted to include other, more specific questions on the proposal for the binding agreement. Others considered these questions too specific and premature for this stage of the process. The additional questions (see Annex) were uploaded to the PRAIS. The Bureau requested that countries respond to the more general questions in the guide, and provided the option for countries to respond to the additional questions if they so wished.

14. The consultation ran from 25 July to 9 August 2012. However, due to the numerous requests received, the Bureau extended the deadline to 17 August.

Results of the consultation

General observations on contributions received from the Member States

15. Twenty-four health authorities designated focal points for the consultation, who received support from the PAHO Representative Offices in the countries. As of 17 August, 12 countries² had uploaded contributions to the PRAIS. Several countries informed PAHO that the regional consultation had promoted discussion at the national level. In some cases, the inability to hold national consultations prevented countries from providing input to the regional consultation process. However, Barbados discussed the CEWG report during a national consultation in order to prepare its official contribution.

16. The countries expressed their satisfaction with the CEWG report and the call for the international community to promote greater financing and coordination to foster research and development activities geared to Type II and Type III diseases and the specific needs of developing countries for Type I diseases.

17. The countries considered the applicability of the alternatives proposed by the CEWG within the context of the diversity of their societies, considering customs and traditions that provide the framework of social responsibility for the different stakeholders involved. The importance of considering the applicability of the CEWG proposals to the unique national context was underscored, since some of the proposals considered less suitable by the CEWG were considered more suitable by some countries and vice versa. Each country would therefore need to evaluate the different proposals and determine their feasibility.

² Argentina, Barbados, Bolivia, Brazil, Canada, Colombia, Cuba, Ecuador, El Salvador, Trinidad and Tobago, United States, and Uruguay.

18. The transition from “developing country” to “higher-income country” was a matter of concern for some of the participating countries when considering measures that mainly benefitted lower-income countries. It was noted that while in many cases countries had achieved a higher level of economic development, some of those countries continue to face important challenges and vulnerabilities.

National, subregional, and regional initiatives

19. The consultation facilitated information gathering on national, subregional, and regional initiatives that coincide with the proposals issued in the CEWG report and represent valuable experiences within the specific context of the Region of the Americas.

20. The countries underscored the importance of the subregional mechanisms in processes to promote governance, coordination, and financing of research and development. The Andean Health Agency/Hipólito Unanue Agreement (ORAS-CONHU) has promoted the Andean Medicines Policy and the Health Technology Assessment Policy to improve governance and access to health technologies in the subregion. Through a series of resolutions, the Union of South American Nations (UNASUR) countries have demonstrated their commitment to promoting research, the development and production of active pharmaceutical ingredients, and medicines that meet the needs of the countries of the Region.³ UNASUR has specifically analyzed the recommendations in the CEWG report, advocated for the formation of this expert group, recognized the work of the group, and supported the proposal for the binding agreement during the Sixty-fifth World Health Assembly. Through CARICOM and specifically through TECHPHARM and other subregional initiatives, Caribbean countries promote the strengthening of regulatory capacity and harmonization as a critical component of the strengthening of governance in the health technology sector. The subregion has other initiatives, such as the Caribbean Regional Drug Testing Laboratory, that improve access to quality medicines.

21. The countries stressed the importance of PAHO’s revolving funds for the procurement of vaccines and strategic supplies, as well as the importance of networks of supply centers such as CARIPROSUM. Trinidad and Tobago also noted the mechanism for public procurement through the *National Insurance Property Development Company Limited*, the only state drug procurement mechanism, which guarantees prices that facilitate access not only to essential health technologies but also to innovative ones, an experience which could be of use for countries that are at a disadvantage in the marketplace.

22. Several countries pointed to regulatory harmonization and cooperation networks, such as the Pan American Network for Drug Regulatory Harmonization (PANDRH),

³ UNASUR Health Resolutions 02/2009, 09/2009, 11/2010, 2/2012.

acknowledging their impact in terms of strengthening regulatory capacity and regional cooperation and harmonization processes, as well as mechanisms that accelerate entry of and access to new products in the marketplace.

23. Argentina has joined global and regional initiatives that are consistent with the Doha Declaration and fall within the framework of the global strategy, especially within initiatives promoted by PAHO. Argentina has its National Science, Technology, and Innovation Plan 2012-2015 and its Strategic Industrial Plan 2020, which are linked with the health sector through the Ministry of Health. In Argentina, sectoral funds support important and complex projects past the early phase of research, to generate, adapt, and transfer knowledge that can have real impact on production and at the social level. The National Agency for the Promotion of Science and Technology provides funding through nonreimbursable funds (Argentine Technology Fund [FONTAR] and the Trust Fund for Promotion of the Software Industry [FONSOFT]). Through tax credits, Argentina is seeking to improve systems and structures for manufacturing and enhance companies' capacity to innovate, creating technology platforms that serve as reference technology services centers through the vertical integration of groups devoted to research, development, and innovation.

24. Bolivia participated in the negotiations on the WHO global strategy and plan of action on this matter and is now promoting its implementation. The country also submitted several concrete proposals that were considered by the CEWG, such as analysis of the research and development treaty, patent pools, and the awarding of prizes as an alternative to patents.

25. Brazil uses advanced market commitments (AMCs) to create partnerships for production. This has resulted in the production of 33 products since 2009 (28 medicines, three vaccines, an intrauterine device, and a rapid test), an initiative involving 35 partners (including 10 national public manufacturers and 22 national and international private manufacturers) targeting 12 groups of diseases. Brazil's experience in creating public and private partnerships that promote health research with a social impact has aroused international interest. The national industrial complex increases access to products and promotes price reductions, providing an indirect solution to the lack of research and development funding for diseases that mainly affect developing countries. From 1997 to 2007 Brazil applied an indirect tax on financial transactions known as the Provisional Levy on Financial Movements (CPMF), designed to finance the cost of public health, social security, and the Fund to Fight and Eradicate Poverty. Brazil contributed to the development of the patent pool for antiretroviral medicines, to facilitate access to medicines, although the geographical clauses in this mechanism prevent many developing countries from benefitting from it.

26. Canada reported that it participates in numerous activities related to the CEWG proposals, including capacity building and technology transfer; open research,

development, and innovation systems; direct subsidies to small and medium-sized enterprises; and procurement agreements. Through the Canadian International Development Agency (CIDA) and Grand Challenges Canada (Can \$225 million in five years), health projects and innovation are funded in low- and medium-income countries that are working toward a solution to global health problems through initiatives such as the Stop TB initiative. The Global Health Research Initiative (renewed in 2012 for four years) currently funds initiatives in Chile, Colombia, Grenada, Honduras, and Jamaica to strengthen governance and conduct and use research that can improve public health. Since 2007, Canada has invested Can \$87 million to support national and international research, boost capacity in vaccine and policy development, and support community participation.

27. In Cuba, the State prioritizes health research, development, and innovation, investing a substantial portion of the budget in building scientific and technical capacity in health research and development. Emphasizing biotechnology and companies with a closed-loop approach, Cuba works to meet its health priorities. Furthermore, it uses an award system domestically to promote various research and development areas, and it has participated in the transfer of technology to other countries for high-cost products.

28. Ecuador is implementing initiatives with a focus on open research, development, and innovation, while El Salvador is already using an open source code policy for communication technologies and believes it important to promote this policy for health technologies.

29. In 2010, Uruguay's Ministry of Health joined the Ministerial Innovation Cabinet, a clear sign of the importance of steering research toward public health. Through a project tender mechanism, the country's National Research Agency is responsible for funding most of the research, development, and implementation carried out in the public sphere.

30. The United States has met the research and development funding goal recommended by the CEWG. Federal health agencies contribute approximately 45% of the total global research, development, and innovation budget, and 70% of government contributions. The National Institutes of Health fund 40% of the total global research, development, and innovation budget for neglected tropical diseases. The government was involved in the development of 24 of the 45 products introduced between 2000 and 2010 and is supporting 200 of the 365 products currently in development, such as malaria and HIV vaccines and new tuberculosis drugs. Some of the main U.S. initiatives are capacity building and voluntary technology transfer for mutual benefit, direct subsidies to small and medium-sized enterprises in developing countries, priority review vouchers, regulatory harmonization, product development partnerships, orphan drug legislation, and procurement agreements. At the regional level, the U.S. Agency for International Development (USAID) intends to support the Health Technology Assessment Network of

the Americas (RedETSA), a regional network.

Salient issues addressed in the regional consultation on the CEWG proposals

31. Several Member States emphasized the importance of building capacity in research, development, innovation, and technology transfer with local and international resources from the public and private sector. The countries underscored the need to improve governance in developing countries so that they can manage all aspects of health innovation systems; this is key to supporting decision-making, priority setting, and the creation of an environment conducive to coordinating the sectors involved in the research, development, and innovation cycle. They also underscored the need to expand the scope of the research considered in this debate to include operational innovation as well as innovation in services to increase access and rational use of health technologies.

32. Some countries noted that regardless of the source, funding should be allocated to the creation and development of technical and scientific capacity, with specific objectives based on an evaluation of real needs and priority setting, employing statistical methodologies to evaluate the effectiveness of the intervention.

33. Another factor that should be taken into account is the strengthening and ongoing development of a nation's regulatory framework to guarantee the quality of products and their ready introduction to the market. Many countries noted the advantages of regulatory convergence initiatives based on national realities as a means of improving the diffusion and access to health technologies throughout the Region.

34. Some countries received the proposal for open approaches to research favorably, noting potential advantages over the traditional application of intellectual property rights. Some countries also emphasized contributions made toward eliminating impediments to research, development, and innovation, and noted the impact of delinking the price of a product from the cost of research, development, and innovation.

35. The idea of creating a global health research, development, and innovation observatory also elicited favorable comments. This was considered an attractive alternative for some countries, as it would be an independent mechanism that could provide scientific foundation for decision-making. For other countries, it could serve as a monitoring mechanism that would complement the implementation of a framework agreement on research, development, and innovation. Some countries also indicated the need to carefully analyze the governance and operational structure of this mechanism.

36. Prizes were also favorably considered because of the potential to dissociate product prices from the cost of research, development, and innovation. The need for the award components of the prize to be complementary rather than isolated was highlighted, as was the need to avoid competition among similar awards. The CEWG suggestion to

develop a series of pilot projects based on prizes was favorably received by some countries.

37. The proposal for a global research and development framework or convention received mixed reviews. Some countries considered this proposal to be the one that would have the greatest impact, noting that an agreement like this should not be implemented in isolation but suggesting that it could provide a comprehensive framework that combines and guides the proposals considered relevant by the CEWG. They also noted that this mechanism could have the advantage of encouraging greater collaboration and efficient information exchange in order to prioritize science, technology, and innovation in a manner that is less asymmetrical to promote equitable access to health technologies. They felt that it should be established within the framework of the Doha Declaration and the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, because, from the perspective of countries likely to implement this framework, it could contribute to sustainability in research and equitable sharing of its benefits.

38. It was recognized that to be effective, this agreement should be global in scope and that the time necessary to achieve such an agreement could be considerable. Citing other major agreements as precedents, they recalled that Article 19 of the WHO Constitution provides for this type of agreement, and that the difficulties of negotiating and implementing such an accord should not prevent countries from agreeing on a framework in a priority public health area. Similarly, they noted the existence of international legal instruments that facilitate the signing of these types of agreements. Some countries thought that the treaty should contain instruments that dissociate the cost of research, development, and innovation from product price in order to improve access. They also emphasized that in the meantime, proposals that have a more immediate effect would have to be considered.

39. Other countries did not share the view that a mechanism such as a binding agreement is suitable for addressing research, development, and innovation priorities, and they expressed opposition to beginning negotiations. They thought that an agreement of this type would not be binding in practice and that the international community should direct its efforts to agreements that could have a more immediate effect. In particular, they were opposed to the agreement establishing a contribution equal to a fixed percentage of GDP, since financial goal-setting should not precede the definition of needs and expected results. Moreover, although increased funding is an objective shared by all, these countries maintain that a predefined percentage of 0.01% of GDP might not necessarily represent a sufficient level of financing for all the countries in the future.

40. The costs and difficulty of negotiating, implementing, and monitoring compliance with the treaty, as well as the lack of flexibility it would impose on countries whose situation is changing, were also cause for concern. Some thought that a voluntary

contribution mechanism might be a more viable alternative.

41. Intellectual property rights were regarded as an incentive for the development of new health products, although insufficient to promote new products in non-commercially viable areas or to guarantee equitable access to health technologies. Some countries favorably viewed the patent pool proposal, since it could facilitate access to research results and technology transfer and improve access in countries still lacking productive capacity. However, other countries thought that this mechanism was not very important in this context, because it would not have an impact on funding and only some countries would benefit from it. There was agreement among some countries on the need to amend the clauses that provide the foundation for the current patent pools. Similarly, the removal of data exclusivity was viewed favorably by some of the participating countries, while transferable intellectual property rights and priority review vouchers were opposed by some Member States.

42. Some countries considered orphan drug legislation to be a feasible alternative but said that it currently tends to favor investment in rare, rather than neglected diseases, so they called for amendment of the relevant clauses.

43. Countries provided varied comments on the different funding mechanisms proposed. Direct subsidies to small and medium-sized enterprises were noted as a viable alternative to encourage entrepreneurship in developing countries. Special emphasis was placed on public-private strategies. Funding mechanisms viewed favorably by some countries included the establishment of pooled funds and increased donor funds. However, some countries without drug manufacturing capacity questioned the value at the national level of proposals that require such capacity for their implementation.

44. Some countries maintained that regardless of the financing mechanism, and especially if it means pooling funds, the mechanism should have specific objectives and timeframes for procurement of the products, meet specific needs, and be subject to periodic independent evaluation to verify its effectiveness. In addition, a proper analysis should consider the advantages of a single fund versus multiple funds that could allow donors greater flexibility and the definition of geographical objectives. At the same time, the participants agreed that whatever the mechanism, scientific progress depends on a peer review system, so that funds are channeled only to projects that demonstrate sufficient scientific merit, regardless of their origin.

45. Some countries thought that the various types of procurement agreements, including advanced market commitments, were suitable mechanisms for technology development, given the incentive they can offer for the manufacture and distribution of the products. Some contributions received mentioned the need to provide adequate product price guarantees.

46. Some countries considered taxes on repatriated earnings by the pharmaceutical industry a way to fund part of health technology research and development for the treatment of Type II and Type III diseases and believed that this could also have a positive impact on transfer pricing practices, although this mechanism should be analyzed in relation to fiscal mechanisms in each country.

Civil society input

47. There were 36 participants in the community of practice and seven contributions were received on behalf of civil society organizations.⁴ Some of the contributions noted that the very short deadline for submitting comment for the consultation presented a challenge and that the methodology did not include opportunities for discussion and dialogue.

48. The organizations' comments reflected general agreement with the CEWG report and revisited several of the issues that the countries had considered important. Their input can be found under "Communities" on the Regional Platform on Access and Innovation for Health Technologies (PRAIS, www.paho.org/prais) in a community of practice called "CEWG Consulta Sociedad Civil/CEWG Civil Society Consultation." Highlighted below is a summary of the comments received.

49. The participants considered that the limited availability and access to health technologies required for treating patients in vulnerable situations or suffering from neglected diseases are a direct consequence of the current system for medical innovation. Unless existing research, development, and innovation systems are improved, millions of people will continue to have unmet needs and the cost of health care will continue to rise unsustainably. These participants suggested that a research, development, and innovation system based on public health needs rather than market incentives is absolutely necessary.

50. The participants underscored that higher spending on research, development, and innovation has not translated into more treatment options for patients and that the number of new molecules discovered has been very low in recent decades. Existing intellectual property systems allow patents to be acquired for products that are not innovative through simple modifications of the products, a factor that limits access to technologies.

51. Governments play a critical role in financing solutions to the health problems of the most vulnerable populations. Ninety percent of all research, development, and innovation funding for neglected tropical diseases comes from public sources and

⁴ Universities Allied for Essential Medicines (UAEM), Alianza LAC-GLOBAL por el acceso a medicamentos, Knowledge Ecology International (KEI), Global Health and Technology Access, Duke University, Drugs for Neglected Diseases (DNDi), Grupo de Trabalho sobre Propriedade Intelectual (GTPI), Doctors without Borders.

nonprofit organizations. Collaborative research, development, and innovation models require an increase in global funding and technical resources as well as a reduction in their costs through open innovation, the management of intellectual property rights in favor of access, the harmonization of regulatory strategies, and transparency in research and development costs. Accordingly, it is suggested that promising CEWG proposals be thoroughly considered.

52. Most of the contributions received suggested that mechanisms that dissociate the cost of research, development, and innovation from the price of the end product are the most important proposals in the CEWG report.

53. Several participants repeatedly called the proposal for an international agreement on the coordination and financing of drug research and innovation very promising. Such an agreement is seen by many participants as the mechanism that would permit coordination of the Member States' commitment to setting priorities based on health needs in the developing countries and to allocating funds to address those needs.

54. Establishing a binding agreement would enable countries to agree on a sustainable system for medical innovation to develop products based on the priority health needs of developing countries, thereby making new pharmaceutical products available and accessible. Some participants suggested that this system should be binding in terms of financial contributions and that potential mechanisms for facilitating collection of these should be explored. Many did not agree that "soft" treaties are appropriate for the proposed objectives. In addition, they suggested that the range of diseases that could be financed through the agreement be expanded, since including diseases that are prevalent in developed countries could elicit greater commitment from these countries.

55. Open innovation systems, open licensing, publicly funded innovation, patent pools, and the use of prizes are some of the mechanisms that would help dissociate the cost of research, development, and innovation from product prices, increasing product availability and accessibility. Some participants also thought that a global health research and development observatory could support decision-making on financing in the countries.

56. The advantages of harmonizing regulations to accelerate research and access led some participants to recommend the inclusion of this component in a possible international research and development treaty, bearing in mind that this does not mean that the regulatory authorities in developed countries are best positioned to evaluate the quality of products for diseases prevalent in developing countries.

57. The feasibility of many of these proposals is evidenced through current experience, including product licensing for research, the awarding of publicly funded prizes to encourage innovation, and the success that other industries such as the

information technology industry have had in adopting many of these practices without adversely affecting commerce. Regional efforts to establish a prize in the area of Chagas' disease are pertinent examples.

Action by the Pan American Sanitary Conference

58. The Conference is requested to take note of this report and issue recommendations.

Annex

QUESTIONS FOR THE REGIONAL CONSULTATION ON THE CEWG

General Questions

- (a) What proposals evaluated by the CEWG are most relevant to the context of the Americas?
- (b) Are there CEWG proposals that may not be applicable to the national or regional context?
- (c) Are any of the CEWG proposals currently in development within your country?
- (d) Does your country participate in any regional initiatives aligned with the CEWG proposals?

Additional Question from Colombia

- (e) What is the position of your country regarding the proposal of the CEWG to initiate negotiations of a binding international instrument on research and development in health? What should this instrument contain?

Additional question from the United States

- (f) Have you had national-level discussions with your finance ministry and other relevant government entities regarding the recommendation to commit 0.01% of your country's GDP to this effort? Is your government prepared to commit to allocate such funds?
- (g) Should this financing mechanism set explicit goals in terms of developing products through to the point of demonstrating health impact? Should the financing pool include a requirement for periodic evaluation of its effectiveness?
- (h) Do you support the recommendation for a pooled financing mechanism to be managed by WHO?
- (i) The process of promoting access to new products may require additional interventions not covered by the scope of the CEWG report, particularly toward the end of the pipeline for product development and access. Are there any additional concepts that you believe WHO Member States should include in their discussion of financing and coordination activities moving forward?

- (j) If you support a binding instrument, in what sense should it bind states?
- (k) What enforcement mechanisms or incentives would you suggest if a country fails to meet its financing obligation?

- - -