



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

WTO SECRETARIAT TECHNICAL COOPERATION IN THE TRIPS AREA

NOTE BY THE SECRETARIAT

This document has been prepared under the Secretariat's own responsibility and is without prejudice to the positions of Members or to their rights and obligations under the WTO.

This document reports on the WTO Secretariat's technical cooperation activities concerning TRIPS undertaken between 1 September 2015 and 30 October 2016. It covers activities that specifically relate to intellectual property (IP) and the TRIPS Agreement, as well as contributions to other activities of a broader character which have a significant IP or TRIPS component. It follows the previous report to the Council for TRIPS contained in document IP/C/W/608, dated 3 August 2015. This cover note provides a general overview. More information for each activity is provided in the Annex I.

1 MAIN ORIENTATIONS, TRENDS AND DEVELOPMENTS

1.1. The Secretariat's technical cooperation activities in relation to the TRIPS Agreement continued to focus on assisting Members and Observers to understand the rights and obligations, including the available options, which flow from the TRIPS Agreement and relevant decisions of WTO bodies, in order to enable them to meet their developmental and other domestic policy objectives, including in relation to broader areas of trade policy as it relates to other public policy dimensions, including innovation and industrial policy, health, regulation, competition policy and the environment. These capacity building activities also aim to support Members to participate fully and substantively in the WTO's ongoing work on TRIPS matters, in particular building their capacity to assess what is at stake for them in issues under examination or review. In addition, Members and Observers continued to receive assistance regarding notifications and reviews of national legislation.

1.2. Technical cooperation on TRIPS has been delivered through information and advice given to Members in Geneva, and through study programmes, training courses, seminars and workshops for developing countries in Geneva and elsewhere. It is driven essentially by demand from Members, as well as from countries preparing to accede to the WTO. Growing diversity of the needs and interests identified by Members has led to increased tailoring and focusing of technical assistance activities on specific areas of interest or sectoral policy themes, including through more focused and thematic national and regional workshops. At the same time, the Secretariat has adopted a more holistic approach to its capacity building activities in general, putting the TRIPS Agreement and its policy choices into a broader context, and building policy skills through case studies and the involvement of a wider range of policy expertise and the infusion of practical perspectives on the implementation of TRIPS and the IP system. This approach also takes into account the interface between the TRIPS Agreement and other WTO agreements, such as agriculture, TBT and SPS. It requires closer collaboration between and participation of various divisions in the Secretariat with a view to offering participants solution-oriented training activities that address all relevant dimensions in an integrated way. The TRIPS modules of the Advanced Trade Policy Courses and the Workshop on Trade and Public Health, both held in Geneva, illustrate this approach.

1.3. In line with this holistic approach, complementarity and cooperation with other intergovernmental organizations has been continuously ensured, especially through coordination with WIPO and the WHO in the field of IP and public health. In particular, the WHO-WIPO-WTO Trilateral Study on "Promoting Access to Medical Technologies and Innovation" (http://www.wto.org/english/res_e/publications_e/who-wipo-wto_2013_e.htm), launched in February 2013¹, provided a comprehensive information resource to support a multidimensional approach in relation to the intersections between public health, intellectual property and trade.

2 SEMINARS, WORKSHOPS, TRAINING COURSES AND OTHER TECHNICAL COOPERATION ACTIVITIES

2.1 In Geneva

2.1. Many broader WTO training courses, seminars and workshops included a significant TRIPS component, such as the regular WTO Advanced Trade Policy Courses, the "Geneva Weeks" for Non-Residents, and other events held in Geneva. Three Advanced Trade Policy Courses held during the reporting period also included a visit to WIPO, enabling participants to learn about that Organization, its treaties and activities.

2.2. The thirteenth joint WIPO-WTO Colloquium for Teachers of Intellectual Property from Developing Countries and/or countries with economies in transition formed part of the wider Secretariat's approach towards cooperation with the academic community in developing countries aimed at local capacity building on WTO matters. The main objective of the Colloquium was to update university teachers of IP in developing countries and countries with economies in transition on the activities and instruments of the WIPO and the WTO with focus on important policy issues under negotiation or discussion in the two Organizations, and to set these issues in their wider legal and policy context. In addition to speakers from the two Secretariats and from the WHO, UNFCCC, ITU and UPOV, two representatives of the judiciary were invited to participate as main speakers on IP Jurisprudence, which largely enhanced and enriched the quality of the Colloquium. Participating university teachers also made presentations on selected topics. The building of an active alumni network, and the development of the Colloquium papers as a quality academic journal², together ensure that this activity will have a significant long-term impact, particularly in strengthening indigenous capacity both for teaching IP with an international and policy-rich perspective, and for analysing and assessing current IP policy issues.

2.3. The eighth joint WIPO-WTO Advanced Course on Intellectual Property continued to draw on the experience of the Colloquium, and applied a similar programme structure and pedagogic strategy. The target group were, however, government officials and public sector policymakers. The course also applied the notion of gradual and progressive learning: in order to qualify for the course, the candidates had to complete the WTO eTraining TRIPS Course or possess commensurate knowledge or professional experience. The course was thus able to work from a truly advanced baseline and to explore cutting edge issues through an interactive debate and practical case studies, so as to strengthen participants' capacity to review policy options and their implications, and to learn from the wide range of practical experiences covered in the programme.

2.4. With a view to responding to the increased interest in and demand for technical assistance on cross-cutting, thematic issues, the Secretariat, in close collaboration with the WHO and WIPO, and with valuable inputs from other partners, has further elaborated the Workshop on Trade and Public Health. Building on the series of Workshops on Intellectual Property and Public Health convened since 2005, and guided directly by feedback from past participants, this capacity building activity has since 2014 gradually evolved to maintain coverage of key issues concerning medicine innovation and access from a TRIPS perspective, particularly the use of TRIPS flexibilities, but also

¹ Available at: http://www.wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf; http://www.wipo.int/policy/en/global_health/trilateral_cooperation.html; http://www.who.int/phi/promoting_access_medical_innovation/en/. See also the Briefing Note on "Promoting Medical Innovation and Access, Together" at: https://www.wto.org/english/tratop_e/trips_e/who_wipo_wto_e.htm.

² Papers presented at the Colloquium of 2015 will be compiled and published by WIPO and the WTO and will be available online as an edited volume, intended to provide a resource for researchers and analysts covering contemporary IP and TRIPS issues from the perspective of a wide range of developing countries, and enabling to build the academic credentials of participants. This will be the sixth volume in a formal publication series.

to set public health policy within a wider range of trade disciplines as well as the human rights dimension. It therefore enables participants to view the interface between public health objectives and trade agreements in a holistic manner, an aspect receiving strong positive feedback from participants, who are drawn from across health, trade and IP agencies.

2.5. Since their inception in 2005, responding to Members' agreement to establish a new health-related flexibility in the form of the Paragraph 6 System, the capacity building workshops on public health have maintained a concentration on the System, and its operation as a mechanism enabling WTO Members to grant special compulsory licences for export of medicines. For instance, the initial 2005 Workshop provided "information and exercises pertaining to its implementation and application in practice, and to provide a platform for the analysis of issues related to the legislative and institutional framework at the domestic level" and "an opportunity to exchange views and experiences among participants and with representatives from other international organizations, industry and NGOs".³ The evolving pattern of this area of technical assistance has been reported to the TRIPS Council in previous annual updates. Initially general in character, the focus of capacity building has evolved as domestic implementation of the system has proceeded in many Members, with many more now having export provisions in their laws to facilitate the system. Accordingly, more recently the Workshops have focused on how to make effective use of this additional procurement tool in practice so that affordable medicines reach patients (details regarding this part of the Workshop held in 2016 are provided in Annex II), drawing also on capacity building material in the Trilateral Study (paragraph 1.3 above).

2.2 Outside Geneva

2.6. The WTO organized five national workshops devoted to IP matters, in Algeria (on the TRIPS Agreement and distinctive signs); the United Arab Emirates (on intellectual property and public health); Cuba (on certain public policy questions related to the TRIPS Agreement); Bangladesh (on intellectual property); and Saint Kitts and Nevis (on the TRIPS Agreement, focusing on the review of implementing legislation and notifications to the TRIPS Council). In line with the demand driven nature of technical assistance, these activities responded to the specific needs identified by the host country and were organized in cooperation with the respective recipient country.

2.7. Broader WTO technical assistance activities outside Geneva have included a significant TRIPS component. For example, the Secretariat contributed (in partnership with the Universidad Andina Simón Bolívar in Quito, Ecuador; the Ecole Supérieure de Commerce de Tunis, Tunisia; the Shridath Ramphal Centre for International Trade, Law, Policy and Services in Bridgetown, Barbados; and the University of Botswana) to WTO Regional Trade Policy Courses with a significant IP component. In addition, the Secretariat organized a Sub-regional Short Trade Policy Course that contained a significant IP component, for the Asociación Latinoamericana de Integración.

2.3 eTraining

2.8. WTO E-Learning (<https://ecampus.wto.org/default.asp>) currently offers four courses related to TRIPS: Trade-Related Aspects of Intellectual Property Rights, as well as a Short Trip through TRIPS⁴, Copyright in the WTO⁵ and Patents in the WTO⁶, which are new E-Learning courses. They have been developed using the latest pedagogical approach and making use of instructional design methodologies. The learning material includes a wide variety of multimedia, interactive elements and exercises.

2.9. The courses are organized in English, French and Spanish all-year round. Participants have online access to the course material, background documents, interactive sessions (webinars, chat sessions and discussion forum) as well as pre- and post-tests. Successful participants are awarded a certificate. They are assisted throughout the course by a trainer and a helpdesk. In the invitations to workshops and more advanced technical assistance activities on the

³ IP/C/W/454 of 5 October 2005.

⁴ The English version was made available for participants on 3 March 2015 and the French and Spanish versions on 1 September 2015.

⁵ The English version was made available for participants on 1 September 2015. The French and Spanish versions will be made available as soon as possible.

⁶ The English version was made available for participants on 1 February 2016. The French and Spanish versions will be made available as soon as possible.

TRIPS Agreement, the Secretariat has prioritised candidates having successfully completed the WTO TRIPS E-Learning course.

3 COOPERATION WITH WIPO AND OTHER INTERGOVERNMENTAL ORGANIZATIONS

3.1. Cooperation with WIPO continues as a key feature of technical cooperation in the TRIPS area, based on the 1995 cooperation agreement between the two Organizations, and the WIPO-WTO Joint Initiative on Technical Cooperation for Least Developed Countries, launched in June 2001.

3.2. The WTO Secretariat's technical cooperation in the area of TRIPS includes a wide range of coordination and cooperation with other intergovernmental organizations, and contributions to other IGO programs. For instance, the WHO, WIPO and WTO Secretariats have continued their trilateral cooperation with a view to fostering a better understanding of the linkage between public health, intellectual property and trade more generally and to enhance a mutually supportive implementation of the relevant policies in those areas. Among other things, this also included jointly designing and carrying out a number of capacity building activities during the period under review, including two Geneva-based Trilateral Symposia on "Innovation and Access to Medicines; Learning from the Past, Illuminating the Future" and on "Antimicrobial Resistance: How to Foster Innovation, Access and Appropriate Use of Antibiotics?".

3.3. The technical cooperation activities therefore included various forms of partnership, cooperation or invaluable inputs from, in the multilateral sphere, UNAIDS, UNCTAD, UNDP, UNFCCC, UN OHCHR, UPOV, WHO, WIPO and WCO, as well as a wide range of civil society and private sector actors, individual academics and senior judges, and regional organizations, including ARIPO and OAPI.

ANNEX I

Technical Cooperation Activities in the TRIPS Area from 1 September 2015 to 30 October 2016

| Activity | Date | Location | Brief Description | Link to further details |
|---|----------------------------|--------------------------|---|---|
| WTO Regional Trade Policy Course for Latin America (sessions on TRIPS) | 31 August-1 September 2015 | Quito, Ecuador | The purpose of the RTPC, which includes a component on TRIPS, was to ensure that participants were thoroughly exposed to all WTO-related issues, and developed practical skills as well as an extensive network of contacts. It also served as a general introduction for those who may become specialists at a later stage. | http://wtotrta/Activities/ActivityDetailPlan.aspx?ActivityId=RTPC15/7 |
| WIPO National Workshop on Intellectual Property as a tool for Strengthening the productive sector | 2-4 September 2015 | Quito, Ecuador | The WTO contribution to this activity focused on patent provisions in the TRIPS Agreement and their link with public policy issues, such as public health and renewable energy. | |
| Academic Support to WTO Chair | 10-11 September 2015 | Shanghai, China | This TA activity was requested by Shanghai University of International Business and Economics (SUIBE), as part of the WTO Chairs Programme, which aims to support and promote trade-related academic activities by universities and research institutions in developing and least-developed countries. This activity included three segments: two roundtable discussions with Shanghai Intellectual Property Administration (SIPA) and Shanghai Intellectual Property Court respectively and one conference on WTO and Health: Law and Policy of Traditional Chinese Medicines. | |
| WIPO-MCST-KCC Interregional Workshop on Copyright Enforcement | 14-18 September 2015 | Seoul, Republic of Korea | The WTO contributed to this activity through presentations on TRIPS provisions on IPR enforcement and on WTO case law in the field of copyright and enforcement. | |

| Activity | Date | Location | Brief Description | Link to further details |
|--|--------------------|----------------------|--|---|
| WTO Workshop on Trade and Health for Capital-based officials from Developing Countries | 26-30 October 2015 | Geneva | The Workshop laid emphasis on building capacity to analyse and undertake policy choices in the area of intersection between trade and public health. Presentations, discussions and practical exercises therefore looked at relevant trade agreements as part of the wider action to address needs specific to public health. In particular, the Workshop covered key factors that impact on innovation and access in the pharmaceutical sector, including: Public health determinants; intellectual property rights; pricing and procurement policies; competition policy and rules; tariffs, quotas and licensing; and health services. A separate section dealt with regulatory issues, including the approval, quality control and effectiveness of medicines, the protection of clinical test data under the TRIPS Agreement and health-related measures in the TBT and SPS Committees. | http://wtotrta/Activities/ActivityDetailPlan.aspx?ActivityId=TC15/9 https://www.wto.org/english/news_e/news15_e/trip_12nov15_e.htm https://www.wto.org/english/news_e/news15_e/ddgra_26oct15_e.htm |
| WHO, WIPO and WTO Technical Workshop on "Patentability Criteria" | 27 October 2015 | Geneva | The Technical Workshop aimed at complementing the 28 October 2015 Symposium (see below) through providing participants with practical insights into how the main substantive patentability criteria are applied in practice at country level and how different interpretations can impact on public health. | https://www.wto.org/english/tratop_e/trips_e/trilat_workshop15_e.htm |
| Fifth WHO-WIPO-WTO joint Trilateral Symposium on Innovation and Access to Medicines; Learning from the Past, Illuminating the Future | 28 October 2015 | Geneva | The Trilateral Symposium reviewed the information base on access and innovation in medical technologies and identified possibilities and limitations for better integrating data in support of policy makers' future work. | https://www.wto.org/english/tratop_e/trips_e/trilat_symp15_e/trilat_symp15_e.htm |
| WTO Regional Workshop on Intellectual Property, Public Health and Priority Needs | 3-6 November 2015 | Abidjan, Ivory Coast | The Workshop aimed at providing participants with a better understanding of (i) the TRIPS Agreement; (ii) the linkages between the IP regime and public health; and (iii) the WTO needs assessment process in the field of IP. | http://wtotrta/Activities/ActivityDetailPlan.aspx?ActivityId=TRIPS15/2 |

| Activity | Date | Location | Brief Description | Link to further details |
|--|------------------------------|------------------|--|---|
| Advanced Trade Policy Course (sessions on TRIPS) | 9-10 November 2015 | Geneva | The ATPC includes a module on intellectual property. It aims at developing participants' autonomy in conducting WTO-related work by: (i) encouraging critical thinking to explore the linkages between WTO rules and disciplines and countries' trade policies and interests in the multilateral trading system; and (ii) enhancing analytical and negotiating skills to engage in trade policy formulation and implementation, monitoring and surveillance, WTO negotiations or dispute settlement. | http://wtotrta/Activities/ActivityDetailPlan.aspx?ActivityId=ATPC15/3 |
| WTO National Workshop on the TRIPS Agreement and Distinctive Signs | 23-24 November 2015 | Algiers, Algeria | The Workshop addressed issues related to trademarks and geographical indications. | http://wtotrta/Activities/ActivityDetailPlan.aspx?ActivityId=DZA15/4 |
| Introduction Course for LDCs | 12 February 2016 | Geneva | The Introduction Course includes a module on the TRIPS Agreement. It aims at the dissemination of general information about the WTO, its basic rules and disciplines and its functioning. | http://wtotrta/Activities/ActivityDetailPlan.aspx?ActivityId=IC16/1 |
| Advanced Trade Policy Course (sessions on TRIPS) | 12 February and 1 March 2016 | Geneva | The ATPC includes a module on intellectual property. It aims at developing participants' autonomy in conducting WTO-related work by: (i) encouraging critical thinking to explore the linkages between WTO rules and disciplines and countries' trade policies and interests in the multilateral trading system; and (ii) enhancing analytical and negotiating skills to engage in trade policy formulation and implementation, monitoring and surveillance, WTO negotiations or dispute settlement. | http://wtotrta/Activities/ActivityDetailPlan.aspx?ActivityId=ATPC16/1 |
| WTO National Workshop on Intellectual Property and Public Health | 17-18 February 2016 | Dubai, UAE | The purpose of the Workshop was to provide participants with a better understanding of the provisions of the TRIPS Agreement relevant to public health. | http://wtotrta/Activities/ActivityDetailPlan.aspx?ActivityId=ARE16/1 |

| Activity | Date | Location | Brief Description | Link to further details |
|---|------------------|-----------------------|--|---|
| Eighth WIPO-WTO Advanced Course on Intellectual Property for Government Officials | 7-18 March 2016 | Geneva | The main objective of the WIPO-WTO Advanced Course on Intellectual Property for Government Officials is to update government officials on the activities and instruments of WIPO and the WTO, and to provide a forum for them to exchange information and ideas with the two Secretariats and with a range of organizations based in Geneva. | http://wtotrta/Activities/ActivityDetailPlan.aspx?ActivityId=TC15/6 |
| WTO Regional Trade Policy Course for French-speaking African countries (sessions on TRIPS) | 18-20 April 2016 | Tunis, Tunisia | The purpose of the RTPC, which includes a component on TRIPS, was to ensure that participants were thoroughly exposed to all WTO-related issues, and developed practical skills as well as an extensive network of contacts. It also served as a general introduction for those who may become specialists at a later stage. | http://wtotrta/Activities/ActivityDetailPlan.aspx?ActivityId=RTC16/2 |
| WTO National Workshop on Certain Public Policy Questions Related to the TRIPS Agreement | 19-21 April 2016 | Havana, Cuba | The purpose of the Workshop was to provide participants with a greater understanding of the TRIPS Agreement and the multilateral intellectual property regime. | http://wtotrta/Activities/ActivityDetailPlan.aspx?ActivityId=CUB16/1 |
| UNCTAD/Ministry of Industry/Ministry of Health Workshop on 'The Use of Intellectual Property Rights' Flexibilities to Promote Local Pharmaceutical Production in Ethiopia | 3-4 May 2016 | Addis Ababa, Ethiopia | As a contribution to the implementation of the National Strategy and Plan of Action for Pharmaceutical Manufacturing Development (2015-2025) that the Government of Ethiopia has put in place in collaboration with the WHO, the Workshop aimed at enhancing the understanding of how intellectual property relates to local pharmaceutical production. The WTO Secretariat contributed to the Workshop through a video link. It provided an update on the state of play of Ethiopia's accession to the WTO, an introduction to the TRIPS Agreement and how intellectual property rights relate to innovation and investment, as well as the transition periods currently available to LDCs. | |

| Activity | Date | Location | Brief Description | Link to further details |
|---|-----------------|----------------------|--|--|
| WTO Regional Trade Policy Course for the Caribbean (sessions on TRIPS) | 9-11 May 2016 | Bridgetown, Barbados | The purpose of the RTPC, which includes a component on TRIPS, was to ensure that participants were thoroughly exposed to all WTO-related issues, and developed practical skills as well as an extensive network of contacts. It also served as a general introduction for those who may become specialists at a later stage. | http://wtotrta/Activities/ActivityDetailPlan.aspx?ActivityId=RTPC16/5 |
| WHO/Ministry of Health and Population/Institut Français Égypte: International Conference on IP and Counterfeit, Falsified and Substandard Drugs | 29-30 May 2016 | Cairo, Egypt | The themes discussed at the Conference included IP and patent issues in Egypt, as well as the role of law and law enforcement in controlling counterfeit, falsified and substandard drugs. Presentations were made by representatives of the Government of Egypt, French experts and private sector representatives. The WTO contribution to the programme included a presentation on the TRIPS Agreement and Counterfeit Medicines. | |
| WTO Academic Support Programme – Lectures on TRIPS in Summer Academic at Centre for WTO Studies, Indian Institute of Foreign Trade | 30 May 2016 | Delhi, India | This training course was sponsored by the Indian Government through the Indian Institute of Foreign Trade, New Delhi, in the form of a Summer Academy on trade law in cooperation with the World Trade Institute. It aimed at strengthening India's capacity on trade law. | http://wtotrta/Activities/ActivityDetailPlan.aspx?ActivityId=AS16/6 |
| 13 th WIPO-WTO Colloquium for Teachers of Intellectual Property from Developing Countries | 13-24 June 2016 | Geneva | The aim of the WIPO-WTO Colloquium is to help teachers of IP from developing countries become more aware of the Geneva institutions, negotiations and other activities dealing with intellectual property law and policy, and to strengthen their countries' independent research, policy analysis and teaching in international intellectual property law and economics with its diverse policy contexts. | http://wtotrta/Activities/ActivityDetailPlan.aspx?ActivityId=TC16/13 https://www.wto.org/english/atratope/trips_e/colloquium_main_e.htm |
| WTO Regional Trade Policy Course for English-speaking African countries (sessions on TRIPS) | 20-22 June 2016 | Gaborone, Botswana | The purpose of the RTPC, which includes a component on TRIPS, was to ensure that participants were thoroughly exposed to all WTO-related issues, and developed practical skills as well as an extensive network of contacts. It also served as a general introduction for those who may become specialists at a later stage. | http://wtotrta/Activities/ActivityDetailPlan.aspx?ActivityId=RTPC16/1 |

| Activity | Date | Location | Brief Description | Link to further details |
|--|-------------------------|-----------------------|--|---|
| Advanced Trade Policy Course (sessions on TRIPS) | 24 June and 4 July 2016 | Geneva | The ATPC includes a module on intellectual property. It aims at developing participants' autonomy in conducting WTO-related work by: (i) encouraging critical thinking to explore the linkages between WTO rules and disciplines and countries' trade policies and interests in the multilateral trading system; and (ii) enhancing analytical and negotiating skills to engage in trade policy formulation and implementation, monitoring and surveillance, WTO negotiations or dispute settlement. | http://wtotrta/Activities/ActivityDetailPlan.aspx?ActivityId=ATPC16/2 |
| Lectures for MIP programme with Queensland University Technology | 17-19 August 2016 | Brisbane, Australia | The WTO contribution to the WIPO Masters of intellectual property programme focussed on the TRIPS Agreement, including current issues such as public health and climate change, and its interplay with other areas of policy and regulation, such as innovation policy and the TBT and SPS Agreements. It centred on a multidimensional case study illustrating the interface between intellectual property, trade and food policy. | |
| WTO National Workshop on Intellectual Property | 23-24 August 2016 | Dakha, Bangladesh | The purpose of the Workshop was to provide participants with a better understanding of the TRIPS Agreement, with a particular focus on the pharmaceutical sector. | http://wtotrta/Activities/ActivityDetailPlan.aspx?ActivityId=BGD16/2 |
| WIPO Regional Meeting of Representatives of Export Offices and Heads of IP offices from Latin American Countries | 14-15 September 2016 | Santa Maria, Colombia | The WTO contribution consisted in particular in a participation in a roundtable on "Trade, IP and Export / Challenges for Competitiveness". | |
| Lectures for LL.M in Intellectual Property programme with WIPO-University of Turin | 26 September 2016 | Turin, Italy | The WTO contribution to the WIPO-Turin LL.M in Intellectual Property focused on dispute settlement in the field of IP. | |

| Activity | Date | Location | Brief Description | Link to further details |
|---|----------------------|------------------------|---|---|
| WTO National Workshop on Intellectual property: Intellectual property to Meet South Africa's Developmental Objectives | 26-27 September 2016 | Pretoria, South Africa | The purpose of the Workshop was to build capacity among government officials who are members of the newly established Inter-Ministerial Committee on Intellectual Property (IMC). They were expected to gain a better understanding of TRIPS flexibilities and how they can address South Africa's developmental objectives. The activity took into account the IP Consultative Framework that was adopted by Cabinet on 6 July 2016 and which served as the basis for consultations with a broad range of stakeholders in order to review and further develop South Africa's IP policy. | http://wtotrta/Ar/ActivityRequest.aspx?ActivityRequestId=745 |
| UNCTAD/UNDP Workshop on the Consultative Framework for IP in South Africa | 28 September 2016 | Pretoria, South Africa | This activity consisted in assisting the Department of Trade and Industry in collecting stakeholder feedback on the Intellectual Property Framework with a view to formulating a national Intellectual Property Policy. The WTO contribution included a presentation on geographical indications and on the special compulsory licensing mechanism to export medicines. | http://wtotrta/Ar/ActivityRequest.aspx?ActivityRequestId=767 |
| WTO Course on Enhancing LDC Participation in the Multilateral Trading System | 10-14 October 2016 | Geneva | This Course includes a module on intellectual property. It aims at deepening the understanding of the participants on trade and development issues being discussed in the WTO. | http://wtotrta/Activities/ActivityDetailPlan.aspx?ActivityId=TC16/19 |
| WTO Workshop on Trade and Health for Capital-based officials from Developing Countries | 17-21 October 2016 | Geneva | The Workshop aimed at building national decision-makers' capacity to analyse policy choices in the area of intersection between trade, intellectual property (IP) and public health, based on a comprehensive understanding of overlapping policy issues with bearing on public health, and an analysis of their relationship with multilateral trade agreements. It reviewed the system of multilateral trade agreements as part of the wider action to address needs specific to public health, and set this system in the context of the broader factors that impact on innovation and access to pharmaceuticals and medical technologies. | https://www.wto.org/english/news_e/news16_e/trip_17jun16_e.htm |

| Activity | Date | Location | Brief Description | Link to further details |
|--|---------------------|-----------------------------------|--|---|
| WHO, WIPO and WTO Technical Symposium on "Antimicrobial Resistance – How to Foster Innovation, Access and Appropriate Use of Antibiotics?" | 25 October 2016 | Geneva | The Symposium offered a forum for stakeholders and representatives of relevant sectors to exchange views and experiences, to discuss and allow participants to achieve a better understanding of the global challenge of AMR and to envisage possible ways forward. | https://www.wto.org/english/news_e/news16_e/heal_29aug16_e.htm |
| WTO National Workshop on the TRIPS Agreement | 25-27 October 2016 | Basseterre, Saint Kitts and Nevis | The purpose of the Workshop was to provide participants with a better understanding of the TRIPS Agreement, as well as to assist the Government to prepare pending responses to the review of implementing legislation and to notify relevant legislative measures to the TRIPS Council. | |
| WTO E-Learning Courses on Trade-Related Intellectual Property Rights: - Trade-related aspects of Intellectual Property Rights, level 2 - A Short Trip through TRIPS, level 2 - Copyright in the WTO, level 2 - Patents in the WTO, level 2 | throughout the year | online | Interactive course over the Internet; 24/7 access to training material from any location in the world; dedicated WTO tutor; WTO certification. | https://ecampus.wto.org/default.asp |

ANNEX II**WTO Workshop on Trade and Public Health, Geneva, 17 to 21 October 2016****Session on Practical Use of the Paragraph 6 System**

Building on the preceding eleven workshops in this series which had covered implementation of the Paragraph 6 System, the 2016 WTO Workshop on Trade and Public Health included updated capacity-building material on making effective use of special compulsory licences for export as a procurement tool for medicines. This material was tailored for the mix of public health, trade and intellectual property officials taking part in the workshop. In anticipation of the System's expected entry into force in the near future, and in light of the extensive implementation of enabling legislation by potential exporting countries, this Annex provides an overview of the session. It has been prepared as a background resource only on the responsibility of the Secretariat, and no views are attributable to any participant in the session.

By way of **introduction**, the WTO Secretariat gave a presentation covering the following points:

- The Paragraph 6 System was the first ever amendment agreed to the WTO Agreement and the full package of multilateral trade law, with the express purpose of facilitating access to medicines by those facing particular challenges. Encouragement for its use had been voiced at the highest levels within the multilateral system and it was a concrete contribution to the achievement of the UN Sustainable Development Goals which refer to the full use of TRIPS flexibilities for access to medicines.
- Upon its entry into force, the Paragraph 6 System would provide for a secure legal pathway to affordable medicines and put it on par with other pro-health TRIPS flexibilities. An important recent development has been the great increase in pharmaceutical exporting countries putting in place the necessary legislation to enable its use for export: this had gone from one Member at the time of first use to over 52 today, covering about 80 % of current medicines export capacity.
- The System comes into play when the best option for access to a medicine is production specifically for export under a compulsory licence in a foreign country (it did not apply, for instance, where some of the production under "regular" compulsory licences could be exported, such as when production under compulsory licence for a relatively large home market could also serve a smaller export market).
- As a dedicated "trade-related" compulsory licence, such compulsory licensing specifically for export was a relatively new development with no antecedents in domestic law, unlike conventional compulsory licensing to service domestic needs which was more established in many countries. Apart from the direct use in creating legal pathways for access to medicines, one other use of compulsory licensing mechanisms was to exert leverage during negotiations with patent owners or licensees to agree on lower prices.
- The System was not a stand-alone procurement mechanism, and would not operate in isolation from procurement of medicines in general. This additional TRIPS flexibility now formed an important part of the medicines procurement toolkit, but did not in itself remove any separately applicable procurement procedures or regulation for safety and efficacy, which may still apply to production and supply of medicines whether or not the System as such is used.
- A key element was notifying expected demand for medicines, and this could be done early in the procurement process, opening up a wider range of potential suppliers and potentially enabling the pooling of demand by different Members with similar needs. Notification under the System could be used at the stage of identifying all possible sources of supply, so as to ensure the most competitive and sustainable range of options for access to medicines.
- The need for economies of scale was foreseen in the System, and this would be a factor particularly when the needs of relatively small populations are concerned. Whatever the procurement pathway used, if the scale of demand is low, then low-cost production may be difficult (unless it is an already established product), in view of tooling up for production and meeting any regulatory requirements (including where regulations are applied by the country of export). The System makes clear that an export compulsory licence can serve the needs of multiple Members. Where countries share the same needs and the same constraints (e.g. in

the same region), they could pool demand. This would be particularly effective if their regulatory requirements were compatible (e.g. through use of the WHO Prequalification Programme). The System could also be used as part of efforts to build local production capacity where this production could be used to serve countries in the same region, enabling economies of scale and thus lower cost and more sustainable production of medicines.

- Discussions and analysis were continuing on how to make effective use of the System. Reference was also made to the UN High Level Panel Report on Access to Medicines that had reported on differing views on the System and called upon WTO Members to revise it. (The High Level Panel Report was also presented by a member of its Secretariat and discussed at a session on Human Rights Dimension and Access to Medicines).

As regards the operation of the System, **key issues and questions for further consideration** that were raised in subsequent discussions included:

- Awareness raising: it was noted that competent authorities in developing countries, in particular procurement agencies, would often not be sufficiently aware of the Paragraph 6 System. It could be expected to be used more extensively once it was routinely considered as part of procurement procedures and there was more information about the specific practical scope of its use.
 - What is needed to raise awareness about the System as a potential procurement tool in developing countries?
 - Specifically, what medicines, especially those on the WHO Essential Medicines List, are currently patented in all potential producing countries: which specific procurement needs correspond to the specific scenario that the System responds to?
- Context: it was recognized that the System could not work in isolation from procurement programmes and regulation of medicines.
 - How to ensure that the System functions effectively as an integral part of other relevant policies, both at domestic and regional level, including as regards needs identification, procurement and regulation of medicines?
- Implementation at domestic/regional level: it was noted that compulsory licences tailored for export were a novel component in TRIPS and generally required exporting countries, in particular, to amend their legislation. This was happening, increasingly, in many key pharmaceutical production countries, but it was necessary to draw information on these arrangements together so that procurement programmes and companies could make clear choices about production and export possibilities.
 - How to ensure that domestic implementing measures are designed in a manner that ensures that the Paragraph 6 System is easy to use, and did not impose unnecessary obstacles to its use, particularly from the export point of view, including to service multiple countries?
- Information resources: it was reported that potential importing countries often lacked knowledge about potential supply sources. It was also recognized that data-driven decisions were important to support access to affordable medicines through procurement systems at domestic and regional level. Further support may be needed to facilitate forecasting of expected need, so that these needs could be notified under the System.

Useful tools and information resources at the disposal of WTO Members that were mentioned during the Workshop include (i) WIPO Patent Landscape Reports, as they can help to establish the legal status of patents, as well as mapping innovation patterns and patenting trends in a specific technological field or geographical area; and (ii) WHO Databases which can provide strategic information, *inter alia*, on pricing, regulatory status, market forecast, local production and procurement supply management.

- How to make best use of existing information resources?
- What other information resources, if any, are required to support the use of the Paragraph 6 System?
- How to accurately forecast domestic/regional needs?

- How best to identify supply sources, including by making early notifications to the WTO as way to open up additional supply opportunities?
 - Economic viability: it was observed that the use of the System was the object of strict conditions, including as regards the products covered, the importing countries, the duration of the compulsory licence and the quantity that can be manufactured under such a licence. It was also acknowledged that similar constraints applied to standard compulsory licences.
 - How can the predictability of the System be ensured in order for the generic industry to make use of an exceptional tool like the Paragraph 6 System?
 - How to make sure that generic companies engaging in the production of export of medicines under the System can recover their manufacturing costs?
 - How best to pool demands, at regional level and otherwise, in order to boost economies of scale?
 - Exposure to pressure: reportedly, some potential importing countries may be hesitant to implement and use the System due to fear of political pressure by major trading partners, as well as retaliatory measures that might be taken by industry, including as regards investment in local production capacity. It was also noted that the implementation of the System in the laws of potential exporting countries illustrated their practical support for its use, and there had been widespread political support and encouragement for use of the System.
 - Is there a need to further clarify that the use of the System is supported in appropriate circumstances by all WTO Members and the R&D industry and, if so, how could this be achieved?
 - Clarification: a number of issues that would merit further clarification were referred to, including:
 - How to assess whether a country has insufficient or no manufacturing capacity in the pharmaceutical sector?
 - How to use the System in the context of regional settings, including RTAs that qualify for the specific waiver built into the Paragraph 6 System and pooled procurement mechanisms?
 - Whether the System could also apply to medical devices?
 - What kind of regulatory approval is needed (if any) for medicines to be exported under the System, as distinct from the regulation of medicines in the country of use (noting that this question would arise for any medicines produced for export)?
 - Case studies: among the issues that would merit further discussion, the following themes were mentioned:
 - Why has the System not been used more frequently? In this context it was noted that in the one case, the medicines sought proved to be available off-patent, initially at a considerably lower price, from other producers.
 - Can and should the System's success be measured against its impact as a negotiating tool to leverage lowest prices, by enabling greater competition among potential suppliers?
 - In the case of HIV/AIDS, what is the System's potential role to ensure access to second and third line treatment?
 - Whether and, if so, to what extent has the possibility of using the Paragraph 6 System been affected by negotiations of bilateral and regional trade agreements?
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