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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") respectively[2] 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 is required to report annually to the General Council on its operation.

2. The Council for TRIPS undertook the sixteenth annual review in October 2019. The General Council took note of the report of the Council for TRIPS (document IP/C/84) at its meeting on 9-10 December 2019 (document WT/GC/M/181, paragraph 17.9).

3. The present report covers the period from October 2019. At its meeting of 15-16 October 2020, the Council undertook the seventeenth 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 on 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 covers resources to support the review of the functioning of the System and provides an overview of capacity building activities organized by the Secretariat in response to requests by Members to assist them in making the System work effectively in practice.

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]

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[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. Members seeking to use the System are encouraged to submit their notifications using the e-TRIPS Submission System,[6] which is an online tool for WTO Members to submit notifications, review materials and reports related to the TRIPS Agreement. Access credentials to use the e-TRIPS Submission System are available upon request to e-TRIPS@wto.org. Members may also consult a Guide to notifications, including a set of model notifications, on the WTO's webpage.[7] The accessibility of notifications, once circulated, has been further enhanced through their inclusion on the related publicly accessible e-TRIPS Gateway, currently available in beta version.[8]

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 sixteenth annual review in 2019, Barbados, Burundi and Niger 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.[9]

11. As of 1 September 2020, the amended TRIPS Agreement applied to 131 Members. The following 33 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. Cabo Verde
6. Cameroon
7. Chad
8. Democratic Republic of the Congo
9. Djibouti
10. Ecuador
11. Eswatini
12. The Gambia[10]
13. Ghana
14. Guatemala
15. Guinea-Bissau
16. Guyana
17. Haiti
18. Jamaica
19. Kazakhstan

[6] https://www.wto.org/english/tratop_e/trips_e/etrips_e.htm.
[7] https://www.wto.org/english/tratop_e/trips_e/par6_modelnotifs_e.htm.
[8] https://e-trips.wto.org.
[9] http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm.
[10] Since the adoption of this report by the Council for TRIPS at its meeting of 15-16 October 2020, The Gambia has deposited its instrument of acceptance on 20 October 2020 (document WT/Let/1475).

20. Kuwait, the State of
21. Liberia
22. Maldives
23. Mauritania
24. Mozambique
25. Namibia
26. Solomon Islands
27. Suriname
28. Tonga
29. Tunisia
30. Vanuatu
31. Venezuela, Bolivarian Republic of
32. Yemen
33. Zimbabwe

12. At the Council's meetings in February and July 2020, the successive Chairs of the Council for TRIPS updated Members on the state of play of acceptances. 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 18 September 2020, 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 2021 or such later date as may be decided by the Ministerial Conference (document WT/L/1081).

3 MAKING THE SYSTEM WORK

14. TRIPS Council Chairs have repeatedly referred delegations to the Council's 2016 report on the annual review of the System (document IP/C/76), as well as to the WTO Secretariat's 2016 annual report on its technical cooperation activities (document IP/C/W/618) which provide useful information resources for future considerations to make the System work in practice and, in particular, to prepare for the annual review of the System.[11]

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",[12] 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 line with these deliberations of the Council for TRIPS following the entry into force of the amended Agreement in January 2017, the Secretariat has continued to provide technical assistance, in cooperation with multilateral partners, relating to the effective use of the System.[13]

[11] 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); 5-6 June 2018 (document IP/C/M/89, para.59); 8-9 November 2018 (document IP/C/M/91, para. 20); 6 June 2019 (document IP/C/M/92, para.93); and 17-18 October 2019 (document IP/C/M/93, para. 25).

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

[13] See 2019 WTO Secretariat Report on Technical Cooperation in the TRIPS Area (document IP/C/W/658) and the news item reporting on the Annual Workshop on Trade and Public Health organized by the WTO in 2019 (https://www.wto.org/english/news_e/news19_e/heal_15nov19_e.htm).

17. Relevant capacity building activities included a module dedicated to the System at the Trade and Health Workshop that the WTO organizes annually in Geneva. An online workshop organized for capital-based experts from Vanuatu discussed the acceptance of the TRIPS Amendment, as well as the implementation and use of the Special Compulsory Licensing System. The capacity building activities are based on the second edition of the WHO-WIPO-WTO study on "Promoting Access to Medical Technologies and Innovation – Intersections Between Public Health, Intellectual Property and Trade" which was launched on 29 July 2020. It sets out explanatory background material on the implementation and use of the System.[14] Updated background information is also available on the WTO's webpage dedicated to public health.[15] In addition, focused technical assistance materials have been developed to enable interested Members effectively to assess the operational context of the System and to support their effective use of it.

[14] See pages 241 to 244 and Annex III of the study, available at the three organizations' respective websites: https://www.wto.org/english/res_e/publications_e/who-wipo-wto_2020_e.htm.
https://www.wipo.int/publications/en/details.jsp?id=4511.
https://www.who.int/publications/i/item/9789240008267.

[15] https://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm.

ANNEX 1

[EXCERPT FROM THE MINUTES OF THE COUNCIL'S MEETING OF 15-16 OCTOBER 2020 TO BE CIRCULATED AS DOCUMENT IP/C/M/96]

7 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 review had been conducted pursuant to Paragraph 6 System 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, this review was also deemed to fulfil the requirements of Article IX:4 of the WTO Agreement.

3. During the Chair's consultations in September concerning Members' preferences for approaching the annual review, a number of Members had suggested that the discussion focus on concrete problems with the application of the System, rather than an abstract consideration of issues. Some had referred to procedural complexities of the System that needed to be discussed so that the System could ensure access to medicines as intended. Others had cautioned that this agenda item should not be "another COVID-19 item". One concrete proposal that had gathered broad support was the suggestion that the Secretariat give a presentation on how to use the Special Compulsory Licensing System (as opposed to how to accept the Amendment), so as to refresh delegations' memory and provide background to the discussion.

4. The Chair suggested that she would proceed by first informing Members about the status of acceptances of the Protocol Amending the TRIPS Agreement, and then give the floor to the Secretariat to provide a presentation on how to use the Special Compulsory Licensing System to remind everyone about the detail. The floor would then be open to delegations for an exchange of views about the functioning of the System, and finally, the Council would consider its Report to the General Council.

5. The Chair updated Members on the status of acceptances of the TRIPS Protocol. The current period for accepting it ran until 31 December 2021. The amended TRIPS Agreement was thus binding for 131 WTO Members. In other words, 33 Members were yet to accept the Protocol Amending the TRIPS Agreement. She encouraged those Members to complete their domestic procedures as soon as possible.

6. When the TRIPS Amendment had entered into force in January 2017, Members had noted that it would be useful to consider how to make this new procurement tool work effectively in practice. The Chair therefore encouraged Members to engage in a constructive discussion which could also build on earlier reviews. As previous Chairs and she herself had indicated on past occasions, Members might find two documents particularly helpful to facilitate their considerations. The first document was the Council's Annual Review of 2016 (circulated in document IP/C/76); and the second document 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 to support the practical use of the System.

7. The representatives of the WTO Secretariat, Chad (on behalf of the LDC Group), Ukraine, South Africa, India, China, Tanzania (on behalf of the African Group), Japan, Australia, the United States of America, Canada, Chile, and Switzerland took the floor.

8. The Council took note of the statements made.

9. The Chair turned to the Council's report to the General Council. A draft report had been prepared by the Secretariat (circulated in document JOB/IP/38). 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 with past reports, an extract from the Council's minutes on this agenda item would be attached to the report in Annex 1 and Appendix 1.

10. The Council agreed to adopt the draft report and to attach the record of the discussion to it.

APPENDIX 1

[EXCERPT FROM THE ADDENDUM TO THE MINUTES, CONTAINING THE STATEMENTS MADE DURING THE COUNCIL'S MEETING HELD ON 15-16 OCTOBER 2020, TO BE CIRCULATED AS DOCUMENT IP/C/M/96/ADD.1]

AGENDA ITEM 7: 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)

7.1 WTO Secretariat

1. Thank you very much for providing the Secretariat with an opportunity to make a presentation on how to use the Special Compulsory Licensing System.[1]

2. To start with it is useful to put the System into context. Where does it come from? Back in 2001, the Doha Declaration on the TRIPS Agreement and Public Health identified the problem of Members with insufficient or no manufacturing capacity in the pharmaceutical sector to make effective use of compulsory licensing. This can be found in Paragraph 6 of the Doha Declaration, which also explains why many people still refer to the mechanism as the "Paragraph 6 System".

3. The problem identified by the Doha Declaration is about securing adequate supply of affordable generics from third country sources where the needed products are patent-protected. The difficulty does not lie on the importing Member's side because that Member can issue compulsory licences for local production and import under Article 31 TRIPS. It is located on the exporting Member's side because of the restrictive condition in Article 31(f) which requires compulsory licences to be used predominantly to supply the domestic market. Under a normal compulsory licence, only the non-predominant part can be exported. This was considered to be potentially a problem and explains why the System puts in place two distinctive derogations from Article 31(f), as well as a derogation from the calculation of remuneration to be paid to the right holder under Article 31(h).

4. Let's now look at when to use the System [*slide 2*]. There is place for use of the System when there is insufficient or no local manufacturing capacity in the importing Member to produce the needed medicines and this Member therefore needs to rely on imports from a generic supplier in another Member. In the exporting Member, the product needed is covered by a patent and the export of the non-predominant share of the production which would be possible under a normal compulsory licence does not satisfy the need of the importer. Hence, there would be a need to authorize the generic manufacture exclusively for export. This is typically the scenario in which the System could be used.

5. The following are instances in which the System would not be used. This is the case when the potential importing Member has manufacturing capacity to produce what is needed in terms of medicines or pharmaceutical products. On the exporting Member's side, the System would not be used if there is no patent on the products needed by the importer and there would therefore no compulsory licence be required to manufacture for export. The same applies if there is a patent, but the standard compulsory license in the exporting Member would be sufficient to satisfy the needs of the importing country by exporting the non-predominant share of the production. Finally, the System would not be used in situations where anti-competitive practices have been determined by judicial or administrative processes. Under Article 31(k), this would lift the restrictive condition in 31(f).

6. What does the System cover? [*slide 3*] On the 'disease side', it covers public health problems affecting developing countries and LDCs, especially those resulting from HIV/AIDS, tuberculosis and malaria, but not limited to those. It also refers to other epidemics. On the 'product side', the System covers all pharmaceutical products, including active ingredients and diagnostic kits which are patented or manufactured under patented processes.

[1] The PowerPoint presentation is available in Room Document RD/IP/40. References to the relevant slides are added in brackets.

7. Who can use the System? [*slide 4*] LDCs automatically qualify as importers under the System. Other Members will have to notify the intention to use the System as importers. We should bear in mind that developed countries opted out of using the System as importers. There is also a group of 11 high-income developing countries which voluntarily agreed to use the System only in circumstances of extreme urgency. And we should also note that this is different from a standard compulsory license under Article 31 which can be used by all WTO Members for local production or import of all health and other technologies.

8. On the exporting Member's side, any WTO Member is entitled to export under the System as soon as it has export capacities. Usually, this would require implementation of this form of compulsory licence within domestic law, which most WTO Members with established capacity to export medicines have done. The data for world-wide pharmaceutical exports in 2014 for 122 countries confirm that the share of the total exports covered by WTO Members with implementing legislation amounted to more than 85% of the total pharmaceutical exports [*slide 5*]. It can thus be safely assumed that the legislative framework enabling Members with manufacturing capacities to engage in exports under the System is in place.

9. We now come to the key question of this presentation, i.e. how to use the System [*slide 6*]? The use consists of four easy steps. The first two are notifications by the importing Member and the exporting Member. In addition, the product which is manufactured under the System needs to be clearly identified as such through labelling or marking of those products for the purpose of avoiding trade diversion to high income countries so that they will stay in the country that needs the product. And finally, the licensee is required to post the details of the shipment(s) on a website to ensure transparency about what is shipped, the quantity of the shipped product and the distinguishing features applied to it, and the destination.

10. Let’s first look at the notifications in more detail [*slide 7*]. For LDC Members, the notification would provide information about its specific needs, including the names and expected quantities of the needed products and, if the product is patent-protected in the importing LDC Member, the intention to grant a compulsory license or the actual grant of a licence. Alternatively, reference can be made to the extended transition period in the pharmaceutical sector which exempts LDCs from the obligation to protect such patents.

11. Among the points which merit being kept in mind is that the notification merely signals the need of the LDC and does not mean a commitment to procure medicines under this System. In other words, if the LDC Member finds a more affordable source from which to procure the medicines it needs, it does not have to continue the use of the System. There is no need to notify the name of the supplier, nor the expected time frame of supply and use of the medicines. This is an important point, because notifying the name of the supplier would unnecessarily limit the range of potentially interested candidates who could otherwise engage in supply of the medicines. So, keeping it open to a wide range of potential suppliers is important. Joint notifications can be made by importing Members or a regional organization on behalf of its Members with their consent. Finally, this notification is not needed when pharmaceutical products are imported from another Member under the RTA derogation in Article 31*bis*(3).

12. To illustrate how this would like in practice, let’s take the hypothetical example of Aradia, an LDC [*slide 8*]. Its Ministry of Health, in cooperation with an International procurement programme, determined that it needs 15 million doses of 'panaceavir'. It also exercised rights not to protect pharmaceutical patents until 2033. All its notification under the System therefore needs to say is that "Aradia needs to import 15 million doses of panaceavir."

13. For Members that are not LDCs, two notifications would be required to use the System [*slide 9*]. The first notification is about its intention to use the System as an importer. It can be made any time, also together with the notification of its specific needs. This notification is not needed if the importing Member is an LDC or if the import takes place from another Member under the RTA derogation in Article 31*bis*(3). Again, making the notification does not imply a commitment to procure medicines under the System. It is just the first step and the Member remains free to get the medicines from a different source.

14. The second notification is about the importer’s specific needs. This has to be made each time the System is used by a Member for a particular medical need [*slide 10*]. It is almost identical to the

notification requirement for LDC Members with one difference, i.e. the importing non-LDC Member also has to notify that it has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector and how this has been established. The other notes are similar to those set out regarding LDC notification requirements.

15. How would this look like in practice [*slide 11*]? In the hypothetical case for illustration purposes, Sanatos is a developing country. Its Ministry of Health procurement programme determined that it needs 30 million doses of 'elixivir'. The country has insufficient manufacturing capacities in the local pharmaceutical industry. In this case all the notification needs to say is that "Sanatos intends to use the System set out in Article 31*bis* of the TRIPS Agreement and the Annex and the Appendix to it, as an importing Member" and "Sanatos needs to import 30 million doses of elixivir. Sanatos has found that its manufacturing capacity in the pharmaceutical sector is insufficient to meet its needs for this product, on the basis of 'Pharma Sanatos 2016', the most recent report on the pharmaceutical sector prepared by the Ministry of Industry".

16. Optionally, if no patent is in force, the notification could also indicate that "elixivir is not patent protected in the territory of Sanatos". If a patent is in force, the notification would need to confirm that "Sanatos intends to authorize use of the subject matter of the patent or patents in force for elixivir without the consent of the patent owner in accordance with the provisions in Article 31 and Article 31*bis* of the TRIPS Agreement".

17. Let's now turn to the notification requirements for an exporting Member [*slide 12*]. It needs to notify the grant of a compulsory license and conditions attached to it. What exactly does it need to notify? The notification has to include the name and address of licensee; product and quantities for which the compulsory licence has been granted; importing Member(s); duration of compulsory license; website address with information on quantities being supplied and distinguishing features applied to the product manufactured for export; and, on an optional basis, other licensing conditions and patent numbers.

18. It is important to note that in the notification that has to be made by any exporting Member for every compulsory licence issued under the System, information about details can be replaced by a copy of the compulsory license attached to the notification. The notification has to be submitted prior to export. Specific labelling/marking requirements apply to formulated products, active ingredients and finished products using such active ingredients. Before the shipment begins, the licensee may post information about the shipment on its own website or on a dedicated WTO website. This notification is not required if export takes place under the RTA derogation (Art.31*bis*(3)).

19. Finally, how to notify [*slide 13*]? The preferred option would be the use of the e-TRIPS Notification and Submission System. The links in the presentation are active in the room document and can be accessed by Members.

20. The e-TRIPS platform facilitates entry of each of the three notifications. We would encourage Members to use this facility. Other means of making notifications by email, by fax, or by mail remain also available. For Members wishing to use those options, a Guide to Notifications, including model notifications, is available on the WTO webpage. The links are also provided on this slide.

21. The notifications will be circulated by the Secretariat to the TRIPS Council as a formal document and can be accessed either on e-TRIPS or the TRIPS and Public Health webpage, which links to the relevant notifications on Documents Online.

22. Please note that none of these notifications require approval by a WTO body; that the general TRIPS requirements for compulsory license in Article 31 continue to apply such as the requirement to first seek a voluntary license by the right holder in normal circumstances; and, as the System is about intellectual property, that it does not address any procedural issues relating to, for example, procurement of medicines and regulatory approval.

23. For those who are interested in more detail, *slide 14* provides a list of resources which includes very recent material like Annex 3 to the Second Edition of the Trilateral Study. This Annex addresses the operation of the Special Compulsory License System. Also, the Guide to the TRIPS Agreement has a module on TRIPS and Public Health, including a specific section on using the Special Compulsory License System.

7.2 Chad on behalf of the LDC Group

24. Chad is speaking on behalf of the LDC Group, which thanks you for your report. We also thank the Secretariat for the update just provided to us.

25. As you recalled, it is true that the TRIPS Agreement and public health is a highly important matter for LDCs.

26. The entry into force of the amended TRIPS Agreement in January 2017 was a historic development, building integrally into the Agreement, as you reminded us, a valuable public health safeguard for the benefit of developing countries and particularly LDCs, which are extremely fragile and vulnerable.

27. The amendment provides for medicines to be produced under a special compulsory licence, for export to countries particularly reliant on overseas suppliers to meet the needs of their patients. As you know very well, the health needs in our countries, and especially in the least developed countries, are extraordinarily high.

28. It is therefore easy to see why this amendment is important as we face this global health crisis caused by COVID-19.

29. The LDC Group understands the important role that the TRIPS Agreement and public health play in relation to COVID-19. Indeed, we believe that the provisions of this amendment are highly relevant to the current global health crisis. The pandemic is an accelerator rather than a complication arising from the situation.

30. For this reason, the LDC Group is of the view that this issue is particularly important given the current pandemic. Focusing on access to medical supplies and saving human lives is therefore our overarching concern. We are currently facing difficulties due to the restrictions on travel, market access and the movement of goods. We are struggling to access the tools necessary for tackling the pandemic, such as, inter alia, medicines, masks and ventilators.

31. This amendment, in our view, is highly valuable and useful in light of the current situation. By way of conclusion, you reminded us that 33 Members, including LDC Members, are yet to accept this amendment. The LDC Group has therefore begun awareness-raising and mobilization activities to ensure that the Members of our Group accept the amendment by the deadline. We believe that these Members will do so and that it is simply a procedural matter. It is hoped that, by the deadline, this amendment will be validated and accepted by those Members of the LDC Group that have not yet done so.

32. Once again, this amendment is highly useful and important for the LDC Group so that we are able to easily access medicines and pharmaceutical products. In light of this, it is clear that the matter is relevant to the pandemic.

7.3 Ukraine

33. Ukraine expresses its gratitude to the WTO Secretariat for preparing a draft report and the possibility of taking part in the annual review of the Special Compulsory Licensing System.

34. Ukraine follows the discussions on this issue in the TRIPS Council and considers that exchanging information and experiences regarding the implementation and use of the System is very important and valuable, especially in the context of the COVID-19 crisis. Ukraine welcomes this work, hoping that it will ensure the effective operation of the System and encourage all remaining WTO Members to notify their acceptance of the Protocol Amending the TRIPS Agreement.

35. Given the situation with the COVID-19 pandemic, it is extremely important for Ukraine to ensure greater access to affordable medical products by intellectual property mechanisms, as provided in Article 31 of the TRIPS Agreement.

36. Ukraine would appreciate hearing about the experience of WTO Members who have used or considered using the System, any updated information regarding its implementation into domestic

legislative and regulatory framework, as well as thoughts concerning the System's role to address the COVID-19 pandemic. Such exchanges of views, as well as discussions in a broader context of the relationship of intellectual property and public health, will help to raise awareness of practical possibilities of using the System or its alternatives and related TRIPS flexibilities both among WTO Members as well as with interested agencies in charge of public health matters in their territories, and to adopt effective measures necessary to protect public health.

7.4 South Africa

37. The first question I have with respect to the Secretariat presentation refers to the definition of a 'pharmaceutical product' as we find it in the Annex to the TRIPS Agreement. The last sentence of sub-paragraph (a) says "it is understood that active ingredients necessary for its manufacture and diagnostic kits needed for the use would be included". One interesting question that always comes up is that this particular definition does not refer to vaccines. The question I have in context of our discussions around COVID-19 is whether or not we are talking about pharmaceutical products or products of pharmaceutical processes. This essentially would also include vaccines— it would be good if this point could be clarified.

38. The second question is in relation to Members that have implemented regimes for exportation under this System. And just in terms of the statistics, you indicated that 85% of the worldwide exports comes from Members that have implemented the System into their domestic law. Do we have statistics of who those Members are, i.e. the world exporters, the WTO Members with implementing legislation?

39. The last question is in respect of the use by LDCs in an RTA. If I go to the text of Article 31*bis* and I look at paragraph 3, it says and confirms what the slide says. But it goes on to say that where a developing or a LDC Member is party to an RTA within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries, the requirement then is that at least half of the current membership is made up of countries presently on the United Nations list of least developing countries. This creates a more cumbersome requirement for Members to benefit from a producer that may be situated within that RTA. To clarify that it is not just any RTA, it is only RTAs where at least 50% of Members are LDCs. According to my calculations, there are only two of these currently existing, and both of them are situated in Africa.

40. So as indicated I will proceed to read my prepared statement, and noting your introduction, thanking you for the consultations that you have held. We are also appreciative of the Secretariat's interventions including the excellent presentation.

41. The Doha Declaration on the TRIPS Agreement and Public Health, and the Paragraph 6 System established under the 2003 waiver, and the Protocol Amending the TRIPS Agreement through Article 31*bis*, remains a fundamental achievement and a landmark worthy of admiration. Yet, the Paragraph 6 System has stood as a monument to good intentions—pristine and only invoked once during the entire time. There is a recognition that the use of the System is overly cumbersome with too many conditionalities and procedural prescripts to be useful to Members with insufficient or no manufacturing capacity in the pharmaceutical sector.

42. Having studied the recently updated trilateral study, it points out that concerns have been expressed that the System is overly complex and not practical, and the potential use of the System may be deterred by concerns of political or trade ramifications associated with the use of compulsory licences. We agree that the System cannot be a panacea against all eventualities. However, conditioning the use of the Paragraph 6 System to time-consuming and overly burdensome procedures does not make for quick action irrespective of the level of development of a country.

43. Looking at the System through the lens of COVID-19 quickly reveals of the cracks in its construction and application. The System is based on developing countries notifying the WTO of the general intention to use the System, yet we see that there are many factors that might prevent a country from doing so and especially given the COVID-19 circumstances. As we indicated, we remain concerned about the apparent procedural and legal difficulties that continue to exist under this System and we stand ready to continue a discussion on many of these concerns that we have.

44. I just wanted to point out that in the context of HIV/AIDS, South Africa being one of the most affected countries in the world and so too the African continent, it is estimated that between 1997 and 2012, 12 million Africans died waiting for enough life-saving drugs to reach the continent. This is already during the time when the Doha Declaration on the TRIPS Agreement and Public Health had been issued, the 2003 waiver had been adopted and implemented on a provisional basis until it was finally subject to the Amendment of the TRIPS Agreement—yet millions of people still died. What are we to make of a System that allows a humanitarian crisis of this magnitude to continue without abatement? If this many people died in the genocide or an armed war or conflict there would be immediate action. Yet many of these people did not die because they were killed by bullets or artillery shelling, they died because they could not access life-saving medicine in a timely manner. We ask, will we allow this to continue? I hope not. The WTO must be responsive to the needs of its Members, chief amongst them must be counted the poorest and the most vulnerable.

7.5 India

45. We thank the Secretariat for the comprehensive presentation on the use of the Special Compulsory Licensing System.

46. 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. These provisions provide that the TRIPS Council shall review annually the functioning of the Special Compulsory Licensing System with a view to ensuring its effective operation.

47. The impracticality and difficulty in using this System should be self-evident in view of the fact that since 2007 this System has been invoked only once, despite the existing lack of sufficient manufacturing capacities in many countries.

48. We note that while delivering the presentation, it was mentioned that the process to use this System is fairly easy. However, when MSF had actually attempted to use it to export HIV medicines from Canada to Rwanda, it had expressed some pertinent concerns and I quote, "that the mechanism is neither expeditious nor workable and it is so cumbersome and full of red tape that it acts as a major disincentive". The onus, thus, lies on this Council to improve the procedures under this System so as to make it efficient and workable. We hope that Members will engage constructively on this important issue.

49. Lastly, we congratulate Barbados, Burundi and Niger for accepting the Protocol since the sixteenth annual review in 2019 and encourage the 33 Members who are yet to accept the Protocol, to do so expeditiously.

7.6 China

50. China wants to thank the Secretariat for its presentation and the draft report. It is informative and very useful. China supports the discussion on flexibilities provided by the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health, including how to make more effective use of the Special Compulsory Licensing System.

7.7 Tanzania on behalf of the African Group

51. The African Group would like to thank the Secretariat, in particular Mr Roger Kampf for the briefing that he has provided under this important agenda item. The briefing shares the challenges that face potential use of this System in terms of the bureaucratic processes needed before importers or exporters engaged in the use of the System. This is an opportunity to reflect on the importance on how to make the System work effectively.

52. The African Group would like to express appreciation for the Secretariat's continued good work under this important agenda item, which helps shed light on, among other things, ways of making the Paragraph 6 System work.

53. We welcome new developments which saw Burundi and Niger accept the Protocol Amending the TRIPS Agreement, and we also welcome the commitment of the delegation of Zimbabwe who at

their Trade Policy Review a couple of weeks back made a commitment to accept the Protocol Amending the TRIPS Agreement.

54. These are encouraging developments, particularly in Africa where we have been disproportionately affected by the COVID-19 pandemic that has overstretched our financial resources and public health systems. It is, thus, important for Africa to have all the tools at our disposal to address the pandemic and build local pharmaceutical manufacturing capacities and address structural vulnerabilities that arise out of the over reliance on imports of pharmaceutical and medical consumables.

55. We would like to encourage Members that do not have ratified the System yet to do so in the remaining time.

7.8 Japan

56. This delegation would like to express our gratitude to the Secretariat for making a presentation and preparing a draft report so that 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.

57. 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. Therefore, the System should not be considered as the only solution, but rather as just an option we could consider.

7.9 Australia

58. Australia thanks the Council for the Annual Review. As highlighted in the Review, Australia notes that the Secretariat has continued to provide technical assistance, in cooperation with other partners, to support the effective use of the Special Compulsory Licensing System.

59. The Review also notes a number of recent capacity building activities. We recognise that these activities are a useful way to facilitate the implementation and understanding of the System. Australia also commends the TRIPS Council for supporting transparency providing a guide to notifications for the Special Compulsory Licensing System on the WTO website.

60. We welcome the joint WTO-WHO-WIPO study on 'Promoting access to medical technologies and innovation', and note that Annex III provides a helpful overview of the Special Compulsory Licensing System. We look forward to further efforts to promote transparency and understanding for all TRIPS Members.

7.10 United States of America

61. The United States would like to thank the Secretariat for its presentation.

62. The United States welcomed the entry into force of the Protocol Amending the TRIPS Agreement. We welcome the Secretariat's draft Report and its work throughout the year to facilitate and encourage all Members to notify their acceptance of the Protocol.

63. We also congratulate the additional Members that have accepted the Protocol since the entry into force of the amended TRIPS Agreement.

64. While the entry into force of the amended TRIPS Agreement represented an important step in promoting our shared goal of facilitating access to medicines, it is only one piece of the puzzle. For example, the WHO has identified numerous considerations, including pricing and procurement

policies, taxes, markups and tariffs, and other national policies that ultimately result in higher costs for consumers and for health systems.

65. We encourage Members to continue to focus efforts to address other salient barriers to access while also recognizing the important role that intellectual property and international trade liberalization play in incentivizing drug development and expanding access to medicines around the world.

7.11 Canada

66. Canada considers access to medicines to be a key priority in our ongoing efforts to promote global health and prosperity.

67. Canada's Access to Medicines Regime (or CAMR), which implements Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, is one such measure used in Canada to promote access to medicines. Canada also recognizes the 2017 entry into force of the Protocol Amending the TRIPS Agreement which provides countries with an important tool to improve access to affordable medicines. As the only country to have exported a 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 Member who wishes to learn more.

7.12 Chile

68. Our delegation would like to thank the Secretariat for the presentation on the use of the System, as well as the Annual Review. Chile congratulates all the Members that have already ratified the Amendment and we commend those that have not done so to do it before the deadline. Chile is a strong promoter of this Amendment and is willing to share its experiences in how our country ratified the Amendment.

69. Our country is open to hearing more cases with empirical evidence in this area, as well as surrounding elements such as aspects of public procurement and pricing that could eventually have an effect on access to medicines. Our delegation is open to hearing concrete proposals on this issue.

7.13 Switzerland

70. My delegation would like to first thank the Chair, for your consultations held to prepare the review under agenda item 7.

71. I would like to join other delegates to thank also the Secretariat for their technical assistance throughout the previous year and for the very useful, clear and concise overview of the functioning of the 31*bis* System and how beneficiary Members may make use of it. We hope the Secretariat will make the presentation available on the WTO's dedicated webpage, together with the other helpful information and the Guide to Notifications facilitating the use of the System.

72. The presentation of the Secretariat showed that the use of the 31*bis* System by beneficiary countries is straightforward. In contrast, in their interventions India and South Africa called the System complex, cumbersome and not practical, citing as evidence that the System has been used only once so far. We disagree.

73. The Secretariat recalled in its presentation that the purpose of adopting the System in 2003 was to extend the TRIPS flexibility of Article 31 of the TRIPS Agreement to eligible beneficiary Members without relevant manufacturing capacity in the pharmaceutical sector. It has not been conceived for frequent use. The System applies to eligible beneficiary countries, in a specific case scenario and under particular circumstances. There are many instances, where the reasons for a lack of access to needed medicines in potential beneficiary countries are not related to patent protection. And it is misleading to imply that the many casualties that today still – and tragically enough - result from insufficient and untimely access to medicines would be the result of IP or perceived deficiencies in the system provided by Art. 31*bis*.

74. By making the so-called Paragraph 6 mechanism on patents and public health permanent in their decision of 6 December 2005 and amending the TRIPS Agreement formally by adding Article 31*bis* in its Part II Section 5, Members have ensured transparency, clarity and legal certainty.

75. Should eligible beneficiary Members meet with concrete problems when *actually* making use of the System, then it is the Council's duty to examine these specific difficulties in its Annual Reviews and look into how they can be addressed best in a practical manner. So far, we have not heard of such practical problems.

76. We call on those 33 Members who have not yet accepted the Protocol Amending the TRIPS Agreement to do so now without further delay.

77. We were pleased, in this respect, to hear from the distinguished delegate from Chad on behalf of the LDC group that they will undertake additional efforts to encourage their Members to accept the Protocol before the expiry of the extended deadline, and that he considered the 31*bis* System to be very useful from the perspective of a beneficiary country group.

7.14 WTO Secretariat

78. We thank the Chair and delegations for their useful inputs into the debate. Let me start with the questions which were posed by South Africa, which are very pertinent.

79. The first question concerned the definition of pharmaceutical products and whether this included vaccines. This is, of course, a very pertinent question in the current situation, as the pandemic is very much about access to vaccines if and when they become available. As usual, it is, however, not for the Secretariat to interpret relevant provisions. I would therefore turn the question back to South Africa. Is there any serious concern about vaccines not being included in the definition of a pharmaceutical product? Is there any argument being made saying that vaccines are indeed not considered to be pharmaceutical products? In relevant WHO official documents, for example, vaccines are generally included in the legal definition of a pharmaceutical product. Similarly, the WHO Good Manufacturing Practices for Pharmaceutical Products has numerous references to vaccines. So, there are indications out there about what falls within the definition of a pharmaceutical product. But again the question is: is there really any concern about vaccines not being included?

80. The second question referred to the slide with the statistics about Members with export capacity that have implementing legislation in place, seeking an explanation as to how these statistics were put together. These have been taken from industry sources which have records on the export of pharmaceutical products on a country-by-country basis. I did compare this data with the implementing legislation that is compiled in a Staff Working Paper on the key features of WTO Members' implementing legislation regarding the Paragraph 6 System.[2] That led to the figures you see on the slide concerned. While the data merit being updated, newer figures can be expected to confirm the finding that the vast majority of Members with export capacities have implementing legislation in place.

81. The final point was about regional trade agreements and I apologise that the slide may be a bit misleading, although I did present it orally in a more concise manner. As the delegate from South Africa has rightly noted, for RTAs to benefit from the easier procedure in Article 31*bis* to export medicines to other members within the RTA, they need to qualify as an RTA within the meaning of Article XXIV of the GATT 1994. The RTA needs to be composed of 50% or more of least developed countries and also the Members concerned need to share their health problems in question. However, I would rather see what has been described as a cumbersome further condition to use the System as an additional flexibility. It was built into the mechanism when it was adopted to give additional flexibility to those who at the time were most suffering from the HIV/AIDS crisis. One can therefore also see that particular derogation from a positive angle.

82. To conclude, I just wanted to pick up on what our colleague from Chile said, i.e. that there is more need for empirical studies and evidence. Indeed, when it comes to the question as to whether the procedures are cumbersome and bureaucratic, it would actually be good to hear more about the problems and, in particular for least developed countries, the difficulties to submit a one line

[2] Available at https://www.wto.org/english/res_e/reser_e/ersd201507_e.pdf.

notification identifying the products and the quantities needed. This call for empirical evidence or studies seems therefore pertinent and maybe something to be picked up in our future work.