Annex III. Special Compulsory Licences for Export of Medicines

Contents

A. Operation of the System: context and scope

While Chapter IV, section C.3(a)(iii), outlines the policy context of the Special Compulsory Licensing System ("the System", sometimes also referred to as "the Paragraph 6 System") and why the System allows the grant of such licences for export of medicines in limited circumstances, this Annex provides supplementary information setting out its operation and use. The System is the only flexibility in the TRIPS Agreement that specifically entails action by (at least) two members (i.e. an importer and an exporter). It operates on the basis of notifications to the TRIPS Council by these members, which, in turn, result in the various actions described in this Annex.

1. What Is the System?

The 2001 Ministerial Doha Declaration on the TRIPS Agreement and Public Health (paragraph 6) recognized that WTO members with insufficient or no manufacturing capacity in their pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. To overcome those difficulties, WTO members adopted the System. It provides WTO members with an additional flexibility, which is a special type of compulsory licence permitting production of medicines exclusively for export. It waives, in particular, a condition that otherwise applies to compulsory licences under Article 31(f) of the TRIPS Agreement, restricting their use to predominantly for the supply of the domestic market. The System links demand in importing members with supply from exporting members. In addition, it waives the obligation on importing members to pay adequate remuneration to the right holder following the grant of a compulsory licence (Article 31(h) of the TRIPS Agreement), if such remuneration is provided for in the exporting member.

2. What products are covered by the System?

The System is available for any pharmaceutical products (including active ingredients and diagnostic kits) that are patented or manufactured under a patented process and are needed to address public health problems afflicting developing countries and least-developed countries (LDCs), especially those resulting from HIV/AIDS, tuberculosis (TB), malaria and other epidemics. This list of public health problems is based on paragraph 1 of the Doha Declaration and is now reflected in paragraph 1(a) of the Annex to the TRIPS Agreement; it is not intended to be exhaustive.

B. Legal basis

Since the entry into force of the Protocol Amending the TRIPS Agreement (the Protocol) on 23 January 2017, Article 31 *bis* of the amended TRIPS Agreement constitutes the legal basis for the vast majority of members that wish to use this additional flexibility to procure medicines. Members that are yet to adopt the Protocol, however, will continue to operate under the 2003 waiver Decision. Newly acceding members will be automatically bound by the amended TRIPS Agreement upon their accession.

C. Use of the System

This section describes which WTO members can use the System as importers and exporters, and the terms and conditions under which the System may be used.

1. Who can use the System as importers and exporters?

While all WTO members are eligible to use the System as importers, developed countries have elected not to use the System for their imports,[1] and some higher-income developing countries and territories have agreed that they would use the System as an importer only in situations of national emergency or other circumstances of extreme urgency.[2] Nevertheless, the System itself is not restricted to emergency situations for the other WTO members.

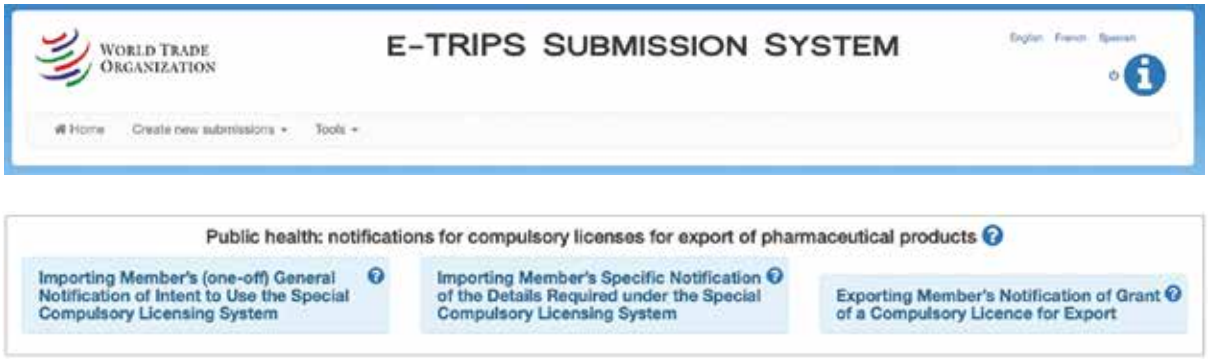
Any WTO member may participate in the System as an exporter but is under no obligation to do so. Many WTO members have implemented the System so as to enable exports to developing countries and LDCs that are not WTO members.[3]

2. How can the System be used by WTO members?

The essence of the System is the grant of a compulsory licence by the exporting member to meet the need(s) identified by the importing member. To do so, the following notifications are required.

1. An importing member's general notification of intent to use the System (not required for LDCs).
2. An importing member's specific notification of needed pharmaceutical product(s).
3. An exporting member's notification of a compulsory licence issued for exports to meet the needs of the importing member(s).

They are sent for information and transparency purposes to the WTO TRIPS Council. The notifications do not require approval by any WTO body.



WTO members are encouraged to use the e-TRIPS Submission System[4] to submit the above notifications to the WTO TRIPS Council. Traditional methods of notifying remain available.

The e-TRIPS Submission System provides guidance to both WTO members that have accepted the Protocol and who operate on the basis of the amended TRIPS Agreement and those that are yet to accept the Protocol and who continue to operate under the 2003 Decision. This guidance includes the information to submit for each notification type. In addition, a detailed explanation of the notifications, including a set of model notifications, is available at the WTO website.[5]

(a) How does an importing member use the System?

(i) Notifying general intention to use the System

The general notification comprises the simple statement by a WTO member that it intends to use the System. A members can submit its notification at any time prior to actual use, and it does not commit it to use the System. Rather, it simply reserves the right to do so in the event of potential future need. LDCs are not required to make this notification.

(ii) Notifying the need to import specific pharmaceutical products

When a member wishes to create the option of importing particular products under the System, it submits a specific notification of its import needs.

The specific notification includes:

- Names and expected quantities of the product(s) the member needs to import
- If a patent is in force in the member for any of the pharmaceutical products listed, an indication that a compulsory licence has been or will be granted. LDCs may simply indicate their intention to use the extended transition period under the TRIPS Agreement
- An indication that the member has established that it lacks the capacity to manufacture the product(s). LDCs are already deemed to have insufficient manufacturing capacity, and thus they are exempt from adhering to this requirement.

This notification can be submitted at an early stage of the procurement process, before any final decision about preferred sources of supply. It does not create any obligation to use the System should a better alternative emerge. A member is therefore free to notify expected medicine requirements as a routine step in the procurement planning process, thus facilitating assessment of the full range of access options, signalling demand for potential suppliers, and clearing the way for actual use of the System should it present the most commercially viable option.

Members pooling their procurement needs can make joint notifications. Given that the System recognizes the need for economies of scale in a regional context, joint notifications by members with similar needs open a pathway for the establishment of commercially viable levels of demand for production and shipment.

If a compulsory licence is needed on a patent in force in the importing member, that member must still respect general TRIPS Agreement requirements for compulsory licensing (see Chapter IV, section C.3(a)(ii)). The importer should thus make prior efforts to obtain authorization from the patent holder on reasonable commercial terms and conditions. This obligation does not apply, however, in cases of public non-commercial use, or if there is a national emergency or other circumstances of extreme urgency. The Doha Declaration clarifies that members have the right to determine when such situations exist. Furthermore, there is no obligation to seek a voluntary licence if the compulsory licence was issued to remedy an anti-competitive practice. To avoid double payment to the patent holder, the licensee in the importing member is exempted from the requirement under Article 31(h) of the TRIPS Agreement to pay remuneration for a compulsory licence to the patentee if payment has already been made in the exporting member.

(b) How does an exporting member use the System?

Any member can export under the System if its domestic law allows the grant of a compulsory licence to export. If there is no patent in force for the products in the exporting member, then there is no need to resort to the System. Equally, if the product is already being produced under a compulsory licence for the domestic market, the non-predominant portion of the production quantity can be exported without using the System.

Once a compulsory licence for export under the System has been issued, the exporting member submits a notification.

The exporting member's notification of the licence(s) for export contains the following details:

- name and address of the licensee(s)
- product(s) for which the licence(s) has/have been granted
- quantity(ies) for which the licence(s) has/have been granted
- country(ies) to which the product(s) is/are to be supplied
- duration of the licence(s)
- optionally, any other licence conditions and other information, such as the patent number(s)
- address of a website providing information on quantities shipped and distinguishing features of the product(s).

When granting the special licence for export, the exporting member needs to apply the standard requirements under the TRIPS Agreement for compulsory licences as implemented into domestic law, except that:

- the quantity that can be exported under compulsory licence is no longer limited to the non-predominant part of the production; rather, it requires the entire production quantity to be exported to the beneficiary countries
- the requirement for adequate remuneration in the exporting member is calculated on a different basis, namely, the economic value of the authorization in the importing member.

3. Do regulatory authorities have to approve products manufactured under a special compulsory licence?

The System is part of the IP regime and does not deal with marketing authorization for pharmaceutical products. It remains a separate responsibility of health authorities to determine whether products are of appropriate quality, safety and efficacy, and it is up to the exporting and importing members to decide whether their respective pharmaceutical regulatory authorities will review the products manufactured under the System or whether they will rely on regulatory reviews carried out by counterpart authorities, either in the members using the System or even in another jurisdiction.

4. Which safeguards against diversion need to be put in place?

In order to ensure that products exported under the System are used to address the public health problems afflicting the importing member(s), specific safeguards against diversion apply:

- Production carried out in the exporting WTO member as a result of a special compulsory licence is limited to the quantity necessary to meet the needs of the importing WTO member(s), and the entire quantity produced must be exported to the importing WTO member(s).
- The products must have specific labelling or marks. They should have distinctive packaging and/or be specially coloured or shaped – as long as these latter requirements are feasible and do not have a significant impact on price. Before shipment, the manufacturer must post on a website details of the quantity of products it has manufactured under the compulsory licence, as well as details of the way in which it has specially labelled or packaged them. The WTO website is available for the manufacturer to publish this information, but such use is not mandatory.
- Importing WTO members must take reasonable measures within their means to prevent re-exportation. Such measures should be proportionate to these members' administrative capacity and the risk of trade diversion. Importing WTO members are entitled to receive technical and financial assistance from developed-country WTO members so as to meet this obligation.
- Other WTO members need to have in place effective legal procedures and remedies in order to prevent importation into their markets of diverted pharmaceutical products produced under special compulsory licences for export, using the means that are already to be made available under the TRIPS Agreement.

5. How can the System be used at the regional level?

Under a regional mechanism established by the System, the condition that the products produced under the compulsory licence must be used predominantly to supply

the domestic market is also waived. The purpose is to allow WTO members that are party to a regional trade agreement (RTA) to better harness economies of scale in their regional economic community and also enhance their purchasing power by combining demand to facilitate bulk imports or local production of pharmaceutical products for distribution within the relevant region. The regional mechanism enables the exporting and re-exporting of products that have been manufactured locally or elsewhere under a compulsory licence to take place more easily among WTO members that are party to an RTA, provided that:

- the RTA complies with the General Agreement on Tariffs and Trade (GATT) and the so-called Enabling Clause (the name given to a 1979 GATT Decision permitting preferential arrangements among developing countries and LDCs in goods trade)
- at least half the WTO members that are party to the RTA are LDCs
- they share the public health problem(s) in question.

The WTO does not determine which RTAs satisfy these requirements, and thus no list of RTAs qualifying for this regional mechanism is available.

The regional mechanism can thus cover pharmaceutical products manufactured within the regional trade area under compulsory licence. It can cover products manufactured elsewhere under compulsory licence and imported by one RTA party under the System. Either way, the products can be traded among the parties to the RTA without any further notification or adherence to any additional requirements other than those that apply at the time of the production in an RTA member or importation into the regional trade area under the System.

The regional mechanism does not override patents or national marketing approval requirements. Where a patent is in force for any country in the region, either a voluntary or compulsory licence would be required in the country that is seeking to use the mechanism to import medicines from another RTA member. Equally, the product should still be approved for distribution in each of the countries concerned, although this is not a TRIPS Agreement requirement.

6. What does the WTO General Council Chairman's statement add?

The General Council decisions to establish the System (2003 waiver Decision and 2005 Protocol Amending the TRIPS Agreement) were both adopted in light of statements by the General Council Chairman that reflected several key shared understandings of WTO members,[6] notably:

- The System should be used in good faith to protect public health and should not be used to pursue industrial or commercial policy objectives;
- The requirements on product differentiation apply to active ingredients produced and supplied under the System. They also apply to finished products containing such ingredients. In general, special packaging and/or special colouring or shaping should not have a significant impact on the price of pharmaceuticals;
- In relation to the prevention of diversion of products, members and producers are encouraged to draw from and use best practices guidelines and to share information on their experiences and practices in preventing diversion;
- Importing members should include information in their notification to the TRIPS Council on how they established that they have insufficient or no manufacturing capacities in their local pharmaceutical sector.

The Chairman also noted that developed countries had agreed to opt out of the System as importers (also reflected in footnote 3 of the Annex to the amended TRIPS Agreement/2003 waiver Decision)[7] and that 11 higher-income developing countries and territories had agreed to restrict the use of the System as importers to situations of national emergency or other circumstances of extreme urgency.

D. Domestic implementation

Members can implement the System as importers, exporters, or both.[8] There is no obligation on WTO members to use the System in either capacity, and it remains one option among many that can be used to enable access to medicines.

1. Importing members

Importing WTO members will generally need to make legislative changes in order to exercise the option of dispensing with remuneration on imports under a compulsory licence, where remuneration has already been paid in the exporting member. While the required notification to the WTO TRIPS Council does not necessitate special legislation, such notification requirement and how to process it domestically may be usefully addressed in laws or implementing regulations. Importing WTO members are obliged to take reasonable measures to prevent the re-export of imported products but do not need to adopt special legislation. In the Philippines, the law simply

requires that the compulsory licence "shall also contain a provision directing the grantee of the license to exercise reasonable measures to prevent the re-exportation of the products imported under this provision".[9]

2. Exporting members

Exporting WTO members typically need to make limited legislative changes in order to use the System, unless Article 31*bis* of the TRIPS Agreement is directly applicable under national law. Members that have already incorporated the TRIPS Agreement standards into their law have conditions in place that apply to compulsory licences, namely, that products manufactured under compulsory licence must be predominantly for supply of the domestic market. Therefore, at a minimum, this limitation will need to be amended so as to allow for the export of the entire quantity produced under a compulsory licence issued under the System. At the same time, the implementing legislation needs to limit the grant of the compulsory license to the quantity which is necessary to meet the needs of the eligible importing member (as referred to in the importing member's notification(s) to the TRIPS Council) and needs to require that the compulsory licence obliges the licensee to export the full quantity of that production and to specially mark or label the products.

Exporting members implementing the System may adopt specific provisions governing the calculation of, and procedures for, the payment of adequate remuneration to the right holder (e.g. a fixed maximum royalty or prescribed calculation taking into account the economic value of the authorization in the importing member or any other reference). These provisions may specify that the licensee is obliged to pay the remuneration or that it shall be proportionally shared among all right holders in the case of multiple patents. They often also specify the competent authority, if any, to determine the level of adequate remuneration (Kampf, 2015).

3. Regional mechanism

Implementation of the regional mechanism would entail ensuring that the relevant legislation in exporting members in the region does not require that the production of the products under compulsory licence must predominantly supply the domestic market, as would be the case for standard compulsory licences under the TRIPS Agreement. For members that intend only to import, changes may be required in their domestic law so that the licensee can be exempted from paying remuneration to the right holder in a situation where a compulsory licence to import has been granted and where remuneration has already been paid in the exporting member.

Endnotes

1 See footnote 3 to the Annex to the amended TRIPS Agreement/the 2003 Decision (WTO document WT/L/540).

2 See the list contained in the Chairman's Statement, WTO documents WT/GC/M/82, para. 29 and WT/GC/M/100, para. 29.

3 See Kampf (2015).

4 The e-TRIPS Submission System is an optional online tool for WTO members to submit TRIPS-related notifications, and review materials and reports, available at: https://nss.wto.org/tripsmembers. WTO members must have log-in credentials provided by the WTO in order to use the e-TRIPS Submission System. To receive log-in credentials and for any other enquiries regarding notifications under the System, the WTO Secretariat may be contacted at e-TRIPS@wto.org.

5 See Guide to Notifications, available at: www.wto.org/english/tratop_e/trips_e/par6_modelnotifs_e.htm.

6 WTO documents WT/GC/M/82, para. 29 and WT/GC/M/100, paras. 28–29.

7 WTO document WT/L/540.

8 A collection of laws implementing the System is available at: www.wto.org/english/tratop_e/trips_e/par6laws_e.htm.

9 Rule 13 of the Implementing Rules and Regulations of Republic Act 9502 otherwise known as the "Universally Accessible Cheaper and Quality Medicines Act of 2008", notified in WTO document IP/N/1/PHL/I/10.