

Intergovernmental Working Group on Public Health, Innovation and Intellectual Property

Report of the first session Geneva, 4–8 December 2006

Agenda item 1 Opening of the session, and adoption of the agenda and method of work

1. The Intergovernmental Working Group on Public Health, Innovation and Intellectual Property, established by virtue of resolution WHA59.24, held its first session from 4 to 8 December 2006 and elected Mr Peter Oldham (Canada) as Chairman. The Officers of the Working Group are listed at Annex 1. The meeting was attended by more than 100 delegates, and by invited experts, observers and nongovernmental organizations (see Annex 2). The Group adopted its provisional agenda¹, and agreed on arrangements governing participation in the sessions by nongovernmental organizations in official relations with WHO.

2. After the opening remarks, some Member States commented that on the manner in which experts and concerned entities had been identified and invited to attend. In the view of one delegation the process had not been carried out in strict accordance with paragraph 4(3) of resolution WHA59.24, while others pointed out the lack of an equitable geographical balance among the experts.

3. In response to their concerns, it was explained that, in conformity with paragraph 4(3) of resolution WHA59.24, the Secretariat had invited experts and a limited number of concerned public and private entities to attend the session. Conflict of interest was unlikely since the representatives of entities attending clearly reflected the views of those entities, whereas individual experts covered a broad spectrum of interests. Any behaviour that delegations deemed incompatible with an expert's role in the Intergovernmental Working Group should be reported to the Secretariat. With regard to ensuring equitable geographical balance, some of the experts from developing countries who had been invited had been unable to attend. Member States would be invited to propose possible candidates for the next session of the Working Group to the Secretariat before the end of February 2007, in order to ensure a balance in terms of gender, regions and developed and developing countries. A final decision on their selection would rest with the Director-General, in accordance with resolution WHA59.24.

¹ Document A/PHI/IGWG/1/1 Rev.2.

Agenda item 2 Development of the global strategy and plan of action

2.1 Review of recommendations of the Commission on Intellectual Property Rights, Innovation and Public Health (Documents A/PHI/IGWG/1/2 and A/PHI/IGWG/1/INF.DOC./1)

4. The Secretary of the Commission on Intellectual Property Rights, Innovation and Public Health, said that, although the Commission's mandate had referred principally to intellectual property rights, it had also examined many other factors that contributed to innovation for the improvement of public health in developing countries, including regulation and the determinants of access to new and existing medicines, and the importance of political commitment. The Commission had found that in industrialized countries there was a largely self-sustaining innovation cycle in biomedical research that was generally not present in low-income countries and had provided an agenda of key issues that should be considered in order to build up research and development in diseases that predominantly affected the developing world.

5. The Working Group was informed of the action that WHO had already carried out on issues covered by the Commission's recommendations in the areas of discovery, development, delivery, fostering innovation in developing countries and sustaining global efforts.

6. Delegations pointed out that developing countries should be given a clear role in implementing the Commission's recommendations. It might also be useful to have a guidance document dealing with, for example, regulation. Consideration should be given to establishing a framework, in particular to assist countries in applying the provisions of the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS). A number of delegations stressed the importance of prioritizing the recommendations contained in the report in order to facilitate development of the global strategy. It was noted that policies other than those on health also had a significant impact on public health in general, on health systems and on access to medicines.

2.2 Status of implementation of resolution WHA59.24 (Documents A/PHI/IGWG/1/3, WHA59/2006/REC/1, resolution WHA59.24 and A/PHI/IGWG/1/INF.DOC./2)

7. In order to obtain inputs from interested stakeholders, the Secretariat had held a web-based public hearing. Submissions had been received from governments, academia, public-private partnerships, product-development partnerships and industry, and had proven constructive.

8. Several delegations welcomed the steps that were already being taken in some countries to implement resolution WHA59.24, although one delegation questioned the suitability of the Working Group as a forum for reporting on countries' progress. In that regard, it was suggested that a structured framework for reporting on the status of implementation of the resolution should be established. In order to increase access to medicines, the importance of a multifaceted approach, periodic review, and collaboration at national and international levels were emphasized, as was the negative impact on neglected diseases of certain patent strategies such as "evergreening", that involved multiple patents on a single product. A number of initiatives had been useful in introducing medicines into developing countries, such as the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases. One delegation reported that the Commission's recommendations had been analysed with a view to their inclusion in a national plan of action. WHO should focus on a needs-driven approach to research in its work.

9. It was pointed out that the 2003 decision of the TRIPS Council that permitted compulsory licensing for export purposes had permitted countries without their own production capacity to secure the supply of relevant medicine. Some Member States had made provision for compulsory licensing; parallel importation had also been introduced in several countries in order to stimulate competition and reduce prices, in particular for pharmaceutical products. A number of delegations noted that intellectual property rights could be beneficial for public health, highlighting, in particular, by acting as an incentive for research.

2.3 Elements of the global strategy and plan of action (Documents A/PHI/IGWG/1/4 and A/PHI/IGWG/1/4 Add.1)

General statements

10. Most delegations felt that the document setting out the elements of the global strategy and plan of action provided a good basis for further discussion. Two delegations, however, attributed an apparent lack of breadth in the document's perspective to the fact that insufficient attention had been paid to WHO's earlier work in the area, as set out in the relevant Health Assembly resolutions.¹ One of them also pointed out the need for a time line for completion of the plan of action. The Commission's recommendations should be prioritized as it was not realistic to expect to implement them all in the medium term. In addition, the transfer of technology and the management of intellectual property should be included as core elements of the global strategy and plan of action, with separate areas for action. Some delegations noted that the recommendations targeted many actors, and emphasized the importance of engaging all relevant stakeholders. The positive role that public-private partnerships could play in implementing the Commission's recommendations was noted, as was the importance of tackling shortcomings and impediments in health systems in developing countries, such as lack of qualified nurses and physicians, poor distribution and transport systems, and the need to strengthen clinical trial and regulatory regimes.

11. One delegation identified the lack of medicines available for women, particularly pregnant women, as a major gap in current research and development. Although it was generally recognized that WHO should play an important role in enabling countries to take advantage of the flexibilities contained in TRIPS, it must guard against duplication of effort when working with other international organizations and certain programmes. One delegation, whose Member State was a founding partner in the International Drug Purchase Facility (UNITAID), described the latter's function to improve the safety and availability of medicines for malaria, tuberculosis and HIV/AIDS, including second-line antiretroviral agents. Another outlined the steps its country had taken to encourage the use of generic medicines and to ensure uniform prices for essential medicines. The interdependency between countries resulting from the spread of communicable diseases and the need to develop new products to prevent possible outbreaks was mentioned.

12. Three delegations noted an apparent lack of structure and perspective in the organization of the Working Group's first session, and two of them felt that the concept of affordability needed to be more clearly defined by the Group so as to facilitate the attainment of its objectives.

13. Delegations supported the view that the Working Group should seek to outline the major strategic directions before embarking on a detailed workplan. Some delegations pointed out that the

¹ Resolutions WHA39.27, WHA41.16, WHA43.20, WHA45.27, WHA47.12, WHA47.13, WHA47.16, WHA47.17 and WHA49.14.

main problem was not the question of intellectual property, but rather the need to ensure access to treatment. Efforts should be directed towards fostering innovation and capacity building in order to ensure that individuals and health systems, particularly in developing countries, were supplied with the vaccines, medicines and diagnostic tools required. Having access to generic medicines could make a useful contribution in that regard in the short term. Several delegations emphasized the need for an umbrella body to be established under the auspices of WHO to guide research in the public domain; one observer pointed out that any benefits from scientific research should be shared, particularly with developing countries. The possibility of establishing a financing mechanism to generate sustainable funding for research and development was also highlighted. It was suggested that a workshop might be held during the Sixtieth World Health Assembly to give Member States unable to attend the first session of the Working Group an opportunity to contribute.

14. One nongovernmental organization observed that the drive towards higher levels of protection for intellectual property had failed to stimulate research into diseases that mostly affected developing countries. Moreover, stricter intellectual property rights were leading to higher prices, making developing countries less likely to benefit from new innovations in treatment for both communicable and noncommunicable diseases. Another affirmed that the global intellectual-property system had made possible much of the research and development carried out by the pharmaceutical industry relating to diseases of the developing world, including African trypanosomiasis, dengue fever and malaria; it would therefore be counterproductive to undermine the research-based industry. The real barriers to access to medicines were not intellectual property rights, but rather a lack of funding, infrastructure and political will.

15. Four experts contributed to the discussion, drawing attention to the following aspects: the need to enhance access to the treatments needed in developing countries through the transfer of generic drugs between developing countries and to speed up delivery of new technologies and medicines; the need to make knowledge freely available, in order to encourage the production of new and innovative treatments and diagnostic tools for HIV/AIDS and tuberculosis, and to enhance research and development and capacity-building at local level; the need for the Working Group to devise a plan of action to implement the Commission's recommendations and draw up a framework for needs-driven research and development in order to bridge the gap in research and development related to neglected diseases; and the question of access, which also encompassed pricing, quality and manufacturing issues and the possibility that, rather than being a barrier to research and development, the intellectual property system could facilitate the transfer of technology.

Elements of the plan of action

16. Several delegations noted that it was essential to link all the strategic elements and the respective areas for action with the relevant recommendations contained in the Commission's report in order to clarify the appropriate actors in each case and capture certain actions that might not have been included. During the discussion, a number of linkages relating to individual elements were proposed.

17. **Prioritizing research and development needs.** Delegations were in favour of a coordinated long-term, needs-driven approach to research and development support in which the views of developing countries were prominently represented. Although some delegations stressed the importance of providing open access to compound libraries, and of possibly dedicating public funding to that end, for others the issue was highly sensitive, for example in the case of libraries that were not in the public domain. Some delegations were concerned about the vagueness of the drafting of the elements, as it was not clear who would set the priorities identified in the areas for action or on what they would be based. The need to deepen the overall understanding of health systems was mentioned

specifically in the context of prioritizing research and development needs, although it was also relevant for other elements.

18. **Promoting research and development.** One delegation drew attention to a lack of clarity in some of the areas for action and the difficulty of avoiding mandatory formulations when countries came to drawing up their own action plans. Another delegation emphasized that the promotion of research and development should be needs-driven and encompass diseases that were not regarded as financially attractive. Once the capacity of health systems became clearer, bridges could be built between researchers in developed and developing countries. Some delegations recommended adoption of a global research and development treaty to fund upstream research and development for diseases that disproportionately affected developing countries. One delegation regretted that the benefits of traditional medicine were not being more fully exploited in some countries. In the context of ensuring the sustainability of funding, advance-purchase commitments and establishment of a dedicated research and development fund were mentioned.

19. **Building innovative capacity.** One delegation observed that building innovative capacity was an area of interest for several organizations and stressed the need to avoid duplication of activities. With regard to the promotion of patent pools, the upstream technologies should be clarified and the rights of patents-holders should not be disregarded. The importance of strengthening regulatory capacity in developing countries was highlighted and current work in that regard should be taken into account. A number of delegations observed that better management of intellectual property and investment in human resources were essential in order to attain the objectives of the global strategy and plan of action, and pointed out the need to avoid the “brain drain” or migration of health workers and its damaging effect on health systems. The benefits of recognizing, developing and promoting traditional medicines were highlighted. One delegation noted that the recommendation for developed countries to comply with their obligations under TRIPS and paragraph 7 of the Doha Ministerial Declaration on the TRIPS Agreement and Public Health should also have been reflected in the areas for action.

20. **Transfer of technology to improve innovation capacity.** According to several delegations, the transfer of technology was the province of other organizations and did not need to be included as a separate element. Other delegations highlighted the role of human resources and capacity building in technology transfer. It was disappointing to some that the national reports submitted in accordance with Article 66.2 of TRIPS appeared to indicate that a minimal amount of health-specific technology had been transferred. In response, it was explained that the Article did not refer specifically to the promotion of technology transfer in the field of public health, and that it was for the developed countries to decide what to transfer. One delegation pointed out that, in its country’s experience, technology transfer could be beneficial not only to the recipient country but also to the country transferring the technology. Another sought clarification of the mechanism envisaged in the areas for action, and the view was expressed that it might be more appropriate to make use of existing mechanisms to promote the transfer of technology rather than to devise a new one. A number of delegations suggested amendments to the areas for action, with one observing that the work carried out in universities, research institutes and public-private partnerships should not be overlooked.

21. **Management of intellectual property.** Some delegations felt that the management of intellectual property did not fall within WHO’s remit. However, another accorded it strategic importance given that the intellectual property system was poorly understood in some parts of the world, noting that collaboration between health, trade and intellectual property officials at a regional level would help to promote a better understanding of its implications for health. The need to strike a balance between protection of intellectual property and innovation in public health while avoiding the creation of obstacles for developing countries was highlighted, as was the importance of education and

training in that area. Although the patent system successfully promoted innovative interventions for a number of diseases, it was widely acknowledged that it did not provide enough of an incentive where neglected infectious diseases were concerned. One delegation suggested that the areas for action might therefore also include establishment of alternative incentive systems for research and development to address public-health needs in developing countries. One delegation stressed that each country should be free to decide how to implement the flexibilities contained in TRIPS, while another said that countries should be advised to incorporate all the flexibilities contained in TRIPS and the Doha Declaration into their national legislation, in particular with regard to research and the experimental use of patented drugs. It was suggested that flexibilities contained in other international agreements should also be taken into account.

22. There was support for the inclusion, in the areas of action, of the Commission's recommendation that bilateral trade agreements should not seek to incorporate "TRIPS-plus" protection in ways that might reduce access to medicines in developing countries. Three delegations requested clarification of the regional institutional frameworks envisaged in the areas for action, while another stressed the need to avoid duplication and make use of the information on patent status held by other organizations. Any databases compiled should be updated regularly. One delegation also highlighted the need to increase transparency, in particular with regard to bilateral agreements.

23. **Improving delivery and access.** Some delegations stressed that delivery of, and access to, medicines, vaccines and diagnostic tools should be the top priority. One recalled that a proposal had been made within the WTO framework to eliminate customs duties and charges on pharmaceutical products. It would be useful for the Working Group to have at its next session an assessment of the implementation in developing countries of legislation on application of the flexibilities contained in TRIPS. Emphasis should be placed on mechanisms to provide affordable and accessible products rather than on consideration of how health systems could support the needs of product development. One delegation drew attention to the Commission's recommendation to encourage generic entry on patent expiry. The question was raised as to why, even though a number of the Commission's recommendations related to prices, none of the areas for action had addressed that sensitive issue. Several delegations observed that good manufacturing practices should be encouraged in all countries, not just the developing ones.

24. **Ensuring sustainable financing mechanisms.** Some delegations suggested that both the scope of the financing mechanisms and the actors envisaged should be clarified, and emphasized the need to avoid duplication. One delegation questioned the value of a funding mechanism for research and development for neglected diseases in view of the existence of the Special Programme for Research and Training in Tropical Diseases. Another suggested that reference should be made to advance-market commitments. It was pointed out that if the target for developed countries to contribute 0.7% of gross domestic product to official development assistance were met, such resources could be used for research and the acquisition of medicines. Several delegations noted that it would be difficult to estimate the financing requirements of the plan of action before it had been drawn up. The emphasis in the element as a whole appeared to be on additional, rather than sustainable, funding. In that respect, the Working Group might wish to study the working of such innovative mechanisms as UNITAID and the International Finance Facility for Immunization.

25. Two nongovernmental organizations emphasized that the Working Group should identify research and development priorities, and should make commitments to establishment of new mechanisms to provide support for essential medical research that could not count on high product prices.

26. **Establishing monitoring and reporting systems.** A number of delegations stressed the importance of intersectoral cooperation in all matters related to health and health systems in order to ensure better coordination of international work. It was pointed out that in view of the difficulties inherent in evaluating the impact of the intellectual property system on development and access to medicines in countries at different stages of development, it might be feasible to focus on monitoring the availability of medicines for diseases that disproportionately affected developing countries. In response, it was explained that WHO was currently working with WTO to devise a methodological framework for developing countries. Two delegations raised the question of how the proposed plan of action would be monitored after its implementation.

27. One expert described the efforts being made to improve the health innovation process by accelerating research and development in the area of neglected infectious diseases, by developing patent pools, open access to data and research tools, and by creating knowledge markets. The second expanded on his foundation's involvement in advancing a number of global financing mechanisms.

28. Two intergovernmental organizations described their respective roles in enhancing the availability and use of patent information, promoting capacity building in the area of intellectual property in developing countries, and stimulating technical cooperation in developing countries by focusing on public health in national and regional workshops.

29. Two nongovernmental organizations highlighted the benefits of technology transfer. One also pointed out that weakening intellectual property rights acted as a disincentive to technology transfer and that local manufacturing alone did not necessarily serve public-health purposes. The second raised the issue of improving support to developing countries so as to enable them to implement the flexibilities contained in TRIPS and to avail themselves of provisions for compulsory licensing, patent pools and prize funds. The adverse impact of exclusive rights to pharmaceutical test data for drug registration in terms of access to medicines and unnecessary human experimentation was also mentioned.

30. From the general discussion it was noted that the Working Group should take account of the need to promote and prioritize research and development focused on products for diseases that disproportionately affected developing countries; to ensure that such products were of guaranteed quality, affordable and accessible within health systems; and to ensure that countries would be able to make full use of the flexibilities built into TRIPS. One delegation, noting that the main objective was to ensure accessibility and affordability of medicines for neglected diseases, pointed out the merit of harmonization in cutting costs and speeding up processes, and suggested inclusion of harmonization as a separate element.

31. The Working Group, reviewing a discussion paper containing the above elements, agreed that it could form part of its report that would serve as a basis for further discussion during the intersessional period, but that should not be used for negotiation.¹ The view was expressed that although it was acceptable to add to the text, nothing should be deleted at the present time, to avoid changing the meaning. Several delegations proposed changes that would more accurately reflect the earlier discussion on the elements and, in some areas, the Commission's recommendations. In particular, delegations drew attention to new text relating to work in progress in WIPO and WTO, pointing out that both WHO and the Working Group should remain focused on health and should not stray into areas that were the purview of other international organizations. Other delegations felt that such

¹ See Agenda item 3, Draft progress report.

concerns were unfounded because neither WIPO nor WTO dealt with intellectual property in the context of its impact on access to affordable medicines and health treatment in developing countries. A possible solution agreed by a number of delegations would be to include a general paragraph indicating that none of the proposed work would duplicate the activities of other organizations.

32. With regard to the reference to “brain drain” in the text, one delegation suggested that, in the interests of clarity, it would be preferable to refer to the migration of health professionals; however, other delegations said that the intention had been to indicate all skilled health workers. The view was expressed that the action plan should place more emphasis on the needs of developing countries where noncommunicable diseases posed a significant challenge. One delegation understood that the focus of the plan of action would be on Type II and III diseases.¹ The importance of explicitly recognizing the contribution of philanthropic organizations in promoting innovation and securing access to medicines was also mentioned. One delegation listed issues to be considered by the Working Group in the future, including exclusivity of test data related to intellectual property, patent linkages, parallel imports, and the strict enforcement of existing flexibilities in intellectual property agreements.

33. One expert observed that the most effective way to combat counterfeit products was to ensure that essential medicines were affordable and available. Work on patent databases needed to be expanded and updated; moreover, information on the patent status of products should provide assistance in overcoming the barriers to access posed by patents.

34. One nongovernmental organization observed that Member States appeared to be reluctant to explore new and possibly more effective mechanisms to stimulate further research and development for neglected diseases, perhaps because they threatened existing systems of intellectual property rights.

35. In the light of the discussion, an explanation was given of WHO’s work in the following areas: the treatment of both communicable and noncommunicable diseases, patent status, and counterfeit products. In response to concern expressed by a Member State over WHO’s efforts to combat counterfeiting, it was emphasized that the most effective approach was to ensure that all medicines in the marketplace were safe and of high quality.

Areas for early implementation

36. In accordance with resolution WHA59.24, paragraph 3(3), the Working Group would give particular attention to potential areas for early implementation. One delegation submitted a list of suggestions based on some of the Commission’s recommendations that might lend themselves to early implementation. Although most of the suggestions were welcomed, several delegations expressed the view that a number of additional recommendations should be taken into account. In response to the proposal that the list of suggestions should be closed at the end of the meeting, one delegation was concerned that because of the limited time available and the large number of oral suggestions that had been made, it would not be possible for the Working Group to consider all the proposals and take a definitive decision on them without having a document containing all the new suggestions to which to

¹ Type II diseases are prevalent in both rich and poor countries, but with a substantial proportion of the cases in poor countries; Type III diseases are those overwhelmingly or exclusively prevalent in developing countries.

refer. It was noted that Member States would be able to offer further views at the 120th session of the Executive Board.¹

Elements of the global strategy

37. The Working Group reviewed a discussion paper containing elements of a global strategy drawn mostly from international instruments, the Commission's report and relevant Health Assembly resolutions.² Although many delegations considered that it constituted a good basis for future work, a number proposed substantial amendments. According to one delegation, reference should have been made to the "brain drain", which had significantly undermined the capacity of developing countries in the health domain. There was also disagreement on the inclusion of a reference to access to medicines as a human right.

38. One expert pointed out the importance of opening up access to compound libraries and the benefits that research on noncommunicable diseases could have for neglected diseases. A second added that the development of products for neglected diseases could be promoted through innovative collaboration between different actors in the public and private sectors.

Agenda item 3 Draft progress report (Document A/PHI/IGWG/1/5)

39. In reviewing its progress report, several delegations stressed that the attribution to Member States of comments and suggested additions in the appendix to Annex 2 of the document was misleading because it did not include a number of countries that had also contributed to the discussion. It was agreed that Member States would be able to make additional comments and suggestions before the end of February 2007. Their input would be posted on WHO's web site, and the names of contributing Member States would be listed. The new information would be compiled with the existing documentation, and a uniform format would be followed throughout. A text, based on the revised document, would be available in July 2007, before the Working Group's second session, and would provide the basis for negotiation.

40. The Working Group adopted its progress report with the above provisions.

Agenda item 4 Closure of the session

41. **Next steps.** The second and final session of the Working Group would be held in Geneva in October/November 2007. In order to benefit from the expertise of some nongovernmental organizations that were not in official relations with WHO, a "fast-track" process, similar to the one employed during negotiations on WHO's Framework Convention on Tobacco Control, would be proposed to the Executive Board to facilitate their participation in the Working Group's next session.

42. Intersessional consultations, including at regional and subregional levels, would be held. Delegations might wish to avail themselves of other opportunities to hold additional consultations.

¹ See document EB120/INF.DOC./1.

² See Agenda item 3, Draft progress report.

ANNEX 1

**OFFICERS OF THE INTERGOVERNMENTAL WORKING GROUP ON
PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY**

Chairman

Mr P. OLDHAM (Canada)

Vice-Chairmen

Mr B. WIJNBERG (Netherlands)
Dr H. GASHUT (Libyan Arab Jamahiriya)
Dr A.E.O. OGWELL (Kenya), *Rapporteur*
Mr JAYA RATNAM (Singapore)
Mr N. DAYAL (India)

Secretary

Mr D. AITKEN, Office of the Director-General

ANNEX 2

**LIST OF PARTICIPANTS
LISTE DES PARTICIPANTS**

**REPRESENTATIVES OF MEMBER STATES
REPRESENTANTS DES ETATS MEMBRES**

ALGERIA – ALGERIE

Chief delegate – Chef de délégation

M. I. Jazaïry
Ambassadeur, Représentant permanent,
Genève

Delegate(s) – Délégué(s)

M. M. Bessedik
Ministre Conseiller, Mission permanente,
Genève

M. E.-H. El Bey
Conseiller diplomatique, Mission permanente,
Genève

Alternate(s) – Suppléant(s)

M. B. Mahi
Secrétaire diplomatique, Mission permanente,
Genève

M. S. Stiti
Secrétaire diplomatique, Mission permanente,
Genève

ANGOLA – ANGOLA

Chief delegate – Chef de délégation

Dr A. do Nascimento
Ambassador, Permanent Representative,
Geneva

Delegate(s) – Délégué(s)

Dr S. Neto de Miranda
Assistant for Health, Permanent Mission,
Geneva

ARGENTINA – ARGENTINE

Chief delegate – Chef de délégation

Sr. A.J. Dumont
Embajador, Representante Permanente,
Ginebra

Delegate(s) – Délégué(s)

Sr. E. Martínez Gondra
Ministro, Representante Permanente Alterno,
Ginebra

Srta. A. de Hoz
Ministro, Misión Permanente, Ginebra

Alternate(s) – Suppléant(s)

Srta. I Fastame
Secretario de Embajada, Misión Permanente,
Ginebra

AUSTRALIA – AUSTRALIE

Chief delegate – Chef de délégation

Ms L. Addison
First Assistant Secretary, Regulatory Policy
and Governance Division, Department of
Health and Ageing

Adviser(s) – Conseiller(s)

Ms R. Lopert
2006-7 Harkness Fellow in Health Care Policy,
Department of Health Policy, George
Washington University

Ms C. McCarthy
Director, International Policy Section, IP
Australia

Mrs T. Brink
Second Secretary, Permanent Mission, Geneva

Mr S. Thom
Second Secretary, Permanent Mission, Geneva

AUSTRIA – AUTRICHE

Chief delegate – Chef de délégation

Ms C. Kokkinakis
Chargée d’Affaires, Minister, Deputy
Permanent Representative, Geneva

Delegate(s) – Délégué(s)

Dr H. Friza
Attaché, Permanent Mission, Geneva

Mrs B. Spiess
Attaché, Permanent Mission to WTO, Geneva

BANGLADESH – BANGLADESH

Chief delegate – Chef de délégation

Dr T. Ali
Ambassador, Permanent Representative,
Geneva

Delegate(s) – Délégué(s)

Mr M.E. Mowla
Counsellor, Permanent Mission, Geneva

Mr N.U. Ahmed
Second Secretary, Permanent Mission, Geneva

BARBADOS – BARBADE

Delegate(s) – Délégué(s)

Ms E. Marcus-Burnett
Counsellor, Permanent Mission, Geneva

BELGIUM – BELGIQUE

Chief delegate – Chef de délégation

M. A. Van Meeuwen
Ambassadeur, Représentant permanent,
Genève

Delegate(s) – Délégué(s)

Mme B. Minart
Représentante permanente adjointe, Genève

Mme L. Meulenbergs
Conseiller, Service des Relations
internationales, Service public fédéral, Santé
publique, Sécurité de la Chaîne alimentaire et
Environnement

Alternate(s) – Suppléant(s)

Mme K. Wouwe
Conseiller, Service public fédéral, Economie

M. A. Delie
Conseiller, Mission permanente, Genève

Dr J. Laruelle
Conseiller, Direction générale de la
Coopération au Développement

M. M. Gerebtzoff
Premier Secrétaire, Mission permanente,
Genève

M. J. de Preter
Premier Secrétaire, Mission permanente,
Genève

Mme M.-H. Timmermans
Attaché principal, Délégation Wallonie-
Bruxelles, Genève

M. D. Maenaut
Délégué du Gouvernement de la Flandre
auprès des Organisations multilatérales,
Genève

M. D. van de Roost
Coordinateur, Institut de Médecine tropicale,
Anvers

BELIZE – BELIZE**Chief delegate – Chef de délégation**

Ms A. Hunt
Chargé d’Affaires, Permanent Mission Genève

Delegate(s) – Délégué(s)

Mr M. Tamasko
Permanent Mission, Geneva

Mr T. Tichy
Permanent Mission, Geneva

BENIN – BENIN**Delegate(s) – Délégué(s)**

M. V. Goyito
Secrétaire général adjoint, Ministère de la Santé

BOLIVIA – BOLIVIE**Chief delegate – Chef de délégation**

Sra. A. Navarro Llanos
Embajadora, Representante Permanente,
Ginebra

Delegate(s) – Délégué(s)

Sra. Z. Rodríguez
Primer Secretario, Misión Permanente,
Ginebra

Sr. F. Rosales Lozada
Primer Secretario, Misión Permanente,
Ginebra

**BOSNIA AND HERZEGOVINA –
BOSNIE-HERZEGOVINE****Chief delegate – Chef de délégation**

Mrs J. Kalmeta
Ambassador, Permanent Representative,
Geneva

Delegate(s) – Délégué(s)

Ms A. Kundurovic
First Secretary, Permanent Mission, Geneva

BOTSWANA – BOTSWANA**Chief delegate – Chef de délégation**

Dr S.V. Tamati
Pharmacist I, Ministry of Health

Delegate(s) – Délégué(s)

Mrs M.S. Matlho
Counsellor, Permanent Mission, Geneva

BRAZIL – BRESIL**Chief delegate – Chef de délégation**

Mr C.A. da Rocha Paranhos
Ambassador, Alternate Permanent
Representative, Geneva

Delegate(s) – Délégué(s)

Mr P. Buss
President, Oswaldo Cruz Foundation

Mr S.L. Bento Alcázar
Minister, Head of Department of International
Affairs, Ministry of Health

Alternate(s) – Suppléant(s)

Mr S. Gaudêncio
Head, Division for Multilateral Affairs,
Ministry of Health

Mr G. Patriota
Counsellor, Permanent Mission, Geneva

Mr R. Estrela de Carvalho
Second Secretary, Permanent Mission, Geneva

Mr C. Berbert
Second Secretary, Permanent Mission, Geneva

BULGARIA – BULGARIE**Delegate(s) – Délégué(s)**

Mrs D. Parusheva
Second Secretary, Permanent Mission, Geneva

BURKINA FASO – BURKINA FASO**Chief delegate – Chef de délégation**

M. B.M. Nébié
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Dirección de Relaciones Económicas
Internacionales, Ministerio de Relaciones
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de la Salud, Ministerio de Salud Pública

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Alternativo, Ginebra

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Ginebra

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Adviser to the Minister of Health and
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Ginebra

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Ministerial Adviser, Health Department,
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Counsellor, Ministry for Foreign Affairs

Alternate(s) – Suppléant(s)

Ms H. Tanhua
Senior Officer, International Affairs Unit,
Ministry of Social Affairs and Health

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First Secretary, Permanent Mission, Geneva

Dr M. Koivusalo
Senior Researcher, Research and Development
Centre for Welfare and Health

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l'OMC, Genève

Alternate(s) – Suppléant(s)

M. G. Delemos
Bureau des Politiques de Santé et de la
Protection sociale,
Direction générale pour la Coopération
internationale et le Développement, Ministère
des Affaires étrangères

Mme I. Virem
Cellule des Affaires européennes et
internationales, Direction générale de la Santé,
Ministère de la Santé et des Solidarités

Mme G. Bonnin
Bureau des Relations internationales,
Délégation aux Affaires européennes et
internationales, Ministère de la Santé et des
Solidarités

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Genève

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Conseiller, Mission permanente, Genève

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Deputy Head of Unit, Multilateral Cooperation
in the Field of Health, Federal Ministry of
Health, Bonn

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Officer, Multilateral Cooperation in the Field
of Health, Federal Ministry of Health

Mr J. Tillmanns
Officer, Patent Law and Intellectual Property
Rights, Federal Ministry of Justice

Adviser(s) – Conseiller(s)

Mr A. Lemmer
Officer, International Pharmaceutical
Questions, Federal Ministry of Health, Bonn

Mr M. Hauschild
Counsellor, Permanent Mission, Geneva

Mrs A. Kratzer
Officer, Multilateral Cooperation in the Field
of Health, Federal Ministry of Health, Bonn

Mr C. Schreiner
Officer, Multilateral Cooperation in the Field
of Health, Federal Ministry of Health, Bonn

Mr J.P. Eckendorf
Adviser on Health, Permanent Mission,
Geneva

Mr A.D. Ernert
Permanent Mission, Geneva

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Geneva

Deputy chief delegate – Chef adjoint de la délégation

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Chief Director, Ministry of Health

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Dr G. Amofa
Director, Public Health, Ministry of Health

Alternate(s) – Suppléant(s)

Mr E.K. Agyarko
Chief Executive Officer, Ghana Food and
Drugs Board

Professeur L.K.N.A. Okine
Director, Centre for Scientific Research into
Plant Medicine

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Geneva

Deputy chief delegate – Chef adjoint de la délégation

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Geneva

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Ms A. Damigou
Counsellor (Health Affairs), Permanent
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Embajador, Representante Permanente,
Ginebra

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Ginebra

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Conseiller (Affaires sociales et humanitaires),
Mission permanente, Genève

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Secretary, Ministry of Health and Family
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Director General, Indian Council of Medical
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Geneva

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Ambassador, Deputy Permanent
Representative, Geneva

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Adviser to the Deputy Minister for Food and
Drug

Mr A. Nasim Far
Expert, Ministry of Foreign Affairs

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Counsellor, Permanent Mission, Geneva

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Second Counsellor, Permanent Mission,
Geneva

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Geneva

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Deputy Director General for Regulation of
Health Care Organizations, Ministry of Health

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Genève

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Bureau des Rapports internationaux, Ministère
de la Santé

Mme V. Fossa
Dirigeant administratif, Evaluation des
Médicaments et Vigilance pharmacologique,
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Director, Multilateral Policy Office,
International Affairs Division,
General Administration Department, Japan
Patent Office

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Deputy Director, International Cooperation
Office, Minister's Secretariat, Ministry of
Health, Labour and Welfare

Mr S. Sasago
Deputy Director, Economic Affairs Division,
Health Policy Bureau,
Ministry of Health, Labour and Welfare

Mr Y. Nakaya
Deputy Director, Multilateral Policy Office,
International Affairs Division, General
Administration Department, Japan Patent
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Administration

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Counsellor (Medical), Permanent Mission,
Geneva

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Dr A.E.O. Ogwel
Head, Office for International Health
Relations, Ministry of Health

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Geneva

Dr J. Mukabi
Personal Assistant to the Director of Medical
Services, Ministry of Health

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 Médicament et de la Pharmacie, Ministère de
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Mr H. Andreassen
 Senior Adviser, Ministry of Foreign Affairs

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 Social and Health Issues

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Adjunta, Ginebra

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Alternativo, Ginebra

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Ginebra

Sr. A. Neyra
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Ginebra

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Chief Expert, Drug Policy and Pharmacy
Department, Ministry of Health

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Institut National Pharmacie et Médicaments

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Institut Ricardo Jorge

M. J. Sousa Fialho
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Ms Kim Sun-young
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Ministry of Health

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Geneva

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Dr C. Rodica
Director General, Ministry of Health

Alternate(s) – Suppléant(s)

Mrs M.L. Georgescu
Senior Patent Examiner, Deputy Head,
Chemistry-Pharmacy Examining Division,
Romanian State Office for Inventions and
Trademarks

Adviser(s) – Conseiller(s)

Ms L. Puscaragiu
Second Secretary, Permanent Mission, Geneva

Mr F. Pironea
Second Secretary, Permanent Mission, Geneva

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Dr E.A. Varavikova
Deputy Chief, Division for International Cooperation, Department for International Cooperation and Public Relations, Ministry of Health and Social Development

Deputy chief delegate – Chef adjoint de la délégation

Mr V.M. Zimyanin
Senior Counsellor, Permanent Mission, Geneva

Delegate(s) – Délégué(s)

Dr N.G. Kurarova
Senior Researcher, Federal Public Health Institute, Ministry of Health and Social Development

Alternate(s) – Suppléant(s)

Dr A.V. Pavlov
Counsellor, Permanent Mission, Geneva

Adviser(s) – Conseiller(s)

Mr L.V. Kulikov
First Secretary, Permanent Mission, Geneva

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Mrs P. Toelupe
Chief Executive Officer, Ministry of Health

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Ambassadeur, Représentant permanent, Genève

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Ministre Conseiller, Mission permanente, Genève

M. M. Seck
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Chargé d'Affaires a.i., Deputy Permanent Representative, Permanent Mission, Geneva

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First Secretary, Permanent Mission, Geneva

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First Secretary, Permanent Mission, Geneva

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Mr I. Jukic
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Ambassador, Permanent Representative,
Geneva

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Counsellor (Health), Permanent Mission,
Geneva

Ms P. Netshidzivhani
Director, Health Research, Department of
Health

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Mr S. Qobo
First Secretary (Economic Development),
Permanent Mission,
Geneva

Mr S. Sooklal
Counsellor (Trade), Permanent Mission,
Geneva

Ms T. Mlangeni
Counsellor (Trade), Permanent Mission,
Geneva

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Sr. J.A. March Pujol
Embajador, Representante Permanente,
Ginebra

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Sr. G. López Mac-Lellan
Consejero, Misión Permanente, Ginebra

Sra. M.J. Guilló Izquierdo
Consejera Técnica, Dirección General de
Farmacia y Productos Sanitarios, Ministerio de
Sanidad y Consumo

Alternate(s) – Suppléant(s)

Sra. I. Lombardero Lasarte
Técnico Superior, Subdirección General de
Programas Internacionales de Investigación y
Relaciones Institucionales,
Instituto de Salud Carlos III

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ACCORDANCE WITH RESOLUTION
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