



**Council for Trade-Related Aspects of
Intellectual Property Rights**

ANNUAL REVIEW OF THE SPECIAL COMPULSORY LICENSING SYSTEM

REPORT TO THE GENERAL COUNCIL

1. Paragraph 7 of the Annex to the TRIPS Agreement as amended by the Protocol Amending the TRIPS Agreement ("the Protocol")¹ and 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") respectively² provide that the Council for TRIPS shall review annually the functioning of the Special Compulsory Licensing System ("the System")³ established under Article 31*bis* of the amended TRIPS Agreement and the 2003 Decision with a view to ensuring its effective operation. The Council shall annually report on its operation to the General Council.

2. The Council for TRIPS undertook the fourteenth annual review in October 2017. The General Council took note of the report of the Council for TRIPS (IP/C/79) at its meeting on 30 November 2017 (WT/GC/M/170, paragraph 8.9).

3. The present report covers the period since October 2017. At its meeting of 8-9 November 2018, the Council undertook the fifteenth annual review. Annex 1 and Appendix 1 to this report record the review and the statements made by delegations.

4. Sections 1 and 2 below set out factual information regarding the implementation and use of the System, as well as the entry into force of the Amendment to the TRIPS Agreement and the status of acceptances of the Protocol. Section 3 summarizes views expressed by Members with respect to possible next steps to ensure that the System works effectively in practice and action taken by the Secretariat.

1 INFORMATION ON IMPLEMENTATION AND USE OF THE SYSTEM ESTABLISHED UNDER THE DECISION

5. Since the last annual review, no Member has notified the Council for TRIPS of an amendment to its legislation implementing the System into its domestic law. An overview of all notified implementing laws and regulations, including hyperlinks to the legal texts, is available on a dedicated page on the WTO website.⁴

6. During the period covered by the present report, no notifications by importing or exporting Members pursuant to paragraphs 1(b), 2(a) and 2(c) of the Annex to the amended TRIPS Agreement and the 2003 Decision respectively have been made to the Council for TRIPS. The Secretariat regularly updates a page on the WTO website to ensure the public availability of notifications made under the System.⁵

¹ The Protocol which was adopted on 6 December 2005 (document WT/L/641) entered into force on 23 January 2017 (see below under Section 2).

² Note that the TRIPS Agreement as amended on 23 January 2017 only applies to WTO Members who have accepted the Protocol. For other Members who are yet to accept it, the General Council Decision of 30 August 2003 (document WT/L/540 and Corr.1) continues to constitute the legal basis, including as regards the Annual Review of the Special Compulsory Licensing System. For the purposes of the 2003 Decision, this review is deemed to fulfil the review requirements of Article IX:4 of the WTO Agreement.

³ See also the definition in paragraph 1 (b) of the Annex to the amended TRIPS Agreement.

⁴ http://www.wto.org/english/tratop_e/trips_e/par6laws_e.htm

⁵ http://www.wto.org/english/tratop_e/trips_e/public_health_e.htm

7. In line with the deliberations of the Council for TRIPS following the entry into force of the amended Agreement,⁶ the Secretariat has further bolstered its technical assistance, in cooperation with multilateral partners, relating to the effective use of the System.⁷ This work builds on the 2013 WHO-WIPO-WTO study on "Promoting Access to Medical Technologies and Innovation – Intersections Between Public Health, Intellectual Property and Trade" which sets out explanatory background material on the implementation and use of the System.⁸ Updated background information⁹ and a Guide to Notifications, including a set of model notifications, to further facilitate the use of the System¹⁰ have been made available on the WTO's webpage dedicated to public health. Focused technical assistance materials have also been developed to enable interested Members effectively to assess the operational context of the System and to support their effective use of it.

2 AMENDMENT TO THE TRIPS AGREEMENT

8. In accordance with paragraph 3 of Article X of the WTO Agreement, the Protocol entered into force on 23 January 2017, by which date two thirds of the WTO Members had accepted it.

9. Pursuant to paragraph 3 of Article X of the WTO Agreement, the Protocol takes effect for each other Member upon its acceptance. Since the fourteenth annual review in 2017, the Russian Federation, Congo, Madagascar, Gabon, the Plurinational State of Bolivia, the Kyrgyz Republic, Guinea, Côte d'Ivoire and Paraguay have accepted the Protocol.

10. Information on the status of acceptances of the Protocol can be found on a dedicated webpage which is regularly updated by the WTO Secretariat.¹¹

11. As of 15 September 2018, the amended TRIPS Agreement applied to 126 Members. The following 38 WTO Members were yet to accept the Protocol and continued to operate on the basis of the 2003 Decision:

1. Afghanistan
2. Angola
3. Antigua & Barbuda
4. Armenia
5. Barbados
6. Burundi
7. Cabo Verde
8. Cameroon
9. Chad
10. Cuba
11. Democratic Republic of the Congo
12. Djibouti
13. Ecuador

⁶ See minutes of the TRIPS Council meeting of 30 January 2017 (document IP/C/M/84).

⁷ See 2017 WTO Secretariat Report on Technical Cooperation in the TRIPS Area (document IP/C/W/634, para.1); the news item reporting on the Annual Workshop on Trade and Public Health organized by the WTO in 2017 (https://www.wto.org/english/news_e/news17_e/health_06nov17_e.htm) and the Regional Workshop on Trade and Public Health With a Special Focus on Compulsory Licences for Export of Medicines for Countries from the Latin American Region held in Brazil from 21-23 November 2017 (see Section 3 below).

⁸ See pages 177 to 180 and Annex II of the study, available at the three organizations' respective websites: https://www.wto.org/english/res_e/publications_e/who-wipo-wto_2013_e.htm
http://www.wipo.int/edocs/pubdocs/en/global_challenges/628/wipo_pub_628.pdf
http://www.who.int/phi/promoting_access_medical_innovation/en/.

⁹ https://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm.

¹⁰ http://www.wto.org/english/tratop_e/trips_e/par6_modelnotifs_e.htm.

¹¹ http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm.

14. Eswatini
15. The Gambia
16. Georgia¹²
17. Ghana
18. Guatemala
19. Guinea-Bissau
20. Guyana
21. Haiti
22. Jamaica
23. Kazakhstan
24. Kuwait, the State of
25. Liberia
26. Maldives
27. Mauritania
28. Mozambique
29. Namibia
30. Niger
31. Solomon Islands
32. Suriname
33. Tonga
34. Tunisia
35. Vanuatu
36. Venezuela, Bolivarian Republic of
37. Yemen
38. Zimbabwe

12. At the Council's meetings in October 2017, as well as in February and June 2018, the respective Chairs of the Council for TRIPS updated Members on the state of play of acceptances that had been submitted. They also encouraged delegations that were yet to accept the TRIPS amendment to take the necessary steps so that the domestic procedures could be completed as soon as possible. In addition, the TRIPS Council Chair, by means of a letter of 10 August 2018, invited Members concerned to proceed with the acceptance of the Protocol as this represented a significant contribution to further strengthening the legal foundation for the effective exercise of this additional public health flexibility in the TRIPS Agreement.

13. The Protocol is currently open for acceptance by these Members until 31 December 2019 or such later date as may be decided by the Ministerial Conference (WT/L/1024).

3 NEXT STEPS

14. TRIPS Council Chairs have repeatedly referred delegations to the Council's 2016 report on the annual review of the System (IP/C/76), as well as to the WTO Secretariat's 2016 annual report on

¹² Since the adoption of this report by the Council for TRIPS at its meeting of 8-9 November 2018, Georgia has deposited its instrument of acceptance on 21 November 2018 (WT/Let/1420).

its technical cooperation activities (IP/C/W/618) which provide useful information resources for future considerations and, in particular, to prepare for the annual review of the System.¹³

15. Echoing the former TRIPS Council Chair's note of the importance "to look into how to make this new procurement tool work effectively so that it delivers concrete results in practice",¹⁴ Members have called for awareness raising and capacity building for potential users of the System, targeting, in particular, procurement officers in charge of buying medicines and representatives from IP offices, as well as the provision of legislative assistance to countries that were considering implementing the System in domestic law.

16. In response, the WTO Secretariat organized a Regional Workshop on Trade and Public Health with a special focus on compulsory licences for export of medicines for countries from the Latin American region in Brazil from 21 to 23 November 2017. This activity complements the module dedicated to the System at the Trade and Health Workshop that the WTO organizes annually in Geneva. Noting the positive evaluation of the activity, the WTO Secretariat is exploring the possibility of convening similar workshops in other regions.

¹³ See minutes of the TRIPS Council meetings of 30 January 2017 (document IP/C/M/84, para.9); 13 June 2017 (document IP/C/M/86, para.38); 19-20 October 2017 (document IP/C/M/87, para.21); and 5-6 June 2018 (document IP/C/M/89, para.59).

¹⁴ See minutes of the TRIPS Council meeting of 30 January 2017 (document IP/C/M/84, para.9).

ANNEX 1

[EXCERPT FROM THE MINUTES OF THE COUNCIL'S MEETING OF 8-9 NOVEMBER
CIRCULATED AS IP/C/M/90]

6 ANNUAL REVIEW OF THE SPECIAL COMPULSORY LICENSING SYSTEM (PARAGRAPH 7 OF THE ANNEX TO THE AMENDED TRIPS AGREEMENT AND PARAGRAPH 8 OF THE DECISION ON THE IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH)

1. The Chair recalled that, in the past, the Special Compulsory Licensing System had been conducted pursuant to paragraph 6 of the 2003 Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. Since the entry into force of the Protocol Amending the TRIPS Agreement on 23 January 2017, the review also responded to the requirements that had now been incorporated into the amended TRIPS Agreement.
2. Paragraph 7 of the Annex to the amended TRIPS Agreement and paragraph 8 of the 2003 Waiver Decision required the Council to review the functioning of the System annually, with a view to ensuring its effective operation. They also required the Council to report annually on the System's operation to the General Council. In the case of the Waiver Decision, the review was also deemed to fulfil the requirements of Article IX:4 of the WTO Agreement.
3. The Chair informed Members about the status of acceptances of the Protocol Amending the TRIPS Agreement.¹ The current period for accepting the Protocol ran until 31 December 2019. Since the last meeting in June 2018, Paraguay had deposited its instrument of acceptance with the Director-General on 4 July. The amended TRIPS Agreement was binding for 126 WTO Members. In other words, 38 Members were yet to accept the Protocol Amending the TRIPS Agreement. He encouraged those Members to complete their domestic procedures as soon as possible.
4. When the TRIPS Amendment had entered into force in January last year, Members had noted that it would be useful to consider how to make this new procurement tool worked effectively in practice. He encouraged Members to engage in a constructive discussion, which could also build on earlier reviews. Members might find two documents particularly helpful to facilitate their considerations. The first was the Council's annual review of 2016 (circulated in document IP/C/76); and the second was the Secretariat's 2016 report on technical cooperation activities (circulated in document IP/C/W/618). Annex II of that report summarized key issues that delegations might wish to consider supporting the practical use of the System.
5. The representatives of Brazil, India, Japan, Canada, the United States of America and Switzerland took the floor.
6. The Council took note of the statements made.
7. The Chair turned to the Report to the General Council. A draft cover note had been prepared by the Secretariat (circulated in document JOB/IP/32). It was modelled on previous years' reports and contained factual information on the implementation and use of the System. Under the section on the Amendment to the TRIPS Agreement, it also included a list of Members who were yet to accept the Protocol Amending the TRIPS Agreement. As for past reports, an extract from the Council's minutes on this agenda item would be attached to the cover note.
8. The Council agreed on the draft cover note to the Report and to attach the record of the discussion to it.

¹ Document WT/L/641.

APPENDIX 1

[EXCERPT FROM THE ADDENDUM TO THE MINUTES, CONTAINING THE STATEMENTS MADE DURING THE COUNCIL'S MEETING HELD ON 8-9 NOVEMBER 2018, TO BE CIRCULATED AS IP/C/M/90/ADD.1]

6 ANNUAL REVIEW OF THE SPECIAL COMPULSORY LICENSING SYSTEM (PARAGRAPH 7 OF THE ANNEX TO THE AMENDED TRIPS AGREEMENT AND PARAGRAPH 8 OF THE DECISION ON THE IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH)**6.1 Brazil**

1. The entry into force of the Protocol Amending TRIPS was an important signal for the multilateral trading system that the protection of IP can go hand in hand with measures to ensure access to medicines. The Protocol provides a legally secure and predictable option for those countries wishing to use the TRIPS flexibilities to get affordable medicines. We would like to highlight the importance of this periodic review of the implementation of the System, which became even more necessary after the Protocol entered into force.

2. While we reiterate our concern that the Special Compulsory Licensing System was used only once so far, it would be important to reflect on ways to improve it. According to reports provided by participants in the single case of use of the System, it is considered too complex and administratively unwieldy. In 2017, Brazil, India and South Africa organized a side event to the TRIPS Council in order to receive the assessment of the System from representatives of industry, government, non-governmental organizations and academia. Future discussions in the Council could benefit from additional information that can be provided by stakeholders other than Member States.

3. We believe it is important that this Organization continues to provide technical support to Member States, including through the provision of legal assistance, awareness-raising activities and capacity-building. This will ensure that the System becomes a practical option for the procurement of medicines in countries without industrial capacity, allowing that the fruits of the IP system are enjoyed in an inclusive way. The regional event held last year in Brasília for Latin American countries was considered a great success by participants and we will continue to support those actions by the Organization, including through the provision of experts from Brazil. We also support that the Secretariat continues its efforts to reach out to those Members not yet parties to the Protocol. Member States could also act through the periodic Trade Policy Review mechanism.

4. We have always been of the view that the Doha Declaration on the TRIPS Agreement and Public Health constitutes a major landmark in the history of the WTO, because it recognized the primacy of public health needs and the preparedness of the Organization to take up the problems faced by the poor and developing countries. The recent agreement on the United Nations' Sustainable Development Goals clearly reinforces that agenda, as its Goal number 3 mandates the global community to ensure healthy lives and promote well-being for all at all ages. To attain the goals of reducing child mortality and end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases, access to medicines is a fundamental part of that. The global community needs to act together through a multitude of ways, including through the Special Compulsory Licensing System before us.

6.2 India

5. India attaches high importance to the Doha Declaration on the TRIPS Agreement and Public Health, the Paragraph 6 System as established under the 2003 Waiver Decision and the Protocol Amending the TRIPS Agreement. India is one of the first countries that notified its acceptance of the Protocol in March 2007.

6. India has always been of the view that the Doha Declaration on TRIPS and Public Health constituted a major landmark in the history of the WTO because it recognized the primacy of public health needs and the preparedness of the Organization to address the problems in access to medicines faced by the poor in developing countries. The 2003 Waiver Decision was expected to address the public health concerns faced by Members with insufficient or no manufacturing capacities

in the pharmaceutical sector. It may have sounded prophetic at that time when India voiced certain apprehensions in the General Council meeting of August 2003 by stating: "the results accruing from this mechanism should not be negated by the creation of cumbersome systems that would lead to huge delays in getting medicines across at reasonable cost to those that needed them or discourage Members from using the System for the benefit of the people. In order to make this System successful, a sincere collective effort is required on the part of all Members and the entire pharmaceutical industry". Regrettably, we have been proven right. The export of HIV/AIDS medicines by the Canadian pharmaceutical company Apotex to Rwanda in September 2008 has been the first and only use of the System so far.

7. The UNSG High Level Panel on Access to Medicines, in its report released in September 2016, also recognized that the Paragraph 6 System is complex and cumbersome.

8. My delegation urges Members to constructively engage on improving the Paragraph 6 System for making it more workable and effective, so that it can benefit Members with insufficient or no manufacturing capacities in the pharmaceutical sector.

6.3 Japan

9. This delegation would like to express our gratitude to the Secretariat for preparing a draft report so we can review the Special Compulsory Licensing System. We welcome this work, hoping that it will encourage all remaining Members to notify their acceptance of the Protocol.

10. This delegation would like to reiterate the importance of access to medicines, which needs to be discussed in a broader context, taking into account not only the Special Compulsory Licensing System, but also various other relevant measures and factors, such as procurement and tariffs. Japan supports the Paragraph 6 System as established under the 2003 Waiver Decision and the 2005 Protocol Amending the TRIPS Agreement. The very objective of the System is to support WTO Members in obtaining greater access to medicines, specifically Members that have either insufficient or no pharmaceutical manufacturing capacity. Compulsory licenses are, whether granted under the System or not, just one of the potential means that can be utilized for this objective under an exceptional circumstance and, therefore, the System should not be considered as the only solution, but rather as just an option we could consider.

11. In addition, this delegation would like to mention that voluntary efforts to streamline access to medicines have been increasing. For example, in September WIPO and IFPMA collaboratively launched a new medicinal patent information database, Pat-INFORMED, to help procurement agencies better understand the global patent status of medicines. We believe such a voluntary and collaborative effort will be one of the possible ways forward to respond to better access to medicines.

6.4 Canada

12. The Government of Canada considers access to medicines to be a key priority in our ongoing efforts to promote global health and prosperity. Canada recognizes that improving access to medicines needs to be achieved through the promotion of health equity, stronger health systems, and universal health coverage. Indeed, Canada's international development priorities and significant investments in strengthening health systems and the health and rights of women and children are contributing to improved access in this regard.

13. Canada is a global leader in supporting partnerships such as the Global Fund to Fight AIDS, Tuberculosis and Malaria; the Global Drug Facility; and Gavi, the Vaccine Alliance, which strengthens health systems and provides targeted programming to increase access to medicines and vaccines.

14. In September 2016, Canada hosted the Fifth Replenishment Conference of the Global Fund and pledged CAD 804 million, which is roughly USD 613 million for 2017-2019. Canada is also the sixth largest donor to Gavi having pledged CAD 520 million for 2016-2020.

15. Canada's Access to Medicines Regime (CAMR), which implements paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, is another measure Canada uses to promote access to medicines. Canada continues to believe that CAMR is a useful and effective tool to enhance access to medicines in the specific circumstances the System was designed to address. In 2015,

Canada amended the list of medications covered by CAMR to add three new antiretroviral drugs. Canada notified this Amendment to the TRIPS Council in June 2016.

16. Canada also recognizes the 2017 entry into force of the Protocol Amending the TRIPS Agreement. The Amendment provides countries with another important tool to improve access to affordable medicines. As the only country to have exported medicine pursuant to the temporary waiver, Canada has always been a strong proponent of the Amendment, and would be pleased to share our experiences and lessons learned in implementing our own system with any Members who wish to learn more.

17. It is also important to recall that no single factor is responsible for preventing access to medicines. As the Doha Declaration emphasizes, the WTO is part of wider action required to improve access to medicines. This is why Canada relies on a variety of measures to promote access to medicines. Our view is that only by addressing all of the factors affecting access to medicines can we end the tragedy of people suffering from treatable illnesses. To this end, Canada is open to discussing how best to promote access to medicines that considers all relevant factors and effective tools to promote access. Canada looks forward to learning more about the views of other Members on this issue, including with respect to Members' experiences, challenges, and other considerations.

6.5 United States of America

18. The United States thanks the Secretariat for the update regarding the status of notifications of acceptance of the 2005 Protocol Amending the TRIPS Agreement contained in JOB/IP/32.

19. We congratulate the Members that have accepted the Protocol since last year's review.

20. We welcomed the entry into force of the Protocol Amending the TRIPS Agreement in January 2017 and are pleased that the amended TRIPS Agreement applies to 126 Members, as of September 2018.

6.6 Switzerland

21. My delegation would like to first thank the Secretariat for circulating the draft annual report; for the helpful, detailed information and the Guide to Notifications facilitating the use of the System offered on the dedicated WTO web page, as well as for the technical assistance it has provided, throughout last year, relating to the functioning of the Special Compulsory Licensing System and its effective use.

22. Incorporating the System into the TRIPS Agreement by way of adding Article 31bis and the Annex provides welcomed transparency, clarity and legal certainty. The System is there and ready for use by eligible beneficiary Members.

23. The Secretariat's draft annual report indicates that no notifications for the use of the System have been received in the year under review. No quick conclusions should be drawn from this fact with regard to the workability of the System. It has not been conceived for frequent use.

24. Its purpose is to extend the TRIPS flexibility of Article 31 of the TRIPS Agreement to eligible beneficiary Members without relevant manufacturing capacity in the pharmaceutical sector. The System applies to a certain number of WTO Members, in a specific case and under particular circumstances. There are many instances where the lack of access to needed medicines in potential beneficiary countries is not related to patent protection. In such cases, recourse to the System will not and cannot provide a remedy.

25. Should eligible beneficiary Members meet concrete problems when actually making use of the System, then it would be the Council's duty to examine these specific difficulties in its reviews and look into how they can be addressed best in a practical manner. Until we have heard in this Council of such concrete problems from eligible beneficiary Members, it is not helpful for the Council's review of the System if some delegations claim in the abstract that the System is not workable or should be amended.
