EXTRACT FROM THE WHO-WIPO-WTO TRILATERAL STUDY

THE PARAGRAPH 6 SYSTEM: SPECIAL EXPORT LICENCES FOR MEDICINES

This extract is taken from Chapter IV ('Medical Technologies: The Access Dimension'), under Section C ('IP-related determinants of access'), and from Annex II of the study. The full text of the publication is available at www.wto.org/trilateralstudy

Key points

- In 2003, WTO members agreed to introduce a new flexibility into the TRIPS Agreement. The flexibility, known as the Paragraph 6 System, is designed to enhance access to medicines by removing a potential barrier for countries that need to import medicines.

- While the reasons for the limited use of the Paragraph 6 System are still under consideration, it could be more widely used in the future, for example, following the introduction of the product patent regime in key potential exporting countries, or in the case of a pandemic or some other health security event where effective treatments may be patented in all major supplier countries.

The Paragraph 6 System: an additional flexibility aimed at enhancing access to medicines

A new pathway for access to medicines …

Paragraph 6 of the Doha Declaration mandated the TRIPS Council to find a solution to the difficulties faced by countries with insufficient or no manufacturing capacities in the pharmaceutical sector in making effective use of compulsory licensing. This resulted in the 2003 WTO General Council decision to establish the framework for special compulsory licences, which is an additional flexibility aimed at enabling exports of medicines to these countries. The System – informally dubbed the "Paragraph 6 System" – initially took the form of a waiver of certain conditions regarding compulsory licences. In 2005 WTO members adopted it by consensus as the Protocol Amending the TRIPS Agreement. This outcome, providing an additional legal pathway for access to medicines, has special significance as the sole amendment proposed to any of the WTO

multilateral trade agreements since their adoption in 1994. The System has already been available for use since the 2003 waiver decision and will become a permanent feature of the TRIPS Agreement once two thirds of WTO members formally notify their acceptance. A wide cross-section of the WTO membership has already taken this step, with many notices of acceptance received from developing countries, including several LDCs, and virtually all developed countries.[1] Accepting the Protocol is distinct from incorporating the System into national law or choosing to make use of the System. It expresses legal consent that all WTO members should be permitted to use this additional flexibility if they so choose.

Intended by WTO members to contribute to global efforts to strengthen the legal framework for access to medicines, the new System has been endorsed in a number of multilateral forums:

- The 2008 WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI) identified the use of the System as a specific action.

- The Ministerial Declaration – 2009 High-Level Segment of the Economic and Social Council of the United Nations reaffirmed the right to use the Paragraph 6 System, encouraging the provision of assistance to developing countries in this regard. It expressly called for a broad and timely acceptance of the TRIPS amendment.

- Similarly, the 2011 UN Political Declaration on HIV/ AIDS: Intensifying our Efforts to Eliminate HIV/AIDS called for early acceptance of the TRIPS amendment.

- The 2012 Declaration "The future we want", an outcome document from the United Nations Conference on Sustainable Development ("Rio+20"), reaffirmed the right to use the System along with other TRIPS provisions.

… that addresses a particular procurement scenario.

The System applies in a particular access scenario where an importing country needs medicines to deal with a public health problem, but a potential exporting country faces a legal impediment because Article 31(f) of the TRIPS Agreement limits supply under a compulsory licence predominantly to the domestic market. The special export licence under the System is free of this constraint, enabling and indeed requiring the full production under a compulsory licence to be exported. Accordingly, the situation addressed by the System would arise only when a country wishes to obtain a particular pharmaceutical product, and:

- The product cannot be produced domestically at all, or in sufficient quantities, due to lack of capacity.

- The preferred producer of the particular product (normally, the cheapest supply that best meets regulatory and quality requirements) is located in a country where a patent is in force on that product and needs a compulsory licence in that country to produce for export.

The System does not apply to most procurement scenarios: for example, when affordable supplies are already available from countries where no patent is in force (this has been the experience with older ARV treatments for HIV/AIDS, the bulk of which have been imported at highly competitive prices by countries from generic producers in India (see Chapter IV, Section A.2(a), on HIV/AIDS); and when prices for the originator product can be reduced through negotiation to an affordable level without recourse to a compulsory licence, or when the originator company agrees to grant a voluntary licence to a generic producer.

How has it been used in practice …

By 2012, one special export licence under the System has been exercised. In that instance, the licence was used by a Canadian company to ship medicines to Rwanda (see Box 4.15). Ghana reportedly considered using the System in 2005 when it declared an emergency situation with regard to HIV/AIDS and granted a government use authorization order to import generic HIV/AIDS medicines (although a declaration of emergency is not a requirement for using the System).[2] Imports were initially intended to be sourced from Canada, where the products were patented, but Ghana later chose to import the products from generic manufacturers in India, where no patent

applied. Another potential use[3] concerned an Indian company's applications, filed in September 2007 with the Indian patent office, to manufacture and export to Nepal several anti-cancer pharmaceuticals patented in India, including erlotinib. Reportedly, the applicant later withdrew the applications. As an LDC, Nepal was automatically entitled to use the System, but it had not notified the WTO that it wished to import these medicines which is a prerequisite for the use of the System.

Box 4.15. case study on supply of ARVs to Rwanda

In 2004, Médecins Sans Frontières (MSF) approached a Canadian company to produce a triple-combination ARV (zidovudine, lamivudine and nevirapine). MSF initiated this move in the absence of any specific request from an importing country. The company obtained marketing approval in Canada in 2006, less than six months after the date of its application. Canada's Access to Medicines Regime (CAMR), which implements the Paragraph 6 System, had to be amended to cover the product because Canada limits the scope of its law to a specified list of products. The three medicines combined in the product were each covered by a separate patent owned by a separate company. In July 2007, the company sought, without success, voluntary licences from the three patent holders.

In July 2007, Rwanda sent the WTO a brief notification of its intention to import 260,000 packs of the triple-combination ARV, reserving the right to modify the estimated quantity. It said it would not allow patent holders to enforce any patents on the product that may have been granted in its territory. As an LDC, Rwanda was not obliged to state anything else, nor did it need to notify its intention to use the System.[4] In September 2007, the company applied for a compulsory licence in Canada which, under the System, would allow it to export 15,600,000 tablets (the equivalent of 260,000 packs) over a two-year period. The compulsory licence was granted two weeks later. The Canadian government notified the WTO in October that it was using the System as an exporting country.[5]

Canada reported that in October 2007 the Rwandan government issued a public tender for this triple-combination ARV.[6] The Canadian company had originally offered its ARV at the no-profit price of US$ 0.39 per tablet. There were indications that at least four Indian generic manufacturers could supply the product at a lower price. Canada reported that if Rwanda had procured the ARVs from these manufacturers, it would not have needed to use the System at all, since the products were not patented in India. However, during the tender process, the Canadian company halved its price to US$ 0.195 per tablet. In May 2008, the company announced that it had won the tender.

In line with the terms of the CAMR and the System itself, the tablets shipped to Rwanda were distinguished from the version manufactured for the domestic market by the mark "XCL" and white colouring, instead of the standard blue. The packaging bore an export tracking number issued by the Canadian government. Details of the product and its distinguishing characteristics, as well as details of the shipment, were posted on the web.[7] A royalty was payable by the Canadian company for the right to use the patent, but the patent holders waived payment. A total of 6,785,000 tablets were shipped to Rwanda in September 2008, and an additional 7,628,000 tablets were shipped in September 2009, i.e. within the two-year validity period of the compulsory licence.[8]

… and is it really working as expected?

The TRIPS Council reviews the System each year and reports to the WTO General Council on how the System has been implemented and used, its operational context, and the status of the TRIPS amendment. The discussions have become more detailed since 2010, after Canada and Rwanda used the System, and they now also cover a wider range of issues such as the operational requirements of the System and alternatives to ensure access to medicines. While no firm conclusions have been reached as a result of these discussions, various WTO members have voiced a range of views (WTO, 2010; WTO, 2011), including the following diverse observations on whether the System is fulfilling its intended function:

- By 2012, the System was only used once, and it took three years before the shipments in question proceeded. The System is too complex and administratively unwieldy for

further use, and a multi-stakeholder workshop is needed in order to discuss the operation of the System. It is essential to clarify whether constraints on its use were built into the System, thus necessitating its reform, or whether such constraints were a consequence of how individual countries chose to implement it.

- Potential users of the System may be deterred by concerns about political or trade ramifications associated with the use of compulsory licensing.

- The CAMR was successfully utilized, and only a very small portion of the three-year time period was taken up with procedures associated with the System. Much of the time that elapsed between the regulatory review of the medicine in question and the actual shipments was attributable to other factors.

- The limited use of the System is not an appropriate measure of its success, as no delegation demonstrated evidence of obstacles to its use when such use was required. A single case demonstrated that the System could work when necessary, and that it could play a supportive role in the wider effort to improve access to essential medicines, given that alternative ways of procuring the needed medicines are often available.

- The System is not a panacea to solve all public health-related problems. Rather, it is part of a broader picture which includes other important aspects that have an impact on innovation and access, such as infrastructure, tariffs, innovative financing mechanisms, partnerships and cooperation (including at the regional level), and regulatory frameworks.

- Implementation of full patent protection for pharmaceutical products in India, coupled with the approaching expiry of transition periods in LDCs, could make it more difficult in the future to procure generic versions of new medicines. Under such circumstances, the Paragraph 6 System might assume a greater significance.

… while its full operational context is still being mapped …

While the System provides an avenue to respond to demand for medicines in a specific procurement scenario, there has been negligible notification of demand from potential beneficiaries who are faced with this particular scenario. This is against a backdrop of widespread expressions of concern about affordable access to medicines. No developing country has notified the WTO that it has a general intention to use the System, although LDCs need not take this step and other countries could also do so at the same time they notify details of the needed product. Countries are entitled to notify their expected needs for medicines at an early stage in the procurement planning process, without having to give a commitment to adhere to the quantities notified or commit to proceed with imports under the System should preferable alternatives arise even at a late stage in the procurement process. In cases where the product needed is patented in the preferred supplying country(ies) – for example, where generic companies have the ability to copy the product, and where importing countries' combined effective demand is sufficient – such early notification may increase the practical likelihood of potential exporters responding to the opportunity to use the System.

One key question is whether, and, if so, in what circumstances, the particular "Paragraph 6" scenario has so far arisen in practice. A further question concerns the extent to which affordable medicines are already available without the need for compulsory licences for export. Reported procurement experiences suggest that many medicines were already available as generic exports from countries where no patent was in force. For example, Brazil, Ecuador and Thailand reportedly issued compulsory licences for the importation of products outside the System from countries where the products were not patented and were already in production as generics. Rwanda's use of the System also took place against a background of lower generic prices being available from other sources. Where generic medicines are available from non-patented sources, the System does not need to be used. This situation may change in future as the progressive impact of changes to pharmaceutical patentability in key export countries such as India makes it less likely that newer generations of medicines will be so readily available in generic versions for export (see Chapter IV, Section A.2(a)).

In the future – for example, in response to a pandemic or some other health security event – effective treatments are more likely to be patented in established major supplier countries. In such a scenario, the System could well assume greater importance and be used more extensively. The availability of the System provides a more credible basis for effective use of compulsory licensing for countries with either no production capacity or limited capacity, thus strengthening their hand in negotiations on price. Past experience with procurement processes (such as Brazil's threat to use compulsory licensing for the ARV drug nelfinavir in 2001) shows how effective use of compulsory licensing can succeed in inducing lower prices without the actual final grant of a licence. The limited role of the System thus far may also partly be due to the fact that many countries procure needed medicines through international procurement programmes which may have other means of leveraging lower prices. Examples of such programmes include those run by PEPFAR, the CHAI, the Global Fund, UNICEF and UNITAID.

One area of current debate centres on the necessity to establish an adequate commercial basis for potential suppliers under the System, in order to respond to needs that have been signalled in notifications to the WTO. The System expressly recognizes the need for economies of scale in the context of its provisions on regional trade agreements, also referring to the possibility for parties to such agreements to make joint notifications.

The special export licence is one legal pathway that can be followed when it represents the optimal route to effective procurement, but, as for any compulsory licence, it does not in itself make the production of a medicine economically viable. Sufficient scale and predictability of demand are prerequisites for making it practically and commercially viable for companies to undertake the regulatory, industrial and commercial steps required to produce and export a medicine under such a licence. Regional approaches to procurement and joint notifications by countries with similar needs for accessible medicines may offer pathways to aggregating demand under the System, thus enabling an effective response to the needs identified.

The System includes measures to ensure that products reach their intended beneficiaries and are not diverted elsewhere. Such measures may include specific labelling or marking, special packaging and/or special colouring/ shaping of the products, but these ways of distinguishing products should be feasible and should not have a significant impact on price. Recent industry experience with other forms of labelling and packaging for specific markets, for example in cases of tiered pricing, donation and philanthropic procurement schemes,[9] may provide practical examples for how to distinguish products without incurring significant costs. Annex II provides more detailed information on the operation and use of the System.

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[1] See www.wto.org/english/tratop_e/trips_e/amendment_e.htm.
[2] See www.cptech.org/blogs/drugdevelopment/2006/11/ noah-novogrodsky-on-compulsory.html.
[3] WTO document IP/C/64, para. 104.
[4] WTO document IP/N/9/RWA/1.
[5] WTO document IP/N/10/CAN/1.
[6] WTO document IP/C/M/64, para. 116.
[7] See www.apotex.com/apotriavir/default.asp.
[8] Source: WTO document IP/C/M/64.
[9] See Annex to the Chairman Statement in WTO document WT/GC/M/82.

ANNEX II.

SPECIAL COMPULSORY LICENCES FOR EXPORT OF MEDICINES

A. Operation of the System: context and scope

While Chapter IV, Section C.3(a)(iii), outlines the policy context of the Paragraph 6 System and why it allows special compulsory 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 countries (i.e. an importer and an exporter). It operates on the basis of notifications to the TRIPS Council by these countries, which, in turn, result in the various actions described in this annex.

1. What is the Paragraph 6 System?

As outlined in Chapter IV, Section C.3(a)(iii), the 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, as the agreement then stood. To overcome those difficulties, WTO members adopted the Paragraph 6 System. It addresses a particular scenario for access to medicines:

- A country needs to import a medicine from a foreign supplier because it lacks sufficient manufacturing capacity in its pharmaceutical sector.
- The medicine can be produced under a compulsory licence in another country.
- Export of the non-predominant part of the production in that country does not satisfy the needs of the importing country.
- Therefore, the importing country has to use the Paragraph 6 System in order to import medicines produced under a compulsory licence from another country.

The System provides WTO members with an additional flexibility, which is a special type of compulsory licence permitting production of medicines exclusively for export. The System links demand in importing countries with supply from exporting countries. In addition, it waives the obligation on importing countries 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 country.

2. What products are covered by the System?

The System is available for any pharmaceutical sector 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 not intended to be exhaustive.

B. 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. Which countries 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. Most WTO members have not indicated that they would limit its use to such situations. Some WTO members have implemented the System so as to enable exports to developing countries and LDCs that are not WTO members. While any WTO member may participate in the System as an exporter, they are not under any obligation to do so.

2. How is the System used?

The essence of the System is the grant of a compulsory licence by the exporting country to meet the need(s) identified by the importing country. The entitlement to do so is triggered by notifications sent for information to the WTO TRIPS Council, including:

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

Notifications need only be very brief, and may be in the form of a letter sent by fax or email, and signed by any authorized government official. Such notifications are required for transparency purposes. It is expressly provided that they are not subject to approval by any WTO body. No standard form is established. The WTO Secretariat provides model notifications on its website (see Figure A.1).[3] Further guidance is also provided by the World Bank (Abbott and Van Puymbroeck, 2005) and the WHO (Correa, 2004).

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

(i) Notifying general intention to use the System

Countries other than LDCs need to submit a general notification of intent to use the System. This can be done at any time prior to actual use, and it does not commit these countries to use the System. Rather, they simply reserve the right to do so in the event of potential future need. The general notification comprises the simple statement by a WTO member that it intends to use the System.

(ii) Notifying the need to import specific pharmaceutical products

When a country 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:

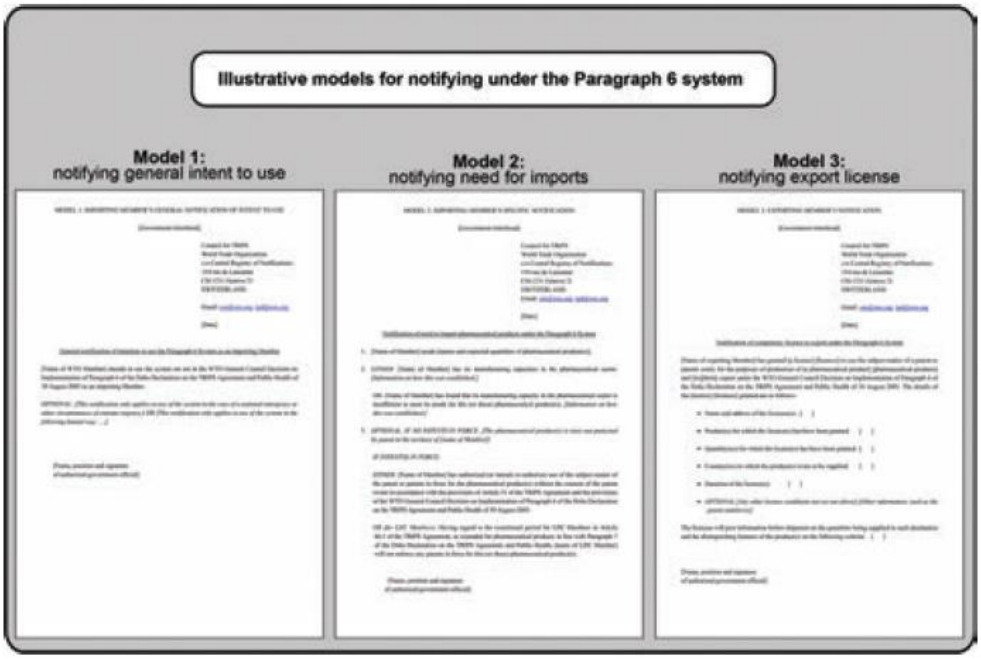
- Names and expected quantities of the products the country needs to import.
- If a patent is in force in the country for any of the pharmaceutical products listed, an indication that a compulsory licence has been or will be granted. LDCs may simply indicate an intent to use the extended transition period under the TRIPS Agreement.
- An indication that the country has established that it lacks the capacity to manufacture the product. 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 country 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.

Countries 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 countries with similar needs may provide a pathway for the establishment of commercially viable level(s) of demand for production and shipment.

Figure A.1. **Screenshot from WTO web site providing practical guidance on the system**



Source: www.wto.org/medicinesnotifications.

If a compulsory licence is needed on a patent in force in the importing country, that country must still respect general TRIPS Agreement requirements for compulsory licensing. There is no obligation to seek a voluntary licence from the patent holder 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 countries 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. However, in all other cases, the importer should make prior efforts to obtain authorization from the patent holder on reasonable commercial terms and conditions. To avoid double payment to the patent holder, the licensee in the importing country is exempted from the requirement to pay remuneration under a compulsory licence if payment has already been made in the exporting country.

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

Any country can export under the System if it has a pharmaceutical industry with the capacity to manufacture the needed product – and 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 country, then there is no need to resort to the Paragraph 6 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 country submits a notification.

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

- name 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 website providing information on quantities shipped and distinguishing features of the product(s).

When granting the special licence for export, the exporting country needs to apply the standard TRIPS Agreement requirements for compulsory licences, except that:

- the limit is removed on the quantity that can be exported under compulsory licence, and the entire production quantity is exported to the beneficiary countries
- the requirement for adequate remuneration is calculated on a different basis, namely the economic value of the authorization in the importing country.

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

While the System does not deal with marketing authorization for pharmaceutical products, use of the System may entail facilitating regulatory clearances. It remains a separate responsibility of health authorities to determine whether products are safe and effective, and it is up to the exporting and importing countries 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 countries 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 country or countries, specific safeguards against diversion apply:

- Production carried out in the exporting WTO member as a result of a 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 utilize for the purpose of publishing 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 available to them under the TRIPS Agreement.

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

Under a regional mechanism established by the System, the condition otherwise applicable to compulsory licences (i.e. that they be used to predominantly supply the domestic market), is also waived. The purpose is to allow WTO members who 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 under a compulsory licence to take place more easily among WTO members who 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 who are party to the RTA are LDCs

- these WTO member share the public health problem(s) in question.

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

The regional mechanism can cover pharmaceutical products manufactured within the regional trade area under compulsory licence. It can also cover products manufactured elsewhere under compulsory licence and imported by one RTA party under the Paragraph 6 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 importation into the regional trade area under the Paragraph 6 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 seeking to use this mechanism, either a voluntary or compulsory licence would be required in the country that is seeking to use the mechanism. Equally, the product should still be approved for distribution in each of the countries concerned.

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

The General Council decisions to establish the System were both adopted in light of a statement by the General Council Chairman which reflected several key shared understandings of WTO members,[4] 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 countries should include information on how they established that they had 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 2003 Decision/ Protocol Amending the TRIPS Agreement)[5] 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.

C. Domestic implementation

Countries can implement the Paragraph 6 System as importing countries, exporting countries, or as both.[6] 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 country. While the required submission of a notification to the WTO does not necessitate special legislation, such notification requirement may be addressed in laws or implementing regulations. Importing WTO members are obliged to take reasonable measures to prevent the re-export of imported products but, again, this is possible without the need to use special legislation. For example, 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".[7]

2. Exporting members

Exporting WTO members typically need to make limited legislative changes in order to use the Paragraph 6 System, except where it is directly applicable under national law (this is reportedly the case in Japan, for example). Countries that have already incorporated the 1994 TRIPS Agreement standards into law will have restricted compulsory licences (i.e. predominantly to supply 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. Implementation of compulsory licences for export under the System would also need to take account of the need to limit the volume of production to that referred to in the importing country(ies) notification(s), the obligation to export the full quantity of production, and special marking or labelling of the products.

3. Regional mechanism

Implementation of the regional mechanism would entail ensuring that the relevant legislation in exporting countries in the region does not limit the proportion of exports under a compulsory licence, as would be the case under the limitation predominantly to supply the domestic market, which applies to standard compulsory licences under the TRIPS Agreement. For countries 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 country.

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[1] See footnote 3 to the 2003 Decision/Protocol Amending the TRIPS Agreement, WTO documents WT/L/540 and WT/L/641.

[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 www.wto.org/medicinesnotifications

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

[5] WTO documents WT/L/540 and WT/L/641.

[6] A collection of laws implementing the Paragraph 6 System is available at www.wto.org/english/tratop_e/trips_e/par6laws_e. htm.

[7] 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.