WORLD TRADE ORGANIZATION

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Council for Trade-Related Aspects of Intellectual Property Rights

ANNUAL REVIEW OF THE DECISION ON THE IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Report to the General Council

1. Paragraph 8 of the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health of 30 August 2003 (the "2003 Decision") provides that the Council for TRIPS shall review annually the functioning of the System set out in the Decision with a view to ensuring its effective operation and shall annually report on its operation to the General Council. This review is deemed to fulfil the review requirements of Article IX:4 of the WTO Agreement.

2. The sixth annual review took place in October 2009 and the General Council took note of the report of the Council for TRIPS (IP/C/53) at its meeting on 17 December 2009 (WT/GC/M/124, paragraph 178). The present report covers the period since October 2009.

3. At its meeting of 8-9 June 2010, the Council for TRIPS agreed to set aside the second day of its meeting of 26-27 October for the annual review. The Annex to this report records the statements made in the review at the October meeting. The paragraphs below set out factual information regarding the implementation and use of the 2003 Decision, discussions on the operation of the System and the acceptance of the Protocol Amending the TRIPS Agreement.

1. Information on implementation and use of the System established under the Decision

4. The following Members have formally notified the Council for TRIPS of the relevant changes to their domestic legal regime in order to implement the 2003 Decision:

- Norway (see explanatory note in IP/C/W/427): Amendments to the Patent Act of 15 December 1967 No.9 and to Patent Regulations of 20 December 1996 No.1162 provide the legal basis to act as an exporting Member;

- Canada (IP/N/1/CAN/P/5-7; see also explanatory note in IP/C/W/464): Amendments to Patent Act and Food and Drugs Act, as well as the Use of Patented Products for International Humanitarian Purposes Regulations provide the legal basis to act as an exporting Member;

- India (IP/N/1/IND/P/2): the Patents (Amendment) Act 2005 provides the legal basis to act as an exporting Member;

- European Communities[1] (IP/N/1/EEC/P/5): Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems provides the legal basis for EU Member States to grant compulsory licences for export of patented medicines;

- Hong Kong, China (IP/N/1/HKG/P/1/Add.6; see also background information in IP/N/1/HKG/17): the Patents (Amendment) Ordinance No.21 of 2007 provides the legal basis to act as exporting Member, as well as importing Member in situations of extreme urgency;

- Switzerland (IP/N/1/CHE/P/9 and IP/N/1/CHE/4): the consolidated version of the Federal Law on Patents for Inventions of 1 July 2008 and the Ordinance on Patents for Invention provide the legal basis to act as an exporting Member;

- Philippines (IP/N/1/PHL/I/10): Republic Act No. 9502 (also known as the "Universally Accessible Cheaper and Quality Medicines Act 2008") and the Implementing Rules and Regulations of Republic Act No. 9502 provide the legal basis for the grant of a special compulsory licence for the import of patented drugs and medicines, as well as for their manufacture and export;

- Singapore (IP/N/1/SGP/P/1/Rev.1): the Patents Act 2005 Revised Edition provides the legal basis to act as an importing Member in situations of national emergency or other circumstances of extreme urgency;

- Albania (IP/N/1/ALB/I/2): Law No.9947 of 7 July 2008 on Industrial Property provides the legal basis to act as an exporting Member;

- Croatia (to be circulated as IP/N/1/HRV/P/2): the Act on Amending the Patent Act of 2009 provides the legal basis to act as an exporting Member; and

- China (to be circulated as IP/N/1/CHN/P/2): the amendment to the Patent Law of the People's Republic of China, which was adopted on 27 December 2008 and entered into force on 1 October 2009, provides the legal basis to act as an exporting Member, as well as an importing Member in situations of national emergency or other circumstances of extreme urgency, or if public interest so requires.

5. On 17 July 2007, the delegation of Rwanda submitted a notification under paragraph 2(a) of the Decision, informing the Council for TRIPS of its intention to import a pharmaceutical product from Canada under the System (IP/N/9/RWA/1). On 4 October 2007, the delegation of Canada notified the Council for TRIPS in accordance with paragraph 2(c) of the Decision that it had authorized the manufacturing and export of the pharmaceutical product concerned to meet Rwanda's

[1] On 1 December 2009, the Treaty of Lisbon amending the *Treaty on European Union and the Treaty establishing the European Community* (done at Lisbon, 13 December 2007) entered into force. On 29 November 2009, the WTO received a Verbal Note (WT/L/779) from the Council of the European Union and the Commission of the European Communities stating that, by virtue of the *Treaty of Lisbon*, as of 1 December 2009, the European Union replaces and succeeds the European Community.

needs (IP/N/10/CAN/1). No notifications have been made to the Council for TRIPS of the intention to use the System as an importer pursuant to paragraph 1(b) of the Decision.[2]

6. Detailed information on the use of the System by Canada to ship a fixed-dose combination medicine for the treatment of HIV infection to Rwanda was provided by the delegation of Canada to the Council for TRIPS at its meeting on 2 March 2010 (IP/C/M/62, paragraphs 185-195; for more details see also the Communication from the delegation of Canada, IP/C/W/526, as well as reports in earlier annual reviews IP/C/53, paragraph 6; IP/C/49, paragraph 6; and IP/C/46, paragraphs 4-5).

7. As foreseen in the 2003 Decision, the Secretariat regularly updates a page on the WTO website dedicated to this Decision, notably to ensure the public availability of notifications made pursuant to it (http://www.wto.org/English/tratop_e/public_health_e.htm).

2. Discussion on the operation of the System established under the Decision

8. In line with the decision taken by the Council for TRIPS at its annual review in October 2009, the Chair held a round of informal consultations on the operation of the System on 12 February 2010. The Chair reported on the outcome of those consultations under the agenda item "Other Business" at the Council's formal meeting on 2 March 2010 (IP/C/M/62, paragraphs 168-175). Subsequent discussions confirmed Members' readiness to share experiences on the use of the System and to engage in practical fact-based discussions in order to have a full understanding of its functioning (IP/C/M/62, paragraphs 176-212). Members stated their substantive positions concerning the operation and review of the System. Some delegations expressed concern that the System had only been used once since 2003 and that it had taken some three years to deliver the medicines from Canada to Rwanda in this context. They also noted that only a limited number of Members had accepted the Protocol Amending the TRIPS Agreement (see the list of notified acceptances in Section 3 below). The delegation of Canada shared its experience in using the System, including a detailed timeline of events which, in its view, demonstrated the fact that Canada's Access to Medicines Regime (CAMR) had been successfully utilized and only a very small portion of the three year time period had been taken up by procedures associated with this regime. It said that much of the time that had elapsed between the regulatory review of the medicine in question and the shipment to Rwanda could be attributed to other variables. Other delegations noted that the limited use of the System so far was not an appropriate measure of its success. Its use in one case had demonstrated that it could work effectively and that the System could play a supportive role in the wider effort to improve access to essential medicines.

9. Various issues were suggested for further discussion, but no agreement could be reached on the appropriate format for such discussions, beyond the existing review process within the Council for TRIPS. While agreeing that annual reviews constituted a good platform for sharing experiences and evaluating the operation of the System, some delegations proposed that the reviews could be usefully complemented by a dedicated workshop to allow for an in-depth study of any potential obstacles to the System's effective and expeditious operation. In order to gather information on all aspects and concerns, the workshop should be open to all relevant stakeholders, including non-governmental organizations, pharmaceutical industry and other experts. Other delegations considered that the review process was a Member-driven process. It already offered a platform to share experiences and to examine the System's functioning, and the initial focus should be on Members reporting directly on their experience, positive or negative, with the System. While the usefulness of the existing review process could be enhanced, including through more factual input, there was therefore no need to open

[2] Least developed country Members automatically qualify as "eligible importing Member" under the System and are therefore exempted from notifying the Council for TRIPS of their intention to use the System as importers.

a new process. Given that at the March meeting the matter was raised under the agenda item "Other Business", the Council limited itself to taking note of the statements made.

10. At the request of the delegations of Brazil, China, Cuba, Ecuador, India, Indonesia, Peru and Venezuela, an item on "Implementation of Paragraph 6 System" was put on the agenda of the Council's meeting on 8-9 June 2010. The Chair reported on the consultations he had held with interested delegations on how best to proceed with the preparations of the next annual review at the Council's meeting in October. In subsequent discussions, delegations reiterated their positions regarding the format of future work in this area (IP/C/M/63, paragraphs 184-247). While no consensus could be reached on any complementary process, the Council agreed to set aside the second day of its meeting in October for the annual review to enable a special focus on the issue, with possible involvement of health experts on national delegations.

3. Decision on the Amendment to the TRIPS Agreement

11. As called for in paragraph 11 of the 2003 Decision, the General Council adopted a Protocol Amending the TRIPS Agreement, by a Decision of 6 December 2005 (WT/L/641). The Protocol is open for acceptance by Members until 31 December 2011 or such later date as may be decided by the Ministerial Conference (WT/L/785). In accordance with Article X:3 of the WTO Agreement, the Protocol will enter into force upon acceptance by two thirds of the WTO Members.

12. As of 30 September 2010, the following Members have notified their acceptance:

- United States, 17 December 2005, WT/Let/506;
- Switzerland, 13 September 2006, WT/Let/547;
- El Salvador, 19 September 2006, WT/Let/548;
- Republic of Korea, 24 January 2007, WT/Let/558;
- Norway, 5 February 2007, WT/Let/563;
- India, 26 March 2007, WT/Let/572;
- Philippines, 30 March 2007, WT/Let/573;
- Israel, 10 August 2007, WT/Let/582;
- Japan, 31 August 2007, WT/Let/592;
- Australia, 12 September 2007, WT/Let/593;
- Singapore, 28 September 2007, WT/Let/594;
- Hong Kong, China, 27 November 2007, WT/Let/606;
- China, People's Republic of, 28 November 2007, WT/Let/607;

- European Communities[3], 30 November 2007, WT/Let/608;
- Mauritius, 16 April 2008, WT/Let/619;
- Egypt, 18 April 2008, WT/Let/617;
- Mexico, 23 May 2008, WT/Let/620;
- Jordan, 6 August 2008,WT/Let/630;
- Brazil, 13 November 2008, WT/Let/636;
- Morocco, 2 December 2008, WT/Let/638;
- Albania, 28 January 2009, WT/Let/639;
- Macao, China, 16 June 2009, WT/Let/645;
- Canada, 16 June 2009, WT/Let/646;
- Bahrain, 4 August 2009, WT/Let/652;
- Colombia, 7 August 2009, WT/Let/650;
- Zambia, 10 August 2009, WT/Let/651;
- Nicaragua, 25 January 2010, WT/Let/663;
- Pakistan, 8 February 2010, WT/Let/664;
- Former Yugoslav Republic of Macedonia, 16 March 2010, WT/Let/671;
- Uganda, 12 July 2010, WT/Let/678; and
- Mongolia, 17 September 2010, WT/Let/684.

Information on the status of acceptances of the Protocol is periodically updated in revisions of document IP/C/W/490.

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[3] The text of the instrument of acceptance reads as follows:

"THE PRESIDENT OF THE COUNCIL OF THE EUROPEAN UNION,

HAVING regard to the Treaty establishing the European Community, and in particular Article 133(5) in conjunction with the first sentence of the first subparagraph of Article 300(2) and the second subparagraph of Article 300(3) thereof,

NOTIFIES by these presents the acceptance, by the European Community, of the Protocol amending the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), done at Geneva on 6 December 2005,

CONFIRMS, in accordance with Article 300(7) of the Treaty establishing the European Community, that the Protocol will be binding on the Member States of the European Union.

The Secretary-General/High Representative — The President of the Council of the European Union"

ANNEX

Excerpt from the Minutes of the Council's meeting
of 26-27 October 2010 to be circulated as IP/C/M/64[1]

F. REVIEW UNDER PARAGRAPH 8 OF THE DECISION ON THE IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

1. The Chairman recalled that, at its meeting of 8-9 June 2010, the Council for TRIPS had agreed to set aside the second day of the present meeting for the annual review under paragraph 8 of the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health ("the Decision"). In preparation of the review, he had held consultations with a number of Members on how to structure the Council's discussion in order to make the review as useful as possible. In the light of those consultations, he had faxed a list of topics for discussion in the annual review to delegations on 11 October.

2. He further recalled that paragraph 8 of the Decision provided that the Council for TRIPS should annually review the functioning of the System set out in the Decision ("the System") with a view to ensuring its effective operation and report on its operation to the General Council. Furthermore, the paragraph provided that this review should be deemed to fulfil the review requirements of Article IX:4 of the WTO Agreement.

3. He said that the Secretariat had circulated a draft cover note for the Council's report modelled on previous years' reports (JOB/IP/1). This document contained factual information on the implementation and use of the System established under the Decision, on discussions held earlier in the year regarding its operation, and on the acceptance of the Protocol Amending the TRIPS Agreement. In accordance with the way that the Council had prepared its reports in previous years, the part of the minutes of the meeting reflecting the discussions held under this agenda item would be attached to the cover note as an annex.

4. With respect to the status of acceptances of the Protocol Amending the TRIPS Agreement that was done at Geneva on 6 December 2005, the Chairman said that, since the Council's meeting in June 2010, Uganda and Mongolia had notified their acceptance of the Protocol on 12 July and 17 September (documents WT/Let/678 and WT/Let/684, respectively). So far 31 notifications of acceptance of the Protocol, including from the European Communities, had been received. The Secretariat had also circulated an update to the note on the status of acceptances of the Protocol (IP/C/W/490/Rev.7) which it would continue to update periodically. The Protocol would enter into force for the Members that had accepted it upon acceptance of the Protocol by two thirds of the Members. The Protocol was open for acceptance by Members until 31 December 2011 or such later date as might be decided by the Ministerial Conference.

5. He said that he had prepared the list of topics for discussion in the annual review in the light of consultations he had held with a number of Members. He had made every effort to ensure that there were appropriate headings under which all the topics delegations had mentioned could adequately be discussed. It was his hope that this way of structuring the discussion would ensure that the Council would have a productive and useful discussion of the System that would help it better understand its operation and any concerns related to it. Bearing in mind that Members had expressed interest in making the review as useful and productive as possible, he had encouraged them in the cover note to the fax to make introductory presentations under topics 1, 2 and 5. He expressed his

[1] The paragraph numbering of this excerpt will not correspond with that of the minutes of the TRIPS Council but has been included for the convenience of users.

appreciation to those delegations that had volunteered to make introductory remarks under various headings, and also thanked the secretariats of UNCTAD, the WHO and WIPO, as well as of the WTO, for their willingness to contribute to the discussion.

1. Experience of Members who have used or considered using the system

6. The Chairman said that, in the Council's earlier discussions and his own consultations, Members had expressed an interest in hearing about the experience in the case of export of medicines from Canada to Rwanda, and also about the experience of any other Members who might have considered using the System as potential importers or exporters and reasons why the System had not been used. In particular, Members had indicated that they wished to better understand any obstacles or concerns about notifying their needs to the WTO, as well as any other obstacles or concerns faced by Members.

7. The representative of Canada recalled that the 2003 WTO Decision on TRIPS and Public Health was an intensely negotiated decision that had garnered unanimous support from all WTO Members. His delegation was very pleased with this historic and multilateral solution. It had implemented its Access to Medicines Regime (CAMR) in 2005 to facilitate the export of affordable generic drugs to developing countries. It had also been the first, and to date only, WTO Member to ship generic medicines under the waiver. An HIV antiretroviral drug – Apo-TriAvir – had been sent to Rwanda in two shipments by the Canadian pharmaceutical company Apotex Inc. in September 2008 and 2009. This example clearly showed that Canada's regime and the System were efficient, effective and timely.

8. He said that, in the Apotex-Rwanda example, the role of the Government of Canada and CAMR had been very limited in the overall process. This process could be divided into three components: first, the issuance of an export authorization under CAMR; second, Apotex's role; and third, Rwanda's own domestic requirements.

9. Apotex had undertaken to develop Apo-TriAvir, a new triple combination HIV/AIDS drug, before any recipient country had been identified, and had sought Health Canada's safety and efficiency review of the drug, as per CAMR's requirement. In December 2005, Health Canada had received a submission from Apotex to manufacture Apo-TriAvir. No recipient importing country had been identified at that point in time. In June 2006, Health Canada completed its review of Apotex's Apo-TriAvir submission, less than six months after it had been received, although CAMR would allow for a time-period of 12 months.

10. After an eligible importing Member had identified its needs to the WTO, the CAMR process was completed in just over two months, starting with a request for voluntary licences and ending with the granting of the export authorization by means of a compulsory licence. On 13 July 2007, Apotex had sent letters to three pharmaceutical companies, namely GlaxoSmithKline, Boehringer Ingelheim and Shire BioChem Inc., seeking voluntary licences to use their relevant patents to produce and export 15,600,000 tablets of Apo-TriAvir to Rwanda.

11. On 19 July 2007, Rwanda had notified the WTO of its intention to import 15,600,000 tablets of Apo-TriAvir under the waiver (IP/N/9/RWA/1). On 4 September 2007, Apotex had filed an application with the Commissioner of Patents for authorization under CAMR to produce and export Apo-TriAvir to Rwanda. On 19 September 2007, 15 days after receiving the application from Apotex, Canada's Commissioner of Patents had granted Apotex an authorization to produce and export Apo-TriAvir under CAMR. Once such authorization had been given, the role of the Canadian Government and CAMR in the process had been substantively complete. On 4 October 2007, Canada had notified the WTO of the first authorization issued under the Waiver (IP/N/10/CAN/1).

12. In October 2007, Rwanda had opened a public tender for the supply of Apo-TriAvir. In May 2008, Apotex announced that it had won the Rwanda public tender to supply Apo-TriAvir. Apo-TriAvir had been manufactured by Apotex in May-September 2008, and in September 2008 Apotex had sent its first shipment of 6,785,000 tablets to Rwanda, followed by the second shipment of 7,628,000 tablets in September 2009, completing the country's order.

13. The representative of Canada said that in the Apotex-Rwanda case, CAMR represented a small part of the more than two years which had lapsed between the WTO notification by Rwanda and the final shipment by Apotex. The shipments of Apo-TriAvir to Rwanda had occurred within the timelines specified in the export authorization that had been granted by the Canadian Commissioner of Patents. To evaluate CAMR and the System, it was necessary to return to the basic premises. The purpose of the System and domestic implementation mechanisms, such as CAMR, was to ensure that TRIPS and patent rules did not prevent exports for humanitarian purposes of more affordable generic medicines to those countries that did not have manufacturing capacities.

14. Taking into account his delegation's experience, he concluded that CAMR or any similar exporting regime that a WTO Member implemented under the Waiver could only assist in supplying low-cost drugs if a demand was notified to the WTO by an eligible importing Member for generic drug(s) that required use of the System. This was a demand-driven process by countries in need, and only applied to instances where countries were seeking generic versions of patented drugs. He noted that, since the adoption of the Decision in 2003, many options had become available to importing countries. The international environment for procurement of drugs had changed significantly with the introduction of a variety of global mechanisms and alliances which offered greater choice to countries to obtain medicines. The role and effectiveness as well as the potential for broader use of the Waiver needed to be understood in this broad global context.

15. He said that the System had never been intended to solve the issue of access to medicines on its own, but was seen as part of a broader international strategy to combat diseases impacting the developing world. The System and CAMR functioned well. They played a supporting role and were not a panacea to the challenges faced on global access to medicines and were not designed to generate global supply.

16. The representative of India presented some examples of cases in which there had been an attempt to use the Paragraph 6 System. In September 2007, three applications under Section 92A of the Patents Act 1970 had been received for the grant of a compulsory licence for the manufacture and export of patented drugs to a least developed country in Asia. After the process envisaged under the Act had been initiated, the applicant had subsequently withdrawn the applications. This had apparently been caused by the non-availability of the corresponding compulsory licences or notifications from the importing country. His delegation had delved deeper into the reasons for the withdrawal and had discovered that one of the reasons was the additional burden of compliance with the conditions in paragraphs 2(a), (b) and (c) of the WTO Decision, which included the notification requirements and anti-diversion measures. He wondered why such notification requirements were needed when they were not needed for a routine compulsory licence. Moreover, the detailed requirements for suppliers to distinguish products produced under the System, such as pill colouring, labeling and website tracking did not only seem costly and time-consuming but were also a disincentive for generic producers.

17. The System required notification to the WTO of both the quantity of the pharmaceutical products to be manufactured and the period of supply. He said that ideally, when the quantity was specified, it should not be necessary to restrict the period of supply, which would depend on a number of factors related to manufacture of medicines, quantity of shipment and trade. If an additional quantity was required, the process had to be initiated again, which was time-consuming.

18. He also reported that in 2004, the Doctors Without Borders (Médecins Sans Frontières, MSF) had attempted to place an order with the Canadian company Apotex for a fixed-dose combination drug, but had found it too cumbersome and, after trying in vain for two years, had procured the generic version of the same fixed-dose combination drug, which had been WHO pre-qualified and reasonably priced, from two Indian generic companies.

19. The representative of Brazil said that her country had not tried to use the System either as an importer or an exporter. In 2007, following a case of abuse of price, a compulsory licence had been issued for an anti-retroviral medicine called Efavirenz that was part of the cocktail of drugs freely distributed by the Ministry of Health to HIV/AIDS patients. For a number of reasons, including lack of sufficient disclosure in the patents description, it had taken two years for the Oswaldo Cruz Foundation, an international reference institution in medical research in her country, to be able to produce the medicine. During this time, Brazil had imported the medicine from a supplier in India.

20. The representative of the United States asked whether Canada had carried out any activities to promote the waiver process and/or CAMR to potential importing countries and asked it to share any experiences in this regard.

21. The representative of India asked the delegation of Canada how much time it would take for CAMR processes to be completed the next time a request was submitted by a least developed country, counting from the receipt of the request, taking into account the voluntary licence process, and ending with the grant of an export authorization. Furthermore, his delegation's understanding was that the list of products for which a compulsory licence could be issued was set out in Schedule 1 of Canada's amended Patent Act which did not cover the full scope of products envisaged by the Decision. He asked whether this meant that the Decision could not be entirely implemented under Canadian law. He also inquired as to the status of Bill C-393 to amend CAMR, and the issues which were under consideration and whether the amendment would completely address the limitations of CAMR. As the Decision was sufficiently detailed, he asked why it was considered necessary to impose additional qualifications, such as the limited list of medicines, the approval required from Health Canada, a two-year limit on compulsory licensing and the list of eligible countries.

22. According to his information, Ghana had expressed an interest in 2005 in using CAMR in collaboration with two Canadian NGOs to import generics both for itself and as a regional importer for the ECOWAS countries. It had even issued a regular compulsory licence in 2005. He asked whether Canada could share any experience as to why the effort had not fructified.

23. The representative of Malaysia asked the delegation of Canada to clarify whether the fourth event on the timeline outlined by it, i.e. the review of the Apotex submission, referred to the review of the safety and efficacy of the drug and, if so, whether Apotex had generated its own clinical data when submitting the application or whether it had relied on the data submitted by the patent owner.

24. The representative of Angola, speaking on behalf of the LDC Group, said that the adoption of the Decision of 6 December 2005 to amend the TRIPS Agreement in order to respond to difficulties experienced by countries with no or insufficient manufacturing capacity was an important milestone. However, five years had elapsed since this Decision had been adopted, and few Members had deposited instruments of acceptance of the Protocol Amending the TRIPS Agreement. It was important to establish why countries were not coming forward so that collective measures could be taken. The LDC Group welcomed the informal consultations undertaken by the Chairman in September and October 2010 to facilitate dialogue between Members on the opportunity to hold a workshop on the implementation of the System. This could help to get a sense of where impediments lay with regard to the acceptance process and how the removal of such impediments could be facilitated including through expedited acceptance of the amendment by individual Members. Issues related to the acceptance of the TRIPS amendment could also be incorporated into the national and

regional technical assistance and capacity-building activities undertaken by the WTO Secretariat. He noted that the list of topics circulated by the Chairman had been prepared through the consultation process to facilitate the annual review under Paragraph 8 of the Decision. The sharing of experiences and views on the System would enable Members to have clarity on how the System could be meaningfully used and where obstacles lay. Information on alternatives to the System would also be a valuable resource for the LDC Group.

25. The representative of New Zealand said that his delegation's interest in this issue was largely systemic as it did not have significant manufacturing capacity of either brand name or generic pharmaceuticals. He strongly supported the principles that underpinned the Declaration on the TRIPS Agreement and Public Health. He noted that Canada had emphasized that the system was demand-driven and that one year had passed between the authorization by Health Canada and the request by Rwanda. He asked the delegation of Canada why there had been such a delay. He wondered whether Health Canada had done anything to advertise the system to potential applicants, whether any other requests had been received, and whether there were countries that were excluded from eligibility under CAMR. With respect to the reported three applications made under India's legislation implementing the System that were subsequently withdrawn, he requested the delegation of India or the least developed country involved to share more details of their experience.

26. The representative of Venezuela asked why Canada had established CAMR. He noted that the delegation of Canada had said that the System had not been created to resolve the problem of access to medicines in developing countries. He said that, in his view, access to medicines had become worse with the promulgation of the TRIPS Agreement. He asked the delegation of Canada what the intention of the General Council had then been in adopting the System.

27. The representative of Egypt supported the review of the Decision, as well as the proposal by a number of delegations to hold a dedicated workshop in order to facilitate the discussion of the issues arising under the System, including the lack of its use and the limited acceptance of the Protocol. The participation of relevant stakeholders could help to achieve this goal. When the African Group had brought the critical issue of access to medicines to the Council for TRIPS in 2001, this had been an attempt to target an important public health problem. Over the years since then, Members had engaged in laborious work on consulting and discussing draft language as a way out of this critical public health crisis. When the Decision had been reached in 2003, his delegation had hoped that this problem had been resolved. It had notified its acceptance of the Protocol Amending the TRIPS Agreement in 2008, in the belief that it was expedient to do so to provide room for a solution to the urgent public health needs and that Egypt would be able to provide urgently needed medicines to countries in need. His delegation had anticipated itself as both potential beneficiary and supplier under the System. However, the System had not been as helpful as hoped in addressing this critical public health problem. The fact that it had only been used once raised questions as to its effectiveness, let alone expeditiousness. Likewise, the frail drive to accept the amendment Protocol was incomprehensible in its own right. The administrative and regulatory complexity of the system, the lack of appreciation of business methods in supplying markets and associated overhead costs, as well as constraining requirements, would merit further discussion.

28. Canada's experience as one of the two Members having used the System was important in shedding light on the issues. The representative of Egypt put a number of questions to the delegation of Canada. Firstly, in the light of its own experience, did Canada consider the System to be an expeditious solution? Secondly, as part of CAMR's reform process, was the possibility of issuing one compulsory licence for several countries in order to avoid duplication and time lags considered? Thirdly, could the delegation of Canada share any information on the experience of Apotex in seeking a voluntary licence prior to applying for a compulsory licence? Fourthly, to what extent had the anti-diversion measures been onerous on Apotex? He noted that paragraph 7 of the Decision stated that "Members recognize the desirability of promoting the transfer of technology and capacity building in

the pharmaceutical sector in order to overcome the problem identified in paragraph 6 of the Declaration. To this end, eligible importing Members and exporting Members are encouraged to use the system set out in this Decision in a way which would promote this objective..." He asked to what extent CAMR was promoting the objective of transfer of technology as enshrined in paragraph 7 of the Decision.

29. The representative of Brazil noted that, according to the delegation of Canada, Apotex had decided to produce the antiretroviral Apo-TriAvir before there had been a request from any country. Even when Rwanda had identified itself as a potential importer, Apotex still had to go through the process of government procurement with other companies. She asked what the economic incentives had been for Apotex to engage in this process and why it had not attempted to repeat this experience with other countries.

30. The representative of Argentina supported the holding of an open-ended workshop or any other initiative with the objective of evaluating the functioning of the System.

31. The representative of Switzerland considered that the attempt by the MSF to procure generic medicines from Apotex was an important case, and said that it would be useful to know why the attempt had failed. The information available seemed to indicate that price had been the issue between MSF and the potential generic manufacturer. In his view, the price offered by generic manufacturers could not be influenced by the System itself. The challenge was to find the most competitive and thus most affordable price under such a scheme. He asked the delegation of India to provide more detailed information regarding the precise nature of the problem between MSF and Apotex and wondered if the delegation of Canada also had additional information on this particular case.

32. The representative of Indonesia noted that the delegation of Canada had presented the use of the System as effective. However, the use of the System had only been able to help 21,000 patients in Rwanda. He inquired whether the number of patients in need of HIV/AIDS treatment had been increasing at that time and what would have happened if Rwanda had wished to import a greater amount of Apo-TriAvir, i.e. whether it would have had to start the process again from scratch. The utilization of the System was not as easy and expeditious as his delegation had thought. He asked what the situation would be if, due to a miscalculation, further disasters or other reasons, there were a call for more medicines after the licence had been issued. Starting from scratch would require more time and would not fulfil the intention of the System, which was designed to be an expeditious solution to public health concerns.

33. He quoted a September 2008 statement by Mr. Jack Kay, Apotex President and CEO, who had said that, "if other critical medicines are to go to Africa in a reasonable timeframe, the Federal Government must change the CAMR legislation. CAMR is unworkable as it now stands." This was a signal that CAMR might need to be improved in order to expeditiously serve public health needs. His delegation commended the reform process in Canada. However, a complete review or an overhaul of the System should be considered too, if necessary.

34. The representative of Malaysia asked the delegation of Canada how the royalties had been set for the compulsory licence under CAMR, and how that amount had been calculated. He asked whether the methodology used in determining the amount was different from that used in the case of standard compulsory licences.

35. The representative of the European Union welcomed the full day of discussions, based on experiences and facts rather than on alleged obstacles, and which would enable Members to evaluate the operation of the System. He requested the delegation of India to provide more information about the three applications to which it had referred. He agreed with the delegation of New Zealand that the

conclusions drawn by India with respect to the withdrawal of these applications were not obvious. He asked the delegation of Canada whether it had reviewed CAMR since the Apotex case.

36. The representative of Zimbabwe noted that the delegation of Canada had said that it had only taken 15 days for the compulsory licence to be granted by the Commissioner of Patents under CAMR and that the system was very efficient. However, the domestic process in Canada was not the only issue to be considered, given that the System involved various players including small countries, big countries, big and small industries. For a system to be efficient and suitable and user-friendly for even the smallest players, Members needed to look at the bigger picture.

37. The representative of India said that, in September 2007, three applications for compulsory licences had been received by the Indian company Natco for export to Nepal. Detailed discussions between officials at the Indian patent office, Natco and Nepalese authorities had taken place. He agreed with the delegation of Switzerland that pricing was not covered by the System. He said, however, that, pricing had not been the issue in the MSF case which had tilted the balance in favour of the Indian generic companies.

38. The representative of Canada invited potential importing countries to share specific examples of obstacles or concerns with respect to the use of the System. With respect to the question by the delegation of India concerning the MSF's request for Apo-TriAvir in 2004, he noted that CAMR was a demand-driven process. CAMR would be triggered when the importing country as well as the drug and quantities needed had been identified. In the case involving the MSF, these specific elements had not been provided, so Apotex was not in a position to request even a voluntary licence from the patent holders, nor to request an export authorization from the Commissioner of Patents. The question by the delegation of India about hypothetical future instances of use of CAMR could not be answered without specifics. However, the Rwanda case had shown that CAMR operated efficiently and effectively.

39. With respect to the process to amend CAMR, Bill C-393 was a private member's bill, submitted by an individual, in this case a member of Parliament, which was not sponsored by the Government. As part of the ongoing discussions, the Bill was currently before a parliamentary committee. The standing committee on Industry, Science and Technology was scheduled to report back to the House of Commons by 3 November 2010 for a third reading. The Bill suggested a number of changes with respect to CAMR, including the introduction of a single licence, not restricted in time or quantity. It was also proposed that the anti-diversion measures be removed. His Government viewed those particular changes as inconsistent with the way that Members were supposed to interpret the waiver of 2003.

40. With respect to the question from the delegation of India about Ghana's request in 2005, he noted that his Government had not been involved in the discussions. It was possible that some developing countries, Ghana in particular, had contacted a Canadian generic manufacturer to discuss the possibility of importing medicines from Canada. It would be worth addressing the question to the delegation of Ghana, which could have some additional details to offer, including whether the need expressed by Ghana had been filled. According to his information, an Indian generic firm had been able to satisfy the request. He invited the delegations of Ghana or India to confirm this.

41. Regarding Schedule 1 of CAMR, this was intended to be a flexible list of pre-approved drugs for export that remained current with the needs of developing countries and LDCs. Schedule 1 had been modified twice since CAMR had been implemented, to add a fixed dose combination HIV/AIDS therapy and a drug for the treatment of influenza in the case of a pandemic, i.e. Tamiflu. The Canadian Patent Act had also provided for the creation of an advisory committee prior to May 2008, composed of experts from various health disciplines, to facilitate future amendments to Schedule 1.

42. With respect to the additional elements contained in CAMR, the representative of Canada noted that these were related to the interpretation of the waiver. In his delegation's view, the waiver required a number of conditions to be met: namely, that the importing country was required to notify the WTO of its intent to use the Decision, the licensee was required to request a voluntary licence from the patentee prior to seeking an export authorization under the Decision; the quantity produced under a compulsory licence could not exceed the amount notified; adequate remuneration was required to be paid to the patentee, products shipped, under the agreement should not be diverted to other markets, products were required to be specifically marked and labelled, the licensees were required to post on a website the quantities and features of the product being shipped and the intention was to support humanitarian policy objectives, not commercial ones.

43. In response to the question from the delegation of Malaysia, he said that clinical test data had been provided or generated by Apotex itself by way of proof of bio-equivalence.

44. He noted that the delegation of New Zealand had highlighted the fact that CAMR was a demand-driven process. The time in between the safety and efficacy review of Health Canada and the start of voluntary licence negotiations could be explained by the fact that there had been no specific demand made by a country, thus preventing the process from moving to the next level. In response to the second question by the delegation of New Zealand, he said that no additional requests had been received by the Government of Canada either prior to or subsequent to Rwanda's request. He could not provide any definitive information with respect to discussions that may have occurred between Apotex or other Canadian generic manufacturers and countries and/or NGOs. With respect to the eligibility of countries as potential importing Members, he answered that CAMR went beyond the Decision in that it did not have any restrictions with respect to non-WTO Members. Restrictions would only apply to countries which had voluntarily opted out of the system.

45. With respect to the question from the delegation of the United States as to what had been done to publicize CAMR, he said that, since CAMR had received royal assent in 2004, government officials had made numerous efforts to raise the profile of CAMR both nationally and internationally to promote uptake of the regime by generic manufacturers. These efforts were aimed at both eligible importing countries and their party purchasers such as NGOs. In July 2006, these efforts had been reinforced with the launch of a government website (www.camr-rcam.gc.ca) which served as a manual for interested parties.

46. In turn, he asked what potential importing countries had done to publicize the System within their own countries, specifically through discussions between trade and/or patent officials and health officials, whether at a national level or sub-national level.

47. With respect to the question from the delegation of Venezuela as to why CAMR had been established, he answered that his delegation had felt that it was in a position to make a contribution to access to essential medicines in times of public health emergencies, it had a manufacturing capacity, and it had the political will to undertake the necessary domestic legislative changes to ensure that this happened.

48. In response to the questions asked by the delegation of Egypt, he said that his delegation considered the System to be expeditious. In respect of the experience of Apotex, he noted that his Government had not been a party to those discussions. The CAMR process had only been activated when Rwanda had come forward as a potential importing country in July 2007. The three brand-name companies concerned had either entered into voluntary licence discussions, or had confirmed that they would not contest the issuance of an export authorization within two to three weeks of having been approached by Apotex. Apotex had subsequently applied for an export authorization on 4 September 2007, which was granted two weeks later. While he could not fully answer the question with respect to anti-diversion measures, he did not think that a globally competitive pharmaceutical

company like Apotex had encountered difficulties satisfying the very limited anti-diversion measures that were set out in CAMR.

49. The representative of Canada took up the questions asked by the delegation of Brazil regarding the government procurement process in Rwanda, in particular whether the export of the pharmaceutical product concerned had been of any economic interest to Apotex and whether other brand-name companies had competed with Apotex. He noted that, besides the participation of some Indian generic companies, he had no detailed information regarding any other companies that had participated in the Rwanda tendering process. This question could only be fully answered by Rwanda. Apotex had won the supply contract in May 2008, about eight months after the process had been launched. Price had been a key factor. When creating Apo-TriAvir, Apotex had indicated that it would manufacture and sell a useful made-in-Canada AIDS treatment without profit at its production cost of USD 0.39 per tablet. Apotex had said publicly that this price would be competitive with Indian products. However, from 2006 to 2008, Apotex had not been able to sell at that price due to competition from Indian companies who had been selling their own version of TriAvir. Rwanda had at least four alternatives from Indian generic suppliers which had been in a position to offer a lower price than the one which had been offered through CAMR, which would have made the use of CAMR unnecessary. In 2008, as part of this Rwanda tendering process, Apotex had, however, reduced its price by half to USD 0.195 per tablet. Since Apotex had publicly noted that the price of USD 0.39 per tablet would have enabled it to break even, it could be assumed that the sale at the lower price of USD 0.195 implied a loss in this transaction. By accepting Apotex's new offer, Rwanda had become the first user of the System.

50. In response to the question asked by the delegation of Indonesia, the representative of Canada confirmed that Rwanda would have to start the application process anew if it wished to increase its order. The Rwandan authorities would simply have to follow the same procedures as previously. This process would only take a matter of months, or less compared to the initial case. It would also depend on the Rwandan government procurement process. With respect to the quote from the CEO of Apotex, he said that CAMR did function and was therefore workable.

51. With respect to the question asked by Malaysia about royalties, he said that the royalty rates ranged between 0.02 and 3.5 per cent. Under CAMR, the remuneration to be paid by the licensee to the patentee was calculated by multiplying the monetary value of the supply contract by an amount that fluctuated on the basis of the importing country's standing on the UN Human Development Index. According to this formula, the lowest country on the index would pay a royalty of approximately 0.02 per cent, and the highest country of 3.5 per cent. Where patentees disagreed with the royalty fixed on the basis of this formula, it was possible to apply to the federal court for an order setting a higher amount. This had not been the case as regards Rwanda, where the patent holders had entirely waived the royalty fee.

52. With respect to the question from the delegation of the European Union as to whether Canada had reviewed its regime, the representative of Canada explained that a statutory review was incorporated into CAMR. As one of the first countries to implement the Decision, Canada had found itself addressing many key legal and policy issues regarding the Decision for the first time. The review had sought to ensure that CAMR was meeting its humanitarian objectives to make it easier for poorer countries to obtain cheaper generic versions of patented medicines without derogating from international trade obligations or undermining the intellectual property rights necessary for continuing innovation in Canada. It had provided an opportunity to compare Canada's legislation with that of other jurisdictions which had implemented the Decision in the meantime. Information on the review along with numerous other documents, including a discussion paper and submissions from interested parties, were available on the dedicated website (www.camr-rcam.gc.ca).

53. The representative of Canada agreed with the delegation of Zimbabwe about the need to look at the bigger picture.

54. He asked the delegation of India whether it had any information about a possible partnership between Apotex and the Indian company Ranbaxy Laboratories to export to Liberia the same fixed-dose combination that had been sent to Rwanda a year earlier. He was interested to learn whether a voluntary licence had been secured in this case and whether any shipment had taken place. He further asked whether there were other partnerships between Indian generic pharmaceutical firms and other foreign firms under which essential medicines were exported to developing countries, based on either voluntary or compulsory licences.

55. The representative of India thought that Canada had raised a very important point about partnerships between Indian generic pharmaceutical firms and other foreign firms to provide essential medicines to developing countries. Information regarding the partnership between Apotex and Ranbaxy Laboratories would be provided at the next TRIPS Council meeting. He noted that the question raised by the delegation of Canada had also underscored the importance of participation of relevant pharmaceutical companies in TRIPS Council discussions. This strengthened his delegation's call for a dedicated workshop on the System which would also include relevant pharmaceutical companies and civil society organizations.

56. The representative of Venezuela reiterated his question to the delegation of Canada on what, in its view, the intention of the General Council had been in adopting the System.

57. In response, the representative of Canada said that, in his view, WTO Members had been looking to provide another option for developing countries, in particular LDCs, to access essential medicines by allowing those with manufacturing capacity to export such medicines in an efficient and effective manner. This objective had been achieved through the TRIPS Council's work.

58. The representative of Cuba asked what clinical trials and other methods had been used by Apotex, what test data had been referred to and what kind of quality control had been applied.

59. As regards Venezuela's intervention about the General Council's motivation for adopting the Decision in 2003 and the TRIPS amendment in 2005, the representative of Switzerland recalled that the mandate under paragraph 6 of the Doha Declaration instructed the Council for TRIPS to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face. The mandate had not, and could not possibly have been, to solve the problem of affordable access to medicines for the poor in developing countries through such a solution, although some Members seemed to expect the System to achieve exactly that goal and measured its success by this standard. By this standard, the System was deemed to be a failure. In Doha, Ministers had mandated the TRIPS Council to find a solution which would allow WTO Members without manufacturing capacity in the pharmaceutical sector to make effective use of compulsory licensing as provided for in Article 31 TRIPS. This had been achieved through the System, as had been evidenced by its use for exports from Canada to Rwanda.

60. The representative of Brazil noted that it was very important to know that there had been no royalties paid and that Apotex had most probably lost money when it had to reduce its price to USD 0.195 to compete with Indian generic companies. This would raise the question of whether the System was economically viable and if there would be other examples of its use. With the end of the transition period for the implementation of the TRIPS Agreement in 2005 in developing countries except LDCs, affordable generic medicines from suppliers such as India would become more and more scarce. This was particularly important for medicines to treat HIV/AIDS, namely second and third line treatments. In 2008, the report by the Swedish National Board of Trade on "The WTO Decision on Compulsory Licensing" had stated that "HIV is a highly changeable virus and patients

need to switch and update their medicines regularly. Some types of AIDS medicines were launched before the TRIPS rules on patent protection for medicines were introduced in developing countries, and they could therefore be freely copied and sold in these countries. This has resulted in vigorous price competition for many of the older medicines used as the standard 'first line' treatment, even though most of them are still patented in high income countries. With many suppliers to choose from, there has been no need to use the Decision for these medicines." The report had also explained that "the situation in regards to competition and price is different for the second or third line AIDS medicines, i.e. medicines that patients will need when they have developed resistance to the first line medicines. The same holds for new, more effective substitutes for first line medicines. All of these are patented in many countries and the prices are much higher than for older medicines. This is becoming a grave concern for the countries and international agencies that offer treatment. Patients need to switch to the second line medicines within a couple of years after starting treatment and these medicines may cost up to 12 times as much."

61. Therefore, the discussions at this meeting would have a fundamental impact on access to affordable medicines in the near future. Efforts in the TRIPS Council and in other fora should concentrate on analyzing whether the economic and political incentives provided by the System were adequate to secure investment in the production of generic medicines at affordable prices to markets with no manufacturing capacity. TRIPS-plus provisions that adversely affected the right to access to medicines, such as data exclusivity of clinical trials, should also be analyzed. Given that economies of scale were an essential element in incentives for investment in this area, it was also important to design ways to improve the utility of the system to serve small markets.

62. The representative of Venezuela said that his delegation saw the background to the System in a different way to Switzerland. Before looking into the intention of establishing the System, the importance of the Doha Declaration in 2001 for developing countries had to be recalled. The System launched pursuant to paragraph 6 of the Declaration was the only escape valve to protect public health in developing countries. From 2001 onwards, prices of medicines had increased. Before the TRIPS Agreement, there had been no issue with respect to the patenting of medicines. Despite the fact that Canada considered this mechanism to be successful, he believed that it had been a serious failure. He therefore supported the organization of a workshop so that delegates could discuss in an informed manner, taking into account the experience of the pharmaceutical industries and NGOs.

63. Noting that the delegation of Canada had stated that implementing anti-diversion measures had not been onerous on Apotex given that it was a well-established global company with presence in a number of jurisdictions, the representative of Egypt said that while this might be the case for a Canadian company, it would not necessarily apply to generic companies from other countries. While generic companies in his country would be able to produce certain products, they might not have the same global reach or presence in various markets, so the anti-diversion measures could be perceived as onerous by them. In his view, there was no level playing field with regard to such measures. Given that a number of questions had been raised in this discussion that would necessitate replies from the stakeholders, he reiterated his support for the convening of a workshop that would take on board comments and replies from all these stakeholders.

64. With respect to the purpose of the System, he considered it to be part of a constellation of measures that had been adopted in the Doha Declaration, in particular addressed in its first and second paragraphs. He stressed the need for the WTO Agreement and the TRIPS Agreement to be part of the wider national and international action to address the issue of the gravity of public health concerns. He saw the Doha Declaration as part of a constellation of measures to ensure that the TRIPS Agreement played its part and was not an obstruction to addressing the issue of access to medicines. Its Paragraph 6 dealt with an extremely important element of that, addressing the difficulties of Members that had limited or no pharmaceutical manufacturing capacity.

65. While the generic pharmaceutical industry was present in his country, there had been three instances in the past decade when it would not have been able to supply needed medicines in sufficient quantities. These cases included anthrax, the H5N1 avian flu pandemic and finally the H1N1 virus. He thought that this situation was shared by the vast majority of Members. An agile, dynamic and expeditious solution was therefore needed. The fact that the System had only been used once over the past decade and that it had taken many years to provide a measure of workability indicated that it was by no means an expeditious solution. This did not forebode well for the future.

66. The representative of India referred to the statement by the delegation of Venezuela regarding the purpose of the System. Two valid points had been made with respect to the role of the System in access to medicines and regarding the fact that TRIPS was perceived by several developing countries as a problem in the context of public health. This was also reflected in the report of the UN Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of health which had been accepted by the United Nations Human Rights Council in 2009. The report had further mentioned that TRIPS-plus was aggravating the problem of access to medicines and public health. In his delegation's view, the Swiss reading of the System was very narrow. Paragraph 4 of the Doha Declaration clearly said that "we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all." The Doha Declaration was significant, since it was a political assertion signifying that public health concerns overrode intellectual property rights.

67. The representative of Canada expanded upon the discussion on anti-diversion measures. According to the System, products manufactured under a compulsory licence should be physically distinguishable from the patented product and, in addition, the licensee was required to post information on a website describing the distinguishing features, as well as information regarding the quantities being shipped to each destination. CAMR required physical markings as part of the anti-diversion measures. Products exported under the licence had to bear the mark "XCL" for solid oral dosage forms, and had otherwise to be of a colour significantly different from the version sold domestically or had to include certain information on all labelling to distinguish them from the domestic version. Instead of putting its company name on the pill, Apotex had apposed the mark "XCL", and had chosen to make the colour of the pill white, instead of blue.

68. Products were also issued an export tracking number by Health Canada, which was required to be printed on the product label. Since products had to have a product label, Apotex had put this additional information there. Before exporting a pharmaceutical product under CAMR, the licensee was also required to establish a website disclosing the name of the licensed product, distinguishing characteristics, the identity of the importing country and the amount to be manufactured and sold for export, as well as the information identifying every known party that would be handling the product while it was in transit from Canada to the importing country. Large companies were capable of providing or creating a website, as it was not a very onerous demand. To further promote transparency, the licensee was also required to provide to the patentee, the importing country and the purchaser, within 15 days of the product being exported, a note specifying the quantity to be exported and the identity of every known party that would be handling the product while in transit.

69. In his delegation's view, paragraph 2 of the Doha Declaration was very important. In this paragraph, Ministers had stressed "the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights to be part of the wider national and international action to address these problems." Since 2003, there had been a concerted effort amongst WTO Members to take national and international action to address these problems of which the System was just one tool in a growing arsenal of tools. This was a very positive development and reflected a change in the environment that needed to be taken into account as this important issue was discussed.

70. As regards questions relating to safety and efficacy, Canada had taken an early policy decision that drugs exported under CAMR should meet the same standards for safety, efficacy and quality as any drug sold on the domestic market. Health Canada would, in any event, be in charge of undertaking a review, once the patents had expired, to enable off-patent drugs to come to the Canadian market. It was therefore in its best interest to ensure that there was no double standard. In the case of Apo-TriAvir, Apotex had submitted a request for approval of a generic drug, based on the three reference products that it had been using. Safety and efficacy had been established on the basis of bioequivalence, as for any other generic product. The quality of the drug had been established on the basis of a chemistry manufacturing review, which was also applied to drugs for the domestic market, as well as good manufacturing practices which were a worldwide recognized quality standard. The clinical trials to establish bioequivalence of the generic drug and the reference product had been undertaken in Canada under Health Canada's authorization for clinical trials. Such clinical trials came under the Food and Drugs Act and had to be approved by Health Canada, as in any other country. That process had provided the information that had been requested for the establishment of safety, efficacy and quality.

71. The representative of New Zealand noted that there had been a lot of discussion about the Canada-Rwanda case which showed that the System could work. There had been little discussion, however, about instances where the System had been considered but not used. It was necessary to examine those situations at least as closely as the Canada-Rwanda case had been examined. He requested more information from the delegation of India as to the three cases it had mentioned where applications under the System had been initiated but had later been discontinued. He wished to better understand the facts on the basis of which the delegation of India had drawn its conclusions. He also requested more information from the delegation of Egypt as to why it would be easier for generic producers in Canada to comply with the requirements of the System than for generic producers in Egypt.

72. Furthermore, he echoed the request made by the delegation of Canada to hear from potential importers. As it was the TRIPS Council that was responsible for the review of the System, he felt that it was ultimately the responsibility of the Members to communicate and understand the facts. Consequently, he requested to hear more from Members who had considered using the System, but had subsequently not done so.

73. The representative of Malaysia asked the delegation of Canada whether there was any bar under Canadian law which prevented a manufacturer from applying for marketing approval of a drug before the expiry of the patent for the drug. If there was such a bar, he asked whether there was an exception applying in cases where the System would be used.

74. The representative of Indonesia commented on a number of constraints on the System's implementation. Firstly, there was resistance from patent holders. Secondly, for medicines that needed specific technologies, developing and least developed Members would face problems or would even find it impossible to manufacture those medicines. There was therefore a need to look also at Article 7 of the TRIPS Agreement with respect to the objectives of the Agreement which included transfer of technology. This was one of the solutions to address problems currently encountered with the System, because it was necessary to reduce the number of countries who were on the demand side and sought to become manufacturing countries in the future. Thirdly, he shared the concerns raised by the delegation of Brazil with respect to TRIPS-plus provisions which represented one of the constraints in implementing the System. Fourthly, donations from international funding organizations and NGOs, such as the World Bank, UNICEF, the MSF and the Global Fund, generally required that manufacturers needed to be pre-qualified under the WHO pre-qualification system. Pre-qualification involved the national regulatory authority, as well as the respect of pharmaceutical industry requirements which were not easy to fulfil. For developing Members, and least developed Members particularly, pre-qualification requirements were even more difficult to

implement. Therefore, improving their capacity as exporting countries or manufacturing countries was similarly much more difficult. He thought that holding a dedicated workshop on this issue was necessary and very timely.

75. The representative of India noted that his delegation could not provide a complete timeline of events regarding the instances where applications to use the System had been submitted and had later been aborted, as only one step had been taken. First-hand information on this case could best be provided by the delegation of Nepal. He endeavoured to gather more information from NATCO Pharma, the company which had applied for the compulsory licences, to share with Members at the next TRIPS Council meeting.

76. The representative of Canada asked the delegation of Indonesia for specific examples in terms of resistance encountered from patent holders, and asked whether this was in relation to a potential use of the System. He also asked which medicines Indonesia had found difficult to obtain, what efforts it had made to try to obtain them, whether the System was entertained as an option to obtain those essential medicines and, if not, why this had not been done.

77. With respect to Malaysia's question regarding the ability for a generic drug to be marketed in Canada, the representative of Health Canada said that the Patent Act had an early working clause that allowed the development of a generic drug in advance of the patent expiry for the purpose of preparing a submission seeking market authorization. Health Canada would complete the review, but the market authorization would not be granted until such time as all issues related to the protection of patents were addressed. For this reason, Apo-TriAvir could not come to the Canadian market until the patents concerned expired, which explained why Apotex had sought a compulsory licence to export Apo-TriAvir. As regards the comments on the national drug regulatory authorities, their involvement was useful because they played a role in access to medicines. Based on the review by Health Canada, Apo-TriAvir had been included on the WHO's list of pre-qualified drugs by using the alternative procedure available to the European Union, the US Food and Drug Administration and to Canada.

78. The representative of the European Union noted that the System addressed only a specific aspect of the broader issue of access to medicines in the developing world. But this was a mechanism that contributed to improving access to medicines. The approach to this System should be voluntary as Members had to make it work. Other aspects had to be taken into account with regard to access to medicines, such as financing of medicine purchases, the setting-up and financing of health-care systems, the financing of research targeting neglected diseases and the development of appropriate pricing and reimbursement policies. These issues went well beyond intellectual property and patent protection. They exceeded the Council's mandate and were well addressed by other organizations, such as the WHO, in other fora.

79. In response to questions from the delegations of Malaysia and Indonesia regarding marketing authorization, the representative of the United States referred to a policy initiative, which had been launched by the US Food and Drug Administration (FDA) in May 2004 to help ensure that those being served by the President's Emergency Plan for AIDS Relief (PEPFAR) would receive safe, effective and quality manufactured antiretroviral drugs. This initiative included an expedited review process. Through guidance and an active outreach programme to the pharmaceutical industry, FDA actively encouraged any sponsors worldwide to submit US marketing applications for single entity, fixed-dose combination, and co-packaged versions of previously approved antiretroviral therapies, even if there was still patent or exclusive marketing protection for the product in the United States. Drug products used in PEPFAR received a "tentative approval" where the manufacturing of these products met all the FDA's manufacturing quality, clinical safety, and efficacy requirements as required for domestic marketing purposes. After approval or tentative approval from the FDA under the expedited process, a generic antiretroviral would quickly pass onto the WHO's pre-qualification

list, because of a confidentiality agreement that allowed FDA to share its review data with the WHO secretariat in Geneva. This was relevant to the implementation of the System, because this relied not only on what Canada had described as its implementing legislation, but also on other related measures.

2. Implementation of the System into domestic legislative and regulatory framework

80. The Chairman said that under this topic the intention was to focus on the experience of those Members who had implemented the System as potential exporting and/or importing Members. In order to have a full understanding of the situation, Members had indicated that it would also be useful to get some feedback from those Members that had not yet implemented the System, particularly with respect to any problems they had encountered in its implementation.

81. The representative of Canada said that CAMR was the Canadian legislation that implemented the humanitarian objectives of the Decision, balancing often competing policy objectives. The following conditions applied under the Decision: the importing country had to notify the WTO of its intent to use the Decision; the licensee had to request voluntary licence(s) from the patentee(s) prior to seeking a compulsory licence under the Decision; the quantity produced under compulsory licence could not exceed the amount notified by the importing country; adequate remuneration had to be paid to the patentee(s); products shipped under the Agreement should not be diverted to other markets; products had to be specially marked and labelled; licensees had to post on a website the quantities and features of the product being shipped; and, lastly, the intention was to support humanitarian policy objectives, not commercial ones.

82. During the development of legislation in 2003 and 2004, and again during the statutorily mandated review of the legislation in 2006, key stakeholders, including from the R&D industry, the generic industry and civil society, had been consulted. All stakeholders had supported the establishment of CAMR and continued to support it, but diverged on certain aspects of the regime. For example, brand name companies wanted strong anti-diversion measures, generic companies sought streamlined processes with incentives to participate, and NGOs wanted a liberal regime with no restrictions on eligible importing countries or products. CAMR's overriding key challenge was to ensure a delicate balance between facilitating access to medicines while ensuring that incentives for the innovation of new medicines and technologies remained. CAMR pursued several objectives, including to: (i) facilitate access to lower-cost pharmaceutical products in countries facing public health problems; (ii) respect Canada's obligations under TRIPS and other international treaties; (iii) respect the domestic patent system; and (iv) encourage generic companies to participate in CAMR.

83. CAMR's key features concerned eligible importing Members, eligible medicines for export, requirements regarding safety and quality of products, steps required to be taken by a local manufacturer seeking to export under CAMR, distinguishing features of products, royalties, dispute settlement and statutory review. Eligible importing countries were listed under Schedules 2, 3 and 4. All LDCs and WTO Members were eligible to import except those that had opted out, such as his own country, the United States and France. Non-WTO Member developing countries were also eligible to import pharmaceutical products under CAMR upon request.

84. Eligible products for export were listed in Schedule 1. Every product on the WHO's list of Essential Medicines that was patented in Canada was eligible for export. He noted that Schedule 1 had been amended twice since 2005 to include new products such as the HIV/AIDS triple-combination therapy Apo-TriAvir and Tamiflu. CAMR ensured that a product exported under CAMR met the same safety, efficacy and quality standards as those products destined for the domestic market.

85. A local manufacturer who sought to export under CAMR was required to submit the following information to the Commissioner of Patents: (i) the name of the patented product for export, the eligible importing country, the existing patents and the quantity to be manufactured; (ii) a certified copy of the importing country's notification to the WTO or to Canada (if the importing country was not a WTO Member); and (iii) a declaration that the applicant had attempted to negotiate a voluntary licence with the patentee(s) at least 30 days prior to submitting an application for an export authorization.

86. Exported products had to carry prescribed markings and labelling. The name of the product, quantity, markings, and importing country had to be disclosed on the manufacturer's website. The royalties paid to the patentee(s) ranged between 0.02 per cent and 3.5 per cent and were linked to the importing country's level of development as listed on the UN Human Development Index and the value of the contract. If the licensee failed to meet the terms and conditions of the export authorization, or if diversion occurred, termination of the licence by the Federal Court was possible.

87. Recognizing the importance and the groundbreaking nature of CAMR, its enabling legislation included a clause requiring the Minister of Industry to review the relevant sections of the Patent Act two years after CAMR's coming into force. In November 2006, the Government of Canada had launched a 60-day consultation seeking public views and opinions on CAMR. Through this process, the Government had received numerous submissions from the pharmaceutical industry, NGOs, academia, and Parliamentarians.

88. In December 2007, the Minister of Industry had tabled a report in Parliament containing the results of the consultation period and review. The report and submissions were available online at the CAMR website (www.camr-rcam.gc.ca). The report on Canada's statutory review of CAMR had been a comprehensive analysis that considered each element of the regime in the context of relevant international trade rules. It had also taken into consideration circumstances surrounding the Commissioner of Patents granting of an export authorization to Apotex under CAMR. In addition, the report had examined the broader context of disease burden in the developing world, international and country-based initiatives to address that burden, and some economic considerations affecting the supply of antiretroviral drugs used to treat HIV and AIDS. The 2007 report had found that insufficient evidence had accumulated since the coming into force of CAMR to warrant legislative changes at that juncture.

89. However, the report had also highlighted other systemic factors outside the operational aspects of CAMR that appeared to be discouraging its use. These factors included a lack of eligible importing Member notifications to the WTO or to Canada and a lack of awareness of CAMR among eligible importers. In response to the second factor, Canada had varied and intensified its outreach activities to continue to raise awareness of CAMR among eligible importers, pharmaceutical regulatory authorities and generic manufacturers. Mere months before the report had been released, Apotex had applied for and received an authorization to manufacture and export under CAMR in order to fulfil the need identified by Rwanda in its WTO notification. The report had been released well before Apotex had shipped Apo-TriAvir to Rwanda in September 2008. The report had taken note of this and had provided the following assessment: "... for the moment at least, the granting of the first and only export licence under the waiver to Apotex, and the circumstances surrounding it, suggest that CAMR works reasonably well and quickly, provided an importing country has made a requisite notification to the WTO". With no further notifications to the WTO since the report's release in 2007, this observation remained valid.

90. The representative of China provided an overview of the domestic implementation of the System and the main changes relating to public health in the amended Patent Act. The patent law of the People's Republic of China had first entered into force on 1 April 1985 and had been amended in 1992, 2000 and 2008. On 27 December 2008, the Standing Committee of the National People's

Congress had adopted a decision to revise the patent law. The new patent law had come into effect on 1 October 2009. Subsequently, the State Council had promulgated its decision on revising the implementing regulations of the patent law in January 2010. They had come into force on 1 February 2010, concluding the third revision process.

91. The 2003 Decision and the Protocol Amending the TRIPS Agreement provided a means to assist Members who had insufficient or no manufacturing capacities in the pharmaceutical sector to address public health problems. WTO Members could grant a compulsory licence to manufacture and export patented pharmaceuticals to such Members. China had accepted the Protocol in October 2007. To implement it, Article 50 had been added to the Chinese Patent Law, enabling the State Intellectual Property Office (SIPO) to grant compulsory licences to manufacture patented pharmaceuticals for the purpose of exporting to eligible Members. Article 50 provided that, for the purposes of public health, the patent administration department and the State Council could grant a compulsory licence to manufacture a patent-protected pharmaceutical product for export to countries or regions specified in the relevant international treaties to which China was a party. In Article 53, the requirement that compulsory licensing should be used predominantly for the supply of the domestic market was waived with respect to the export of a patented medicine for the benefit of public health. The amendment of Article 57 clarified that royalties had to be paid to the patentee according to relevant provisions in the Decision and the Protocol when a compulsory licence was granted for public health purposes. The implementing regulations provided further details, such as the definition of a pharmaceutical product in Rule 73, paragraph 2. Rule 74, paragraph 4, provided that the grant of compulsory licences pursuant to Article 50 of the Patent Act had to be in accordance with the relevant international treaties to which China was a party. The amendments to the Chinese patent system had fully implemented the System into the domestic law. As of 1 October 2010, no compulsory licence had been granted by the Chinese authorities. SIPO was planning to revise the procedures relating to compulsory licensing to provide specific requirements in line with the Protocol.

92. The representative of the European Union said that his delegation had implemented the System as a potential exporting Member. On 17 May 2006, it had adopted new legislation to that effect. Regulation (EC) No. 816/2006 of the European Parliament and of the Council represented an instrument that allowed the compulsory licensing procedure under the System to fit within the context of EU member States' national patent laws and the respective compulsory licensing procedures. This gave transparency and clarity for those companies operating within the EU internal market and wishing to apply for compulsory licences for export to countries in need. It created a legal basis at the EU level to enable European generic producers to manufacture medicines under compulsory licences for export to countries in need. It did not impose further restrictions on the Decision.

93. The scope was one of the main elements of this regulation. Firstly, the beneficiary countries included both least developed countries and low-income developing countries, including those who were not members of the WTO. Secondly, there were no specific exclusions as to the scope of diseases. The Regulation referred to public health problems and did not target specific diseases. Thirdly, the Regulation applied to any product of the pharmaceutical sector, including medicinal products, active ingredients and diagnostic kits ex vivo. The Regulation also foresaw a role for non-governmental and international organizations who could become involved in any purchasing procedures and could also make requests on behalf of an importing country with that country's approval.

94. An applicant for a compulsory licence under the System was required to submit its application to the competent authority of the EU member State where the medicine was going to be manufactured, or from where it was going to be exported. The applicant was able to avail himself of the EU scientific opinion procedure or equivalent national procedures to ensure the safety and efficacy of the medicine. The EU had felt this was a necessary complement to the licensing mechanism in order to assist importing countries. The application had to contain information as to the

name and contact details of the applicant, the non-proprietary name of the product concerned, the amount of medicine to be produced and the name of the importing country or countries. The competent authority would grant the compulsory licence and determine the remuneration to be paid to the patent holder. In the case of an urgency, the remuneration was a maximum of 4 per cent of the total price to be paid by the importing country. In other cases, the remuneration had to be adequate.

95. The licence had to be non-exclusive, non-assignable and limited in scope and duration. The products had to be clearly identified. The licensee had to inform the authorities of the quantities and distinguishing features of the products and also keep records in order to allow verification of whether the terms of the licence, in particular those relating to the final destination of the product, had been met. The scope and duration of the licence were determined by the needs stated by the importing country or countries. Appeals against competent authorities' decisions and disputes relating to the compliance with the licence conditions were heard by the appropriate body under the law of the member State concerned. Once export had occurred, all parties had an interest in seeing that medicines were not diverted from those in need. The Regulation prohibited re-importation into the European Union and provided for customs authorities to take action against goods being re-imported. The patent holder could use existing national procedures to enforce its rights against re-imported goods if they did enter the European Union. Termination of the licence granted under the Regulation would be notified to the TRIPS Council. No compulsory licence had thus far been granted under the Regulation, but any application from developing countries would be welcome. Moreover, he noted that his delegation had committed itself not to use the System as an importer.

96. The representative of Hong Kong, China said that her delegation had notified its acceptance of the Protocol on 27 November 2007. The Patent Amendment Ordinance 2007 had been passed on 30 November 2007 and had taken effect on 22 February 2008. It had introduced two new parts to the Patents Ordinance, one dealing with the importation of pharmaceutical products under the Protocol and the other dealing with the exportation of such products. Prior to the Protocol coming into effect, the Amendment Ordinance allowed her delegation to rely on the temporary waiver to enable it to import patented pharmaceutical products from a WTO Member to address a public health crisis or to export such products to a WTO Member.

97. Her delegation had declared that it would not use the System as an importer unless in a situation of national emergency or other circumstances of extreme urgency, which the chief executive in Council may declare. During such a declared period of extreme urgency, the Director of Health would be empowered, if he considered there were insufficient or no manufacturing capacity, to grant a non-exclusive compulsory licence to any person to import the pharmaceutical product or to do any other act which would otherwise amount to an infringement of the patents concerned, without the consent of the patentee. The Director of Health would be required to notify the patentee of the grant of the import compulsory licence as soon as was practicable and to publish the grant of the licence and its terms and conditions in the specified official journal.

98. The Amendment Ordinance stipulated that the import compulsory licence would be subject to the following conditions: (a) the entire quantity of the pharmaceutical product imported under the licence should only be used domestically and not be exported to other places; (b) the pharmaceutical product should be clearly identified through specific labelling or marking as being imported pursuant to such licensing system; (c) the licence was not assignable except as part of the business of the assignor that enjoyed the use of the patent under the compulsory licence; and (d) such other terms and conditions as the Director of Health deemed fit, having regard to the public health needs in Hong Kong, China in a declared period of extreme urgency. The Director of Health had the power to terminate an import compulsory licence where there was contravention of any term or condition of the licence. Payment of royalties to the patent owner was only required where he could show that remuneration had not been paid in the exporting jurisdiction and that all legal remedies to recover royalties had been exhausted. The amount of remuneration should be agreed between the Director of

Health and the patentee. Where an agreement could not be reached, the amount of remuneration could be determined by the court. The Amendment Ordinance provided for the disposal of any remaining stocks upon the termination of the period of extreme urgency. The licensee was required to take reasonable steps to recall such stocks and either surrender them to the government or to the Hong Kong Special Administrative Region or dispose of them in such a way as may be agreed with the patentee.

99. The Amendment Ordinance also empowered the Director of Health to grant a compulsory licence for the making and export of a pharmaceutical product to be supplied to a WTO Member recognized as a least developed country or a WTO Member that had given notice to the TRIPS Council that it intended to import pharmaceutical products under the System. Where the importing WTO Member did not declare a national emergency or other circumstances of extreme urgency, the applicant for an export compulsory licence was required to make reasonable efforts to obtain an authorization from the patentee on reasonable commercial terms and conditions before applying for the licence. The grant of the export compulsory licence was subject to the terms and conditions stipulated in the Amendment Ordinance, including as regards (a) the quantity of the pharmaceutical products that could be produced and sold for export; (b) the need to clearly identify the pharmaceutical products through specific labelling or marking as being produced pursuant to such licensing system; (c) the posting on a dedicated website of information relating to the amount of the pharmaceutical product that would be exported to the importing Member and the labelling or marking used to identify the product; and (d) such other terms and conditions as the Director of Health deemed fit. The Director of Health had the power to terminate an export compulsory licence where there was non-compliance with any term or condition of the licence or where any information, documents or evidence specified in or accompanying the application for the compulsory licence was false, incorrect or incomplete. The remuneration payable by the licensee of an export compulsory licence was to be determined by the Director of Health on a case-by-case basis.

100. The representative of India said that his delegation had implemented the System in its patent legislation in the form of Section 92A of the Indian Patent Amendment Act 2005. Under Section 92A, a compulsory licence would be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health issues, provided the compulsory licence had been granted by such a country, or the country had by notification or otherwise allowed importation of the patented pharmaceutical products from India. Use of Section 92A was not restricted to WTO Members and was simple to use. The guiding principle for India had been to make the use of the System as easy as possible. India had accepted the Protocol Amending the TRIPS Agreement on 26 March 2007.

101. The representative of Korea said that his delegation had accepted the Protocol Amending the TRIPS Agreement on 24 January 2007. At the time of the adoption of the Protocol, his delegation had declared that it would not use the System as an importer. In 2005, Article 107(1)(v) of the Patent Act and other relevant provisions had been enacted, and the Regulation on Expropriation and Licensing of Patents had been amended to provide statutory grounds and to set procedures for granting a compulsory licence for export. In July 2010, the Regulation had been further amended to make the procedures easier and more transparent.

102. To obtain a compulsory licence under domestic patent law, an applicant had to make a request for the grant of a compulsory licence. This application had to include the method for calculating remuneration, the reason for the request and supporting evidence, and evidence of failed negotiations with the right holder. In the case of a compulsory licence for export, the applicant additionally had to attach: (i) proof that the compulsory licence request was for the purpose of treating a disease that threatened public health in the importing country; (ii) confirmation of the intent of the importing country; (iii) an evaluation of the economic value of the pharmaceutical product in the importing

country; and (iv) proof that the importing country had notified the WTO of the name and quantity of the pharmaceutical product and its lack of manufacturing capacity. In the case of non-WTO Member LDCs, the applicant additionally had to provide proof that the importing country had notified the Government of Korea of the name and quantity of the pharmaceutical product and the country's lack of manufacturing capacity. In addition, the applicant had to submit the distinguishing features that differentiated the product manufactured for export under the compulsory licence from products manufactured by the patentee or other interested parties, as well as the internet address where such details would be made available.

103. Copies of the request for a compulsory licence had to be delivered by the Commissioner of Patents to the patent right holder and other interested parties in order to provide an opportunity to submit comments. The Commissioner also had to publish the request for the compulsory licence in the patent gazette and proceed to a preliminary registration of the terms of adjudication. If necessary to decide on the grant of the compulsory licence, the Commissioner could seek assistance from the Intellectual Property Dispute Mediation Council which was composed of representatives from different ministries and other expert bodies. The Commissioner had to determine in writing the scope and duration of the compulsory licence, the amount of remuneration, the method of payment, as well as other terms of implementation. The adjudication had to be made within six months of the request. In case of compulsory licensing for export, the licence had to be granted if all the legal requirements were satisfied. This feature differentiated such licences from procedures applying to standard compulsory licences. Following the grant of the licence, a copy of the decision had to be delivered to the patentee and other interested parties, an abstract of the decision had to be published in the patent gazette, and the non-exclusive licence be registered. Remuneration had to be paid or a bond be posted as a security by the licensee.

104. Amendments had been made to the Regulation on Expropriation and Licensing of Patents in July 2010 to make procedures for export compulsory licences easier, more transparent and predictable. To achieve this objective, among others, any competent Minister seeking the grant of a compulsory licence could also request that a search be carried out regarding the patents related to the invention for which a compulsory licence was requested. An additional provision also provided detailed criteria for calculating the amount of remuneration to be paid to the patentee.

105. The representative of Switzerland said that Switzerland was a WTO Member which had manufacturing capacity in the pharmaceutical sector. The Swiss pharmaceutical industry had particular expertise and strength in the area of research and development of innovative medicines and also was active in the generic medicines sector. His delegation had fully opted out of the System as an importing country in 2003. It had implemented the System in its national legislation as a potential exporting country and had been the second WTO Member to notify its acceptance of the Protocol Amending the TRIPS Agreement (WT/Let/547) on 13 September 2006. The Bill implementing the System had met the approval of the various stakeholders, including all relevant Government agencies, political parties, NGOs, industry associations and consumer organizations. The relevant report summarizing the consultations that had taken place could be accessed on the Swiss Government homepage (http://www.admin.ch/ch/d/gg/pc/documents/1167/Ergebnisse_d.pdf). The Swiss Parliament had accepted the amended Patent Act, which included the implementation of the System, on 22 June 2007. The Act had entered into force on 1 July 2008 and had been notified to the WTO (IP/N/1/CHE/P/9).

106. The revised Patent Act contained a new Article 40(d), which provided for the possibility of applying for a compulsory licence for export purposes. The pre-existing and, in the revision, renumbered Article 40(e) contained general provisions on uses without authorization of the patent right holder. It had been revised to incorporate additional and specific terms and conditions for a Paragraph 6-type compulsory licence. The Patent Ordinance, which served as an executive regulation complementing the Patent Act, provided in its Article 111 further terms and conditions to be respected

in the grant of such an export compulsory licence. In addition to the legal provisions in the Patent Act and in the Ordinance, further helpful information and policy guidance on the contents of the amended law as well as the legislator's intention and interpretation of the relevant legal provisions could be found in a so-called legislative dispatch, which was a sort of explanatory report by the Government which had been sent together with the proposed Bill to the Parliament. The substance of the Swiss legislation implementing the System was thus closely following the provisions and requirements as contained in the Protocol. Those were mirrored in a clear and straightforward manner in the amended Swiss Patent Act.

107. Under the Swiss implementing legislation, compulsory licences could be issued for specific medicines, active ingredients, diagnostic kits or vaccines patented or manufactured under a patented process. Any country that met the terms and conditions established by the System could be an importing country under Swiss law. Exclusions applied to WTO Members in accordance with their full or partial opt-out status. A country did not need to be a WTO Member in order to be a beneficiary country. Responsible for the grant of the compulsory licence were the courts responsible for patent matters to which an application had to be submitted. As part of the application, the applicant had to submit the notifications required under the System. The court had to treat the application expeditiously. It was required to submit the details of the licence, if granted, to the Swiss Intellectual Property Office which would notify them to the WTO. As in the case of standard compulsory licences, adequate remuneration was to be determined on a case-by-case basis by the Court. However, the Government's explanatory report had specified that the economic value of the patent's legal use under a compulsory licence in the beneficiary country had to be taken into account, as well as the country's level of development, based on its position on the UN Human Development Index. The owner of a Paragraph 6 compulsory licence had to obtain authorization from the Swiss Agency for Therapeutic Products to manufacture under the Federal Drug Law. The standards of good manufacturing contained in that Law also had to be complied with. Sanctions and criminal penalties would apply if the terms and conditions of the licence were not complied with, including anti-diversion measures. In case of a failure of compliance with the terms and conditions, the Court could also revoke the licence. His delegation had not encountered any particular problems in implementing the System, which provided sufficient guidance.

108. His delegation did not consider the System or its domestic implementation, whether as an importing or exporting country, to be a panacea for affordable access to medicines in developing countries. Rather, it was one contribution that the TRIPS Council had been able to make to combat challenges posed to public health. His delegation had no practical experience using the System, as to date it had not received any request for a compulsory licence thereunder.

109. The representative of Croatia said that Croatia had implemented provisions pertaining to the grant of compulsory licences, supplementary certificates and prohibition of re-importation into its Patent Act in 2007, which was reflected in the Act on Amending the Patent Act of December 2009. Croatian authorities had begun the process of accepting the Protocol Amending the TRIPS Agreement in May 2010. Acceptance of the Protocol had been passed in Parliament and the process would be completed and the outcome be published in the official journal in due course. The instrument of acceptance would soon be notified to the WTO.

110. The representative of Ecuador noted that, under the Ecuadorean Constitution, the State had to guarantee the health of the Ecuadorian people and to facilitate the availability and accessibility of high quality, safe and effective medicines. The Constitution further provided that public health interests prevailed over economic and commercial interests (Articles 3 and 32). It also provided that health was a human right. It was therefore not just a political commitment to promote and secure health, but a constitutional right to which every Ecuadorian citizen was entitled. This implied an obligation for the State to secure the enjoyment of the highest possible standard of health care and the establishment of a health protection system which guaranteed equal health opportunities for all citizens.

111. He said that Ecuador had adopted a common industrial property regime with other Members of the Andean Community, through Decision No. 486 of September 2000. This legislation, which was part of Ecuador's domestic law and had direct legal effect, had enabled all Andean Community member countries to entertain compulsory licensing requests and, where appropriate, to grant them as provided for by Articles 61 to 66 of Decision No. 486. Moreover, Ecuador's Industrial Property Law of May 1998 had established compulsory licensing regulations at the domestic level as per its Articles 154 to 156. These regulations were to be interpreted in conjunction with the Andean Community regulations. Other components of the legal framework for compulsory licensing were Article 31 TRIPS and the Doha Declaration on the TRIPS Agreement and Public Health. All of these elements provided the legal basis for authorizing compulsory licensing for reasons of public interest, emergency or national security in Ecuador.

112. The Government's domestic policy guaranteed universal access to medicines for Ecuadorian people, through the provision of safe and reliable generic medicines under compulsory licence. This health policy was the result of the implementation of the national development plans 2007-2009 and 2010-2013. To grant a compulsory licence for reasons of public interest, emergency, or national security, the law required the President to first make a declaration of a state of emergency or other extreme urgency. Once that had been done, Ecuador's Intellectual Property Authority (IEPI) was authorized to initiate the necessary procedures to consider the request and, if relevant, the granting of compulsory licences. For example, on 14 April 2010, IEPI had granted a compulsory licence for Ritonavir, a first-generation drug for the treatment of HIV/AIDS. He noted that this compulsory licensing process had taken six months, as opposed to three years in the case of export under the System from Canada to Rwanda.

113. He said that the fundamental problem in the use of Article 31 of the TRIPS Agreement was that compulsory licensing under this provision did not cover all public health needs since it did not provide for situations where a country had no capacity, or limited capacity, to produce pharmaceutical products. To address the territorial restrictions in Article 31(f), the System had been adopted. However, whereas it had been intended to provide a viable and expeditious solution to address public health problems of countries with limited or no production capacity in the pharmaceutical sector, it had only resulted in limited access to generic versions of last generation essential medicines, such as those needed to treat HIV/AIDS. As regards the compulsory licence granted for the generic medicine Ritonavir, it was patent-protected in Ecuador, but not in the manufacturing country, which had made it possible to export it to Ecuador under the standard rules of Article 31 of the Agreement.

114. Instead of meeting the objective of expeditiously satisfying the urgent public health needs of developing countries, the implementation of the System would, on the contrary, establish burdensome and excessive processes, conditions and limitations for those countries that had no or limited production capacities, as in the case of Ecuador, thereby further complicating the already demanding conditions imposed by Article 31 and hampering access to imported generic versions of essential medicines. Those considerations explained why his delegation was reluctant to ratify the Protocol and to make the System a permanent part of the Agreement.

115. The representative of Japan said that his delegation had notified its acceptance of the Protocol Amending the TRIPS Agreement in August 2007. He elaborated on the related domestic rules for administering the System as a potential exporting Member. The "Guideline for Administering Award System" was binding on administrative authorities and provided for a comprehensive compulsory licensing scheme in accordance with international obligations which applied to his delegation. Under this guideline, compulsory licences for the purpose of the System could be granted in accordance with the provisions of the TRIPS Agreement, the Decision and the Protocol Amending the TRIPS Agreement. Compulsory licences for the purpose of the System could be requested under Article 93 of the Japanese Patent Act, which allowed for an "award granting non-exclusive licence for public interest".

116. To accept the Protocol, the approval of the House of Representatives, the House of Councillors and the National Diet of Japan had been needed. In the proceedings of the Diet, the question had been posed as to what acceptance of the Protocol would mean, taking account of the fact that pharmaceutical companies already exported pharmaceutical products to LDCs at affordable prices and that, although being the main potential beneficiary, no LDC had accepted the Protocol at that point. The System was nevertheless considered important to increase the options available to LDCs in the case of a national emergency. Acceptance of the Protocol was important to facilitate the entering into force of the TRIPS Amendment.

117. He said that, in this context, his delegation would appreciate receiving further information on the state of play from LDCs who had not yet accepted the Protocol as potential importing Members.

118. The representative of Chile noted that the incentives provided to Members to implement the System could be usefully looked at. Such incentives seemed to be largely for countries that had capacity to produce generic medicines. A large number of developing countries had a well-developed pharmaceutical sector with manufacturing capacity. However, it was unlikely that these developing countries would be called upon to manufacture drugs under the System, as importing countries would prefer to rely on exporting countries where safety and efficacy of the pharmaceutical products was assured. He wondered about incentives to accept the Protocol for a Member who would not use the System as an importing country, and was unlikely to use it as an exporting country. It was therefore important to look at the incentives provided to countries to accept the Protocol and to implement the System, in order to enable a broader discussion of why only a limited number of Members had accepted the Protocol.

119. The representative of Canada said that one benefit of the System was that royalties to the patent holder would have to be paid in the exporting country. He noted that some WTO Members who wished to import under the System might, nevertheless, still be required under their domestic legislation to pay a royalty when a compulsory licence was issued, unless they had made the appropriate changes to their domestic legislation to take full advantage of the System. He asked whether any potential importing countries had had any experiences in that regard.

120. The representative of Nigeria asked whether there had been any efforts made by governments or generic companies to transfer technology to least developed countries. He also asked whether potential exporting Members, other than Canada and the European Union who had specifically addressed this point, had safeguards in place to ensure the safety and efficacy of drugs produced under the System.

3. Process of acceptance

121. A representative of the Secretariat briefed the Council on the procedural requirements of acceptance and current status of acceptances of the amendment to the TRIPS Agreement. He recalled that the TRIPS Amendment was a formal amendment to an international treaty, the TRIPS Agreement. The amendment process had started with the adoption, on 6 December 2005, of the General Council decision on the Amendment of the TRIPS Agreement. This decision reflected the political consensus reached by all WTO Members to amend the Agreement. In terms of international treaty law, it was the Protocol attached to the General Council decision that amended the TRIPS Agreement. However, for the amendment to have legal effect in the WTO, Members needed to formally express their consent to be bound by the Protocol. The General Council decision and the Protocol explicitly invited Members to accept the Protocol. The WTO Agreement, to which the TRIPS Agreement was attached as Annex 1C, included special rules on amendments in its Article X. Under Article X:7 of the WTO Agreement, formal acceptance of the TRIPS Amendment occurred by Members depositing an instrument of acceptance with the Director-General, who served as the depositary of the multi- and plurilateral trade agreements.

122. He said that there were several requirements for depositing a valid instrument of acceptance. First, the instrument of acceptance had to be a written document. He noted that there was no established form for this document, and that each Member would have its own practice in accepting international treaties and treaty amendments. However, under international law, the instrument of acceptance had to have certain elements in order to give clear and unambiguous expression to the relevant Member's intention and consent to be bound by the relevant instrument, in this case, the Protocol. In particular, the instrument of acceptance had to: (i) reproduce or at least clearly identify the Protocol by its title and by the place and date of its adoption, for example, "the Protocol Amending the TRIPS Agreement, done at Geneva on 6 December 2005"; (ii) indicate that the Member concerned formally accepted the Protocol; (iii) indicate the date and the place of issuance of the instrument of acceptance; and (iv) be issued by one of the "the Big Three", namely the head of state, the head of government, or the foreign minister of the Member concerned, depending on the Member's constitution and practice. Alternatively, the instrument of acceptance could be issued by another person, provided that one of the Big Three had formally issued what was known in treaty law as "full powers", which was a document specifically authorizing this person to accept the Protocol on behalf of the Member concerned. In any event, the instrument of acceptance had to be signed and had to indicate the name and title of the person signing the instrument.

123. He noted that the instrument needed to be deposited within the period of acceptance. Following two extensions of the original acceptance period, the current deadline for depositing acceptances was 31 December 2011. In other words, a Member had until this date to provide its signed instrument of acceptance to the Director-General.

124. On the question of the current status of acceptances, the representative of the Secretariat said that, as the General Council Decision and the Protocol provided, the Protocol was due to take effect in accordance with Article X:3 of the WTO Agreement. Pursuant to Article X:3, the amendment to the TRIPS Agreement resulting from the Protocol "shall take effect for the Members that have accepted [it] upon acceptance by two thirds of the Members and thereafter for each other Member upon acceptance by it". He noted that two thirds of the Membership would need to deposit an instrument of acceptance for the Protocol Amending the TRIPS Agreement to enter into force; this had not, as yet, occurred.

125. He said that there was a need to clearly distinguish between acceptance of the Protocol and implementation of the Paragraph 6 System in Members' domestic legal framework. He noted that it had been brought to the attention of the Secretariat that certain Members had postponed the acceptance of the Protocol because they had linked it to the adoption of domestic implementing legislation. Acceptance of the Protocol was an international treaty law act expressing a Member's consent to be bound by the Protocol on the international plane. It represented a Member's consent that WTO Members were entitled, i.e. permitted but not required, to use the system incorporated in the TRIPS Agreement through the Amendment. This process of acceptance needed to follow the relevant Member's constitutional requirements and the international treaty law requirements.

126. He noted that the act of acceptance was not dependent upon domestic implementation of the Protocol. The international act of accepting the Protocol needed to be clearly distinguished from the domestic implementation of the Paragraph 6 System. WTO Members could choose to take advantage of the flexibility provided in the Protocol and, if they did so, there could be a need to put it in place through a domestic legislative and regulatory process as governed by each Member's domestic procedures. Legally speaking, those two processes were therefore entirely separate. Members could choose to deal with them either jointly or separately. For example, a Member could choose to deposit an instrument of acceptance for the Protocol without adopting domestic legislation implementing the Paragraph 6 System, because the Member was only committing itself to accept that additional flexibilities became an integral part of the TRIPS Agreement. Similarly, a Member could put

implementing legislation into place without having accepted the Protocol. There were examples for both approaches.

127. The representative of the Secretariat noted that the purpose of his presentation was to facilitate Members' understanding of the procedural implications of accepting the Protocol Amending the TRIPS Agreement. To further assist Members in drawing up their instruments, the information he had provided together with a model instrument of acceptance would be made available in writing. If particular Members had queries on how to accept the TRIPS Amendment, they could contact the Legal Affairs Division of the WTO Secretariat to seek further information.

128. The Chairman emphasized the importance of the final point made by the representative of the Secretariat, namely that it was not necessary for a Member to have taken any decision whether and, if so, how to implement the TRIPS Amendment at the time when it would deposit its instrument of acceptance. In essence, the acceptance only expressed the willingness of the Member to be bound to accept that other Members were entitled to use the mechanism. It was his understanding that some Members had postponed acceptance of the amendment because they had linked it to domestic implementing legislation. While there could be domestic reasons to do so, it was not necessary for the purposes of acceptance.

129. The representative of Argentina informed the Council that the draft law for the approval of the Protocol Amending the TRIPS Agreement had passed the first steps in the relevant procedures of the Senate. In the chamber of deputies, the Commissions of Foreign Affairs, Religious Affairs and Industry had expressed a favourable opinion. On 28 September 2010, the draft law had been included on the agenda for the plenary meeting.

130. The representative of the United States said that his delegation would find the circulation of draft templates for acceptance of the Protocol and related legal materials to be a very helpful contribution to the Council's work. His delegation had been the first Member to notify its acceptance of the Amendment, and looked forward for other Members to follow as expeditiously as possible so that the two thirds requirement would be met in order for the amendment to enter into force.

131. The representative of India said that the presentation by the Secretariat had made it clear that the acceptance of the protocol and the implementing legislation were two different, not sequential, procedures. He asked whether this distinction was reflected in the technical assistance activities of the Secretariat and whether the Secretariat was planning to circulate a list of Members who had adopted implementing legislation?

132. Another representative of the Secretariat responded that, with respect to the first question by the delegation of India, a distinction was made in technical assistance activities of the Secretariat between the use of the system and its implementation, including through domestic law, and the separate procedure of preparing and submitting a formal acceptance of the Protocol Amending the TRIPS Agreement. Technical assistance was a major priority for the Secretariat. It was constantly evolving depending on demand.

133. With respect to the second question, he noted that the Secretariat had an informal list of Members that had adopted implementing legislation, based on the notifications to the Council. The Secretariat had not analyzed the laws and regulations notified by Members in detail. Informal materials had been compiled which provide a general overview of choices made by Members to implement the System.

134. The representative of Brazil noted that her delegation was interested in receiving this informal compilation of countries that had implemented domestic legislation and asked if the Secretariat could provide it informally.

135. The representative of India said that his delegation was also interested in receiving a copy of the informal compilation of countries who had implementing legislation in place.

136. The representative of the Secretariat noted that there was a formal list of countries with implementing legislation, which was contained in the draft report to the General Council on the annual review of the Paragraph 6 System. While the list of formally notified legislation was therefore on the record of the Council, the informal material to which he had referred was merely a summary of the details of such legislation.

4. Capacity building on the Paragraph 6 System and related TRIPS flexibilities

137. The Chairman noted that the Council had held the annual review of technical cooperation and capacity building on the previous day. He recalled that, on the previous day, the Council had held its annual review of technical cooperation and capacity building. He drew attention to the written reports that the Secretariats of the WTO, UNCTAD, WHO and WIPO had provided to the Council (IP/C/W/553, and IP/C/W/549 and addenda 3, 4 and 5, respectively) which also contained useful information relevant for the discussion of this topic.

138. The representative of the Secretariat provided an overview of the technical cooperation undertaken by the WTO Secretariat in relation to public health and access to medicines, with a particular focus on the System, supplementing the more comprehensive report on technical cooperation that had been provided the previous day under agenda item K (IP/C/W/553). Public health and the TRIPS provisions most directly relevant to innovation and access to medicines had formed an integral part of technical assistance activities undertaken by the Secretariat in relation to the TRIPS Agreement. In general, technical cooperation activities relating to TRIPS were directed towards assisting Members to understand the rights and obligations, including the available options, which flowed from the TRIPS Agreement and relevant decisions of WTO bodies and dispute settlement jurisprudence. This covered TRIPS flexibilities and policy options under TRIPS, including the System, and the interplay between TRIPS standards and policy choices. Technical cooperation activities had also developed an increasing practical focus, so that presentations and descriptive materials were supplemented by practical exercises and simulations, and dialogue between participants.

139. Since the adoption of the TRIPS waiver in 2003 and the TRIPS amendment in 2005, virtually all technical cooperation activities concerning TRIPS had addressed the System, whether they took the form of regional workshops, Geneva-based events, national seminars, or more tailored activities. He estimated that the number of relevant activities certainly exceeded one hundred. Over such a wide range of activities, the extent to which the System was covered, and the specific aspects which were explored, varied considerably, dependent on several factors, including the level of the participants, ranging from introductory overviews to detailed reviews of the operation of the system, and on the particular thrust of the programme, i.e. whether it was, for example, a dedicated workshop on TRIPS and public health, or a general overview of current TRIPS issues. The coverage of such activities would typically include: (i) the negotiating history and policy background of the Doha Declaration and the System, based on WTO documents; (ii) the specific scenarios in which the System was intended to operate; (iii) the operational details of the System, including the content and procedures for filing the required notifications; (iv) practical group exercises on the use of the System; and (v) the legal acceptance of the TRIPS amendment and the nature of the steps required to give effect to it.

140. Strong emphasis had been laid on cooperation with other international organizations in the conduct of such technical assistance. Following the Doha Declaration and the development of the System this meant, for instance, that the World Health Organization had become a regular participant in virtually all regional and Geneva-based activities, the only constraints being the inevitable

logistical ones, bringing a vital public health perspective to each of these programmes. The larger or more focussed programmes had been enhanced further by the participation of the full spectrum of those concerned with access to medicines: civil society, public sector procurement initiatives, industry representatives, public-private partnerships, and policy analysts. Events, such as the Colloquium and Advanced Course had included presentations from participating scholars and policy analysts from a wide range of countries, many of whom had chosen to address access to medicines and related issues.

141. He highlighted the series of six workshops on the TRIPS Agreement and Public Health that had been convened in Geneva. These programmes had opened with expert overviews from the WHO, WIPO and WTO Secretariats on the interplay between intellectual property and public health, and had included extensive material on the public health-related elements and flexibilities in the TRIPS Agreement. They had dealt with the wider context of public health and intellectual property and the full range of relevant TRIPS standards, policy options and flexibilities. They had naturally covered extensively the implementation and application of the System, including through case studies. These workshops had drawn on experts with a wide range of experiences and backgrounds to provide sessions on a range of key issues in the interplay between public health and intellectual property, including regulatory approval and quality control of medicines, the role of competition rules, procurement policy and strategies for essential medicines, and the use of patent landscaping to guide policymakers. The workshops had emphasized dialogue and diverse perspectives. Recent sessions had concluded with a wide-ranging panel discussion on the relationship between TRIPS, innovation and public health. This discussion had provided an opportunity for representatives of the research and generic industries, access to medicines programmes, not-for-profit product development, and innovation and production capacity programmes for developing countries to share their views and for participants to engage actively with them. Substantive contributions had been made by the WHO and WIPO, and presentations by speakers with different backgrounds (including a range of Geneva-based missions, NGOs and academia), so as to afford a comprehensive overview of the key players' views and the most important aspects related to public health. These workshops had also aimed to bring together participants (not only speakers) with different backgrounds (from the areas of health policy, intellectual property and trade) so that they could learn from each other and to promote understanding that interdepartmental cooperation was beneficial on the domestic front just as it was internationally.

142. The increased focus on technical cooperation relating to public health and intellectual property had been assisted through active dialogue, coordination and partnership with the WHO and WIPO. This very productive cooperation had facilitated further involvement of WHO and WIPO experts in WTO technical cooperation activities, which had enabled more effective and more tailored technical cooperation from a richer and more well informed factual background. This cooperation had also led to joint technical cooperation activities, including a technical symposium jointly organized by the three secretariats on "Access to Medicines: Pricing and Procurement Practices" in Geneva on 16 July 2010. The purpose of the symposium had been to gather experiences in the pricing and procurement of medicines as important determinants of access and to examine how and where to obtain information on access to medicines, their prices and their availability. It had provided an opportunity for participants with different backgrounds, coming from governments, international and philanthropic initiatives on the procurement of medicines, civil society organizations and industry, to share experiences, take stock of the present situation and examine future needs.

143. Three future directions might be considered with respect to the technical cooperation work of the WTO Secretariat. First, the increasing trend towards partnership with other organizations, both within the established trilateral partnership, and beyond it, would be highly desirable, at the level of planning, coordination and programme delivery, so as to ensure the necessary breadth of expertise was available and to leverage the investment of resources more effectively. Second, a practical understanding of the relevant elements of the TRIPS Agreement and the System in particular might be embedded in a practical way into operational procurement programmes, with greater interconnection between the technical cooperation activities and those who undertook procurement of medicines, for

instance to facilitate the communication of demand for medicines through the System. Third, the enhanced and more integrated information base that was gradually emerging concerning, for example, patent coverage, prices and access to medicines by vulnerable populations, would enable technical cooperation to be more focussed, tailored and practically oriented towards specific drug procurement objectives.

144. The representative of UNCTAD noted that his organization's initial mandate on issues related to access to medicines had come from the Commission on Investment in 2005. The 2005 Commission had requested UNCTAD to initiate work on local production of pharmaceuticals in developing countries, with particular reference to the role that IP and technology transfer might play. That mandate had been taken up later at the Accra Accord, by which UNCTAD had been given a broader mandate to work on the development dimensions of intellectual property. The Accra Accord mandate, which governed UNCTAD's activities directly, had also mentioned the WIPO Development Agenda and had called upon UNCTAD to cooperate with WIPO on issues related to the development dimension of intellectual property. Finally, UNCTAD had been named as a stakeholder in the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, in particular for issues related to technology transfer, intellectual property and local production of pharmaceuticals. UNCTAD defined intellectual property broadly, looking at where to draw the line between the grant of exclusive rights and what should be in the public domain, and not just covering the exclusive rights themselves. Intellectual property formed part of larger development concerns including health, education, industrial development, technology transfer, innovation, agricultural development and various other areas of development. There was a need to ensure that the intellectual property system functioned to support important development objectives. Intellectual property was therefore not an objective in its own right, but rather a means to an end. In the context of flexibilities for public health, the strategic use of flexibilities balanced with obligations under international treaties could help to ensure better alignment of intellectual property policies with development objectives.

145. UNCTAD's intellectual property advisory services were based on requests from developing countries and LDCs. They resulted in advisory reports, which contained analysis, recommendations to the country based on research field missions and wide stakeholder consultations in the country. These advisory reports could be either published, such as the report on Uganda's Development Dimensions in IP, published in June 2010 (accessible at http://www.unctad.org/ddip), or they could be private. The output would be given only to the requesting government Ministry. In addition to advisory services, UNCTAD had run a series of regional workshops on TRIPS and local production of pharmaceuticals in developing countries. UNCTAD had held four regional workshops, two for Eastern Africa, one for Southern and Western Africa, and one for South-East Asia. These workshops had had a total of 203 participants, 33 in 2009, 52 in 2008, 74 in 2007 and 44 in 2006. The audience for these workshops had been government officials, local pharmaceutical producers, health NGOs and academia. In total, the beneficiaries had included 19 countries and three regional organizations. The textbook that had been used to conduct these workshops had been developed in-house and would soon be published in a document called the "Reference Guide on Intellectual Property and Local Production of Pharmaceuticals". Follow up courses to these regional workshops had been organized by a German NGO called INVENT, with the support of a German grant.

146. UNCTAD's technical assistance activities were backed up through an active programme of research and analysis. Examples of the products of this programme had included joint publications with the International Centre for Trade and Sustainable Development (ICTSD) on issue papers, a paper series on Technology Transfer for Successful Integration into the Global Economy and UNCTAD-ICTSD policy briefs on WIPO Development Agenda issues. UNCTAD had considered the possibility of a policy brief on the IP and medicines issue in the future. Presently, UNCTAD was engaged with the WHO and the European Union in a series of case studies on local pharmaceutical production and related technology transfer. All research was either commissioned or written in house by staff and then peer-reviewed. UNCTAD had engaged in a limited amount of consensus building

activities, with respect to TRIPS and public health issues. With respect to the WHO Global Strategy and Plan of Action, UNCTAD had co-hosted with UNIDO, WHO and ICTSD an ECOSOC Ministerial Breakfast Roundtable on global public health, high quality, low cost pharmaceutical production in developing countries. UNCTAD had also had a few expert seminars on an ad hoc basis in 2006 and 2007, dealing specifically with the question of local production of pharmaceuticals.

147. The representative of the WHO outlined the foundation of his organization's perspective on access to medicines. The Constitution of WHO stated that the enjoyment of the highest attainable standard of health was one of the fundamental rights of every human being. In recent years, the scope and content of the right to health had been further clarified in international law. Access to essential medicines today was established as a part of the right to health that obliged governments to work for its progressive realization and intellectual property rights were one of the many determinants for access to medicines. WHO had a longstanding mandate to work at the interface of public health and intellectual property. This had been reinforced by the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property that had stated that "WHO shall play a strategic and central role in the relationship between public health and innovation and intellectual property…"

148. The Global Strategy had recognized the importance of patents as an incentive for the development of new health-care products, but had concluded that "this incentive alone does not meet the need for the development of new products to fight diseases where the potential paying market is small or uncertain." The Global Strategy had also affirmed that "there is a crucial need to strengthen innovation capacity as well as capacity to manage and apply intellectual property in developing countries, including, in particular, the use to the full of the provisions in the TRIPS Agreement and instruments related to that agreement, which provide flexibilities to take measures to protect public health." In fulfilling this mandate, the WHO had worked continuously in collaboration with other relevant international organizations and with WHO Country and Regional Offices, to support its member states in their endeavours to apply and manage intellectual property in a manner that maximized health-related innovation, protected public health, and promoted access to medicines for all.

149. In accordance with the Global Strategy, the WHO had strengthened its efforts to coordinate work in the field of public health and intellectual property with other relevant international organizations. The Director-General of the WHO had exchanged letters with the Directors-General of the WIPO and the WTO to enhance collaboration and coordination of respective activities in this field. Based on this exchange of letters the Secretariats met every month to coordinate activities and to discuss possible areas of cooperation and joint work around public health and intellectual property.

150. The WHO's priorities in technical cooperation had been to provide member states with information, training and technical assistance on how to apply and manage intellectual property in a manner that maximized health-related innovation and promoted access to medical products. Special emphasis had been given to the implementation and use of flexibilities and public policy options in accordance with the TRIPS Agreement and the Doha Declaration to promote implementation of the TRIPS Agreement that supported access to medical products and needs-driven innovation. Further details of the activities carried out since 2008 were contained in the WHO's report on its technical and financial cooperation activities.

151. The representative of the UNAIDS noted that the work of the UNAIDS and its co-sponsoring agencies was guided by the health-related Millennium Development Goals (MDGs) with special attention to MDG 6 which was "to halt and reverse the spread of HIV, Malaria and other epidemics by 2015". With AIDS being the leading cause of death worldwide among women of reproductive age, and with the possibility of virtually eliminating mother-to-child transmission of HIV, an integrated approach to the AIDS response was central to improving maternal and child health.

152. This TRIPS Council discussion was timely for a number of reasons, not least because of the increasing number of people living with HIV in need of antiretroviral treatment, and concerns about increasing costs. Antiretroviral treatment for HIV infection was significantly reducing mortality for people living with HIV. At the end of 2009, 5.2 million people were on HIV treatment, a twelve-fold increase from 2003 when the WHO and UNAIDS had first launched the historic 3-by-5 Initiative. According to estimates, the number of additional people for whom antiretroviral treatment would be needed could soon reach 15 million. The global economic crisis had begun to adversely affect prospective commitments to AIDS from both donors and low- and middle-income countries. For the first time in a decade, disbursements from donors for HIV/AIDS actually fell in 2009 from a high of USD 7.7 billion one year earlier. The 2009 report of the inquiry of the United Kingdom's All-Party Parliamentary Group on AIDS into long-term access to HIV medicines had reported that "we are sitting on a 'treatment time bomb.'" The cost of the least expensive first generation regimen had dropped to less than USD 70 per patient, per year. But as increasing numbers of people moved towards more efficacious and tolerable treatment regimens, some experts projected drug prices to double compared to first generation regimens. As patients developed drug resistance and required more expensive and more highly patent-protected second- and third-line antiretroviral medicines, some projections saw treatment costs escalating as much as twenty-fold.

153. In addition to the important work being undertaken by the WHO, under the UNAIDS division of labour, UNDP had been given a mandate to serve as the lead cosponsoring agency within the UNAIDS in providing support to governments to incorporate public health-related TRIPS flexibilities into domestic legislation. In cooperation with the WHO and on behalf of the UNAIDS, the UNDP had provided policy and technical support to countries reforming domestic intellectual property legislation in this area. As part of its capacity building activities on the System, the UNDP had recently provided assistance to civil society organizations advocating for a revised Access to Medicines Regime in Canada. Canada had been the first country to amend its law to give effect to the Decision. Bill C-393 had been proposed to streamline the practicability of CAMR. Together with the Canadian HIV/AIDS Legal Network, UNDP had co-organized consultations to explore opportunities to strengthen the CAMR in February 2010. The focus of the discussions had been on ensuring compliance of Bill C-393 with the TRIPS Agreement and on giving more flexible and rapid effect to the Decision. In addition, a the UNDP staff member had been invited by and had appeared before the Canadian Parliament to provide technical information.

154. In 2003, the UNAIDS had welcomed the multilateral consensus among WTO Members regarding access to affordable medicines for countries without sufficient manufacturing capacity in the pharmaceutical sector. We had appreciated that the consensus covered other public health problems in addition to AIDS, since people living with HIV were prone to a host of opportunistic infections, such as tuberculosis, cancers, fungal infections and others, and these diseases were important health problems in themselves. The UNAIDS had urged that the arrangements under the Decision be implemented in the most flexible manner possible, so that countries could utilize the System easily and efficiently in their efforts to ensure greater access to HIV medicines for their peoples. In reality, very few importing countries had introduced provisions that would facilitate the System's use. In 2007, the UNDP had provided assistance for the introduction of such provisions to the legislator in Zanzibar, United Republic of Tanzania. The Industrial Property Act 4 of 2008 had come into operation in the second half of 2008 and contained a number of important TRIPS flexibilities, including the exclusion of pharmaceutical patents until 2016 or such other time as might be agreed by WTO Members. Similar technical assistance had been provided by the UNDP to other sub-Saharan African countries in the process of amending legislation.

155. The UNDP had provided technical and policy support on the utilization of non-voluntary licences under Article 31 TRIPS. In partnership with the Intellectual Property Institute of Ecuador, UNDP had held stakeholder consultations on compulsory licensing in Quito in March 2010. Similar assistance had also been provided to the Government of Thailand through a WHO mission in 2008 in

which resource persons from the UNDP, UNCTAD and WTO had participated to provide technical information with regard to the TRIPS Agreement. The UNDP had provided capacity development activities to assist States to implement their intellectual property commitments made either through the process of acceding to the WTO or during negotiations on free trade agreements. Examples of such technical co-operation had included a regional conference on access to essential medicines, HIV and intellectual property, held in Kiev in September 2009, organized by the UNDP and the Open Society Institute. The UNDP had supported capacity development trainings for patent examiners focusing on the examination of pharmaceutical patents. Those had been carried out in Africa, the Arab States and Latin America. He noted that the UNDP, WHO and UNAIDS would soon be issuing a joint briefing paper on the use of TRIPS flexibilities to improve access to HIV treatment.

156. The UNAIDS and UNDP had also provided technical and policy support to recipients of Global Fund Grants in using public health-related TRIPS flexibilities to increase the availability of affordable antiretroviral medicines. The procurement policy of the Global Fund called for its beneficiaries to obtain quality medicines at the lowest possible price and encouraged grantees to utilize the TRIPS flexibilities to this end. As donors faced a period of extended financial uncertainty and understandably heightened their focus on accountability and value for money, the UNAIDS expected continuing and even heightened interest in TRIPS flexibilities, including the System.

157. The representative of WIPO said that his organization's activities comprised studies and documents on flexibilities and options, legislative and policy assistance related to patents, as well as national and regional seminars, meetings and workshops, which also addressed flexibilities, including the System. Among the studies that WIPO had prepared as part of the first group was a document presented to the Committee on Development and Intellectual Property (CDIP) on patent-related flexibilities in the multilateral legal framework and their domestic implementation. Another example was a document presented to the Standing Committee on Patents, containing an experts' study on exclusions from patentable subject matter and exceptions and limitations to patent rights. Some of the topics covered were closely related to the TRIPS Council's discussions. He also noted the existence of other studies related to health. For example, there had been a WIPO study on patents and their relationship with viruses, influenza and other health issues, that had been prepared by WIPO upon the request of the WHO in 2007. There had also been a joint study by WHO and WIPO on innovation and public health.

158. With respect to legislative assistance and public policies, WIPO's work had looked at 114 Member countries' national legislation. In those countries, WIPO had identified 19 cases where the Decision had been implemented domestically. Out of those 19 countries, one group, including Canada and the EU, had implemented the Decision with a purely exporting vision. Another group, including Singapore, had implemented it with an importing country's approach. From October 2009 to October 2010, the WIPO Secretariat had reviewed the respective draft laws of ten Member countries on their request, looking at the way in which the rules included flexibilities, in particular with reference to the System. During the same period, upon request by certain member states, WIPO had also drafted six laws focusing exclusively on patents, including the domestic implementation or proposed implementation of the System. Six expert missions and two visits to Geneva had been carried out in order to discuss details relating to flexibilities, in particular the System, with the authorities concerned. Among the issues that had been studied, and the different options that had been explored, was the Decision and how to make full use of the System even before acceptance of the Protocol Amending the TRIPS Agreement had taken place. Furthermore, the waiver regarding the payment of remuneration in the importing country had also been considered. Finally, WIPO had also provided legislative advise with respect to the identification of enforcement mechanisms to ensure that products were not diverted from their intended markets under the System.

159. As regards the organisation of and participation in national and regional workshops and meetings. WIPO's Legislative and Policy Advise Section, Patent and Innovation Division, had taken

part in 4 regional meetings and 6 regional seminars from October 2009 to October 2010, most of which had been organised in cooperation with the WTO. The topic of flexibilities, in particular the System, had been discussed at length. The Secretariat of WIPO was currently carrying out a series of other activities, including several colloquia on selected patent issues, such as the research exemption (October 2006) and flexibilities in the patent system (February 2007), as well as the Symposium on intellectual property (December 2008) and the conference on intellectual property and public policy issues (July 2009).

160. Another representative of WIPO noted that new pharmaceutical products resulted from innovation. Innovation systems were increasingly global and this had profound implications for technology transfer, market competition, economic development and public policy. Many policy debates saw science, technology and innovation as crucial to identify threats and find solutions. This posed two main challenges: first, ensuring that policy responses worked, and second, ensuring that critical innovations did not bypass the developing world. WIPO had created the Global Challenges Programme to contribute to these policy debates. The approach built upon the contribution of intellectual property to economic growth and societal benefit. The goal was to ensure that the mechanisms operate effectively and that the needs of the poor in developing countries were not overlooked. Intellectual property was not seen as an end in itself but as an instrument of public policy, i.e. an instrument to stimulate innovation and to support the diffusion of innovation. This required transparent and effective structures, national and multilateral policies, intellectual property management capacity, and support for licensing structures that enhanced the use of intellectual property. WIPO's activities focused on four areas: (i) reinforcing interactions with WIPO's member states; (ii) promoting informed policy discussions; (iii) strengthening WIPO's networks; and (iv) developing effective concepts and mechanisms and facilitating their implementation.

161. Cooperation and dialogue with partners from other international organizations, such as the WHO, WTO, and UNCTAD, and also with regional and national organizations, NGOs and civil society, the private sector and academia were important aspects of WIPO's work in the area of public health. WIPO had engaged actively with WHO in the context of the adoption of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property. It was working actively with WHO and WTO to identify and provide its contribution to the implementation of the Global Strategy. To this effect the three organizations met on a regular basis to discuss and exchange on their relevant programme activities. A technical Symposium on "Access to Medicines: Pricing and Procurement Practices" had been jointly organized on 16 July 2010.

162. WIPO supported WHO's Intergovernmental Meeting on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and other Benefits (IGM) with its intellectual property expertise. Upon request by WHO, it had contributed a working paper on "Patent issues related to influenza viruses and their genes", published on WIPO's website (http://www.wipo.int/patentscope/en/lifesciences/ip_health.html) and on the WHO Avian influenza website (http://www.who.int/csr/disease/avian_influenza/wipo_ipdoc/en/index.html). WIPO was equally engaged in providing intellectual property expertise to the initiative of the Special Programme for Research and Training in Tropical Diseases to set up an African Network for Drugs and Diagnostics Innovation, the African Union Pharmaceutical Manufacturing Plan for Africa, and the UNITAID Medicines Patent Pool Initiative.

163. He noted that it was a particular challenge to show how intellectual property systems and policies could enable access to medicines. A central aspect was information about (i) applicable laws, (ii) the existence or absence of rights and (iii) technology. A special focus was on information generated in developing countries. Such information remained difficult to obtain. WIPO worked to improve capacity in national offices to administer the patent system. Increasingly, information was available via the Patentscope portal (http://www.wipo.int/patentscope/en/lifesciences/ip_health.html), WIPO's gateway to patent information. The challenge was to appropriately use that information.

This required capacity in making the information available, as well as finding and analyzing the information. It required capacity to proactively use the information to get access to technology and innovation. Intellectual property was not the goal but the tool. An intellectual property right could also be an indication for an opportunity. WIPO remained committed to continue working with all stakeholders in the context of intellectual property and public health.

164. The representative of India asked the representative of WIPO how technical assistance had changed following the adoption of the development agenda, particularly the focus on the exercise of TRIPS flexibilities. With respect to the presentation by the WHO, he noted that it had been stated that special emphasis had been given to the implementation and use of TRIPS flexibilities and public policy options. However, the WHO's annual report (IP/C/W/549/Add.4) did not reflect this emphasis. He asked the representative of the WHO how the WHO assessed the System and whether it had conducted a study as to why the System had only been used once in the past seven years. Noting that the System provided for measures to harness economies of scale, he asked whether the WHO factored this into its programmes, particularly for LDCs. Finally, he wondered how free trade agreements promoted by developed Members which circumscribed TRIPS flexibilities impinged on efforts made by the WHO.

165. The representative of the European Union acknowledged that developing and least developed countries might have faced structural challenges in implementing the System. In many instances, technical assistance and capacity building had been crucial to enable those countries to recognize and act on the implications of the TRIPS Agreement on public health policies and establish workable laws, procedures and practices to give effect to the Doha Declaration and the Decision. This had required sound technical advice on how to best integrate the Doha Declaration and the Decision into intellectual property policies and practices. His delegation had integrated sound legislative advice and clarification on how to give effect to the System in order to facilitate access to medicines into its intellectual property technical cooperation programmes with developing countries.

166. In response to the question from the delegation of India, the representative of WIPO noted that, within the CDIP, the Secretariat had been requested to prepare a document on patent-related flexibilities and legislative implementation at the national and regional level. This had been submitted to the previous session of the Committee. WIPO was currently working on forthcoming documents that would include all the flexibilities regarding patents and related technological fields. WIPO provided information to Member countries with respect to the implementation of legal frameworks of which flexibilities within the multilateral framework were part. Efforts had been made to identify those flexibilities that would fit into the development goals of each of the countries that requested WIPO's advice.

167. The representative of the WHO noted that his organization's work emphasized the use of TRIPS flexibilities. The way in which member states implemented Article 27 of the TRIPS Agreement, how they defined what was new, what was an inventive step and what was capable of industrial application, had a great impact on what could be patented under national patent laws. This provision, therefore, offered public policy options, which might be called flexibilities under the TRIPS Agreement. The WHO had not studied or commissioned a study as to why the Paragraph 6 System had only been used once. Member states had not requested such a study, perhaps because the System was part of the WTO framework.

168. He said that the needs of LDCs received particular attention in the WHO's work. It had participated actively in the workshops on the LDCs needs assessment organized by the WTO Secretariat, including the recent workshop in Bangladesh and the forthcoming workshop in Senegal which was directed to the needs assessment of French-speaking African LDCs. However, the WHO had not received any request with regard to the implementation of the System from LDCs or other developing countries, nor had it received any request with respect to the regional dimension of the

System. With regard to the bilateral free trade agreements and their impact on the WHO's work, he referred to the Global Strategy, which urged governments to take into account, where appropriate, of the impact on public health when considering adopting or implementing more extensive intellectual property protection than was required by the TRIPS Agreement, without prejudice to the sovereign rights of member states. The WHO gave advice and technical assistance to its member states to the effect that, when they entered into agreements that went beyond the level of protection provided by the TRIPS Agreement, they should carry out a public health impact assessment in order to take an informed decision on the agreement they were envisaging to enter into.

169. The representative of Brazil noted that the TRIPS Agreement contained many more exceptions than those contained in its Article 27, citing a recent WIPO study on exclusions, exceptions and limitations to patentable subject matter. Supporting India, she called for a broadening of the discussion.

170. The representative of Ecuador noted that technical cooperation programmes of international organizations seemed to increasingly take into account flexibilities. However, such programmes continued to be focused on institutions such as intellectual property offices. It would be beneficial to know whether similar technical assistance activities were planned to broaden participation to involve other stakeholders and how the development dimension was covered with respect to the effective implementation and use of TRIPS flexibilities, in particular as regards compulsory licences and the System. He asked the representative of WIPO for more details on their projects under the development agenda, including relevant items related to TRIPS flexibilities. He also wondered how international organizations, such as the WTO and WIPO, could make better use of their resources for technical cooperation in collaboration with other organizations, including UNCTAD, WHO and UNAIDS, to implement the flexibilities.

171. As regards the inclusion of stakeholders outside the intellectual property offices, the representative of WIPO said that national policy makers were primarily in charge of legislating and incorporating TRIPS flexibilities into domestic law. Beyond this initial implementation stage, there might well be other actors who could be involved in the intellectual property system. With respect to WIPO's work in the area of flexibilities, he noted that it provided assistance not just in implementing laws, but also in identifying the most appropriate public policies for a country.

172. The representative of India requested the representative of the WHO to prepare a detailed study on TRIPS flexibilities pertaining to public health in its technical cooperation activities.

173. Supporting the statement made by the delegation of Ecuador regarding WIPO's intervention, the representative of Venezuela quoted from a lecture on TRIPS flexibilities which had stated that "almost all the national patent regimes in developing countries were based on the European and American systems. Patent rights in developing countries were often based on colonial laws or on drafts elaborated with technical assistance from WIPO and patent offices from developed countries. Most of the technical assistance provided to developing countries focused more on conformity with the provisions of the laws relating to rights of patent holders than on the implementation of flexibilities within a multilateral framework that protected public health. The inability to access information about optimal practice were another problem that explained the lack of technical knowledge to implement TRIPS flexibilities in national laws. As a result, developing countries were unaware of the measures and successful strategies put in place by other developing countries to overcome problems with access to medicines. Consequently, countries from the same region which encountered similar or identical difficulties, applied different strategies with varying degrees of success. More importantly, while the majority of developed countries offered technical assistance and best practices on how to protect patent rights, no manual or technical assistance had addressed best practices with respect to compulsory licensing and competition law, looking at, for example, the

extensive use made of it by the United States to stop the abuse of patent rights and to address other public interests.

5. Any alternatives to the use of the Paragraph 6 System to achieve the objective of access to medicines, procurement policies, and other related aspects affecting access to medicines

174. The representative of the Secretariat informed Members about its recent technical cooperation activities that shed light on the broader context affecting procurement strategies to promote effective access to medicines. In July 2010, the WHO, WIPO and WTO had jointly organized a technical-level symposium on access to medicines, pricing and procurement practices. This symposium had aimed to promote understanding as to the experience of international and regional agencies in the pricing and procurement of medicines as an important determinant of access. It had provided an opportunity to discuss where to obtain information on access to medicines, their prices and availability, covering core questions on drug procurement, pricing and relevant intellectual property issues. Arising from technical level dialogue between the organizations, the activity had been planned to lay the groundwork for continuing dialogue among the collaborating organizations and their partners and the ongoing trilateral cooperation, which included the implementation of the WHO Global Strategy and Plan of Action. The event had heard the perspectives of the three Directors-General and from technical-level officials from the three Organizations, as well as representatives from global procurement agencies and NGO procurement initiatives, other active NGOs and several industry perspectives.

175. The WTO's technical-level contribution had been to set out an overview of the practical information available on trade-related measures that had a bearing on all aspects of the access equation. These included information on intellectual property policy settings, procurement and competition policies, tariffs and regulatory matters ensuring the quality, safety and efficacy of medicines. The aim had been to provide as complete a factual picture as possible. Hence the emphasis had been on strengthening the information base for practical cooperation on drug access and procurement questions. Director-General Pascal Lamy had commented that "global public health is a complex puzzle; getting it right is a teasing challenge, involving effective use of the full set of applicable policy tools, but it is also a practical craft, rather than a theoretical excursion meaning that we can and should learn from the actual experience of others in their efforts to create and disseminate needed treatments. The pooled perspective needs to cover the international trade dimension but also consider domestic policies and practices, and above all the evolving state of the actual global disease burden, a priority setting for front-line treatments and patents for the production and dissemination of medicines". He had expressed the hope that the programme of the technical symposium would help illuminate this far bigger picture so that each organization could complete its specific areas of work with the benefit of greater understanding about how all the elements interacted and what priority targets should be aimed at, a task that could only be undertaken by public health colleagues.

176. The symposium had not been intended as a policy forum and accordingly no conclusions or outcomes had been intended to emerge. However, the improved flow of data and the ideas for more effective use of diverse sources that had been explored during the symposium should allow for technical cooperation to be better designed and for a firmer empirical base for understanding access to medicines issues to be built. It was clear that, to progress the goal of access to medicines, strengthened cooperation and improved information resources from diverse resources would make a significant difference. The technical symposium had reviewed a number of available resources of information, covering prices, availability and quality of medicines, concerning patents and the scope of patent coverage, and a range of trade and intellectual property policy issues and measures available in various WTO notifications and databases.

177. Based on the Secretariat's practical experience with technical assistance in the field, the current trend had appeared to be to try to marry the understanding about legal options and legal mechanisms with the broader perspective of procurement strategies and an improved information base. For example, since patents were national and territorial in scope, effective procurement practices entailed understanding what relevant patents were in force and in what jurisdictions. Similarly, information about pricing trends was helpful both in understanding the existing state of play regarding access and in undertaking practical procurement activities. Information about the broader regulatory framework, including on tariffs, taxes, health regulation, competition policy, and intellectual property matters, helped to illuminate the operational context of procurement programmes, in turn enabling them to be more effective and to derive better health impact from available resources.

178. The representative of the WHO presented his organization's experience from a public health perspective. Among its most important missions was the improvement of access to quality essential health services and products, including essential medicines, vaccines, diagnostics, medical devices and equipment, especially for disadvantaged people. Reliable and sustainable access to health products was determined by different macro health system factors. These included strong, accountable and transparent health governance with well-developed health policies for national health systems, health financing, social protection mechanisms, trained and available health workforce, health care delivery infrastructure, and reliable health management and information systems.

179. He said that, more specifically, access to medicines was determined by four factors: (i)rational selection of medicines; (ii) affordable prices; (iii) sustainable financing; and (iv) reliable supply systems. The rational selection of medicines required a country to decide, according to well-defined criteria, which medicines were most important to meet existing public health challenges. Through its model list of essential medicines, WHO provided guidance to member states in the development of their national essential medicine lists. An essential medicine had to be a safe and effective product and should represent the best rational choice, regardless of its price, to address a specific health problem. As regards affordable prices, while in high-income countries a high percentage of expenditures on medicines was publicly financed or reimbursed by health insurance, a high percentage of expenditure came directly from the pockets of patients in low- and many middle-income countries. The public sector was not always a viable alternative. In a number of low- and middle-income countries, the average availability of medicines in public health facilities turned around 35 per cent. When patients therefore had to turn to private pharmacies, the price of medicines became one of the most important determinants of access to medicines. With respect to sustainable financing, per capita expenditure on medicines in real terms remained regrettably very low in poor countries, despite governments spending a large proportion of recurrent health budgets on buying medicines. As regards reliable medicine supply systems, these included forecasting needs, procurement, storage, transportation and inventory keeping of medicines. All these areas remained weak in many developing countries. Without investing in and improving supply systems, access to medicines would remain a formidable challenge.

180. The representative of the WHO noted that his organization was involved with its member states in improving access to medicines in each of those four areas, both by developing norms and standards, and by providing direct technical assistance. It used availability and prices of medicines as indicators to measure access to medicines. Looking at access to high-priced patent-protected essential medicines, especially in countries with no or limited manufacturing capacity, he noted that more than 90 per cent of medicines on the WHO model list of essential medicines were not patent-protected. Nevertheless, a majority of patients in low-income countries continued to suffer and to die due to lack of access to treatment interventions, including lack of supply of generic medicines. Nearly 30,000 children died every day from diseases that could easily be treated if they had access to a range of basic patent-free essential medicines. Also 1.8 million children under the age of five years died every year of pneumonia alone that could be treated with cheap inexpensive antibiotics. Only 20 per cent of

children received these antibiotics. This was a long and tragic list of circumstances where inexpensive generic medicines were available, but did not get to the people when they needed them the most. These issues needed urgent attention.

181. High prices of patent-protected essential medicines also constituted a barrier to access to medicines, especially in the case of second-line HIV/AIDS medicines and tuberculosis in Africa and other poor countries and for non-communicable diseases like cancer. Generic competition in the market was one of the most efficient mechanisms to bring prices down, as seen in the case of first-line antiretroviral medicines for the treatment of HIV/AIDS. Because of generic competition, the cost of one year of treatment for one patient with first-line antiretroviral medicines had dropped from more than USD 10,000 to around USD 100 between 2002 and 2010. This drastic decrease in the cost of medicines had resulted in increased access to those medicines. As of December 2009, an estimated 5.2 million people in low- and middle-income countries living with HIV had been receiving antiretroviral therapy, a twelve-fold increase since 2003. The importance of affordable prices of antiretroviral therapy would increase in the near future. Because of changes in the newly published WHO HIV treatment guidelines, the number of people for whom treatment would be needed could increase to 15 million.

182. The System addressed a very specific situation when a country without sufficient manufacturing capacity wanted to procure a patented medical product, and there were no generic producers in other countries that could supply the product. Other ways of obtaining the needed medicines could be explored before invoking the System, for example, through a search of therapeutic equivalents which were not patent-protected or through negotiation with the patent holder. However, where no other possibility existed, the System could be legitimately put into action to procure the needed medicines. The WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property had been very explicit about the right of the member states to make optimal use of TRIPS flexibilities. Element 5.2 of the Strategy had urged governments to "consider, where appropriate, taking necessary measures in countries with manufacturing capacity to facilitate through export, access to pharmaceutical products in countries with insufficient or no manufacturing capacity in the pharmaceutical sector in a manner consistent with the TRIPS Agreement, the Doha Declaration and the WTO Decision of 30 August 2003".

183. He noted that, although the System had rarely been used to date, it might be considered more frequently in the future, given the changing requirements for new medicines to treat diseases, and the implementation of the TRIPS Agreement in member states. A recent study had revealed that Indian generic manufacturers had accounted for more than 80 per cent of donor-funded annual purchase volumes of antiretroviral medicines between 2003 and 2008. The implementation of full patent protection for pharmaceutical products in India and the approaching expiry of transition periods in LDCs might make it more difficult in the future to procure generic versions of new medicines. Under such circumstances, the System might assume a greater significance. He confirmed that to date the WHO had not formally received any request from any member state for technical assistance in the use of the System. He concluded that access to medicines was determined by many factors and the situation was far from perfect even for those medicines which were not patent-protected. All possible legitimate measures had to be considered when access to patent-protected medicines of public health importance was at stake, especially when countries did not have sufficient local manufacturing capacity. In such situations, the System was definitely one of the possible options and it might become more important in the future.

184. The representative of India appreciated the positive references that had been made to the Indian generic industry. The latter had undoubtedly brought a paradigm shift in changing the global discourse about access to life-saving medicines at affordable prices. A recent study, published in the Journal of the International AIDS Society of September 2010, had noted that, over the last seven years, 80 per cent of donor-funded AIDS medicines had been supplied by Indian generic

manufacturers to developing countries. The same study had also mentioned that the cost of the Indian generic version of the most commonly used first-line adult regimen for HIV/AIDS treatment (Lamivudine/Nevirapine/Stavudine) had dropped from USD 404 per person per year in 2003 to USD 74 per person per year in 2008. However, the credit could not be entirely attributed to the Indian generic industry, given that the largest generic manufacturer was in the European Union and the second largest in Israel. But these manufacturers might not be price-competitive in all generics. He cautioned that the Indian generic industry was not a panacea for addressing the reasons which had necessitated the establishment of the System. Many life-saving medicines were off-patent in India and therefore were readily available as generics. He noted that most first-line antiretroviral medicines predated the TRIPS Agreement and were therefore not patented in India. This situation might change in the future, as more product patents were filed and block-buster drugs were invented. This might lead to a decline of the present generic advantage, making the developing world, including the LDCs, dependent on high-priced patented drugs. Switching to second-line antiretroviral medicines was at least three times more expensive, costing about USD 465 per person per year. Possible third-line drugs like Etravirine, for which there was no generic alternative, cost USD 3,204 per person per year. Those medicines represented the real challenge for the System and other TRIPS flexibilities that could be invoked for public health reasons.

185. With respect to voluntary contributions and tiered pricing by some developed Members, he noted that, while these attempts were appreciated, they were not lasting solutions. The Report of the UN Special Rapporteur had indicated that one third of the world's population did not have access to affordable medicines. The number of patients being treated for HIV/AIDS in developing countries had jumped to 5.2 million in 2010 from 400,000 in 2003. Given the breadth of the problem, he noted that, while voluntary efforts and tiered pricing made an important contribution, they could not be the entire solution and did not obviate from the need to use the System. He wondered whether the futile attempts of MSF and Ghana to use the System through CAMR had had a chilling effect.

186. The representative of India said that Articles 30 and 31(k) of the TRIPS Agreement represented possible alternatives to the use of the System to achieve the objective of access to medicines. During the preparatory work in the TRIPS Council which had led to the adoption of the System, the European Union had presented a concept paper (IP/C/W/339). One of the two possible solutions proposed had been the interpretation of "the limited exceptions clause of Article 30 of the TRIPS Agreement in a way which would allow production for export, to certain countries and under certain conditions, of products needed to combat serious public health problems". The EU had acknowledged that "the advantage of this approach would be that it could fit within the flexibility offered by the existing TRIPS Agreement, without there being a need to amend any of its provisions". He noted that this option was always available to Members. In the September 2002 meeting of the TRIPS Council, the WHO representative had said that "the solution... that was most consistent with the principle was the provision of a limited exception under Article 30. Such an exception would meet the mandate of the Declaration and provide expeditious authorization to third parties to make, sell, and export patented drugs and other technologies to meet public health needs" (IP/C/M/37).

187. He noted that Article 31(k) performed the same purpose as the Decision in that it waived the restriction imposed by Article 31(f) on compulsory licensing for export when a Member issued a compulsory licence "to remedy a practice determined after judicial or administrative process to be anti-competitive". This provision had been used three times in the last five years by a developed country Member of the EU. Interestingly, the Member concerned had opted out as an importing country under the System. Both Articles 30 and 31(k) were existing provisions in TRIPS and were covered by Paragraph 4 of the Doha Declaration which stated that "we reaffirm the right of WTO Members to use, to the full, the provisions of the TRIPS Agreement, which provide flexibility for this purpose".

188. The representative of Japan believed that the objective of the System, which was to facilitate access to medicines by Members with insufficient or no manufacturing capacity in the pharmaceutical sector had to be kept in mind. The System should not be considered in an isolated manner but as part of a broader effort to contribute to access to medicines. At the trilateral Symposium on "Access to Medicines: Pricing and Procurement Practices", organized by the WHO, WIPO and WTO, it had been noted that elements other than intellectual property rights were important to access medicines, such as procurement and tariffs. It had also been noted that only five per cent of medicines included in the WHO list of essential medicines were protected by patent.

189. He informed Members of Japan's efforts to contribute to access to medicines. In September 2010, Mr. Kan, the Prime Minister of Japan, had announced the "Kan commitment" to contribute USD 800 million in the coming years to the Global Fund to Fight AIDS, tuberculosis and malaria which Japan had co-founded. In order to accelerate progress towards the Millennium Development Goals by halting the spread of HIV/AIDS, tuberculosis and malaria, Japan would scale up effective interventions through the Global Fund. To do so, it would promote an integrated approach, combining the Global Fund efforts with strengthening health systems and maternal, newborn and child survival programmes, utilizing Japan's bilateral assistance. Although the number of people receiving life-saving antiretroviral therapy against HIV/AIDS had increased from 0.4 million in 2003 to 5.2 million in 2009, he recognized that there was an urgent need for expanded efforts to address the issue. His delegation had contributed USD 1.04 billion to the Global Fund. Furthermore, as part of the Global Plan "Stop TB 2006-2015", Japan had provided anti-tuberculosis drugs and testing tools to tuberculosis-affected countries, designated by the WHO as high burden countries. Japan had also contributed to combating other infectious diseases, such as influenza and polio. It had also provided an emergency grant aid of approximately JPY 1.1 billion through the WHO in September 2009 to carry out immunizations in developing countries with the H1N1 influenza vaccine. In addition, in order to prepare for a pandemic influenza, Japan was stockpiling and providing antiviral medicines in cooperation with ASEAN and the ASEM. It supported the provision of polio vaccines through UNICEF to some countries that had been designated as countries of prevalence. The importance of local production in developing countries was also recognized. Japan had cooperated with the Government Pharmaceutical Organization of Thailand to locally produce influenza vaccine. He reiterated the importance of access to medicines, and the importance of keeping the bigger picture in mind when discussing this issue.

190. The representative of the United States said that the TRIPS Agreement provided an important balance between providing incentives to research and develop new medicines and promoting access to existing patented medicines. The Doha Declaration had stated that the TRIPS Agreement "does not and should not prevent members from taking measures to protect public health". His delegation was a global leader on improving public health. US funding for global health had increased significantly over time, particularly in the last decade. Funding had more than doubled between 2004 and 2008, reaching USD 9.6 billion in 2008. In 2009, the United States had been the largest donor in the world for the global response to HIV/AIDS, accounting for more than half of disbursements by governments. As part of the US Government's global health programme, his delegation was committed to promoting equitable access to safe and effective medicines of assured quality around the world. It was also fully committed to helping countries that were experiencing public health crises to find real and comprehensive solutions.

191. He said that his delegation had strongly supported the General Council Decision of August 2003 to implement the Doha Declaration so that drugs could be exported under a compulsory licence under the terms set out in the Decision and the accompanying Chairman's Statement. It had also lent strong support to the Protocol Amending the TRIPS Agreement in 2005 to make the System a permanent part of the Agreement and to appropriately preserve reference to the Chairman's Statement. He recalled that the System had been the result of robust discussions and had attracted the consensus of the Members; other prior proposals had been left behind. His delegation had been the

first Member to notify its acceptance of the amendment. The System was intended to be only one tool to assist in promoting access to medicines and provided an important failsafe in Members work to improve access to medicines. In the past, some delegations had shared their view that the System had been used sub-optimally and that an analysis of its functioning was needed. As his delegation had affirmed at previous meetings, the Council's annual review was the forum at which Members had intended reviews of the operation of the System to be conducted. It was also the place where Members, who were the users of this intergovernmental system, should share their experiences regarding any concerns.

192. He noted that in the past some delegations had attached importance to the fact that the System had been used only once. Counting the frequency of use was, however, not the right metric to measure the effectiveness of the System. Instead, the results had to be evaluated. Members needed to look at the extent to which medicines were reaching affected populations. With respect to that question, the number of times that Members had relied on the System as a safety valve mechanism did not provide the right focus. Instead, the System should be viewed in its proper, larger prism. This principle had been reflected in paragraph 2 of the Doha Declaration. He noted that the majority of the drugs on the WHO's Model List of Essential Medicines were off-patent. Additionally, it was also important to recall that the System's development had been one element of a larger international exchange of ideas that WTO Member governments, the donor community, companies, and other stakeholders had had, and continued to have, in order to improve access to medicines. That work had led to real and measurable progress over the past decade in improving access to medicines. Further, it had led to partnerships between governments, between governments and stakeholders, and between stakeholders themselves.

193. In his delegation's discussions with stakeholders across the spectrum, he had consistently heard that access to medicines was being improved through numerous means. Those means included developed country policies and programmes that placed greater emphasis on building sustainable capacity in the public sectors of developed country partners and at their national and community levels to provide basic services over the long term. They also included efforts to expand research and development of innovative drugs and production capacity for both innovator and generic drugs in developing countries. Further, those means included donations of health products by Members, the private sector, and international bodies, as well as tiered pricing, bulk purchase mechanisms, innovative licensing models and other measures by innovative and generic companies and multilateral bodies. The United States, through the National Institutes of Health (NIH), had been the first patent holder to share its patents with the newly established Medicines Patent Pool Foundation. The initial contribution by the NIH and its co-patent owner, the University of Illinois, had embodied these commitments and had taken an important step toward making affordable and appropriate HIV medicines available to patients around the world. It had built on the US President's previous commitment to support humanitarian licensing policies to ensure that medications developed with taxpayer dollars were available off-patent in developing countries.

194. With respect to measures undertaken by innovative and generic companies to meet the needs of LDCs and others, he noted that in many cases, innovator companies simply did not apply for patent protection in many developing countries. There had been widespread tiered pricing of pharmaceutical products tied to individual and sub-regional developing country markets. Tiered pricing was linking the price of a pharmaceutical product in a market to what the consumer or purchasing government could afford to pay. While tiered pricing was not a new strategy, its frequency of use had dramatically increased in the past decade. For example, Bristol Myers Squibb, partnering with many Health Ministries, had announced a number of years ago that it would make all of its HIV medicines available at no-profit prices in sub-Saharan Africa. In 2005, the company had announced that paediatric formulations would be priced below cost, in order to further reduce barriers to provide access to this treatment. He understood that other companies, such as GlaxoSmithKline, had offered certain antiretroviral drugs at not-for-profit prices in 64 different countries. A number of other

companies were reportedly working together to provide a "single tablet a day" product at significantly reduced prices. These examples made it clear that private actors were improving access to medicines in a manner that simply had not been present five to seven years ago.

195. Many patent owners also reported that they had partnerships with generic manufacturers to make their products more generally available. They relied upon these generic manufacturers, often in developing countries, to scale up their manufacturing. The partnership between Gilead, an innovative pharmaceutical company, and Indian and South African generic manufacturers represented one example in this regard. It had increased the number of people receiving various treatments from 100 at the time of the Doha Declaration in 2003, to 700,000 in 2010. Gilead had entered into licensing agreements with those pharmaceutical companies to transfer its patented technology for the formulation of the medicine. These treatments addressed HIV infection and chronic Hepatitis B in adults. With respect to its Indian partners, Gilead had entered into licensing agreements to produce and distribute a generic version of the drug to 95 low-income countries much earlier than otherwise possible, due to India's production capacity and capable generics industry. The licensing revenue from these agreements was also reinvested to fund medical education, safety reporting, and product registration/marketing approval in destination markets. He noted that a number of companies around the world had granted licences to generic pharmaceutical companies to make generic versions of their drugs. He understood that licensing contracts were being explored by pharmaceutical companies in Bangladesh, Ethiopia, Kenya, Tanzania and Zimbabwe, as well as other countries.

196. Another example of a partnership between innovators and generics was the global Meningitis Vaccine Project (MVP). The MVP had been established in 2001, using technology licensed by the NIH. In 2001 and 2002, the MVP had approached various vaccine manufactures, seeking a manufacturer who could agree to manufacture the vaccine for 50 cents a dose, the price that NIH had been told by countries in Sub-Saharan Africa was necessary for the vaccine to be affordable in their marketplaces. The Serum Institute of India had accepted the challenge, and, after about eight years of work, had begun to ship the vaccine to Mali, Burkina Faso, and neighbouring Niger in September 2010. This eight year lag did reveal a larger point, i.e. that the procurement of medicines was a long process. Any measure of length of obtaining a licence under the System should take this into account. The results of this collaboration spoke for themselves. With respect to the MVP project, over a recent 17-day period, over 1 million people had been vaccinated. The target was to distribute 40 million doses. The Gilead and MVP approaches were just two examples of partnership trends that were increasing and delivering real results. These approaches had not existed ten or 15 years ago. There were many such cutting-edge partnerships that were promoting access to medicines. Other similar partnership trends that had been reported included an increase in the number of research collaborations targeting areas of need and increased voluntary sharing of intellectual property, such as "compound libraries" for research purposes. One company had launched a knowledge pool, now run independently by a third party, that had placed approximately 80 patent families in a pool to help others develop new medicines for neglected diseases.

197. In addition to collaboration with innovator companies, the generic drug industries had also had a significant role to play in improving access. For example, generic companies were engaging in more research activities for adapting existing products to the needs of developing countries as well as assisting in capacity advancement in poor countries. Many of those partnerships also provided jobs, access to doctors and nurses, and training for medical staff, schools and hospitals. He said that the ability to patent an invention was critical to ensure that there was an incentive for developing the medicine and that its benefits could be shared widely. The development of new, life-saving drugs was a risky and expensive process, and it was necessary to provide incentives for the private sector to undertake this effort. Intellectual property rights were essential to provide this incentive so that new drugs could be brought to the market. Moreover, patent systems could provide important incentives to reward innovators who had identified ways to adapt medicines to many different challenging circumstances, such as a lack of refrigeration or a need for more patient-friendly ways of

administering a drug that might be particularly relevant in developing country markets. Many actors were working to promote access to medicines. The intellectual property system played a critical role in assisting this effort.

198. Time had shown that intellectual property rights were not often the determining factor in the larger issue of access to medicines, as had sometimes been asserted. Many complex factors hampered access to medicines in developing countries, including sub-optimal procurement systems and poor distribution networks for medicines, caused by lack of basic infrastructure, hospitals, clinics and healthcare professionals, among others. The goal of equitable access to medicines was not achievable or sustainable without fostering improvements to the health systems themselves to ensure that patients could actually receive the drugs. Additionally, systemic problems, taxes and tariffs on imported medicines, and a lack of cold-chain storage, were often overlooked problems in many multilateral discussions.

199. With respect to problems that inhibited access to medicines, he noted that in some cases taxes or tariffs were levied on products being supplied at cost, or on donated products, the cost of which was passed directly to patients. Moreover, health care was often delivered far from the community being served. Weak drug procurement and delivery systems were another barrier to access to medicines. Lack of transportation and infrastructure also made it difficult to distribute pharmaceutical products and for a patient to see a doctor. Backlogs, regulatory redundancy, as well as other non-tariff barriers also hindered the distribution of both generic and innovative drugs where they were most needed. Finally, if the healthcare system was flooded with counterfeit products, true access was not achieved. Because of weak regulatory regimes and global criminal networks, counterfeit and substandard medicines harmed or killed sick people across the globe, with the developing world being disproportionately affected. The WHO had estimated that "in over 50 per cent of cases, medicines purchased over the Internet from illegal websites that conceal their physical address have been found to be counterfeit". These were all problems that could be solved. Many of the issues would require action by both developed and developing countries. It was clear that, without accounting for the full range of problems that existed, Members could not make the improvements that would foster improved access.

200. With respect to some of the solutions with which the United States was involved, he said that on 22 September 2010, President Obama had announced a new US global development policy, the first ever for a US Administration. Through the policy, President Obama had made it clear that sustainable development was a long-term proposition, and progress depended on the choices of political leaders and the quality of institutions in developing countries. Where leaders governed responsibly, set in place good policies, and made investments conducive to development, sustainable outcomes could be achieved. Where those conditions were absent, it was difficult to engineer sustained progress, no matter how good the intentions or the extent of engagement. The policy had placed greater emphasis on building sustainable capacity in the public sectors of US partners and at their national and community levels to provide basic services over the long term. The United States would continue to provide medicine, emergency food aid, humanitarian relief and other assistance where it was urgently needed. But the United States would also strive to help increase the capacity of its partners to meet those needs by investing in systemic solutions for issues such as service delivery and public administration. President Obama's six-year, USD 63 billion Global Health Initiative (GHI), had focused on sustainable service delivery where the needs were greatest and the conditions were right to build effective health service delivery systems. As to shortages of skilled health care professionals, the US Government, as well as many private companies, had undertaken significant efforts to improve healthcare systems in developing countries. In the President's Emergency Plan for AIDS Relief (PEPFAR) and the President's Malaria Initiative (PMI), the United States was training a significant number of health workers in support of sustainable health systems. The United States was also a leader in the implementation of task-shifting initiatives in Africa. The PEPFAR had promoted access to medicines and other products through many means, including by improving supply chain

management. This approach was saving lives; through PEPFAR, 2.5 million people were being supported for life-saving antiretroviral treatment.

201. The PMI was working to improve access to malaria medicines through their procurement and distribution in the 15 PMI focus countries (Angola, Tanzania, Uganda, Malawi, Mozambique, Rwanda, Senegal, Benin, Ethiopia, Ghana, Kenya, Liberia, Madagascar, Mali and Zambia), distributing over 80 million treatments. With respect to government tariffs, as part of the WTO NAMA negotiations, Switzerland, Singapore, the United States and Chinese Taipei had proposed an Enhanced Healthcare Initiative for Members to jointly reduce or eliminate tariffs on medicines and key medical equipment and supplies. He hoped that other Members would join in this effort, as it would result in lower medicine prices. Similarly, the use of transparent, competitive and non-discriminatory procurement procedures and practices would provide governments with more choices from a broader array of suppliers that could mean lower prices and more effective use of limited financial resources. Access to medicines was a complex issue that required a multifaceted, and often multi-sectoral approach, that addressed all aspects in a meaningful way. The System must be located in this larger prism. The United States' experiences on approaches that were producing results were an illustration that Members should not focus only on reliance on the System as a proper or meaningful gauge of its operation.

202. The representative of Canada said that the trilateral Symposium jointly organized by the WTO, WHO and WIPO had been very useful. He disagreed with India's characterization of the Ghana case as having had a "chilling effect". According to his information, when Indian generic firms had first brought TriAvir to the market, the triple ARV combination which had eventually been exported to Rwanda had been priced between 30 and 40 cents. There had also been shipments from Indian generic firms to African countries. When Apotex had become a viable option and CAMR could be exercised by interested parties, the price of TriAvir from Indian firms had dropped substantially to 19 to 20 cents per pill. Instead of a chilling effect, CAMR and the System as a whole could have had a beneficial effect on price.

203. Since the System had come into existence, a number of international procurement systems had been developed, such as the Clinton Foundation, which had been key to delivering medicines to people in need. He asked potential importing countries whether they had taken advantage of such international procurement systems and if they could relate their experiences in this regard. Many pharmaceutical companies also had charitable programmes by which they donated medicines. This alternative was actively promoted by Canada through tax incentives made available to brand name and generic pharmaceutical companies which donated medicines. However, tariffs had a chilling effect on such initiatives. It would therefore be interesting to hear from potential importing Members whether they still imposed tariffs or duties on donated medicines which were imported. There also continued to be growing manufacturing capacities of the pharmaceutical industry in developing countries which were able to produce drugs at lower costs. This had been a factor in the Rwanda case. His delegation was interested to learn whether Members had increased their domestic manufacturing capacities since 2003.

204. Voluntary licences were another available alternative for obtaining essential medicines. Although the information was difficult to obtain, as these were transactions between private parties, there was some evidence that voluntary licences were being successfully deployed. In the Rwanda case, if a voluntary licence had been secured by Apotex, it would not have been necessary for Apotex to request an export authorization from the Commissioner of Patents. Nevertheless, this would still have constituted a success for CAMR. With respect to Canada's 2007 Statutory Report on CAMR, he noted that it had stated that Canada should continue to pursue non-legislative measures to improve access to medicines in the developing world. The Canadian International Development Agency (CIDA) was working with the global community to address health needs in developing countries. ClDA worked with qualified, experienced organizations and partners to improve health in the most

effective and cost-efficient way. For example, Canada was a founding donor of the global drug facility in 2001 and had been the largest single donor country for first-line tuberculosis drugs since the facility had been created. The global drug facility, a programme of the "Stop TB" Partnership, worked to improve access, supply and distribution of low-cost quality-assured anti-tuberculosis drugs in developing countries and was the only bulk procurer of such drugs. CIDA also provided significant support for initiatives such as the GAVI Alliance, the WHO's universal access plan, and the Global Fund to fight AIDS, tuberculosis and malaria. He was pleased to note that Canada's commitment to the Global Fund had recently been enhanced. In September 2010, Canada had announced that an additional commitment of USD 540 million would be provided over the next three years. This was in addition to the USD 978.4 million that Canada had already committed and disbursed to the Global Fund since 2002.

205. Under its G8 Presidency in 2010, Canada had championed the Muskoka initiative, a major global effort to improve maternal, newborn and child health in developing countries. Eighty per cent of Canada's contribution of USD 1.1 billion would go to sub-Saharan Africa which had the greatest burden of maternal and child mortality. However, some countries simply could not afford essential medicines, no matter how low the costs were. Moreover, the health delivery systems in some developing countries were inadequate to deliver and administer medicines, among others, because of an insufficient number of well-trained medical staff and lack of modern infrastructure. This was another reminder that the main problems of access to medicines were the result of poverty, not patent laws.

206. With respect to counterfeit and sub-standard medicines, the representative of Canada referred to a statement by Minister H.E. Prof. Dr. Hatem El-Gabaly of Egypt. At a conference in 2009, the Minister had provided some important remarks regarding the scourge that counterfeit and sub-standard medicines had had with respect to their effect on the health of citizens. He had also made some remarks about the economic aspects. He quoted the Minister who had said: "counterfeit medicines also inflict serious damage and injury to national economies and manufacturers. These negative economic consequences are not limited to depriving legitimate businesses and their workers of income. Discouraging innovation and creativity can provide an easy source of revenue for organized crime, but they also entail loss of national tax revenues. As such, both governments and the private sector stand to lose from proliferation of trade in counterfeit medicines. As part of our collective endeavours to address this global challenge, we must be cognizant of the underlying factors that feed such illicit trade. These factors can be technical, economic or legal. However, the inescapable fact is that counterfeiting of medicines is a lucrative business due to the continued high demand for medicines and low production costs. Experts indicate that when prices of medicine are high and price differentials between identical products exist, there is a greater incentive for the consumer to seek medicines outside the normal supply system. In this context, poverty and lack of awareness appear as important issues to be addressed in our fight against counterfeit medicines. No country is immune from the threat posed by counterfeit medicine, and Egypt is no exception. Therefore it is our firm conviction that counterfeiting medicines, including the entire range of activities, from manufacturing to providing them to patients, is a serious criminal offence that puts human lives at risk and undermines the credibility of health systems. Let me shed some light on our response strategy. At the international level, Egypt supports global efforts aiming at eradication of the threat of counterfeit medicines. In the face of this trans-boundary threat, we continually coordinate with our international partners to design more effective collaboration mechanisms that involve international organizations, enforcement agencies, national drug regulatory authorities, customs and associations for consumer protection. We also promote sharing of information and exchanging best practices amongst all stakeholders. More importantly, tightening border controls to diminish the risk of trans-shipment of counterfeit medicines should be a priority for regional and international cooperation." The representative of Canada asked whether the delegation of Egypt could expand upon these timely initiatives of the Egyptian Government.

207. He also quoted the Indian Minister of Health and Family Welfare, Ghulam Nabi Azad, who had stated: "I propose to introduce a whistleblower policy to involve the public to provide information on any kind of unlawful activity in the manufacture of drugs. There is no dearth of good intentioned people who may wish to work for his country's interests as a whistleblower in eradicating this menace. People's participation is imperative in this regard." The media report had also indicated that a country-wide survey in India was under way to assess the exact size of India's spurious counterfeit drug industry. The study had apparently already identified 61 popular drug brands from nine therapeutic drug categories that were being tested. Canada asked the delegation of India whether there were any specific results from this study that could be shared with Members. Apparently, the Indian Health Ministry had estimated that 5 per cent of the drugs sold in India were counterfeit while 0.3 per cent were spurious. A counterfeit medicine was one that had no active ingredient or was an expired drug that had been relabelled or sold. It was different from a fake drug which might resemble the original in any way, according to the report. The Minister had also stated that the Drugs and Cosmetics Act had recently been amended to provide stricter penalties for offences under the Act, particularly to those engaged in making spurious, adulterated, misbranded and sub-standard drugs. The maximum penalty was life imprisonment and a fine of three times the value of confiscated goods. Some of the offences were now cognizable and non-bailable. His delegation was interested in any updates about this particular Act and any other Indian initiatives.

208. The representative of Brazil shared her delegation's experience with the System. Paragraph 7 of the Decision of August 2003 had established that "Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem identified in paragraph 6 of the Declaration". Her delegation regarded this as an essential element of the Decision. While not directly related to the System's implementation, she referred to a recent initiative funded by Brazil in an attempt to solve the problem of countries with limited manufacturing capacity. The Brazilian Government was helping Mozambique set up a small manufacturing unit for the production of first-line antiretroviral medicines based on the portfolio of drugs produced by the Oswaldo Cruz Foundation. The output of this unit was initially intended for the local market. In the future, the producing platform of Mozambique might also supply other neighbouring markets.

209. The representative of Cuba said that her delegation was not in a position to accept the Protocol Amending the TRIPS Agreement until the operation of the System had proven to be fully effective. Moreover, regulatory aspects, including a quality examination regarding safety and efficacy, did not form part of the System. Other aspects had to be clarified which had a bearing on the lengthy period needed to manufacture and export pharmaceutical products under the System. The preparation and approval by the relevant government authorities of the legal instrument that was required to apply the System at national level entailed a complex process. There was therefore no justification for undertaking such a process until it had been demonstrated that the System complied with the objectives of paragraph 6 of the Doha Declaration. Some Members considered this system to be an historic milestone which it undoubtedly was. The mandatory patent protection of pharmaceutical products had made it necessary to find a solution to ensure that profit-making interests of patent holders were not maximized to the detriment of the right to life and health. Nevertheless, the System was still far from proving its practical effectiveness. Certain clarifications made in this discussion should have already been addressed by the Decision establishing the System. She said that the System had also been distorted bilaterally by developed countries through free trade agreements.

210. The representative of the European Union said that the System was a measure among many others that could contribute to improving access to medicines in the developing world. He highlighted some of the reasons that could explain why the System had not been used frequently. First, a number of medicines were simply no long under patent protection. For those medicines, there was therefore no need for a compulsory licence, and therefore no need to invoke the System. Secondly, least developed country Members were not obliged to implement their obligations under

the TRIPS Agreement regarding patents and undisclosed information in the pharmaceutical sector until 1 January 2016. Until then, those countries who had not implemented the TRIPS Agreement could import medicines without making use of compulsory licensing. Finally, developing countries in need could use all available channels to ensure access to affordable medicines. Those included the use of the existing TRIPS flexibilities, direct negotiations with the pharmaceutical companies, public-private partnerships and donations. With regard to the efforts made by the European Union to facilitate access to medicines, he recalled that his delegation was taking an active part in promoting access to medicines in developing countries. It was the biggest provider of resources to support health policies in developing countries. Projects and programmes funded by the European Union in developing countries covered a wide range of activities, research, production, procurement and delivery, including quality control. It was associated with a number of WHO programmes for research and development and capacity building. It was also one of the oldest and biggest contributors to the Global Fund to fight AIDS, Tuberculosis and Malaria and had donated EUR 872 million since 2002. Under its cooperation programme in the form of the Seventh Research and Development Framework Programme covering the period 2007-2013, the European Union had allocated a total of EUR 6.1 billion to help research and development worldwide. Moreover, it had also set up a tiered pricing mechanism for the supply of cheaper medicines to developing countries. His delegation remained fully committed to facilitating access of medicines in the developing world and to making the System work.

211. The representative of Colombia noted that his delegation was interested in examining whether the international rules that Members had agreed upon genuinely facilitated access to medicines. Access to medicines involved correctly assessing the needs of the population and undertaking research, development, production and supply of medicines to meet those needs, so as to ensure timely access to the medicines in sufficient quantities and at affordable prices for all. The regulatory environment should be both favourable to the industry and in the interests of public health. A balance needed to be found between the incentives for the industry and the creation of a competitive market. The System had sought to achieve this goal in response to the specific situation of Members who had insufficient or no manufacturing capacities in the pharmaceutical sector and faced difficulties in making effective use of compulsory licensing.

212. He questioned, however, whether the System was the only instrument and whether its design and implementation were optimal for achieving the goal of supporting public health. With respect to the first question, the System was clearly not the only intellectual property instrument aimed at attaining these goals. Compulsory licensing, more stringent patentability criteria, exceptions to patentability, parallel imports and control of abuse of intellectual property rights by right owners were other valid tools for protecting public health. Likewise, there were mechanisms beyond the intellectual property sphere that were directed towards the same objective. Accurate and widely available price information and mechanisms to promote competition were powerful tools to that end. With respect to the second question, his delegation viewed the System as both limited and complex. Moreover, its requirements had led to delays and costs which made it a somewhat unattractive option presently. Those aspects should be further discussed in the interests of achieving an effective implementation of the System. He noted that only 30 Members had notified their acceptance of the Protocol Amending the TRIPS Agreement. Colombia had notified its acceptance in August 2009. If the rate of adoption continued at its current pace of six Members per year since 2008, it would take at least three more years for this flexibility to become a permanent part of the Agreement. He urged all Members whose domestic acceptance procedures were still under way to complete the process.

213. Referring to the statement by his Health Minister which had been quoted by Canada, the representative of Egypt outlined his delegation's perspective on the issue of counterfeit medicines. He referred to a statement made by Minister Hatem Elgabaly at the 63rd Session of the World Health Assembly. On this occasion, he had said that "the quality, safety, and efficacy of medicines is a primary concern of national drug regulatory regimes. Likewise, the World Health Organization has

an important role to undertake in supporting these efforts of its member States. We believe that the activities of the WHO in this regard should be given more focus and clarity. There needs to be a clear distinction between on one hand, ensuring the quality, safety and efficacy of medicine, which is a public health issue directly within the remit of the WHO, and on the other hand, the issue of counterfeiting, which is a term pertaining to the field of intellectual property, and specifically, a problem of trademark violation, as referred to in the World Trade Organization TRIPS Agreement. As such, this latter issue should be dealt with under relevant national IP legislation, and pertinent national IP enforcement procedures, and multilaterally, it should be dealt with at the more competent Geneva-based organizations, chiefly the WTO and WIPO. At the WHO, attention should be paid and solutions must be urgently found from a public health perspective and not through the lens of intellectual property rights. By bringing more clarity to the issue at hand, we can note that sub-standard medicines lacking in quality, safety and efficacy represent a far larger risk to public health than counterfeit medicines. These two classes should not be confounded and particularly so at the WHO which has a clear mandate relating to public health."

214. The representative of Venezuela noted that the delegation of Canada had described poverty as the main problem for access to medicines. He questioned this statement, noting that poor patients in developing countries sometimes resorted to counterfeit drugs out of despair. The problem therefore was high prices applied by multinational companies which they placed above the public health interests of the poorest nations.

215. In reaction to the quotation of the Indian Health Minister by the delegation of Canada, the representative of India noted that his Government attached high importance to the issue of spurious, sub-standard and falsified medicines, which posed a big challenge for public health and access to medicines. This was backed by the Minister's statement which had referred to deterrent punishments under the Drugs and Cosmetics Act. With respect to counterfeit medicines, he endorsed the statement made by the delegation of Egypt. At the World Health Assembly, as well as at other international fora, his delegation had deplored the deliberate confusion which was being created between intellectual property rights and public health-related issues.

216. The representative of Ecuador queried what budgets private actors had for the distribution of essential medicines, compared with the budgets of member states. He also asked to what extent such donations and grants made by pharmaceutical companies which were usually profit-driven businesses could be compared. He was also interested to know more about questions of government procurement. In Ecuador, a compulsory licence had been issued and in less than a month contracts had been exchanged. Moreover, he asked how many voluntary licences had been granted and what the time-frame was for the negotiations leading to the grant of such licences. As regards the discussion of benefits, he noted that these were about access to essential medicines and human lives at stake, not about trade and profitability. He supported the statement by the delegation of Venezuela regarding poverty and access. He said that issues related to public interest as discussed in the TRIPS Council were the responsibility of all Members and therefore different from donations from private business, companies or initiatives. With respect to counterfeit and sub-standard medicines, he cautioned Members not to target or undermine generic medicines.

217. The representative of Norway said that his delegation fully supported the intention behind the System which had been duly implemented domestically. He noted that his delegation was a major donor to a number of public and private partnerships that had improved access to medicines such as the Global Fund to fight AIDS, Tuberculosis and Malaria, the GAVI Alliance and the drug purchase facility UNITAID.

218. The representative of Switzerland supported a number of points made by the US delegation. In particular, his delegation had co-sponsored the enhanced healthcare initiative which targeted the elimination of tariffs on medicines and medical devices in the WTO. An obvious alternative to the

System was a favourable outcome of procurement negotiations with the patent holder itself. This would result in direct delivery from the patent holder or alternatively, in the grant of a voluntary licence to a potential manufacturer, who would, in cooperation with the patent right holder, provide the medicines required to the recipient country at a more affordable price. This alternative was often a more expeditious process and a better guarantee for the safety and efficacy of the medicines. The Government's position to negotiate the terms of such a licence agreement was strengthened by the System's very existence as an alternative to such a mutually agreed solution with the right holder. The System enabled countries without manufacturing capacity in the pharmaceutical sector to effectively consider issuing a compulsory licence as a policy tool and as a fallback option to contractual agreements.

219. However, to advocate compulsory licences, whether under Article 31 or the new Article 31bis of the TRIPS Agreement as a simple solution to provide easy and sustainable access to medicines was not only simplistic but also a misleading message to countries in need of medicines to address a pressing public health problem. Compulsory licences posed a number of practical problems that were time consuming to solve. The search for an appropriate generic manufacturer who was ready, capable and available to produce a generic medicine was a challenge in itself and could be time-consuming. Some generic producers were also not in a position to provide more affordable or competitive prices. The issue of high-quality medicines and regulatory review of the quality and efficacy of medicines produced under a compulsory licence constituted another set of considerable challenges. It would therefore be simplistic to present compulsory licences as a panacea for access to medicines for developing countries. Where it was possible to find a mutually agreeable and affordable solution for the supply of the needed medicines by the original manufacturer holding the patent right, this was the most efficient and expeditious solution for a country facing an urgent public health problem. Thus, the production lines would already be there and the respect of tested and reliable standards regarding health and efficacy would be assured. However, sometimes a compulsory licence, which was available to Members under the TRIPS Agreement, was a useful policy tool. The System had facilitated the use of compulsory licensing by WTO Members without manufacturing capacities in the pharmaceutical sector on a level playing field with all other Members.

220. With respect to India's intervention, he noted that in 2002, Article 30 TRIPS had been considered as a potential solution. However, this approach had been quickly discarded, and had not reached consensus. In any event, his delegation did not consider Article 30 to be a viable alternative to the System which covered new ground.

221. The representative of Australia recalled that the System had been developed to improve the ability of countries without manufacturing capacity to access affordable medicines. It had not been intended to be a panacea solution to the problem of access to medicines. Her delegation would be interested to hear from those Members who had spoken of occasions when the availability of alternative sources of medicine, including generics, had vitiated their need to utilize the System. The availability of effective alternatives to the System provided no evidence of its failure, but constituted a useful example of alternative pathways through which access to medicines could be realized. The operation of the System could therefore not be considered in a vacuum, as it represented but one weapon in the armoury of mechanisms and policies intended to improve access to medicines. Any assessment of its effectiveness had to take into account the specificities of what the System was intended for and was able to achieve, as well as the way in which it impacted upon, and was impacted upon by, a diverse range of bigger picture issues affecting access to medicines. These were much broader than the intellectual property issues discussed in the Council. They included the rate and relevance of innovation, the reliability of procurement and supply chains at both the national and international level and the safety, affordability and appropriate use of medicines. These and other issues were affected by and had implications for the System's operation. They were also being considered in other multilateral fora, such as under the WHO's Global Strategy and Action Plan on Innovation, Public Health and Intellectual Property. These discussions could usefully inform the

Council's debate, including with respect to how WTO Members could more effectively use the system. Her delegation looked forward to continuing the consideration of the System's operation in the context of the broader discussion of access to medicines, bearing in mind the issues which could be addressed by the System.

6. Next steps and recommendations

222. The Chairman said that the purpose of this topic was to provide the Council an opportunity to discuss whether there was a need for follow-up to the present annual review and, if so, what it should be.

223. The representative of India noted that the meeting had provided a good opportunity to discuss in greater detail the implementation of the System and several other associated issues, but discussions had not been exhaustive. With the track record of a single use in seven years, he remained unconvinced that the System was workable. It could certainly not respond to public health emergencies. He regretted that key stakeholders, including pharmaceutical companies and civil society organizations which had first-hand experience of using or attempting to use the System, had not participated in the discussion. At the Council's previous meeting, some developed country Members had made a discussion among Members a prerequisite to enlarging participation. He considered that this condition had now been met. He therefore recommended that a dedicated workshop be held with an enlarged participation, including pharmaceutical companies and civil society organizations. Further details regarding matters such as participation, timing and scope should be discussed in informal consultations to be held by the Chair.

224. Moreover, he recommended that international organizations, which had made presentations at the meeting, be invited to respond to the remaining questions at the Council's next meeting. In particular, he requested the WHO to prepare a detailed report on the coverage of flexibilities in its technical assistance activities. He also requested the delegation of Canada to report on further developments regarding efforts to amend CAMR. In addition, Members might make submissions for future focused discussions. He also invited developed country Members to report at the Council's next meeting on how they had implemented paragraph 7 of the Decision, which was part of their obligations under Article 66.2. He added that it would be useful if the Chair could prepare his own summary of the discussion.

225. The representative of Mauritius, speaking on behalf of the ACP Group, supported India's recommendation to hold a dedicated workshop with the participation of pharmaceutical companies, NGOs and other relevant actors. Lessons drawn from experiences discussed at this meeting should be used to prepare the grounds to improve the System. The implementation of practical solutions and the avoidance of ideological stances was important. While alternatives to the System should be pursued, it should remain a main pillar to enable access to essential medicines, especially in times of pandemics and health crises. He encouraged the WTO, WHO and WIPO to increase coordination, focusing more on flexibilities. Their activities should incorporate the regional perspective regarding the use such flexibilities with a view to enabling access to medicines, and should also provide more targeted advice as opposed to general seminars.

226. The representatives of Brazil, Venezuela, Ecuador, Argentina, Peru, Chile, Egypt and China supported India's recommendation that a dedicated workshop be held with an enlarged participation, including pharmaceutical companies and civil society organizations. The representative of Peru also supported India's suggestion that the Chair prepare his own summary of the discussion.

227. The representative of Canada said that his delegation would be prepared to provide an update with respect to Bill C-393 in future Council meetings. His delegation had some ideas with respect to matters such as information dissemination and how it could better publicize its work, particularly as

an exporting Member. Some of this work dovetailed with other aspects of the Council's work, particularly under Articles 66.2 and 67 TRIPS. He invited Members who had not done so to respond to the questions raised by his delegation under the first and second topics. The Council had not yet met its full potential with respect to the engagement of Members, in terms of providing their specific national experiences. He proposed that the Chair undertake consultations in the near term to further explore some of these questions and how best to proceed. He did not rule out the possibility of a workshop, but thought that more time was needed to assess what had been done and to enable Members to provide responses. His delegation was open to meet bilaterally, and would be happy to accept written responses and would welcome further input.

228. The representative of the United States associated his delegation with the points made by Canada. The WTO was a Member-driven organization and the System was a Member-based solution. Members' experiences were therefore the most important. Before other stakeholders were brought in, it was incumbent upon the TRIPS Council to continue to work through some of the issues. He noted that, while the Council had heard from exporting Members, it still needed to hear the experiences of potential importing Members, as the System had been designed for their benefit. Therefore, there was no need for the Council to organize a workshop at this point.

229. The representative of Australia noted the absence of the voice of potential importing countries in the discussions, and the identification by such countries of obstacles or alternatives to the use of the System. This would be an essential contribution that would greatly facilitate the Council's work in its review of the System. Her delegation supported Canada's proposal that consultations on next steps be held by the Chair. These could include holding a workshop, provided that it were sufficiently broad to allow meaningful and frank discussions of all the issues related to access to medicines. The issues to be considered went beyond the narrow question of intellectual property rights and included aspects in the field of government procurement, supply chains and gender issues.

230. The representative of Japan requested further information from potential importers and in that regard supported the delegations of Canada, Australia and the United States with respect to next steps.

231. The representative of India reiterated his request for a dedicated workshop which could probably feed into the Member-driven discussions at the Council's next meeting. Even in a Member-driven organization like the WTO, there was scope for presentations and workshops involving external stakeholders. For example, the US delegation had in the past requested to have a workshop held by Caterpillar in the NAMA negotiations. An open-ended workshop before the Council's next meeting would further enrich discussions at that meeting.

232. The representative of the European Union said that more feedback from potential importing countries as to why they had not used the System thus far would be useful. While not perfect, the System offered a mechanism that could be helpful to developing countries in getting medicines they needed. He supported India's suggestion that the Chair conduct further consultations to discuss next steps.

233. The representative of Switzerland regretted the absence of interventions from potential importing countries on potential concerns or obstacles they may have met when wanting to make use of the System. He supported the suggestion that delegations respond to outstanding questions at the Council's next meeting. His delegation was also interested in being associated with any informal consultations the Chair might conduct.

234. The representative of Mexico said that it would be useful to receive in writing information about the experience of national pharmaceutical sectors, including multinational pharmaceutical companies. He also wished to be associated with any informal consultations the Chair might conduct.

235. The Chairman said that he had found the discussion of the topics under the annual review very useful. As to next steps, there were two distinct views. Some delegations were in favour of a workshop with an enlarged participation, while others believed that the Member-to-Member process had not yet been exhausted. As recommended by a number of delegations, he suggested that he consult on follow-up to the review, including both the question of a workshop and other proposals made.

236. The Council took note of the statements made and so agreed.

237. Turning to the Council's report to the General Council on the Annual Review of the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, the Chairman recalled that the WTO Secretariat had prepared a draft cover note to this report (JOB/IP/1). It contained factual information on the implementation and use of the System established under the Decision, on discussions earlier in the year regarding its operation, and on the acceptance of the Protocol Amending the TRIPS Agreement. He proposed that, in accordance with the way that the Council had prepared its report in previous years, the part of the Minutes of the meeting reflecting the discussions held under this agenda item be attached to the cover note as an annex.

238. As he had noted under item A, Croatia had just notified its amended Patent Act which implemented the System. In addition, Albania had notified its new Law on Industrial Property, which also implemented the System. Therefore, Croatia and Albania would be added to the list of Members who had notified their domestic implementation, contained in paragraph 4 of the draft cover note. Furthermore, Uganda had notified its acceptance of the Protocol and would, therefore, be added to the list of Members in paragraph 12 of the draft cover note.

239. The delegation of Canada requested that some minor changes be made to the draft report, which had been submitted to the Secretariat. Specifically, he suggested that the sentence in paragraph 8 of that report reading "The delegation of Canada shared its experience in using the System, including a detailed timeline of events" be removed, and the subsequent sentence modified to read "Some delegations expressed concern that the System had only been used once since 2003 and that it had taken some three years to deliver the medicines from Canada to Rwanda in this context". He suggested that the following sentence remain the same, and suggested inserting a subsequent sentence which would read: "The delegation of Canada shared its experience in using the system, including a detailed timeline of events which, it its view, demonstrated the fact that Canada's access to medicines regime CAMR had been successfully utilized and only a very small portion of this three-year time period had been taken up by procedures associated with that regime. It said that much of the time that elapsed between the regulatory review of the medicine in question and the shipping to Rwanda could be attributed to other variables".

240. The representative of China asked whether its amended Patent Act could be added to the draft cover note in the section listing Members who had notified their implementing legislation to the Council, if notified to the Council by the end of November.

241. The Chairman proposed that the Council agree to the cover note to the report as contained in JOB/IP/1, together with the updated information concerning Croatia, Albania and Uganda and the changes suggested by Canada, and also that the Council minutes containing the record of the discussion be attached thereto. In addition, he proposed that the cover note be updated to include a reference to China's amended Patent Act, provided that it was notified in time.

242. The Council took note of the statements made and so agreed.