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SPECIAL COMPULSORY LICENCES FOR EXPORT OF MEDICINES: KEY FEATURES OF WTO MEMBERS' IMPLEMENTING LEGISLATION

Roger Kampf
WTO

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Roger Kampf[1]

Abstract

In 2003, the WTO General Council decided to provide an additional legal pathway for WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector to access medicines. Two years later, in 2005, WTO Members unanimously agreed to give this mechanism, often referred to as the "Paragraph 6 System", a permanent legal status when they adopted the Protocol Amending the TRIPS Agreement.

The implementation and use of the additional pro-public health flexibilities provided by the System is optional, not mandatory. To take advantage of them, as of July 2015, 51 WTO Members have adopted specific implementing measures with a variable degree of detail and complexity which incorporate the Paragraph 6 System in their respective legal frameworks and provide the basis for them to act either as exporter or as importers, or as both. This represents almost a third of the WTO Membership, and the predominant bulk of existing pharmaceutical exporters.

Given that, unlike other flexibilities in the TRIPS Agreement, the Paragraph 6 System was devised as a new mechanism without previous domestic experience to draw upon, there seems to be an exceptional need for an in-depth discussion of how it has been implemented at country level to which this paper attempts to respond. There is, indeed, often limited knowledge in the policy and procurement communities about the wide range of specific measures that have been introduced in many major exporters of medicines and the importance of this information both from a practical point of view, to facilitate exports of needed medicines, and from a policy point of view, to understand the implementation of this novel tool for access to medicines.

To contribute to a better understanding of how the System has been implemented in practice, this paper surveys domestic measures that WTO Members have put in place. By doing so, it can inform the broader dialogue about access to medicines and provide practical information for procurement programmes. It can also put a valuable source of information and inspiration at the disposal of those Members who are yet in the process of considering whether and how best to implement the Paragraph 6 System in their domestic legal framework.

While the survey illustrates that a robust framework supportive of the export of generic medicines to meet public health needs has been put in place by a significant number of WTO Members, there is an obvious need to move a step forward and engage in a substantive review of the System, including if and how better, more frequent use could be made of it. To conclude, the paper therefore offers some elements for reflection regarding the way forward in order to support the functioning of the Paragraph 6 System.

Keywords: TRIPS, Paragraph 6 System, special compulsory licences, export of medicines, implementing legislation

***JEL* classification**:

[1] The author is Counsellor in the Intellectual Property Division at the World Trade Organization. He can be reached at Roger.Kampf@wto.org. The author thanks Mr Antony Taubman, Director of the Intellectual Property Division at the WTO, for his valuable comments and drafting suggestions that helped to significantly improve the paper.

Special Compulsory Licences for Export of Medicines:

Key Features of WTO Members' Implementing Measures

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Introduction

When Ministers adopted the Doha Declaration on the TRIPS Agreement and Public Health at the WTO Ministerial Conference in 2001[2], they recognized the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector may face in making effective use of compulsory licensing under the TRIPS Agreement. In order to deal with these difficulties, the WTO General Council decided in 2003 to provide an additional legal pathway for WTO Members to access medicines.[3] In 2005, WTO Members unanimously agreed that this mechanism, initially in the form of temporary waivers, should have a permanent legal status when they adopted the Protocol Amending the TRIPS Agreement.[4]

This mechanism, often referred to as the "Paragraph 6 System", entitles WTO Members to grant a special type of compulsory licence permitting the production of medicines exclusively for export to meet the needs of other WTO Members.[5] Compulsory licenses under the patent system have in the past been focused on servicing domestic needs: with this innovative mechanism, WTO Members created a new form of 'trade-related' compulsory license which is expressly issued for the export of medicines. As set out by the WHO-WIPO-WTO Study on "Promoting Access to Medical Technologies and Innovation" launched in 2013[6], it was intended by WTO Members to contribute to global efforts to strengthen the legal framework for access to medicines and has been endorsed in a number of multilateral fora since its adoption. To do so, certain conditions otherwise applying to standard compulsory licences have been relaxed: in particular, the requirements regarding the use of compulsory licences "predominantly for the supply of the domestic market of the Member authorizing such use" (Article 31(f) TRIPS) and the payment of adequate remuneration to the right holder (Article 31(h) TRIPS).[7]

The implementation and use of these additional flexibilities is optional, not mandatory. To take advantage of them, a number of WTO Members have specifically adopted implementing measures which incorporate the Paragraph 6 System in their respective legal frameworks and provide the basis for them to act either as exporter or as importers, or as both (see **Annex I** for a world map of WTO Members with specific implementing legislation). The adoption of such legislation follows the normal domestic legislative and regulatory processes.

This said, there is often limited knowledge in the policy and procurement communities about the wide range of specific measures that have been introduced in many major exporters of medicines and the importance of this information both from a practical point of view, to facilitate exports of needed medicines, and from a policy point of view, to understand the implementation of this novel tool for access to medicines.

Since the System essentially concerns a distinct new form of compulsory licence expressly for *export*, it should also be noted that countries intending to use it to import medicines are less likely to implement specific legislation. Given the tendency to take out patents only in major producing countries, in many instances of potential use of the System, there may not even be a patent in force in the importing country so that the adoption of implementing measures becomes irrelevant. Similarly, even where a patent has been granted in the importing country, it could use a standard compulsory licence for import purposes that would not require any change to domestic legislation, except if the country wanted to make use of the possibility to waive the otherwise applicable requirement under Article 31(h) TRIPS to compensate the right holder. Moreover, LDCs are

[2] WTO Document WT/MIN(01)/DEC/2.
[3] WTO General Council Decision of 30 August 2003 regarding the "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health", WTO Documents WT/L/540 and Corr.1.
[4] WTO General Council Decision of 6 December 2005 regarding the "Amendment of the TRIPS Agreement", WTO Document WT/L/641.
[5] See *Aide-mémoire* on "Expected Benefits of the Paragraph 6 System of Special Licences for Export of Medicines, prepared by the WTO Secretariat on its own responsibility, circulated as a formal General Council document in WTO Document WT/GC/W/696 of 20 February 2015.
[6] WHO-WIPO-WTO Study on "Promoting Access to Medical Technologies and Innovation – Intersections Between Public Health, Intellectual Property and Trade", Geneva 2013, p.177, available at: http://www.wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf.
[7] For a detailed description of the Paragraph 6 System, in particular its policy context, operation and use, see the WHO-WIPO-WTO Study (see fn.6 above) pp.177-181 and Annex II, available at: http://www.wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf.

currently exempted from implementing the TRIPS Agreement in general and would therefore not require any specific implementing legislation to import under the System. As the example of Rwanda has shown when the System was used to import generic medicines from Canada, a simple notification to the TRIPS Council that any patents that may have been granted would not be enforced was sufficient.[8] Hence, while the number of laws surveyed confirms the implementation of the System by many, if not most, of the world's major exporting countries (see **Annexes II and III**), it does not give any precise indication of the wider range of countries that may choose to use the System to import medicines, whether or not specific implementing measures have been put in place.

Implementing the System is also distinct from accepting the Protocol Amending the TRIPS Agreement.[9] Both processes can, but need not, be handled separately. On the one hand, acceptance can thus come before implementation since the new flexibilities do not create any new obligations: in accepting the legal amendment, a Member simply recognizes that other Member may use it if they wish, while it is not obliged itself to implement or use it. On the other hand, Members can implement and use the System before acceptance and entry into force of the TRIPS amendment under the terms of the interim waiver.

Objectives

Given that, unlike other flexibilities in the TRIPS Agreement, the Paragraph 6 System was devised as a new mechanism without previous domestic experience to draw upon, there seems to be an exceptional need for an in-depth discussion of how it has been implemented at country level.

This paper therefore surveys domestic measures that WTO Members have put in place to implement the Paragraph 6 System, with a focus on measures for export of medicines as this is where the predominant legal changes have been necessary. It summarizes the main findings and offers some elements for reflection regarding the way forward in order to support the functioning of the Paragraph 6 System. **Annex IV** lists in alphabetical order individual Members' and one Observer's legislative and other measures, as well as the key features as they have been addressed by such measures.

Next to providing a detailed snapshot of how and to what extent the key features of the Paragraph 6 System have been covered by these Members, this survey also aims at putting a valuable source of information and inspiration at the disposal of those Members who are yet in the process of considering whether and how best to implement the Paragraph 6 System in their domestic legal framework. This, on its own, can catalyse a process of mutual learning in the implementation of the System.

As an objective overview of the measures applied by Members, the survey can provide a factual basis for technical assistance activities and building capacity in the implementation and use of the Paragraph 6 System by WTO Members and other stakeholders, such as medicine procurement programmes. Greater transparency about how the System is implemented in practice may also facilitate its practical use, where the need arises. For example, to make effective use of the System, procurement agencies need to have practical understanding of the opportunities under the System, in particular where export under a compulsory licence offers potential as the most effective avenue for procurement.

Working method

Which sources of information have been referred to?

The information collected in this paper is based on notifications that WTO Members have submitted to the TRIPS Council in line with their legal obligation, under Article 63.2 of TRIPS, to notify

[8] See notification submitted by Rwanda, WTO Document IP/N/9/RWA/1 of 19 July 2007.
[9] More information on how to accept the Protocol Amending the TRIPS Agreement and the distinction between acceptance of the Protocol and implementation of the Paragraph 6 System is available at: http://www.wto.org/english/tratop_e/trips_e/accept_e.htm.

relevant laws and regulations.[10] However, only 16 WTO Members have notified relevant domestic implementing measures in this way to the TRIPS Council, even though many others have introduced new laws to give effect to the System. To provide the most complete overview possible, information has therefore also been drawn from national implementing legislation and other legal measures that have not been formally notified to the WTO, but can be found in other databases or information resources. For instance, the survey thus includes implementing measures put in place by 14 WTO Members, including seven EU member States, and by Serbia (which is in the process of acceding to the WTO) that can be viewed on WIPO's database WIPO Lex.[11] In the case of Finland and Latvia, the relevant legislative provisions were directly accessed on the competent government departments' websites.

The survey also draws on additional information on certain Members' implementing legislation recorded in the minutes of the so far most comprehensive annual review of the Paragraph 6 System held on the occasion of the TRIPS Council's meeting of 27 October 2010.[12]

WTO Members and Observers[13] with implementing measures included in the attached survey were also individually invited to verify the information provided regarding their respective domestic legislation or regulation. The tables in **Annex IV** reflect ensuing feedback from Brunei Darussalam; Canada; China; the European Union; Hong Kong, China; India; Jordan; the Republic of Korea; New Zealand; Norway; Serbia; Switzerland and Chinese Taipei.

What are the entries in the table meant to cover?

Annex V contains a model table that explains in more detail the kind of information that has been searched for and, where available, listed for each entry of the tables that summarize individual WTO Members' implementing measures.

Some of these entries indicate that for a specific feature, "no specific provision" has been put in place. Such entries are intended merely to clarify that no sources could be identified that would confirm the implementation of the particular elements concerned into domestic legislation. These entries do not, however, exclude the possibility of other provisions that apply to standard compulsory licences to deal with the specific features concerned. In other words, the existing law of a country may already be sufficient to give effect to these aspects of the System without any specific new legislative steps.

In the case of EU member States, where individual implementing measures do not explicitly cover one or more of the features listed in the attached table, it has been assumed that this is taken care of by the relevant EU Regulation that is directly applicable in its member States, hence the indication "see EU Regulation (EC) No 816/2006". In other cases, some features in the attached table have been covered in member States' domestic legislation by an explicit reference to EU Regulation (EC) No 816/2006; those are reflected in the table by an entry "reference to EU Regulation (EC) No 816/2006".

Finally, where an entry indicates "reference to 2003 Decision", the purpose is merely to flag that some general language has been incorporated in the implementing measure concerned that requires action to be taken in accordance with the 2003 Decision. This, in turn, could be considered as covering individual features listed in the attached table in line with the 2003 Decision where those are not specifically addressed by the implementing measure concerned.

Main findings

How many and which Members have implemented the System?

As of July 2015, 51 WTO Members (and Serbia) have adopted specific implementing measures with a variable degree of detail – almost a third of the membership, and the predominant bulk of existing pharmaceutical exporters. The world map reproduced in **Annex I** provides an overview of

[10] The details of what exactly needs to be notified to the TRIPS Council are elaborated in the TRIPS Council Decision of 21 November 1995, WTO Document IP/C/2.
[11] http://www.wipo.int/wipolex/en/.
[12] See Annex to WTO Document IP/C/57 of 10 December 2010, paras.80 to 120.
[13] Except individual EU member States.

Members that have specifically adopted legislation to use the System either as exporters, importers or both. This list encompasses 35 industrialized country Members[14], two transition countries and 12 developing country Members. It also includes two least developed countries (Burundi and Zanzibar (as part of the United Republic of Tanzania)). Although LDCs are entitled to transition periods currently expiring in January 2016[15] as regards the protection and enforcement of patents and test data in the pharmaceutical sector, and in July 2021[16] with respect to the implementation of the TRIPS Agreement in general, such implementing measures adopted by LDCs provide a useful basis for making effective use of the Paragraph 6 System insofar as they clarify the applicable conditions and procedures under national law.

This survey only encompasses implementing measures that have been *specifically* adopted by WTO Members with a view to incorporating the additional flexibilities provided for by the Paragraph 6 System in their respective domestic legal frameworks. It does not consider any provisions of a general nature in domestic laws and regulations, possibly to be read in conjunction with the international obligations incumbent on the Member concerned, that may be considered as constituting the basis for the grant of compulsory licences to either import or export pharmaceutical products under the Paragraph 6 System and to regulate the conditions applying to such licences.

Lack of specific implementing measures does not imply a Member cannot use the System. Some Members have reportedly not adopted any such measures, but still consider that their legislative framework offers an appropriate legal basis for the use of the Paragraph 6 System, either as exporters or importers; they are not covered by this survey yet this should not suggest that their domestic systems are not ready to make use of it. To the contrary, it is important from a practical and policy point of view to understand the legal basis for this analysis. Japan, for example, views both the 2003 Decision and, upon its entry into force, the amendment to the TRIPS Agreement as applicable without the prior adoption of specific implementing measures.[17] According to the delegation of Japan, the domestic rules which constitute the basis for it to act as an exporting Member under the System are "The Guideline for Administering Award System" and Article 93 of the Japanese Patent Act[18], which provides for the grant of non-exclusive licences for reasons of public interest. These measures are considered by Japan to constitute the legal basis for the grant of compulsory licences in accordance with international obligations, including the TRIPS Agreement and later instruments, and thus for the purposes of using the System. Another example is Ecuador that referred to Articles 61 to 66 of the Andean Community Decision No. 486 of September 2000 and Articles 154 to 156 of the Industrial Property Law of May 1998, as well as Article 31 TRIPS and the Doha Declaration on the TRIPS Agreement and Public Health as providing the legal basis for the grant of compulsory licences for reasons of public interest, emergency or national security.[19]

What are the typical features of implementing measures?

This survey is limited to a systematic overview of the main features that can be found in WTO Members' implementing legislation that have an express reference to the System. These main features typically address at least some, if not all, of the elements listed below. More details are available in **Annex IV** which compiles relevant information in table format for each WTO Member and Observer concerned. For the reasons already discussed, the survey does not include all elements in Members' domestic law that would enable use of the Paragraph 6 System, since in some cases these elements are already effectively present in the existing general patent law without specific measures being needed.

[14] Counting the EU and its member States as 29.
[15] WTO Document IP/C/25 of 1 July 2002. In February 2015, Bangladesh, on behalf of the LDC Group, submitted to the TRIPS Council a request for this transition period to be extended until the time a Member ceases to be an LDC (WTO Document IP/C/W/605 of 23 February 2015).
[16] WTO Document IP/C/64 of 12 June 2013.
[17] See report by the delegation of Japan on the occasion of the annual review of the Paragraph 6 System at the TRIPS Council's meeting on 26-27 October 2010, WTO Document IP/C/57 of 10 December 2010, Annex, para.115.
[18] WTO Document IP/N/1/JPN/P/8.
[19] As reported by the delegation of Ecuador on the occasion of the annual review of the Paragraph 6 System at the TRIPS Council's meeting on 26-27 October 2010, WTO Document IP/C/57 of 10 December 2010, Annex, para.111.

Box: Overview of Main Features in Implementing Measures

Based on the survey, the findings for a selected number of key features in domestic implementing measures can be summarized as follows:

- the vast majority of WTO Members with specific measures to implement the System into domestic law have done so in order to act as exporters;
- national implementing measures generally cover all types of diseases and pharmaceutical products needed to address public health problems;
- in most WTO Members with implementing measures, the special compulsory licensing mechanism can also be used to export to non-WTO Members;
- the requirement under Article 31(b) TRIPS to make prior efforts to obtain a voluntary licence on reasonable terms and conditions forms an integral part of most implementing measures. The reasonable period within which such efforts must be made ranges from 28 days to six months;
- most exporting Members limit the quantity authorized for production under a special compulsory licence to the needs notified by the applicant or the importing country;
- the duration of the special compulsory licence is usually determined either by the period designated by the competent authority or the expiration of the patent, or limited by the intended purpose. In some cases, a renewal of the licence after the initial period is provided for, or a review of the period by means of a simplified procedure. Most implementing measures also provide for the possibility of revoking or terminating the compulsory licence if certain conditions are met;
- many export measures provide that adequate remuneration be paid to the right holder in the exporting country, taking into account the economic value of the authorization in the importing country. Some implementing measures provide for detailed methods for the calculation of adequate remuneration and may fix a maximum royalty rate;
- according to many implementing measures, distinguishing features must be applied to the medicines produced for export under special compulsory licence and information on shipments be posted on a website by the licensee. In order to avoid diversion of the medicines concerned, certain measures also require that the entirety of the production be exported exclusively to the importing country or explicitly prohibit the reimport of such medicines; and
- although not required under the TRIPS Agreement, some implementing measures establish certain regulatory approval or other requirements for the export of products manufactured under the System in order to ensure that these respect safety, quality and efficacy standards, while other measures do not specifically address regulatory matters.

(i) Scope

Among the WTO Members with express implementing laws or regulations, three categories can be observed, including Members that have implemented the System specifically to act:

- exclusively as exporters (41 Members);
- exclusively as importers (3 Members); or
- both as exporters and importers (7 Members).

In the case of Estonia, it is unclear whether the country can act both as exporter and importer. §47(8) of its Patent Act as amended in March 2009 refers to EU Regulation 816/2006 as "applying to filing an action for acquiring a compulsory licence for the manufacture of pharmaceutical products protected by a patent for import or export". At the same time, the EU Regulation clearly only provides the legal basis for the EU and its member States to act as exporting Members under the Paragraph 6 System, thus reflecting the commitment not to use the System as importers.[20]

[20] See footnote 3 to the 2003 Decision (WTO Document WT/L/540) and to the Protocol Amending the TRIPS Agreement (WTO Document WT/L/641).

Because of its observer status within the WTO, Serbia is not counted here, although it is noteworthy that its implementing legislation allows for use of the System for export purposes only.

Where the notion "export" has been entered under "scope" in the table attached, this is only meant to indicate that the specific implementing measures reviewed here have introduced the additional flexibilities provided by the Paragraph 6 System exclusively for the purpose of exporting medicines needed elsewhere. As explained in the previous section, the entry "export" does, however, not necessarily mean that the Member concerned is precluded from using the Paragraph 6 System also as an importer. This may well be possible on the basis of standard compulsory licences without adopting any particular implementing measure, it being understood that the possibility of definitely waiving the requirement to pay adequate remuneration to the right holder pursuant to Article 31(h) TRIPS would be foregone, if not specifically implemented.

For example, Article 49 of the China's Patent Law, similar to provisions in many other WTO Members' patent legislation, provides that "where a national emergency or any extraordinary state of affairs occurs, or public interests so require, the patent administration department under the State Council may grant a compulsory license for exploitation of an invention patent or utility model patent". According to Article 11 of the Patent Law, "grant" includes the action to "import the patented products" or "products that are developed directly through the use of the patented method". China therefore considers these provisions to constitute a sufficient legal basis to use the Paragraph 6 System to import medicines in case of public health problems and insufficient local manufacturing capacities. This said, given the absence of a specific provision that would waive the obligation to pay adequate remuneration in the case of imports, the right holder would still have to be compensated for the grant of the compulsory licence. This is different from WTO Members which have implemented the System to act as importers, such as Singapore, where it is provided that no remuneration is to be paid in respect of the medicines imported under the System if the patentee is compensated elsewhere.

The only exception to importing under the Paragraph 6 System based on a country's existing law applies to those WTO Members that have explicitly excluded themselves from using the Paragraph 6 System as importers.[21] While they may have similar provisions in place that would, in principle, permit the grant of compulsory licences for purposes of importing medicines from other countries under the Paragraph 6 System, they have expressly and formally undertaken not to do so.

(ii) Diseases, products and IPRs covered

With respect to diseases and products covered, most WTO Members' implementing measures follow the definitions provided by the WTO decisions establishing the Paragraph 6 System (see para.1(a) of the 2003 Decision and para.1(a) of the Annex to Article 31*bis* TRIPS in conjunction with para.1 of the Doha Declaration). Thus, no limitation to specific diseases applies and all pharmaceutical products needed to address public health problems are generally covered. Certain implementing legislations elaborate on the meaning of "pharmaceutical products" by also explicitly including active ingredients, diagnostic kits and, in a few cases, vaccines. A notable exception is Canada: it provides for a positive list of products (Schedule 1 of the Patent Act) which are eligible for the grant of a special compulsory licence. However, the list can be and has been amended by an expert committee.

Further, many national measures specify the type of IPRs to which special compulsory licences may be applied. Both product and process patents for pharmaceutical products are thus often explicitly included. Similarly, where supplementary protection certificates are made available in order to compensate for lengthy patent grant or marketing approval procedures, these additional titles typically also fall within the scope of national implementing measures providing for special compulsory licences to export medicines. This concerns a number of WTO Members (Albania; EU; Iceland and FYROM), as well as Serbia.

[21] See footnote 3 to the 2003 Decision (WTO Document WT/L/540) and to the Protocol Amending the TRIPS Agreement (WTO Document WT/L/641) and the respective statements read out by the Chairman of the General Council prior to the adoption of those decisions (WTO Documents WT/GC/M/82, para.29 and WT/GC/M/100, para.29).

(iii) Eligible importing countries

Some implementing measures adopted by WTO Members either do not expressly regulate which countries are eligible to import under the System, in particular where implementation has been limited to the use as an importing country, or refer to the 2003 Decision or the proposed Article 31*bis* TRIPS in order to determine which countries are eligible as importers. In the latter case, all LDCs and WTO Members that have notified the TRIPS Council of their intention to use the System are included, while non-WTO Members are excluded from its use.

40 WTO Members, including the EU and its member States, as well as Serbia, provide for an extension of the special compulsory licensing mechanism for exports to non-WTO Members. In most cases, their implementing measures allow for exports to non-WTO LDCs and non-WTO developing countries eligible for development assistance according to the OECD. In the case of Korea, eligible importing non-WTO Members are determined by Presidential Decree. India, New Zealand, the Philippines, Switzerland and Chinese Taipei have extended the use of the System more generally to allow exports to non-WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector. Non-WTO Members cannot notify the TRIPS Council of imports under the System, but in most cases are subject to certain notification and other requirements that are to be handled directly between the exporting country's government or, in the case of the EU, between the European Commission and the importing country authorities.

In addition, Canada, the EU, Switzerland, FYROM and Serbia explicitly exclude WTO Members from the use of the System that committed themselves not to use it as importers.[22] Similarly, Canada and Switzerland limit the use of the System by partial opt-out countries to emergency situations, thus confirming one of the key shared understandings among WTO Members contained in the General Council Chairman's Statement read prior to the adoption of the 2003 Decision and the 2005 Protocol Amending the TRIPS Agreement.[23]

(iv) Pre-grant conditions

Many WTO Members require the applicant for a compulsory licence to submit at least details with respect to some or all of the following elements: the product concerned, including, where available, the generic name that identifies a pharmaceutical substance or an active pharmaceutical ingredient (the International Non-Proprietary Name[24]), relevant patents or supplementary protection certificates and the name of the patentee(s), the quantity suggested for production, compulsory licences filed in other countries for the same product, intended duration of the compulsory licence, the name of the importing country(ies) and its/their notification to the TRIPS Council or, in the case of non-WTO Members, to the competent national authority in accordance with para.2(a) of the 2003 Decision, the patent status in the importing country and, where applicable, the grant of a compulsory licence there, the identity of the purchaser, as well as distinguishing features to be applied to the generic product and the website address where the licensee makes relevant information available.

Similarly, most implementing measures explicitly reiterate the condition established under Article 31(b) TRIPS, applicable to all categories of compulsory licences, according to which prior efforts must normally be made to obtain a voluntary licence on reasonable terms and conditions. Where specifically addressed (Burundi; Australia; Canada; EU; Hong Kong, China; Iceland; Oman; Serbia; Switzerland; FYROM; Zanzibar/Tanzania), the reasonable period within which such efforts must be made ranges from 28 days to 6 months. In some cases, the circumstances addressed in Article 31(b) TRIPS under which the condition to try to obtain a voluntary licence first does not apply, are also set out (Burundi; EU; Hong Kong, China; Iceland; Korea; Norway; Oman; Philippines; Serbia; Switzerland; FYROM; Zanzibar/Tanzania).

[22] For the list of full opt-out WTO Members see WTO Document WT/L/540, footnote 3 and WTO Document WT/L/641, Annex, footnote 3.
[23] For the list of partial opt-out WTO Members see WTO Documents WT/GC/M/82, para.29 and WT/GC/M/100, para.29. It includes the following WTO Members: Hong Kong, China; Israel; Korea; Kuwait; Macao, China; Mexico; Qatar; Singapore; Chinese Taipei; Turkey and the United Arab Emirates.
[24] See Guidelines on the Use of International Nonproprietary Names (INNs) for Pharmaceutical Substances (WHO/PHAM S/NOM 1570), available at: http://apps.who.int/medicinedocs/pdf/h1806e/h1806e.pdf.

In addition, some legislation specifically requires the granting authorities to provide the patent owner and, in some cases, also any other interested person, with an opportunity to be heard before a compulsory licence is granted (Botswana; Burundi; China; EU; Iceland; Korea; Oman; Samoa; Chinese Taipei; FYROM). India requires the applicant for a compulsory licence to set out the interest in obtaining such a licence and the terms and conditions that are acceptable.

Canada waives the otherwise applicable requirement to pay fees for an application to grant a compulsory licence whereas the implementing legislation in Hungary requires the applicant for a special compulsory licence to pay the fees simultaneously with the filing of the application.

Most WTO Members that have adopted measures to implement the System for the purpose of using it as importers explicitly require a situation of extreme urgency to address public health problems as a prerequisite for the use (Brunei Darussalam; Hong Kong, China; Korea; Singapore), as well as in certain cases an assessment that local manufacturing capacities for the needed medicines are insufficient or non-existent (Hong Kong, China; Korea).

Finally, Jordan's implementing measures do not establish pre-grant conditions that are specific to special compulsory licences to address public health problems in countries with no or insufficient manufacturing capacities.

(v) Quantity

Most exporting Members limit, either explicitly or by reference to the 2003 Decision, the quantity authorized for production under a compulsory licence to the needs notified by the applicant or the importing country. Some implementing measures also require that products manufactured under a compulsory licence in another country to be taken into account for the purpose of calculating the authorized quantity (Albania; EU; Serbia; FYROM). In the EU, the conditions applying to the compulsory licence can be modified by means of a simplified and accelerated procedure in order to permit manufacture and export of additional quantities.

Some WTO Members that have implemented the Paragraph 6 System as importers require the compulsory licence to include an estimate of the quantities needed during the term of the licence (Hong Kong, China; Samoa). In addition, Botswana's implementing legislation specifies that such estimate does not represent a limit to the quantity of pharmaceutical products finally being imported.

Implementing measures adopted by Brunei Darussalam and Korea do not specifically address the question of the quantity authorized for production under compulsory licence.

(vi) Duration of the compulsory licence

Where the duration of the compulsory licence is addressed by implementing legislation, the relevant provision usually specifies that its validity is determined either by the period designated by the competent authority or the expiration of the patent, or that it is limited by the intended purpose. Some Members provide for an initial period of two years that is once renewable (Canada), others include the possibility for the duration to be reviewed by means of a simplified procedure (EU). The implementing measures adopted by Iceland set no initial period, but provide for the possibility of an extension if the licensee has been unable to export the quantities authorized under the compulsory licence. Serbia and FYROM provide for the possibility of modifying the compulsory licence if the importing Member has notified that the quantity of pharmaceutical products has become insufficient to meet its needs. In two cases of implementation as importers, the validity of the compulsory licence is dependent on whether the circumstances of extreme urgency still apply (Brunei Darussalam; Hong Kong, China).

Most implementing measures also provide for the possibility that a compulsory licence be revoked or terminated upon reasoned request (Albania; Australia; Botswana; Brunei Darussalam; Burundi; Canada; China; EU; Hong Kong, China; New Zealand; Oman; Samoa; Serbia; Singapore; Switzerland; Chinese Taipei; FYROM; Zanzibar/Tanzania), including for one or more of the following reasons: the circumstances leading to its grant no longer exist and are unlikely to recur, the licensee fails to comply with the terms of the decision, or diversion of the products concerned has occurred.

The question of the duration of the compulsory licences granted under the relevant measures implementing the Paragraph 6 System has not been specifically addressed by the relevant domestic legislation put in place in Jordan; Korea and Norway.

(vii) Remuneration

Many export measures provide that adequate remuneration be paid to the right holder in the exporting country, taking into account the economic value of the authorization (Albania) in the importing country (Australia; Canada; Hong Kong, China; Jordan; Korea; New Zealand, Norway, Oman, Philippines; Switzerland; Chinese Taipei). In the latter cases, this reflects an implementation of the waiver provided for by the 2003 Decision, which precisely allows the exporting Member to determine the level of compensation to be paid by reference to the economic value of the authorization in the importing Member. In addition, certain exporting Members provide for detailed methods regarding the calculation of adequate remuneration (Canada; Korea; Switzerland; Chinese Taipei), in some cases linked to humanitarian or non-commercial circumstances relating to the compulsory licence (EU; Serbia; Switzerland; FYROM). A number of implementing measures also fix a maximum royalty rate of 3.5% (Canada) or 4% of the price paid in the importing country (EU; Hong Kong, China, Korea; Serbia; FYROM).

Where express legislation has been put in place to use the Paragraph 6 System as an importing Member, the relevant provision usually removes the requirement to pay adequate remuneration, pursuant to paragraph 3 of the Paragraph 6 System, provided that the right holder has received compensation in the exporting country (Botswana; Brunei Darussalam; Hong Kong, China; Samoa; Singapore; Zanzibar/Tanzania), or refers more generally to the procedures and conditions set by the 2003 Decision (Burundi) or the relevant international treaties (China). If, however, the right holder has not been compensated in the exporting country and remuneration has therefore to be paid in the importing Member, Hong Kong, China and Zanzibar/Tanzania apply a ceiling of 4% of the total purchase price.

Some implementing measures also address procedural questions, for example, by determining that the licensee is obliged to pay the remuneration (Canada; EU; Hong Kong, China; Chinese Taipei) and that, in case of multiple patents for the product needed, the remuneration shall be proportionately shared among all right holders (Hong Kong, China). In certain Members, these measures also designate the competent authority, usually a court, the IP office or the health department, whose task includes the determination of the level of adequate remuneration (Hong Kong, China; Iceland; Korea; Chinese Taipei), leaving it in some cases to the right holder and licensee in the first place to agree on such remuneration before a decision may be taken by the court or administration (Albania; China; Hong Kong, China).

(viii) Notification and publication requirements

The most commonly found notification requirement is an obligation to notify the right holder. This is usually mandatory after the grant of a compulsory licence (Brunei Darussalam; Canada; China; Hong Kong, China; Iceland; Korea; Oman; Samoa; Singapore; Chinese Taipei), but may also apply prior to the grant of such licence (China; EU; Iceland; Korea; Oman; Chinese Taipei; FYROM). In Hong Kong, China, the applicant is required to notify the right holder before the application for a compulsory licence to export medicines is made. Some implementing measures also provide for a revocation of the compulsory licence to be notified to the right holder and the licensee (Hong Kong, China; Iceland).

In line with paras.2(a) and 2(c) of the 2003 Decision, many implementing measures also reiterate the requirements to notify the TRIPS Council either of the importing Member's specific needs and, where applicable, the absence of sufficient manufacturing capacities and the grant or the intention to grant a compulsory licence for import purposes, or of the exporting Member's decision to grant a compulsory licence to authorize the production and export of the medicines needed in the importing country and the conditions attached to it (Brunei Darussalam; Burundi; China; EU; Iceland; New Zealand; Norway; Philippines; Samoa; Serbia; Singapore; Switzerland; FYROM; Zanzibar/Tanzania). In addition, some Members also require that the TRIPS Council be notified when a compulsory licence is modified, revoked or terminated (EU; Iceland; Serbia). In some WTO Members, the application for a CL or the decision of the competent authority regarding the grant or revocation of the compulsory licence must be published (India) in an official journal (Hong Kong, China; Iceland; Korea; Oman) or on the IP office's website (Canada; Switzerland (if

the System is used by non-WTO Members)). In the case of Hong Kong, China, the publication requirement also extends to an agreement or the failure to agree on the remuneration to be paid to the right holder.

The implementing measures in Albania; Botswana and Jordan do either not specifically address the issue of notification requirements or merely refer in general terms to the 2003 Decision.

(ix) Transparency and safeguards against diversion

The Paragraph 6 System sets out special requirements to avoid the diversion of products manufactured and exported under the mechanism. For exporting Members, these include labelling and marking requirements and the application of distinguishing features in line with para.2(b)(ii) of the 2003 Decision. However, certain implementing measures do either not specifically address the special requirements (Albania; Botswana; India) or do so by means of a general reference to the 2003 Decision (Burundi; Jordan; Oman; Zanzibar/Tanzania). On the other hand, many other implementing measures explicitly require that distinguishing features be applied and information be posted on a website by the licensee (Australia; Canada; China; EU; Hong Kong, China; Iceland; Korea; New Zealand; Norway; Philippines; Samoa; Serbia; Switzerland; Chinese Taipei; FYROM). Furthermore, Canada also requires the licensee to notify the patent holder, importing country and purchaser 15 days prior to exporting the medicines concerned of the quantity and every known party handling the product while in transit.

In addition, certain other safeguards are established by a number of implementing measures. In case of export measures, these may include a requirement to export the entirety of the production (Australia; China; Korea; New Zealand; Switzerland) exclusively to countries listed in the compulsory licence (Iceland) or a prohibition of importing (EU; Serbia; FYROM) or reimporting (Switzerland) medicines manufactured under a special compulsory licence. The EU, Serbia and FYROM provide an exemption to the import prohibition in case the medicines are transiting their respective territory for the purpose of being re-exported to the importing country. On the other hand, some import measures reflect the requirements in para.4 of the 2003 Decision and prohibit the (re)exporting of the products concerned (Brunei Darussalam; Hong Kong, China; Philippines; Samoa; Singapore). Some WTO Members also provide for specific measures regarding the disposal of medicines produced under the System that are to be taken in case the compulsory licence is terminated or the period of extreme urgency ends (EU; Hong Kong, China; Iceland). Furthermore, the EU and Serbia's implementing measures enable competent authorities to have the possibility to seek access to books and records kept by the licensee in order to check whether the terms of the licence are met.

(x) Other

Under this entry, the survey provides an overview of other relevant provisions that can be found in some WTO Members' implementing legislation that do not fit into any of the above categories. For example, in some cases, reference is made to regulations or other measures to be adopted in order to address details of the use of the System, although such regulations are not always available. Canada provides for a mandatory requirement to grant the compulsory licence if the conditions are met and explicitly includes NGOs as eligible purchasers of licensed pharmaceutical products. The EU provides for a mandatory review of its implementing legislation every three years. Hong Kong, China excludes any liability of public officers regarding the grant of special compulsory licences for import or export purposes. India and the Philippines clarify that the grant of a special compulsory licence is without prejudice to the export of pharmaceutical products manufactured under a standard compulsory licence. Both the Philippines and Switzerland exclude preliminary injunctions from being applied to special compulsory licences. Finally, Zanzibar/Tanzania provides that the measures taken to implement the Paragraph 6 System apply *mutatis mutandis* to pending patent applications.

(xi) Regulatory approval

Neither the TRIPS Agreement nor the 2003 Decision and the TRIPS amendment require regulatory approval of products manufactured under the System (other than the general TRIPS obligation to protect clinical data). This said, some Members have specifically covered regulatory issues in their implementing legislation. Thus, Canada applies the same safety, quality and efficacy standards to pharmaceutical products manufactured for export under compulsory licence as those required for

products made for domestic consumption; it also provides for an expedite approval procedure for applications submitted to Health Canada. The EU provides for the possibility for the licensee to avail itself of EU or national scientific opinion procedures; the otherwise applicable regime of test data exclusivity is also waived in cases of use of the Paragraph 6 System. In the Philippines, the Bureau of Food and Drugs must ensure conformity with international quality standards and imported drugs are to be pre-qualified by the WHO. Switzerland requires manufacturing approval to ensure the respect of Good Manufacturing Practices, while the products manufactured under a special compulsory licence are exempt from the marketing approval that is otherwise required for products for domestic consumption. In Chinese Taipei, the inspection and registration of products concerned is exempted from the protection of test data in form of an exclusivity period of five years that otherwise applies pursuant to Article 40ter Pharmaceutical Affairs Act. Finally, reference is made by Zanzibar/Tanzania to the LDC transition period with respect to the protection of clinical test data submitted for marketing approval purposes.

(xii) Good faith clause

The Chairman's statement read out prior to the adoption of the 2003 Decision and the 2005 Protocol Amending the TRIPS Agreement registered some key shared understandings of WTO Members, which included the recognition that the System be used "in good faith to protect public health and (…) not be an instrument to pursue industrial or commercial policy objectives".[25] This good faith clause is taken up only by a limited number of WTO Members in their implementing legislation. Canada, for example, permits the right holder to challenge any export licence where there is reason to believe that its use is of a predominantly commercial nature, i.e. where the average price is equal to or greater than 25% of the average price on the domestic market. The EU and FYROM also refer to the Chairman's statement, according to which the System is to be used in good faith and to pursue industrial or commercial policy objectives, and require non-WTO Members to make an explicit statement that the System only be used to address public health problems; the possibility of terminating the compulsory licence is included in the implementing measures if the System is abused as an instrument to pursue industrial or commercial policy objective. As an acceding country, Serbia has also put in place language to that extent in its implementing legislation.

What is the sequence between the adoption of implementing measures and the acceptance of the TRIPS amendment?

As noted in the introduction, nothing in the Protocol Amending the TRIPS Agreement requires a specific sequencing of acceptance of the TRIPS amendment and adoption of implementing measures; these are independent steps with different implications and purposes, the one not requiring the other. WTO Members are therefore free to:

- either first accept the TRIPS amendment and only subsequently put in place legislation that implements the Paragraph 6 System into domestic law;
- accept the TRIPS amendment and not implement the Paragraph 6 System at all;
- deal with acceptance and adoption in parallel; or
- first adopt implementing legislation and only later accept the TRIPS amendment.[26]

In the vast majority of WTO Members covered by this survey, the last option prevails. A number adopted implementing measures prior to later accepting the Protocol Amending the TRIPS Agreement (37 Members, including the EU and its 27 member States at the time of implementation/acceptance). Six other Members have implemented legislation without having (yet) accepted the amendment. In addition, one Member appears to have dealt with both processes, i.e. acceptance and domestic implementation, in parallel. Since Serbia is not yet a WTO Member, it cannot notify its acceptance of the TRIPS amendment to the WTO and is therefore not taken into account here.

On the other hand, only seven of the Members surveyed accepted the TRIPS amendment prior to their implementing legislation. However, another 35 Members have accepted the TRIPS amendment but do not seem to have adopted domestic measures to implement the System; they

[25] See General Council minutes, WTO Documents WT/GC/M/82, para.29 and WT/GC/M/100, para.29.
[26] See above fn. 9.

are therefore not covered by this survey.[27] Thus, it can be assumed that at least 42 Members in total have had no implementing legislation in place when accepting the amendment. Hence, the overall trend among many WTO Members is to accept the amendment first, before attending to domestic implementation, if that is undertaken at all. This accords with the understanding that acceptance of the amendment is a formal recognition that other Members are entitled to use the System if they wish, and that domestic implementing legislation is not a prerequisite for accepting the amendment.

What is distinctive about EU implementation?

The EU has implemented the Paragraph 6 System by means of a regulation that is directly applicable in all its member States. Regulation (EC) No 816/2006 is therefore counted in this survey as implementation by 29 WTO Members. This said, it leaves a certain number of issues to the discretion of EU member States. In particular, it is within their responsibilities to determine the competent authority for the grant of special compulsory licences under the Paragraph 6 System, as well as for any decision regarding the character of goods suspended by customs authorities while being imported into the EU. Among other things, this may explain why a number of EU member States have separately adopted additional, more or less detailed implementing measures. They specify, in particular, the authority that is in charge of granting or revoking the compulsory licence and for reviewing any related decisions. For reasons of completeness, their content is therefore also summarized in table format for each individual member State concerned in **Annex IV**, next to the table providing an overview of EU Regulation (EC) No 816/2006.

On the other hand, given the direct applicability of the EU regulation, most national implementing measures remain silent on a number of other key features of the Paragraph 6 System, or simply refer to the EU regulation. A notable difference is Croatia, which can be explained by the fact that the relevant amendments to its Patent Act were adopted prior to adhering to the EU. For the same reason, Croatia is also the only EU member State that notified its acceptance of the TRIPS amendment to the WTO in December 2010 before becoming an EU member State in July 2013. Again except Croatia, none of the other EU member States concerned have formally notified the TRIPS Council of their implementing measures.

The EU has visibly also had an impact on the drafting of implementing legislation in some of its neighbouring countries. Thus, Croatia (prior to becoming a EU member State), Serbia (despite its observer status in the WTO) and FYROM have adopted implementing measures which, in many aspects, are similar or identical to the provisions of Regulation (EC) No 816/2006.

Conclusions and Way Forward

What has been achieved so far?

This survey illustrates that a robust framework supportive of the export of generic medicines to meet public health needs has been put in place by a significant number of WTO Members. Most major exporters of pharmaceutical products, and many other significant producers and traders, have implemented the Paragraph 6 System in their domestic legislation (see **Annexes I and II**). A number of Members have also taken legislative action to use the System as importers, although there is generally much less need or, in certain circumstances, no need at all for specific legislation for importation.[28]

When translating the conditions for use established under the System into domestic law, national implementing measures show varying degrees of detail and complexity. In all cases, a sound legal basis for its use has been established which allows, in particular, generic producers in at least 48 WTO Members (including all EU member States because of the direct applicability of Regulation (EC) No 816/2006) and Serbia to act as exporters. These WTO Members account for about 80% of worldwide pharmaceutical exports (see **Annexes II and III**). They are likely to host most of the worldwide generic manufacturing capacities, so that it can be assumed that the vast majority of generic producers is now in a position to positively respond to demands by other WTO Members in need of patented medicine(s) by seeking compulsory licences exclusively for the purpose of

[27] An updated list of WTO Members that have accepted the Protocol Amending the TRIPS Agreement is available at: http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm.
[28] See above Section on "How many Members and which Members have implemented the System".

manufacturing and exporting these medicines. In addition, a number of other WTO Members, including countries with major generic production capacities, are currently considering the adoption of measures implementing the System into their domestic legal framework.

What role can and should the Paragraph 6 System play?

The System was designed to remove a particular legal hurdle to access to medicines, when a compulsory licence for export offers the best means of securing medicines for countries without the necessary domestic production capacity. Since it is established as a new way of responding to the demand for lower cost medicines, it requires domestic action on the part of beneficiary countries to identify and communicate relevant needs for imports, and to trigger exports by foreign producers to meet this demand. The extensive rollout of implementing measures by WTO Members indicates that the System has the potential to serve as a significant procurement tool for access to medicines by expanding the base of trade opportunities to meet demand for medicines. However, little use of this key function of the System has been made so far. For this to change, it has to be clearly understood that its impact need not be limited to specific shipments expressly made under the System. The fact that most of the world's pharmaceutical producers and exporters now operate in jurisdictions that have arrangements in place expressly permitting the manufacturing exclusively for export of low cost generic medicines under compulsory licenses gives valuable bargaining leverage to procurement programmes. It provides greater formal legitimacy and practical effect to this avenue for access to affordable medicines, enabling concrete plans for its use to meet specific needs. And the implementation of the System can also enhance the coordination of potential suppliers to service unmet demand in the most cost effective way. The System can, in particular, ensure a significant information function, by which the procurement agency or agencies can signal concrete needs in a given country or regional context. This, in turn, should be a useful instrument to trigger the interest of potential generic suppliers to participate in the subsequent tendering process and submit their best offers to respond to these needs. As a result, competition both between originator and generic companies, as well as among generic suppliers, could be achieved. It also offers the opportunity to aggregate demand for a product when a number of countries, for instance in one region, notify the need for the same product, building an economically viable scale for the production and export of a generic version of a pharmaceutical product.

As the example of the use of the System by Rwanda has shown, this initial phase of using the System as a mere information mechanism can already lead to significant price reductions (since the exports originally proposed under the System were undercut by low cost generic producers elsewhere).[29] For this to happen, it is, however, not necessary for the System to be finally used, as the medicine(s) concerned may in a later stage still be obtained at lower or no costs from other sources outside the System, for example, when better offers are made by the originator company or when the medicines are donated. In this case, the initial needs notification would have achieved its objective and further action under the System becomes redundant. However, this would require a more regular notification of intention to use the system and notification of expected demand for medicines by participating countries.

In certain circumstances, the System could also, beyond its foremost priority to address public health concerns, support the development of local production capacities in the pharmaceutical sector. This is recognized by the System itself, in particular in the regional context. Thus, paragraph 6 of the 2003 Decision provides for a waiver of the conditions established by Article 31(f) TRIPS in the case of RTAs that meet certain criteria. Among the declared objectives is the facilitation of local production of pharmaceutical products. The Statement read out by the Chairman of the General Council prior to the adoption of the 2003 Decision[30] confirms this intention: while one of the key understandings among WTO Members is that the System be used in good faith to protect public health and not as an instrument to pursue industrial or commercial policy objectives, it is recognized that this good faith use is without prejudice to the aforementioned RTA waiver, i.e. any efforts made to establish local production in such context.

Finally, the future role of the System will also be influenced by certain external factors. For example, the advent of full patent protection, including for pharmaceutical products, in WTO

[29] See WHO-WIPO-WTO Study (see fn.6 above), Box 4.15 on page 178, available at http://www.wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf.
[30] The Chairman's Statement is reproduced in WTO Document WT/GC/M/82, para.29.

Members hosting major generic suppliers, such as India, is likely to result in future patent coverage of an important number of innovative medicines. In turn, this may augment the need to turn to the Paragraph 6 System in order to produce generic versions of such medicines for export to countries who need them. On the other hand, where attempts to establish local production of certain medicines are successful, the need to rely on the System in order to import medicines may decrease, since its very purpose is to deal with the situation of countries with no or limited production capacity.

What remains to be done to support the functioning of the Paragraph 6 System?

The Paragraph 6 System has a built-in review mechanism: according to paragraph 8 of the 2003 Decision, the TRIPS Council is due to annually review the functioning of the System in order to ensure its effective operation. These reviews have been conducted since 2004 and their outcome is reported to the General Council every year.[31] In principle, they provide an excellent opportunity to put the System into a broader context, that takes equally account of other important elements that impact on innovation and access in the pharmaceutical sector and examines the System's functioning against this background. However, with the exception of the annual reviews held in 2010 and 2011[32], the TRIPS Council has so far witnessed a rather superficial exchange of views on whether the System is functioning properly that, on many occasions, did no more than repeating longstanding and well-known arguments advanced by delegations in previous meetings.

This paper itself is merely intended as a contribution to understanding how the System has been implemented in practice, both to provide practical information for procurement programmes and to inform the broader policy dialogue. Beyond this, there is an obvious need to move a step forward and engage again in a substantive review of the System's functioning, including if and how better, more frequent use could be made of it. In particular, the following issues would seem to merit an in-depth discussion among WTO Members:

- how to ensure that the System does not remain an additional flexibility principally on paper, but is better understood and more widely **used as a practical procurement tool** that can actively support access to affordable medicines by promoting trade in medicines produced in exporting countries that respond to the needs in importing WTO Members, including through the more systematic collection and sharing of information about the practical steps to be taken when arranging exports under the System;

- how to **integrate Ministries of Health and other medicine procurement agencies more actively in the process**, as they will in many countries be the responsible entity for addressing needs in relation to medicines, but may be required to take up these needs with the Ministry of Trade or other responsible Ministries in order to call for the supply of the needed medicines under the System;

- how to **make participation in the System economically more interesting, viable and sustainable** for potential suppliers in order to respond to criticism voiced by generic companies.[33] Further consideration could, for example, be given to possible options that would provide generic producers with effective demands that are backed by the necessary budget and thus offer a viable basis for investment decisions in view of building up new production lines. Among others, pooled procurement initiatives and joint notifications of needs by several WTO Members may also contribute to achieving this objective;

- if there is a need to further **simplify national measures implementing the System** and how this could be achieved. In discussions on the functioning of the System, reference has been repeatedly made to concerns about overly burdensome implementing measures taken at the domestic level which would go beyond what is required by the System itself and the TRIPS Agreement. To the extent possible, further simplifying these measures may also provide the necessary incentives to generic suppliers to engage in production under the System;

[31] For the latest review, see WTO document IP/C/69 of 26 November 2014.
[32] For the comprehensive reviews held at the TRIPS Council meetings in October 2010 and 2011 see the minutes in WTO documents IP/C/57 and Corr.1, as well as IP/C/61).
[33] See, for example, the concerns submitted by Apotex with respect to Canada's implementing legislation, Submission to the Standing Committee on Industry, Science and Technology on "Bill C-393, An Act to amend the Patent Act (drugs for international humanitarian purposes)", 26 October 2010, available at: https://www.apotex.com/global/docs/submission_order_en.pdf.

- what concrete **lessons can be drawn from past experiences**, including any reasons explaining why the System has not been used, not even as an instrument to flag concrete needs in potential importing WTO Members, and any elements of the mechanism that are considered to pose difficulties, as well as other specific elements of the System that have proven to work well, for example, in the case of exports of medicines from Canada to Rwanda;

- what role the System can and should realistically play to **complement the many other initiatives** now available in support of access to medical technologies. The situation has significantly changed since 2003 when the System was first put in place. A considerable number of access initiatives have been initiated since then that are likely to limit the need to rely on the System. Among these are: the availability of enhanced funding, successful efforts to establish local production, the steady increase of product development partnerships, more frequent reliance on price control mechanisms, the introduction of procurement policies and practices that help to acquire medicines at competitive prices, including pooled procurement, etc.[34]. Similarly, a steady increase of the number of voluntary licensing agreements could be observed during the same period, which can also make reliance on the System redundant. Also, where compulsory licences have been used to permit production of a medicine for domestic purposes, particularly in large domestic markets, a less than predominant portion of that production would be available to meet the needs of other countries without use of the System. An in-depth discussion of how the System can reasonably coexist with and complement these other access initiatives and options is therefore needed; and

- if and how the potential use of the System is **affected by higher standards of IP protection and enforcement set by RTAs**. Among other things, the obligation to provide certain exclusivity periods for clinical data has been considered by some as impacting on the actual use of the System. At the same time, provisions in RTAs are considered by others as contributing to innovation and enhanced access, for example, where tariffs on pharmaceutical products are lowered or competition increases because of improved market access conditions. As noted by the WHO-WIPO-WTO study[35], many of the more recent RTAs have also reaffirmed the principles clarified by the Doha Declaration on the TRIPS Agreement and Public Health, in particular the right of WTO Members to take measures to protect public health, as well as the right to use the additional flexibility made available through the Paragraph 6 System. Each of these elements may have an impact on the System's relevance in practice and merit therefore further discussion.

In addition, given that reference has repeatedly been made to political pressure not to use the System in order to explain its limited practical relevance, clarification to the extent that the making available of the option to grant special compulsory licences for export of medicines under the mechanism is seen as a positive step seems needed.[36] This could be achieved through a firm and widespread encouragement to make active use of this additional flexibility made available to WTO Members to address public health problems in countries with insufficient or no local manufacturing capacities.

In parallel, existing training material, including relevant data and experiences, will have to be further developed in order to provide the most comprehensive guidance that can effectively facilitate the implementation and use of the Paragraph 6 System. This survey covers only one of

[34] See, for example, the discussion at the TRIPS Council meeting on 26-27 October 2010, as recorded in WTO-Document IP/C/57 of 10 December 2010, Annex, paras.80 to 120.

[35] WHO-WIPO-WTO Study (see fn.6 above), p.187 and table on p.189, available at: http://www.wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf.

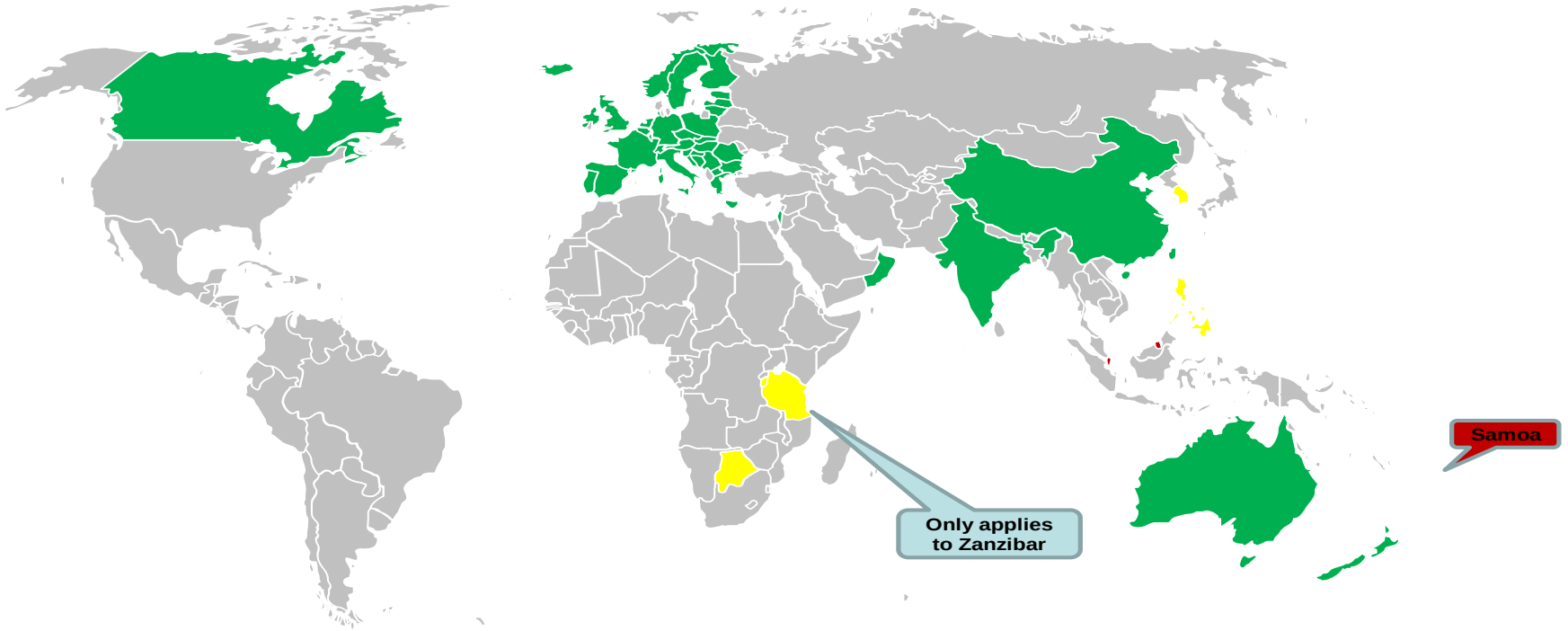
[36] The EU, for example, said that it "would welcome any request from developing countries in view of the use of the System" (TRIPS Council meeting of 27-28 October 2009, IP/C/M/61, para.108). More recently, in its 2014 Special 301 Report (p.25, available at: http://www.ustr.gov/sites/default/files/USTR%202014%20Special%20301%20Report%20to%20Congress%20FINAL.pdf), the USTR explicitly reiterated that "the United States also strongly supports the WTO General Council Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health concluded in August 2003." The research-based pharmaceutical industry also supported the adoption of the System: for example, the then Director General of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), in a letter of 23 January 2007 addressed to the Government of Canada, referred to the "laudable goals of the WTO Decision and amendment" and commended Canada for having implemented the mechanism into domestic law (http://www.camr-rcam.qc.ca/review-reviser/camr_rcam_ifpma_03-eng.pdf).

the many aspects that would merit to be further elaborated. The constant review and update of the existing material could be usefully complemented by specialized capacity building activities organized by the WTO Secretariat on demand of one or more WTO Members.

Abbreviations

2003 Decision	General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health
2005 Protocol	General Council Decision of 6 December 2005 adopting the Protocol Amending the TRIPS Agreement
CL	Compulsory licence
Doha Declaration	Doha Declaration on the TRIPS Agreement and Public Health
EML	WHO Essential Medicines List
EU	European Union
FYROM	Former Yugoslav Republic of Macedonia
IC	Importing country
INN	International non-proprietary names
IPRs	Intellectual Property Rights
LDC	Least developed country
MoH	Ministry of Health
NGO	Non-governmental organization
OECD	Organization for Economic Cooperation and Development
ODA	Official development assistance (OECD list)
RTA	Regional Trade Agreement
SIPO	State Intellectual Property Office (China)
SPC	Supplementary Protection Certificate
TPKM	Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UN	United Nations
UNHDI	United Nations Human Development Index
VL	Voluntary licence
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

WTO Members' and Observer Implementing Measures



WTO Members / Observer with specific legislation to act as exporters

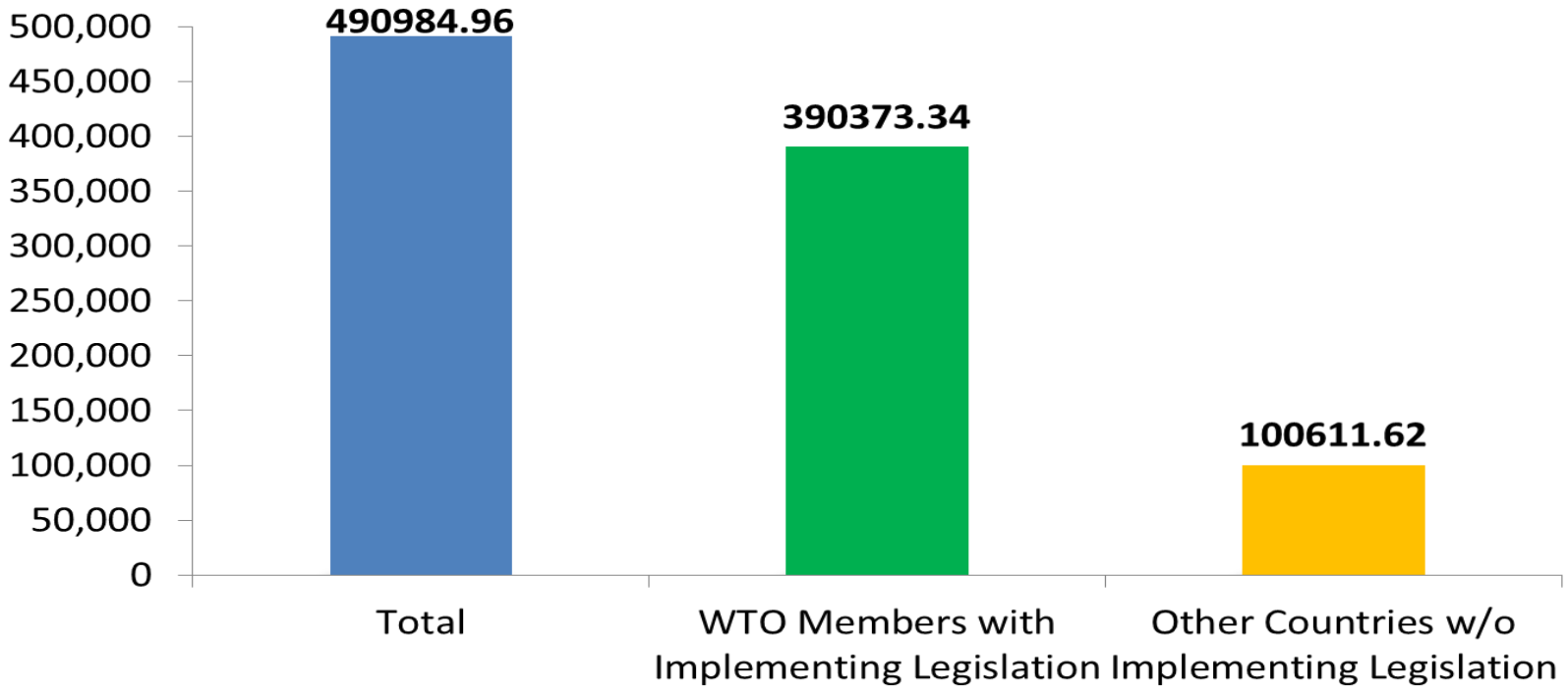
WTO Members with specific legislation to act as exporters and importers

WTO Members with specific legislation to act as importers

Major Exporters of Pharmaceutical Products in 2013

Source: ITC Trade Map (http://www.trademap.org/Country_SelProduct_Map.aspx)

Worldwide Pharmaceutical Exports in 2013 for 149 Countries (in US$MN)



Source: IFPMA, The Pharmaceutical Industry and Global Health, Facts and Figures 2014 (http://www.ifpma.org/fileadmin/content/Publication/2014/IFPMA_-_Facts_And_Figures_2014.pdf)

ANNEX IV

SUMMARY OVERVIEW OF IMPLEMENTING MEASURES

Albania	
Legal Basis	Law No.9947 of 7 July 2008 on Industrial Property (Article 50)
Notification to TRIPS Council	IP/N/1/ALB/I/2
Scope	Export
Diseases/Products/IPRs Covered	• Products needed to address public health problems • Pharmaceutical products covered by patents or SPC
Eligible Importing Countries	No specific provision
Competent authority for CL grant	Court
Pre-Grant Conditions	Prior efforts to obtain VL on reasonable commercial terms and conditions, within a reasonable period of time
Quantity of Production Authorized	Not to exceed what is necessary to meet IC demand, taking into account amount of products manufactured under CL granted elsewhere
Duration of the Compulsory Licence	• Valid until the end of the period designated by the court or until the end of the patent term • Court may, on reasoned request, cancel CL
Remuneration	• Adequate compensation, taking into account the economic value of the authorization • To be agreed between right holder and licensee, or otherwise to be set by the court
Notification / Publication Requirements	No specific provision
Transparency and Safeguards Against Diversion	No specific provision
Other	Subject to implementing regulation (not available)
Regulatory Approval	No specific provision
Good Faith Clause	No
Acceptance of TRIPS Protocol	28 January 2009 (WT/Let/639) – after adoption of implementing legislation

Australia	
Legal Basis	Intellectual Property Laws Amendment Act 2015, Act No. 8 of 2015
Notification to TRIPS Council	• No • Available on WIPO Lex and at: http://www.comlaw.gov.au/Details/C2015A00008
Scope	Export
Diseases/Products/IPRs Covered	• Public health problems • Pharmaceutical products covered by product or process patents • Includes active ingredients necessary for manufacturing such products and diagnostic kits
Eligible Importing Countries	Schedule 1 - to be prescribed by regulation
Competent authority for CL grant	Federal Court
Pre-Grant Conditions	• Pharmaceutical product needed in IC to address public health problem in circumstances of extreme urgency or by public non-commercial use • In case of public non-commercial use, prior effort to obtain VL on reasonable terms and conditions to be made by applicant, limited to 30 days
Quantity of Production Authorized	• Limited to needs of IC • May be amended upon application to Federal Court
Duration of the Compulsory Licence	• Limited to the period of time determined by Federal Court as necessary to address public health problems in IC • May be amended upon application to Federal Court • May be revoked upon application to Federal Court if circumstances that led to CL grant have ceased to exist, licensee has not complied with terms of licence, or remuneration has not been paid by licensee, provided that legitimate interests of licensee or IC are not adversely affected
Remuneration	• Amount agreed between patent right holder and licensee • In the absence of such agreement, amount determined by Federal Court to be adequate remuneration taking into account the economic value to the eligible importing country • Application to amend a determination by Federal Court may, for example, be made in case of amendment of CL terms or revocation of CL • In case of extreme urgency in eligible IC, patented invention may be exploited under CL independently of whether remuneration has been agreed/determined
Notification / Publication Requirements	To be prescribed by regulation which may stipulate different notification requirements for importation of pharmaceutical products into IC of different kinds
Transparency and Safeguards Against Diversion	• CL application to include statement by IC or by the importer acting on behalf of, and with the authorisation of, the IC that it will take reasonable measures in accordance with para.4 of 2003 Decision • Federal Court to be satisfied that CL applicant, IC and importer take all reasonable measures to prevent use of a pharmaceutical product manufactured under CL for a purpose other than the purpose of addressing public health problems in IC in situations of extreme urgency of public non-commercial use • Entire production under CL to be exported to IC • Labelling and marking of the product in accordance with regulations • Licensee to post shipment information on website
Other	CL grant to be consistent with international agreements

Regulatory Approval	For the purpose of assessing an application by the right holder for an extension of the patent term pursuant to Article 70 of the Patent Act, inclusion in Australian Register of Therapeutic Goods to be disregarded if it was sought for the sole purpose of exporting goods to address public health problem in IC in situations of extreme urgency or public non-commercial use Under the Therapeutic Goods Act 1989, medicines that are manufactured under a special compulsory licences exclusively for export to developing countries would usually not be required to be entered in the Australian Register of Therapeutic Goods and would thus be exempted from obtaining prior marketing approval in Australia. This is based on the assumption that such medicines would not be for commercial supply as they are supposed to be used to address a public health problem in the eligible importing country in circumstances of extreme urgency or in situations of public non-commercial use. In other cases where such conditions do not prevail, the Therapeutic Goods Act 1989 would require medicines produced for export only to be entered in the Register as listed medicines; however, these medicines are subject to less stringent approval requirements than those that are registered for the purpose of being marketed in Australia.
Good Faith Clause	CL application to be made in good faith (meaning not further defined)
Acceptance of TRIPS Protocol	(WT/Let/593) – before adoption of implementing legislation

Botswana	
Legal Basis	Industrial Property Act, Act No.8 of 2010 (Sections 31, 32)
Notification to TRIPS Council	IP/N/1/BWA/I/3
Scope	• Export and import • Implements special waiver for RTAs in line with para.6 of the 2003 Decision and Article 31*bis*(3) of the amended TRIPS Agreement
Diseases/Products/IPRs Covered	No specific provision; see reference to paras.1 and 3 of Article 31*bis* TRIPS
Eligible Importing Countries	No specific provision; see reference to paras.1 and 3 of Article 31*bis* TRIPS
Competent authority for CL grant	Minister for Trade and Industry
Pre-Grant Conditions	• Minister to hear patentee and any other interested party • Prior efforts to be made by applicant to obtain VL on reasonable commercial terms and conditions, within reasonable time-frame
Quantity	CL to include an estimate of the quantities to be imported during the term of the licence. However, such estimate shall not limit the quantity required to address the public health problem through import of the pharmaceutical product concerned
Duration of the Compulsory Licence	CL may be revoked if circumstances leading to the grant cease to exist and are unlikely to recur or if the licensee fails to comply with the terms of the decision
Remuneration	• No specific provision for the calculation of remuneration in the case of use of the System as exporter • Obligation to pay remuneration to right holder is waived in case of import of a pharmaceutical product manufactured under a CL in the exporting country for which the right holder has already been compensated
Notification / Publication Requirements	No specific provision
Transparency and Safeguards Against Diversion	No specific provision
Other	Makes explicit reference to waiver for RTAs
Regulatory Approval	No specific provision
Good Faith Clause	No
Acceptance of TRIPS Protocol	18 June 2014 (WT/Let/953) – after adoption of implementing legislation

Brunei Darussalam	
Legal Basis	Patents Order 2011, as published in Government Gazette of 17 October 2011 (Art.58, 61, 62, 63)
Notification to TRIPS Council	• No • Available on WIPO Lex
Scope	Import in situations of extreme urgency
Diseases/Products/IPRs Covered	Any relevant health product
Eligible Importing Countries	Not addressed (as the System is only implemented to act as an IC)
Competent authority for CL grant	In case of government use: Government (whereas the court would be competent for the grant of CL to remedy anti-competitive practices)
Pre-Grant Conditions	Situation of national emergency or other circumstances of extreme urgency
Quantity	Indirectly addressed by reference to para.2(a) of the 2003 Decision
Duration of the Compulsory Licence	• Limited by the period of national emergency or other circumstances of extreme urgency • CL may be terminated by the court if circumstances that gave rise to the CL have ceased to exist or are unlikely to recur
Remuneration	No remuneration to be paid if the patentee has received any other remuneration in respect of the product concerned
Notification / Publication Requirements	• Right holder to be promptly informed of use based on the grant of a CL granted for public non-commercial purpose; in situations of extreme urgency, this shall be done as soon as reasonably practicable • Mandatory prior notification to the TRIPS Council pursuant to paragraph 2(a) of the 2003 Decision / the Annex to the TRIPS Agreement as amended by the 2005 Protocol
Transparency and Safeguards Against Diversion	Prohibition of re-export
Other	./.
Regulatory Approval	No specific provision
Good Faith Clause	No
Acceptance of TRIPS Protocol	10 April 2015 (WT/Let/1037) – after adoption of implementing legislation

Burundi	
Legal Basis	Law No. 1/13 of 28 July 2009 Relating to Industrial Property in Burundi (Chapter VII)
Notification to TRIPS Council	• No • Available on WIPO Lex
Scope	Export and import
Diseases/Products/IPRs Covered	See general reference to 2003 Decision
Eligible Importing Countries	See general reference to 2003 Decision
Competent authority for CL grant	Minister responsible for trade (whereas courts are competent for the grant of standard CLs)
Pre-Grant Conditions	• CL grant to be decided after hearing the patent owner and any interested persons • Applicant to submit evidence of prior attempt to obtain VL on reasonable terms and conditions during a period of no more than six months; this does not apply in situations of extreme urgency, public non-commercial use or anti-competitive practices
Quantity	See general reference to 2003 Decision
Duration of the Compulsory Licence	CL may be terminated if circumstances leading to the grant cease to exist and are unlikely to recur or if the licensee fails to comply with the terms of the decision
Remuneration	Decisions to take into account the procedures and conditions set by the 2003 Decision
Notification / Publication Requirements	See general reference to 2003 Decision
Transparency and Safeguards Against Diversion	See general reference to 2003 Decision
Other	./.
Regulatory Approval	No specific provision
Good Faith Clause	No
Acceptance of TRIPS Protocol	No

Canada	
Legal Basis	Amendment to Patent Act and Food and Drugs Act, Use of Patented Products for International Humanitarian Purposes Regulations, May 2005
Notification to TRIPS Council	• IP/N/1/CAN/1/Add.2; IP/N/1/CAN/P/5 to 7; IP/N/1/CAN/U/4 • Summary provided in IP/C/W/464
Scope	Export
Diseases/Products/IPRs Covered	• Products as listed in Schedule 1 of Patent Act, composed primarily of patented products on WHO EML. • Can be amended by expert committee (since 2005: two amendments to include Tamiflu and triple combination therapy for HIV/AIDS).
Eligible Importing Countries	• Any country listed in Schedules 2 to 4 of Patent Act • As regards WTO Members, all LDCs are automatically included, as well as Members having notified the TRIPS Council of their intention to use the System (see para.1(b) of 2003 Decision); partial opt-out Members are only covered in situations of public health emergency; full opt-out Members are excluded • All non-WTO LDCs and non-WTO developing countries eligible for development assistance according to OECD having notified the Government of Canada of their intention to use the System
Competent authority for CL grant	Commissioner of Patents
Pre-Grant Conditions	• Notification in line with para.2(a) of 2003 Decision made by IC to TRIPS Council or, for non-WTO Members, to the Government of Canada • Prior effort to obtain VL made by CL applicant, limited to 30 days • CL applicant to submit details on product, quantity, details of relevant patent(s) and name of patentee(s), IC notification to TRIPS Council or to the Government of Canada, patent status of product concerned in IC, identity of purchaser • Fees for CL application are waived
Quantity	Limited to CL application or needs notified by IC, whichever less
Duration of the Compulsory Licence	• 2 years; once renewable if the quantities of the pharmaceutical product authorized for production and export were not exported before the date of expiry of the first authorisation • Licence can be terminated earlier by Federal Court, for example, if diversion occurs
Remuneration	• Adequate remuneration to be paid by licensee in accordance with para.3 of 2003 Decision, ranging between 0.02% and 3.5% • Calculation linked to IC level of development (UNHDI) and value of contract
Notification / Publication Requirements	• Commissioner of Patents to post on the IP Office's website each application for authorization • Patent holder to be notified of CL
Transparency and Safeguards Against Diversion	• Distinguishing features to be applied, i.e. distinct labelling, marking ("XCL" mark), packaging, colouring (see para.2(b)(ii) of 2003 Decision) • Licensee to post information on website before exporting (see para.2(b)(ii) of 2003 Decision). 15 days prior to export, licensee to provide notice to the patent holder, IC and purchaser, specifying the quantity and every known party handling the product while in transit

Other	• If content requirements and conditions are met, the Commissioner is required to grant CL to manufacture and export the product in question • Explicit inclusion of NGOs as purchasers of licensed pharmaceutical product, if so authorized by IC • Statutory review in 2007 found that no amendment to Canada's implementing legislation was required. Legislative proposals to reform and streamline Canada's Access to Medicines Regime have been submitted since then, but none of them has been adopted
Regulatory Approval	Same safety, quality and efficacy standards as for domestic consumption apply; subject to expedite approval procedure by MoH and possibility to remit fees for regulatory review process
Good Faith Clause	Explicit reference to Chairman's Statement, providing patent holder with right to challenge export licence where there is good cause to believe in predominantly commercial nature (i.e. if average price is equal to or greater than 25% of average price in Canada, patentee may apply to Federal Court to make an order)
Acceptance of TRIPS Protocol	16 June 2009 (WT/Let/646) – after adoption of implementing legislation

China, PR	
Legal Basis	• Amendment to the Patent Law, adopted on 27 December 2008 and entered into force on 1 October 2009 (Articles 49, 50, 53, 57) • Revised Rules for the Implementation of the Patent Law (Chapter V) • Order of the Director of the State Intellectual Property Office No.64, Measures for Compulsory Licensing of Patent Implementation, in force as of 1 May 2012 (Articles 7, 13, 23, 24)
Notification to TRIPS Council	• IP/N/1/CHN/P/2 and IP/N/1/CHN/P/3 • 2012 Measures not notified to TRIPS Council, available on WIPO Lex
Scope	• Export • Import in situations of national emergency or other circumstances of extreme urgency, or if public interest so requires
Diseases/Products/IPRs Covered	• Public health problems • Any pharmaceutical product subject to product or process patents, including active ingredients and diagnostic kits
Eligible Importing Countries	• LDCs • WTO Members, including developed and developing countries, that have notified their intention to use the System as importers
Competent authority for CL grant	State Intellectual Property Office (SIPO)
Pre-Grant Conditions	• Applicant to submit information regarding the IC, the medicines needed and, where a patent exists in the IC, the grant of CL • Right holder to be invited to make observations prior to grant of CL within time-limit specified by SIPO • But: no requirement to make prior efforts to obtain VL within reasonable period of time applies
Quantity	Not to exceed the amount needed by the IC
Duration of the Compulsory Licence	• Must be specified in the decision according to the reasons justifying the grant of the CL • CL can be terminated by State Council when the grounds for the CL cease to exist
Remuneration	• Reasonable royalties, to be handled in accordance with the provisions of the relevant international treaties to which China is a party[37] • To be decided by SIPO if an agreement between right holder and licensee cannot be reached
Notification / Publication Requirements	• Patent holder to be notified of CL application • Patent holder to be notified in a timely manner of CL grant by the patent administration department under the State Council • Competent department under State Council to submit notification to WTO in line with para.2(c) of 2003 Decision

[37] The term "relevant international treaties" is meant to refer, in particular, to the Doha Declaration on the TRIPS Agreement and Public Health, the 2003 Decision and the 2005 Protocol Amending the TRIPS Agreement. The purpose is to avoid that remuneration is paid twice to the right holder where compulsory licences are granted both in the importing and the exporting country.

Transparency and Safeguards Against Diversion	• Entirety of the products must be exported • Distinguishing features and special marking and labelling to be applied, provided it does not negatively impact on the price • Licensee to publish amount of medicines to be sent to the IC and information about distinguishing features on its webpage or WTO webpage prior to shipment
Other	Decision to grant CL to comply with the provisions of relevant international treaties[38] on granting CL for the purpose of addressing public health issues
Regulatory Approval	No specific provision
Good Faith Clause	No
Acceptance of TRIPS Protocol	28 November 2007 (WT/Let/607) – prior to adoption of implementing legislation

[38] The term "relevant international treaties" is meant to refer, in particular, to the Doha Declaration on the TRIPS Agreement and Public Health, the 2003 Decision and the 2005 Protocol Amending the TRIPS Agreement.

European Union	
Legal Basis	Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems
Notification to TRIPS Council	IP/N/1/EEC/P/5
Scope	Export
Diseases/Products/IPRs Covered	• Public health problems • Any pharmaceutical product[39] covered by product or process patents or SPC • Includes medicinal products (covering vaccines), active ingredients and diagnostic kits ex vivo (see para.1(a) of 2003 Decision)
Eligible Importing Countries	• LDCs on the UN list • Any other WTO Members who have notified TRIPS Council of their intention to use the System as importers (see para.1(b) of 2003 Decision) • Non-WTO Members listed in the OECD Development Assistance Committee's list of low-income countries with a GDP of less than 745 USD that have notified their intention to use the System to the EU Commission • Excluded: WTO Members that have declared not to use the System as importers
Competent authority for CL grant	• National authorities which have competence to grant CL under national patent laws, unless determined otherwise by EU member States • Member States to notify designated competent authorities to the EU Commission. To be published in the Official Journal of the EU
Pre-Grant Conditions	• LDCs and developing country WTO Members: notification of specific needs made to TRIPS Council in accordance with para.2(a) of 2003 Decision, or, in the case of non-WTO Members, to the EU Commission • Applicant to provide information on: applications for CL filed in other countries for the same product; the INN; the IC; the quantity required; evidence of prior negotiations with the right holder; evidence of a request by the IC, an NGO acting with the formal authorization of the IC, or UN bodies or other international health organizations acting with the formal authorization of the IC • Prior effort to obtain VL made by generic manufacturer, limited to 30 days, not applicable in circumstances set out in Art.31(b) TRIPS • Patent holder to be provided opportunity to comment prior to grant of CL
Quantity	• Total amount of production not to exceed IC needs as notified to WTO/EU Commission (see para.2(b)(i) of 2003 Decision), taking into account amount of products manufactured under CL elsewhere • Following IC notification that quantity has become insufficient, CL conditions may be modified by means of a simplified and accelerated procedure to permit manufacture and export of additional quantities
Duration of the Compulsory Licence	• Determined by the needs stated by the IC, to be indicated in CL (see para.2(c) of 2003 Decision) • May be reviewed (e.g. suspension by the competent authority in cases of appeal or modification of conditions through a simplified procedure)
Remuneration	• To be paid by licensee • Max. 4% of total price paid by IC in emergency cases • Otherwise to be determined in accordance with factors in para.3 of 2003 Decision, as well as humanitarian or non-commercial circumstances relating to CL

[39] As defined in Article 1(2) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Medicinal Products for Human Use

Notification / Publication Requirements	• Patent holder to be notified of CL application • EU Commission to notify TRIPS Council of CL and conditions attached to it (see para.2(c) of 2003 Decision) • Termination of CL to be notified to TRIPS Council
Transparency and Safeguards Against Diversion	• Distinguishing features to be applied, unless significant price impact (see para.2(b)(ii) of 2003 Decision); packaging and literature with special marking; characteristics to be made available to customs authorities • Licensee to post information on website regarding the quantities and features of the product(s) concerned (see para.2(b)(iii) of 2003 Decision) • If termination of CL is decided, IP Office must indicate a period of time for the licensee to redirect pharmaceutical products concerned to a country in need of such products • Competent authority may request access to books and records kept by the licensee in order to check whether the terms of the licence have been met • Prohibition of imports into the EU of products manufactured under special CL, except for purpose of re-export to IC. Details for customs intervention regulated
Other	• Possibility of re-export within RTAs recognized (see para.6(i) of 2003 Decision) • Recital 13 recognizes the utmost desirability of promoting the transfer of technology and capacity-building to countries with insufficient or no manufacturing capacities in order to facilitate local production • Mandatory review every three years (not done so far) • For further details at national level, see also implementing measures in EU member States
Regulatory Approval	• Licensee may avail himself of EU/national scientific opinion procedures • Test data exclusivity waived in case of generic medicines
Good Faith Clause	• Recital (6) explicitly refers to the intention of the system to address public health problems, stating that it should be used in good faith and not to pursue industrial or commercial policy objectives • Non-WTO Members to make explicit statement that System will only be used to address public health problems and not as an instrument to pursue industrial or commercial policy objectives; CL may be terminated if IC fails to honour this commitment
Acceptance of TRIPS Protocol	30 November 2007 (WT/Let/608) – after adoption of implementing legislation

EU - Belgium	
Legal Basis	• Patent Act (Lois sur les brevets d'invention), as updated on 22 December 2008 (Article 31ter) • See also the European Union's Regulation (EC) No 816/2006 of 17 May 2006 which implements the WTO mechanism into the EU's legal framework and is directly applicable in all EU member States
Notification to TRIPS Council	• No • Available on WIPO Lex
Scope	Export
Diseases/Products/IPRs Covered	• Public health problems • Pharmaceutical Products
Eligible Importing Countries	No specific provision; see EU Regulation (EC) No 816/2006
Competent authority for CL grant	• The King who may also designate competent authorities to act in line with EU Regulation (EC) No 816/2006 • Decisions to grant, review, terminate CL to be taken by Council of Ministers
Pre-Grant Conditions	No specific provision; see EU Regulation (EC) No 816/2006
Quantity	No specific provision; see EU Regulation (EC) No 816/2006
Duration of the Compulsory Licence	No specific provision; see EU Regulation (EC) No 816/2006
Remuneration	No specific provision; see EU Regulation (EC) No 816/2006
Notification / Publication Requirements	No specific provision; see EU Regulation (EC) No 816/2006
Transparency and Safeguards Against Diversion	No specific provision; see EU Regulation (EC) No 816/2006
Other	• Provisions and procedures applying to the grant of standard CL do not apply to special CL for export of medicines • The King can establish formal and administrative requirements to ensure an effective treatment of applications for the grant of special CLs
Regulatory Approval	No specific provision; see EU Regulation (EC) No 816/2006
Good Faith Clause	No specific provision; see EU Regulation (EC) No 816/2006
Acceptance of TRIPS Protocol	See European Union

EU - Croatia	
Legal Basis	• Patent Act and Act on Amendments to the Patent Act 2009 (Article 69a-h)[40] • See also the European Union's Regulation (EC) No 816/2006 of 17 May 2006 which implements the WTO mechanism into the EU's legal framework and is directly applicable in all EU member States
Notification to TRIPS Council	IP/N/1/HRV/P/2
Scope	Export
Diseases/Products/IPRs Covered	• Public health problems • Pharmaceutical products covered by patents or SPC • Includes medicinal products for human use to treat or prevent diseases, active ingredients and diagnostic kits ex vivo
Eligible Importing Countries	• LDCs appearing on UN list • WTO Members which have notified TRIPS Council of their intention to use the System as importers • Non-WTO Members listed in the OECD Development Assistance Committee's list of low-income countries with a GDP of less than 745 USD that have notified their intention to use the System to the IP Office • Excluded: WTO Members that have declared not to use the System as importers
Competent authority for CL grant	Court
Pre-Grant Conditions	• Notification of specific needs made by IC to TRIPS Council or, in the case of non-WTO Members, to the IP Office • Where patent exists in the IC: CL for import/sale/distribution has been granted • Prior effort to obtain VL made by CL applicant, limited to 30 days, not applicable in circumstances set out in Art.31(b) TRIPS • Applicant to provide information on: applications for CL filed in other countries for the same product; the INN; the IC; the quantity required; evidence of prior negotiations with the right holder; evidence of a request by the IC, an NGO acting with the formal authorization of the IC, or UN bodies or other international health organizations acting with the formal authorization of the IC
Quantity	• Not to exceed the quantities needed in the IC • Where CL have been granted in other exporting countries, the total amount of production under CL must not significantly exceed the amount notified by the IC • Upon notification by the IC, licensee may ask for modification of licence conditions in order to allow the manufacture and export of additional quantities; to be dealt with in expeditious proceedings by the competent court
Duration of the Compulsory Licence	• Limited to the purpose for which the CL is granted • Termination may be requested if licensing conditions are not complied with
Remuneration	• Max. 4% of total price paid by IC in emergency cases • Otherwise to be determined in accordance with factors in para.3 of 2003 Decision, as well as humanitarian or non-commercial circumstances relating to CL
Notification / Publication Requirements	Court to notify TRIPS Council of CL and conditions attached to it (see para.2(c) of 2003 Decision)

[40] Please note that Croatia's implementing measures of 2009 and the acceptance of the TRIPS amendment of 6 December 2010 predate its accession to the EU on 1 July 2013.

Transparency and Safeguards Against Diversion	• No product produced under CL for export to be offered for sale or put on the market in other countries, except where re-export to other RTA members takes place under the RTA waiver • Prohibition of import into Croatia and EU member States, except for purpose of re-export to IC. Details for customs intervention regulated. Not applicable to imports of small quantities contained in traveller's personal luggage • Distinguishing features to be applied, unless significant price impact (see para.2(b)(ii) of 2003 Decision); packaging and literature with special marking required; characteristics to be made available to customs authorities • Licensee to post information on website (see para.2(b)(iii) of 2003 Decision) • Court may request access to books and records kept by the licensee in order to check whether the terms of the licence have been met
Other	./.
Regulatory Approval	No specific provision
Good Faith Clause	• Explicitly only provided for non-WTO Members using the System • CL may be terminated if the System is used as an instrument to pursue industrial or commercial policy objectives
Acceptance of TRIPS Protocol	6 December 2010 (WT/Let/747) – after adoption of implementing legislation

EU - Estonia	
Legal Basis	• Patents Act (Act No. RT I 1994, 25, 406, as last amended by Act No. RT I 28.12.2011 of 7 December 2011) • See also the European Union's Regulation (EC) No 816/2006 of 17 May 2006 which implements the WTO mechanism into the EU's legal framework and is directly applicable in all EU member States
Notification to TRIPS Council	• No • Available on WIPO Lex
Scope	[Import and] Export
Diseases/Products/IPRs Covered	Reference to EU Regulation (EC) No 816/2006
Eligible Importing Countries	Reference to EU Regulation (EC) No 816/2006
Competent authority for CL grant	Court
Pre-Grant Conditions	Reference to EU Regulation (EC) No 816/2006
Quantity	Reference to EU Regulation (EC) No 816/2006
Duration of the Compulsory Licence	Reference to EU Regulation (EC) No 816/2006
Remuneration	Reference to EU Regulation (EC) No 816/2006
Notification / Publication Requirements	Reference to EU Regulation (EC) No 816/2006
Transparency and Safeguards Against Diversion	Reference to EU Regulation (EC) No 816/2006
Other	Government use of patented invention possible in the event of an epidemic within the meaning of the Communicable Diseases Prevention and Control Act and in emergency situations within the meaning of the Emergency Situation Act; conditions for authorization and remuneration to be paid to right holder to be provided by law
Regulatory Approval	Reference to EU Regulation (EC) No 816/2006
Good Faith Clause	Reference to EU Regulation (EC) No 816/2006
Acceptance of TRIPS Protocol	See European Union

EU - Finland	
Legal Basis	• Patents Act No. 550 of 15 December 1967, as amended in January 2013 (Section 50) • See also the European Union's Regulation (EC) No 816/2006 of 17 May 2006 which implements the WTO mechanism into the EU's legal framework and is directly applicable in all EU member States
Notification to TRIPS Council	• No • Text available on the website of the Finish Patent and Registration Office at: http://www.prh.fi/en/patentit/lainsaadantoa/patenttilaki.html
Scope	No specific provision; see EU Regulation (EC) No 816/2006
Diseases/Products Covered	No specific provision; see EU Regulation (EC) No 816/2006
Eligible Importing Countries	No specific provision; see EU Regulation (EC) No 816/2006
Competent authority for CL grant	Market Court
Pre-Grant Conditions	No specific provision; see EU Regulation (EC) No 816/2006
Quantity	No specific provision; see EU Regulation (EC) No 816/2006
Duration of the Compulsory Licence	No specific provision; see EU Regulation (EC) No 816/2006
Remuneration	No specific provision; see EU Regulation (EC) No 816/2006
Notification / Publication Requirements	No specific provision; see EU Regulation (EC) No 816/2006
Transparency and Safeguards Against Diversion	No specific provision; see EU Regulation (EC) No 816/2006
Other	./.
Regulatory Approval	No specific provision; see EU Regulation (EC) No 816/2006
Good Faith Clause	No specific provision; see EU Regulation (EC) No 816/2006
Acceptance of TRIPS Protocol	See European Union

EU - France	
Legal Basis	• Intellectual Property Code, consolidated version of 1 July 2014 (Articles L613-17-1 to 2 and Article R613-25-1 to 4) • See also the European Union's Regulation (EC) No 816/2006 of 17 May 2006 which implements the WTO mechanism into the EU's legal framework and is directly applicable in all EU member States
Notification to TRIPS Council	• No • Available on WIPO Lex
Scope	Export
Diseases/Products/IPRs Covered	• Public health problems • Pharmaceutical products protected by patents or SPC
Eligible Importing Countries	Reference to EU Regulation (EC) No 816/2006
Competent authority for CL grant	• Ministry in charge of industrial property • Prior to decision, commission established in line with Article R.613-10 has to confirm that conditions established by EU Regulation (EC) No 816/2006 are met
Pre-Grant Conditions	Reference to EU Regulation (EC) No 816/2006
Quantity	• Reference to EU Regulation (EC) No 816/2006 • Explicit confirmation that CL conditions may be modified to permit manufacture and export of additional quantities in case of a notification by the IC that quantity has become insufficient
Duration of the Compulsory Licence	Reference to EU Regulation (EC) No 816/2006
Remuneration	• Reference to EU Regulation (EC) No 816/2006 • To be fixed by decision granting compulsory licence
Notification / Publication Requirements	• Patent holder and, where applicable, licensee(s) to be notified of CL application and to be provided opportunity to comment within 15 days upon receipt of the notification • Grant/termination of CL to be notified to EU Commission
Transparency and Safeguards Against Diversion	• Reference to EU Regulation 816/2006 with respect to distinguishing measures and information to be posted on website by licensee • Details of distinguishing features to be established by a decision of the director general of the national drug regulatory authority (Agence nationale de sécurité du medicament et des produits de santé) • Any act infringing the prohibition of imports of products manufactured under a special compulsory licence constitutes an act of counterfeiting that is subject to the criminal provisions in Article 615-14 of the Intellectual Property Code
Other	./.
Regulatory Approval	No specific provision; see EU Regulation (EC) No 816/2006
Good Faith Clause	No specific provision; see EU Regulation (EC) No 816/2006
Acceptance of TRIPS Protocol	See European Union

EU - Germany	
Legal Basis	• Patent Act (as amended by the Act of 31 July 2009, Section 85a) • See also the European Union's Regulation (EC) No 816/2006 of 17 May 2006 which implements the WTO mechanism into the EU's legal framework and is directly applicable in all EU member States
Notification to TRIPS Council	• No • Available on WIPO Lex
Scope	Export
Diseases/Products/IPRs Covered	• Public health problems • Pharmaceutical products protected by patents
Eligible Importing Countries	No specific provision; see EU Regulation (EC) No 816/2006
Competent authority for CL grant	Patent Court
Pre-Grant Conditions	No specific provision; see EU Regulation (EC) No 816/2006
Quantity	No specific provision; see EU Regulation (EC) No 816/2006
Duration of the Compulsory Licence	No specific provision; see EU Regulation (EC) No 816/2006
Remuneration	No specific provision; see EU Regulation (EC) No 816/2006
Notification / Publication Requirements	No specific provision; see EU Regulation (EC) No 816/2006
Transparency and Safeguards Against Diversion	No specific provision; see EU Regulation (EC) No 816/2006
Other	• Procedural steps required under certain provisions of EU Regulation (EC) No 816/2006 to be instituted by legal action • Procedural rules apply *mutatis mutandis* for procedures that are not covered by EU Regulation (EC) No 816/2006
Regulatory Approval	No specific provision; see EU Regulation (EC) No 816/2006
Good Faith Clause	No specific provision; see EU Regulation (EC) No 816/2006
Acceptance of TRIPS Protocol	See European Union

EU - Hungary	
Legal Basis	• Act XXXIII of 1995 on the Protection of Inventions by Patents (consolidated text as of 25 October 2013) (Articles 33/A and 83/A to H) • See also the European Union's Regulation (EC) No 816/2006 of 17 May 2006 which implements the WTO mechanism into the EU's legal framework and is directly applicable in all EU member States
Notification to TRIPS Council	• No • Available on WIPO Lex
Scope	Export
Diseases/Products/IPRs Covered	• Public health problems • Pharmaceutical products
Eligible Importing Countries	Reference to EU Regulation (EC) No 816/2006
Competent authority for CL grant	IP Office (as compared to standard CLs for which the court is responsible)
Pre-Grant Conditions	• Fee to be paid simultaneously with filing of CL application • In addition to requirements pursuant to EU Regulation (EC) No 816/2006, the applicant must submit patent registration number • Patentee to be provided an opportunity to comment on CL application
Quantity	Reference to EU Regulation (EC) No 816/2006
Duration of the Compulsory Licence	• Until expiration of the term of validity fixed by IP Office or the lapse of patent protection • To be indicated in CL • CL may be reviewed or modified upon request by the right holder or licensee; grounds for modification and evidence for prior efforts to obtain VL must be submitted if the additional amount exceeds 25% of the amount authorized by the initial CL
Remuneration	• Decision to grant CL to include the remuneration to be paid to the right holder • No other specific provision; reference to EU Regulation No 816/2006
Notification / Publication Requirements	• IP office to notify the European Commission of the special conditions applying to the grant of a CL in line with para.2(c) of the 2003 Decision or of its termination • IP office to notify the European Commission when the pharmaceutical administrative authority has decided to prohibit the import of products produced under the System.
Transparency and Safeguards Against Diversion	• IP Office to post details regarding distinguishing features applied by licensee on its website • IP Office to inform Customs and the pharmaceutical administrative authority of the grant or termination of CL in Hungary or other EU member States • If termination of CL is decided, IP Office must indicate a period of time for the licensee to redirect pharmaceutical products concerned to a country in need of such products • IP Office to deal with requests regarding access to books and records kept by the licensee in order to check whether the terms of the licence have been met • Pharmaceutical administrative authority to prohibit import of products produced under the System into Hungary, and to inform the IP Office of such decisions

Other	./.
Regulatory Approval	No specific provision; see EU Regulation (EC) No 816/2006
Good Faith Clause	No specific provision; see EU Regulation (EC) No 816/2006
Acceptance of TRIPS Protocol	See European Union

EU - Ireland	
Legal Basis	• European Communities (Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems) Regulations 2008, Statutory Instruments No. 408 of 2008 • See also the European Union's Regulation (EC) No 816/2006 of 17 May 2006 which implements the WTO mechanism into the EU's legal framework and is directly applicable in all EU member States
Notification to TRIPS Council	• No • Available on WIPO Lex
Scope	Export
Diseases/Products/IPRs Covered	• Public health problems • Medicinal products
Eligible Importing Countries	No specific provision; see EU Regulation (EC) No 816/2006
Competent authority for CL grant	• Controller of Patents, Designs and Trade Marks • High Court is designated as appeals body
Pre-Grant Conditions	• Right holder shall be given an opportunity to comment and provide relevant information within reasonable period of time • Applicant to provide (see Schedule attached to Regulations): (i) information on: number of the Patent/SPC concerned; name and address of the right holder; product identity (INN or other description of the product); duration of the licence sought; quantity to be produced; the IC; details of applications made in other countries; authorized agent (if any); and the facts and grounds upon which the request is based (ii) evidence regarding (i) the quantity required by the IC, an NGO or an IGO acting with the formal authorization of the IC; and (ii) prior negotiation with the right holder
Quantity	No specific provision; see EU Regulation (EC) No 816/2006
Duration of the Compulsory Licence	No specific provision; see EU Regulation (EC) No 816/2006
Remuneration	No specific provision; see EU Regulation (EC) No 816/2006
Notification / Publication Requirements	No specific provision; see EU Regulation (EC) No 816/2006
Transparency and Safeguards Against Diversion	• Irish Medicines Board is designated as competent authority under Article 14(1) of EU Regulation (EC) No 816/2006 to review whether pharmaceutical products manufactured under a special CL are imported into the EU • See also EU Regulation (EC) No 816/2006
Other	./.
Regulatory Approval	No specific provision; see EU Regulation (EC) No 816/2006
Good Faith Clause	No specific provision; see EU Regulation (EC) No 816/2006
Acceptance of TRIPS Protocol	See European Union

EU - Latvia	
Legal Basis	• Cabinet Regulation No 76 of 5 February 2008, Regulations of the Health Inspectorate (Section 3.15.3) • See also the European Union's Regulation (EC) No 816/2006 of 17 May 2006 which implements the WTO mechanism into the EU's legal framework and is directly applicable in all EU member States
Notification to TRIPS Council	• No • Text available on the website of the Health Inspectorate of Latvia at: http://www.vi.gov.lv/en/start/_142/regulations-of-the-health-inspectorate
Scope	No specific provision; see EU Regulation (EC) No 816/2006
Diseases/Products Covered	No specific provision; see EU Regulation (EC) No 816/2006
Eligible Importing Countries	No specific provision; see EU Regulation (EC) No 816/2006
Competent authority for CL grant	No specific provision
Pre-Grant Conditions	No specific provision; see EU Regulation (EC) No 816/2006
Quantity	No specific provision; see EU Regulation (EC) No 816/2006
Duration of the Compulsory Licence	No specific provision; see EU Regulation (EC) No 816/2006
Remuneration	No specific provision; see EU Regulation (EC) No 816/2006
Notification / Publication Requirements	No specific provision; see EU Regulation (EC) No 816/2006
Transparency and Safeguards Against Diversion	Health Inspectorate operates as the competent authority under Article 14 of EU Regulation 816/2006 that must be informed of action taken by customs authorities
Other	./.
Regulatory Approval	No specific provision; see EU Regulation (EC) No 816/2006
Good Faith Clause	No specific provision; see EU Regulation (EC) No 816/2006
Acceptance of TRIPS Protocol	See European Union

EU - United Kingdom	
Legal Basis	• The Patents Act 1977 (as amended by The Patents (Compulsory Licensing and Supplementary Protection Certificates) Regulations 2007) (see also unofficial consolidation produced by Patents Legal Section, 1 October 2013) • The Patents Rules 2007 • See also the European Union's Regulation (EC) No 816/2006 of 17 May 2006 which implements the WTO mechanism into the EU's legal framework and is directly applicable in all EU member States
Notification to TRIPS Council	• No • Available on WIPO Lex
Scope	Export
Diseases/Products/IPRs Covered	• Public Health Problems • Pharmaceutical Products
Eligible Importing Countries	No specific provision; see EU Regulation (EC) No 816/2006
Competent authority for CL grant	Patent comptroller
Pre-Grant Conditions	No specific provision; see EU Regulation (EC) No 816/2006
Quantity	No specific provision; see EU Regulation (EC) No 816/2006
Duration of the Compulsory Licence	No specific provision; see EU Regulation (EC) No 816/2006
Remuneration	No specific provision; see EU Regulation (EC) No 816/2006
Notification / Publication Requirements	No specific provision; see EU Regulation (EC) No 816/2006
Transparency and Safeguards Against Diversion	No specific provision; see EU Regulation (EC) No 816/2006
Other	• Application of certain procedural provisions of the Patent Act in relation to applications and other proceedings under EU Regulation (EC) No 816/2006 • Implementation of EU Regulation (EC) No 816/2006 not purported because of its direct applicability
Regulatory Approval	No specific provision; see EU Regulation (EC) No 816/2006
Good Faith Clause	No specific provision; see EU Regulation (EC) No 816/2006
Acceptance of TRIPS Protocol	See European Union

Hong Kong, China	
Legal Basis	Patent (Amendment) Ordinance No.21 of 2007 (Parts IXA and IXB)
Notification to TRIPS Council	IP/N/1/HKG/17 and IP/N/HKG/P/1/Add.6
Scope	• Export • Import in situations of extreme urgency
Diseases/Products/IPRs Covered	• Public health problems (actual or imminent) in Hong Kong, China • Pharmaceutical products covered by product or process patents • Active ingredients required for the making of a pharmaceutical product and diagnostic kits required for the use of a pharmaceutical product are included
Eligible Importing Countries	• LDC WTO Members • WTO Members that have notified the TRIPS Council of their intention to use the System
Competent authority for CL grant	Director of Health
Pre-Grant Conditions	• For imports: declaration of extreme urgency for (threatened) public health problems has to be made by Chief Executive Council; Director of Health to consider that the domestic pharmaceutical industry has no or insufficient manufacturing capacities with respect to the product needed • For exports: the applicant has to make an application to the Director of Health in writing and provide the following information and documents: name and address of applicant; name of pharmaceutical product concerned; quantity for which authorization to manufacture is sought; name of IC; duration of the CL; local patent number(s); proposed labelling, marking, packaging, colouring or shaping; licensee's website address; a copy of the written request from the eligible IC, or any representative, NGO or international health organization authorized by the eligible IC to the applicant, indicating the amount of the product requested; a copy of the IC's notification to the TRIPS Council listing the details required under para.2(a) of the 2003 Decision; a copy of notice of the intended application given to the proprietor of the patent concerned; declaration that reasonable efforts have been made to obtain VL; and documentary evidence of any CL granted by IC for import purposes • If the IC has not notified circumstances of extreme urgency to the TRIPS Council, the applicant has to make reasonable efforts to obtain a VL from the right holder on reasonable terms and conditions starting at least 28 days before submitting the CL application, and must notify the right holder of its intended application for a CL at least 14 days before doing so • If the IC has notified circumstances of extreme urgency to the TRIPS Council, the applicant has to inform the right holder at any time before the application is made or as soon as practicable thereafter • Applicant to take reasonable steps to obtain information from IC on the quantity of the patented products needed that are to be manufactured under CL in other WTO Members
Quantity	• For imports: to be specified in CL • For exports: not to exceed the amount stated in the IC notification

Duration of the Compulsory Licence	• For imports: linked to the duration of the situation of extreme urgency (to be specified by the Chief Executive in Council); to be specified in terms and conditions applying to CL • For exports: to be specified in terms and conditions applying to CL • Can be terminated if the terms and conditions for the CL to import or to export have been contravened (for both import and export CL) or if any information, document or documentary evidence specified in or accompanying the application for an export CL is false, incorrect or incomplete in any material particular (for export CL)
Remuneration	• For imports: no remuneration to be paid, if it has been paid to the right holder in the exporting country. If not and all legal remedies to recover payment of the remuneration in the exporting country have been exhausted, remuneration to be paid by the Government to the right holder. The amount shall be agreed upon between the Director of Health and the right holder and shall not exceed 4% of the total purchase price for the product payable by the licensee to the seller of the product in the exporting country, the percentage of which is subject to variation by the Secretary for Commerce and Economic Development by means of a notice published in the Gazette. In case of multiple patents for the same product, the remuneration shall be proportionately shared among all right holders. If the amount cannot be mutually agreed, the court may determine the remuneration payable to the right holder. In determining the appropriate amount of remuneration, the court has to take into account all factors relevant to the circumstances, including the economic value to Hong Kong, China of the use of the patented product imported under import CL, as well as humanitarian or non-commercial factors relevant to the CL • For exports: amount to be determined by Director of Health after taking into account of any advice given by the Director of Intellectual Property. The amount is not to exceed 4% of the total purchase price for the product payable by the eligible IC to the export compulsory licensee, the percentage of which is subject to variation by the Secretary for Commerce and Economic Development by means of a notice published in the Gazette. In case of multiple patents for the same product, the remuneration shall be proportionately shared among all right holders. Where the amount is reviewed by the court, it shall take into account all factors relevant to the circumstances, including the economic value to the eligible IC of the use of the patented pharmaceutical product exported to it under the relevant export CL, as well as humanitarian or non-commercial factors relevant to the CL
Notification / Publication Requirements	• For imports: agreement or failure to agree on remuneration to be paid to the right holder has to be advertised in official journal • For imports and exports: right holder to be notified of grant/termination of CL as soon as practicable. Notice of the terms and conditions applying to CL (in line with para.2(c) of the 2003 Decision) to be advertised in official journal, as well as termination of CL (where applicable) • For exports: right holder to be notified by the applicant for an export CL at any time before the application is made or as soon as practicable thereafter
Transparency and Safeguards Against Diversion	• For imports: re-export of pharmaceutical products imported to Hong Kong, China under the import CL is prohibited. At the end of period of extreme urgency, licensee has to take reasonable steps to recall products imported under the import CL and surrender them to the Director of Health against reimbursement of purchase price paid by the licensee or dispose of the products in such a way as may be agreed with the right holder • For imports and exports: specific labelling or marking must be applied to identify imported pharmaceutical product as manufactured under the System; special packaging, colouring or shaping must be applied to distinguish the generic medicines from originator products

Other	No liability of Government and public officers regarding the grant of CL for import or export purposes
Regulatory Approval	No specific provisions
Good Faith Clause	No
Acceptance of TRIPS Protocol	27 November 2007 (WT/Let/606) – in parallel with adoption of implementing legislation

Iceland	
Legal Basis	Regulation No. 1011/2006 on Compulsory Licenses Relating to the Export of Pharmaceutical Products to Developing Countries and to Countries Struggling with Severe Public Health Problems of 23 November 2006
Notification to TRIPS Council	• No • Available on WIPO Lex
Scope	Export
Diseases/Products/IPRs Covered	• Severe public health problems in accordance with the 2003 Decision • Pharmaceutical products covered by product or process patents or SPC • Active ingredients • Diagnostic equipment
Eligible Importing Countries	• LDCs as listed by the UN • Developing country WTO Members that have notified TRIPS Council of their intention to use the System pursuant to para.1(b) of 2003 Decision
Competent authority for CL grant	Reykjavik District Court
Pre-Grant Conditions	• Notification by IC regarding its concrete needs pursuant to para.2(a) of 2003 Decision) • Evidence of prior effort to obtain VL, limited to 30 days, or of national emergency or other circumstances of extreme urgency • Details to be submitted regarding applicant, number and name of patent or SPC concerned and its right holder(s), names of pharmaceutical products, including INNs, where available, quantity, IC and their notifications to TRIPS Council, evidence that there is no patent/SPC for the product concerned in IC, or that IC has granted / the intention to grant a CL for import • Patentee to be given an opportunity to comment prior to grant or extension of CL
Quantity	Not to exceed the needs of the IC
Duration of the Compulsory Licence	• No initial period set, extension may be requested if licensee has been unable to export quantities as permitted by CL • CL may be revoked if licensee has not fulfilled conditions outlined in CL
Remuneration	To be determined by District Court
Notification / Publication Requirements	• Patent holder to be notified as soon as possible of CL application and, where applicable, a request to extend the duration of the CL • Grant of CL to be notified to patent holder and Patent Office • CL revocation to be notified to patentee and licensee • Patent Office to record information on CL in patent register and post an announcement in the Patent Gazette • Notification of CL grant to TRIPS Council pursuant to para.2(c) of 2003 Decision and of CL revocation, where applicable, by Patent Office

Transparency and Safeguards Against Diversion	• Special labelling and packaging requirements in line with para.2(b)(ii) of 2003 Decision • Licensee to post information on website in line with para.2(b)(iii) of 2003 Decision; Patent Office and patent holder to be informed that information has been posted on website • Prohibition to sell or export products to countries other than those listed in CL • If CL is revoked, licensee to seek to distribute products as soon as possible to IC or otherwise dispose of them
Other	./.
Regulatory Approval	No specific provision
Good Faith Clause	No
Acceptance of TRIPS Protocol	No

India	
Legal Basis	Patents Act, 1970 (as amended in 2005) (Section 92A) and Patents Rules, 2003 (as amended by S.O. 1418 (E) of 28 December 2004) (Chapter XIII)
Notification to TRIPS Council	IP/N/1/IND/P/2
Scope	Export
Diseases/Products/IPRs Covered	• Public health problems • Any patented product or product manufactured through a patented process of the pharmaceutical sector, including active ingredients and diagnostic kits required for their use
Eligible Importing Countries	Any country with insufficient or no manufacturing capacity in pharmaceutical sector for the concerned product(s) to address public health problems
Competent authority for CL grant	Controller General of Patents, Designs and Trade Marks
Pre-Grant Conditions	• IC has granted CL or it has, by notification or otherwise, permitted importation of the patented pharmaceutical product(s) from India • Application for CL to set out the applicant's interest and terms and conditions of the licence that he is willing to accept
Quantity	Not prescribed by the Patents Act. But: CL is granted solely for manufacture and export of the concerned pharmaceutical product(s) to IC under such terms and conditions specified by the Controller General of Patents, Designs and Trade Marks
Duration of the Compulsory Licence	As per the terms and conditions specified by the Controller General of Patents, Designs and Trade Marks in the decision granting the CL
Remuneration	As per the terms and conditions specified by the Controller General of Patents, Designs and Trade Marks in the decision granting the CL
Notification / Publication Requirements	Terms and conditions of CL to be published by the Controller General of Patents, Designs and Trade Marks
Transparency and Safeguards Against Diversion	• No specific provision • But: CL to be granted solely for manufacture and export of the concerned pharmaceutical product(s), as per the terms and conditions specified by the Controller General of Patents, Designs and Trade Marks in the decision granting the CL which must be published. This is viewed as ensuring transparency and appropriate safeguards
Other	Decision regarding grant of CL under Section 92A is without prejudice to export of pharmaceutical product produced under CL under any other provision of the Patents Act, 1970
Regulatory Approval	• No specific provision in Patents Act, 1970 • Approval is based on Drugs & Cosmetics Act, 1940
Good Faith Clause	No
Acceptance of TRIPS Protocol	26 March 2007 (WT/Let/572) – after adoption of implementing legislation

Jordan	
Legal Basis	Amended Patent Law number 28 of 2007 (Articles 22, 23)
Notification to TRIPS Council	IP/N/1/JOR/P/2
Scope	Export
Diseases/Products/IPRs Covered	Pandemics or epidemic illnesses (in compliance with Jordan's obligations under the WTO agreements and the decisions issued pursuant thereto)
Eligible Importing Countries	Countries suffering from pandemics or epidemic illnesses (in compliance with Jordan's obligations under the WTO agreements and the decisions issued pursuant thereto)
Competent authority for CL grant	Minister of Trade and Industry
Pre-Grant Conditions	General CL conditions apply. Otherwise no specific provisions other than reference to Jordan's obligations under the WTO agreements and the decisions issued pursuant thereto
Quantity	To meet the demands in the IC. See also reference to Jordan's obligations under the WTO agreements and the decisions issued pursuant thereto
Duration of the Compulsory Licence	No specific provision. General provision applies according to which the scope and duration of the licence shall be limited to the purpose for which it was granted
Remuneration	Equitable remuneration to be paid, taking into consideration the conditions and proceedings which are present in the international agreements and decisions which apply to Jordan as a WTO Member
Notification Requirements	No specific provision; see reference to Jordan's obligations under the WTO agreements and the decisions issued pursuant thereto
Transparency and Safeguards Against Diversion	No specific provision; see reference to Jordan's obligations under the WTO agreements and the decisions issued pursuant thereto
Other	./.
Regulatory Approval	No specific provision
Good Faith Clause	No
Acceptance of TRIPS Protocol	6 August 2008 (WT/Let/630) – after adoption of implementing legislation

Korea, Republic of	
Legal Basis	Patent Act (Article 107) and Presidential Decree No. 22306 of 26 July 2010 on "Provisions Regarding the Expropriation and Implementation of the Patent Right"
Notification to TRIPS Council	• IP/N/1/KOR/P/4 (notification of Patent Act) • IP/N/1/KOR/P/7 (notification of Presidential Decree No.22306)
Scope	Import and Export
Diseases/Products/IPRs Covered	• Diseases affecting the majority of citizens in Korea or the IC • Pharmaceutical products subject to product or process patents, active ingredients and diagnostic kits
Eligible Importing Countries	• WTO Members • Non-WTO Members that are prescribed by Presidential Decree, refers to the poorest developing countries as defined by the UN General Assembly Resolution
Competent authority for CL grant	• Commissioner of the Korean Intellectual Property Office • If necessary, supported by IP Dispute Mediation Council
Pre-Grant Conditions	• For imports: (i) insufficient or no manufacturing capacity for the medicine concerned, and (ii) emergency situation in Korea • For exports: IC has notified the TRIPS Council, or, in the case of non-WTO Members, the Korean Government in accordance with para.2(a) of the 2003 Decision • Prior efforts to obtain VL from right holder must be made, except in cases of public non-commercial use • When the System is used to export medicines: applicant to submit details regarding application/patent number; title of the invention; name and address of the applicant; name and address of right holder or his licensee; purpose and grounds of the request for a CL; amount of remuneration for the licence and method and time of payment; scope of non-exclusive licences; evidence showing that prior efforts to obtain a VL on reasonable grounds have failed; name of the IC and a copy of its notification to the TRIPS Council; the name and quantity of the medicine required; evidence that the importing medicines are used to treat diseases that threaten the health of the majority of its citizens; an assessment of the economic value of the medicine concerned in the IC; as well as the address of a website where the distinguishing features, such as applied to packaging and labelling, are disclosed, or such measures are not possible or too expensive, relevant evidence to that extent • Right holder and licensee to be provided with an opportunity to comment on CL application
Quantity	No specific provision
Duration of the Compulsory Licence	No specific provision
Remuneration	For exports: decision by the Commissioner of the IP Office to be based on the economic value in the IC. The exact calculation of the amount is based on the following formula: total estimated unit sales of the product (number of products sold per year during the CL) x unit price of the product (average annual price ex factory) x market share (percentage of utilization of the patent in manufacturing products) x base rate (3%; depending on the practical value of the patents and the industrial applicability, >2% up to < 4% can be considered)
Notification / Publication Requirements	• Copy of the CL application to be submitted to right holder • Decision by the Commissioner of the Korean Intellectual Property Office to grant CL must be notified to the patentee and licensee • Decision must also be published in the Patent Gazette

Transparency and Safeguards Against Diversion	• All medicines produced under the System have to be exported to the IC • CL to specify certain conditions, including the name of the pharmaceutical product, packaging and marking measures and the address of a website that publishes information on the adjudication
Other	./.
Regulatory Approval	No specific provision
Good Faith Clause	No
Acceptance of TRIPS Protocol	24 January 2007 (WT/Let/558) – after adoption of implementing legislation

New Zealand	
Legal Basis	Patents Act 2013, Public Act 2013 No 68 (Articles 171 to 178) (entry into force: 13 September 2014)
Notification to TRIPS Council	IP/N/1/NZL/5 and IP/N/1/NZL/P/5
Scope	Export
Diseases/Products/IPRs Covered	• Public health problems in accordance with 2003 Decision, for example, an epidemic, whether actual or imminent, of HIV/AIDS, tuberculosis, malaria or other disease • Medicines, vaccines, active ingredients and diagnostic kits needed for the use of a medicine or vaccine
Eligible Importing Countries	• WTO Members as defined in para.1(b) of 2003 Decision • Non-WTO Members with insufficient or no manufacturing capacities with respect to the needed product
Competent authority for CL grant	Court
Pre-Grant Conditions	• Notification by IC made in accordance with para.2(a) of 2003 Decision, or, in the case of non-WTO Members, to the Secretary of Foreign Affairs and Trade • Prior effort to obtain VL within reasonable period of time
Quantity	No more than what the court considers necessary to meet the needs of the IC
Duration of the Compulsory Licence	• No specific provision • Termination by court if the grounds for the grant of the CL have ceased to exist
Remuneration	Economic value of the products made under CL to IC to be taken into account
Notification / Publication Requirements	Notification to TRIPS Council pursuant to para.2(c) of 2003 Decision
Transparency and Safeguards Against Diversion	• All products to be exported to IC • Special labelling and packaging requirements in line with para.2(b)(ii) of 2003 Decision • Licensee to post information on website in line with para.2(b)(iii) of 2003 Decision and to submit a statement containing the same information to the TRIPS Council for publication on the WTO website
Other	./.
Regulatory Approval	No specific provision
Good Faith Clause	No
Acceptance of TRIPS Protocol	21 October 2011 (WT/Let/832) – prior to adoption of implementing legislation

Norway	
Legal Basis	Amendment to Patents Act 1967 (Sections 49 and 50) and Regulations No.1417 of 14 December 2007 to the Norwegian Patents Act (Sections 97 to 99)
Notification to TRIPS Council	• IP/C/W/427 • 2007 Regulations not notified to TRIPS Council, available on WIPO Lex
Scope	Export
Diseases/Products/IPRs Covered	Products covered by para.1(a) of the 2003 Decision
Eligible Importing Countries	• LDCs and other WTO Members with insufficient or no manufacturing capacities that have notified TRIPS Council of intention to use the System (para.1(b) of 2003 Decision) • Non-WTO Members including LDCs and countries with insufficient or no manufacturing capacities that have submitted notification of intention to use the System to Ministry of Foreign Affairs
Competent authority for CL grant	Court or the Norwegian Competition Authority
Pre-Grant Conditions	• Notification made by IC to TRIPS Council in accordance with para.2(a) of 2003 Decision, or, in the case of non-WTO Members, to the Norwegian Ministry of Foreign Affairs • Where a patent exists in the IC, a CL has been granted or proceedings have been undertaken to obtain a CL • Prior effort to obtain VL on reasonable commercial terms within a reasonable time made by applicant, except in situations of extreme urgency or public non-commercial use (see Art.31(b) TRIPS)
Quantity	Production only for export in response to IC notification
Duration of the Compulsory Licence	No specific provision
Remuneration	To be determined by taking account of the economic value to the IC of the use of the invention
Notification / Publication Requirements	• Court or the Norwegian Competition Authority to notify TRIPS Council of CL in accordance with para.2(c) of the 2003 Decision • In case of non-WTO Members, notification to be given to the Norwegian Ministry of Foreign Affairs
Transparency and Safeguards Against Diversion	• Distinguishing features to be applied, as well as marking and labelling requirements (see para.2(b)(ii) of 2003 Decision) • Licensee to post information on website (see para.2(b)(iii) of 2003 Decision) • Manufacture and export to cease if licensee knows that products are used for purposes other than those specified in licence
Other	./.
Regulatory Approval	No specific provision
Good Faith Clause	No
Acceptance of TRIPS Protocol	5 February 2007 (WT/Let/563) – after adoption of implementing legislation

Oman	
Legal Basis	• Industrial Property Rights and their Enforcement for the Sultanate of Oman (Royal Decree No. 67/2008) (Section 13) • Regulations No. 105/2008 under the Law on Industrial Property Rights & Their Enforcement for the Sultanate of Oman (Article 37)
Notification to TRIPS Council	• For Royal Decree No. 67/2008, see IP/N/1/OMN/I/2 • Regulations No. 105/2008 only available on WIPO Lex
Scope	Export
Diseases/Products/IPRs Covered	• Public health problems • Pharmaceutical products
Eligible Importing Countries	Country with no or insufficient manufacturing capacity in accordance with 2003 Decision
Competent authority for CL grant	Minister of Commerce and Industry
Pre-Grant Conditions	• Applicant to submit evidence that prior negotiations to obtain a voluntary licence have not been successful within a maximum period of six months. This requirement does not apply in situations of extreme urgency of in cases of public non-commercial use • Right holder to be given an opportunity to submit observations with respect to CL application within 90 days • Reference to 2003 Decision
Quantity	Reference to 2003 Decision
Duration of the Compulsory Licence	• To be specified in decision granting CL • CL may be terminated if the circumstances that led to the grant have ceased to exist and are unlikely to recur or that the licensee has failed to comply with the terms of the decision
Remuneration	• To be determined by decision granting CL • Reference to 2003 Decision
Notification / Publication Requirements	• CL application to be notified to right holder • Applicant to be notified of any observations made by the right holder • Right holder to be notified of CL grant • Decision to grant CL to be published in the Official Gazette
Transparency and Safeguards Against Diversion	Reference to 2003 Decision
Other	./.
Regulatory Approval	No specific provision
Good Faith Clause	No
Acceptance of TRIPS Protocol	No

Philippines	
Legal Basis	• Chapter 2, Sections 74 and 93-A. and Chapter 4, Section 32 of Republic Act No.9502 ("Universally Accessible Cheaper and Quality Medicines Act 2008") • Rule 13 of the Implementing Rules and Regulations of 2008
Notification to TRIPS Council	IP/N/1/PHL/I/10
Scope	Import and export
Diseases/Products/IPRs Covered	• Public health problems • Patented drugs and medicines • For product coverage see also para.1(a) of the Annex to Article 31*bis* TRIPS (based on Rule 13, Section 5 and the Annex to the Implementing Rules and Regulations, incorporating the Annex to the Protocol Amending the TRIPS Agreement)
Eligible Importing Countries	• Any country with insufficient or no manufacturing capacities • Notification by IC of intention to use the System according to para.1(b) of the Annex to Article 31*bis* TRIPS (based on Rule 13, Section 5 and the Annex to the Implementing Rules and Regulations, incorporating the Annex to the Protocol Amending TRIPS)
Competent authority for CL grant	Director General of IP Office, upon written recommendation of the Secretary of the Department of Health
Pre-Grant Conditions	• Prior effort to obtain VL within reasonable period of time, not applicable in circumstances set out in Art.31(b) TRIPS • For exports: notification by IC according to para.2(a) of the Annex to Article 31*bis* TRIPS (based on Rule 13, Section 5 and the Annex to the Implementing Rules and Regulations, incorporating the Annex to the Protocol Amending the TRIPS Agreement); IC has granted CL or otherwise permitted importation from the Philippines in compliance with TRIPS
Quantity	In line with para.2(b)(i) of the Annex to Article 31*bis* TRIPS (based on Rule 13, Section 5 and the Annex to the Implementing Rules and Regulations, incorporating the Annex to the Protocol Amending the TRIPS Agreement)
Duration of the Compulsory Licence	Limited to the intended purpose
Remuneration	• To be paid either by importing or exporting country • See also para.2 of Article 31*bis* TRIPS (based on Rule 13, Section 5 and the Annex to the Implementing Rules and Regulations, incorporating the Annex to the Protocol Amending the TRIPS Agreement)
Notification / Publication Requirements	See para.2(c) of the Annex to Article 31*bis* TRIPS (based on Rule 13, Section 5 and the Annex to the Implementing Rules and Regulations, incorporating the Annex to the Protocol Amending the TRIPS Agreement)
Transparency and Safeguards Against Diversion	• For imports: licensee to exercise reasonable measures to prevent re-exportation • For exports: pursuant to paras.2(b)(ii) and (iii) of the Annex to Article 31*bis* TRIPS, distinguishing features to be applied and information to be posted on a website by the licensee (see Rule 13, Section 5 and the Annex to the Implementing Rules and Regulations, incorporating the Annex to the Protocol Amending the TRIPS Agreement)

Other	• No preliminary injunction available against special CL, except where otherwise decided by the Supreme Court • No limitation to TRIPS flexibilities in general • Without prejudice to export under standard CL
Regulatory Approval	• Bureau of Food and Drugs to ensure conformity with international quality standards of all drugs authorized for marketing in the Philippines • Imported drugs to be pre-qualified by WHO
Good Faith Clause	No
Acceptance of TRIPS Protocol	30 March 2007 (WT/Let/573) – prior to adoption of implementing legislation

Samoa	
Legal Basis	Intellectual Property Act 2011 (Section 15)
Notification to TRIPS Council	• No • Available on WIPO Lex
Scope	Import
Diseases/Products/IPRs Covered	• Public health problems • Pharmaceutical product, including ingredients and diagnostic kits
Eligible Importing Countries	Not addressed (as the System is only implemented to act as an IC)
Competent authority for CL grant	• Minister for Commerce, Industry and Labour • Review by Supreme Court
Pre-Grant Conditions	• Applicant to provide evidence that prior efforts to obtain a VL on reasonable commercial terms and conditions and within a reasonable time have failed • Right holder and any interested person to be heard by Minister
Quantity	To be specified by decision granting CL
Duration of the Compulsory Licence	• To be specified by decision granting CL • CL to be terminated if the circumstances which led to the grant have ceased to exist and are unlikely to recur or if the licensee has failed to comply with the terms of the decision
Remuneration	• No remuneration to be paid to the right holder, if compensation has already been paid in the exporting country • If no remuneration has been paid in the exporting country, adequate remuneration has to be paid to the right holder
Notification / Publication Requirements	• Intention to issue CL and conditions attached to it, including quantity of medicines needed, duration of the CL and requirement to apply distinguishing features, to be notified to TRIPS Council • Right holder to be notified as soon as practicable after CL grant
Transparency and Safeguards Against Diversion	• Specific marking and labelling to be applied in order to identify the product as being imported under the System • CL grant must not include a right to export the pharmaceutical product concerned
Other	./.
Regulatory Approval	No specific provision
Good Faith Clause	No
Acceptance of TRIPS Protocol	No

Serbia[41]	
Legal Basis	Patent Law, in force since January 2012 (Articles 30 to 37)
Notification to TRIPS Council	• No • Available on WIPO Lex
Scope	Export
Diseases/Products/IPRs Covered	• Public health problems • Pharmaceutical products covered by patents or SPC • Includes medicinal products for human use to treat or prevent diseases, active ingredients and diagnostic kits *ex vivo*
Eligible Importing Countries	• LDCs as listed by UN • WTO Members that have notified TRIPS Council of their intention to use the System as an importer • Non-WTO Members listed in the OECD Development Assistance Committee's list of low-income countries with a GDP of less than 745 USD that have notified its intention to use the System to the Government • Excluded: WTO Members that have declared not to use the System as importers
Competent authority for CL grant	Ministry of Health
Pre-Grant Conditions	• Notification of specific needs made by IC to TRIPS Council or, in the case of non-WTO Members, to the Government • Where patent exists in the IC: CL for import/sale/distribution has been granted • Prior effort to obtain VL made by CL applicant, limited to 30 days, not applicable in circumstances set out in Art.31(b) TRIPS • Applicant to provide information on: applications for CL filed in other countries for the same product; the INN; the IC; the quantity required; evidence of prior negotiations with the right holder; information on applicant and its representative; evidence of a specific request by the authorized representative of the IC, an NGO acting with the formal authorization of the IC, or UN bodies or other international health organizations acting with the formal authorization of the IC, indicating the quantity of the product required
Quantity	• Not to exceed the quantities needed in the IC • Where CL have been granted in other exporting countries, the total amount of production under CL must not exceed the amount notified by the IC
Duration of the Compulsory Licence	• To be indicated in the decision granting the CL • Modification may be requested if the IC has notified that the quantity of pharmaceutical products has become insufficient to meet its needs • Termination may be requested if licensing conditions are not complied with
Remuneration	• Max. 4% of total price paid by IC in emergency cases • Otherwise to be determined in accordance with factors in para.3 of the 2003 Decision, as well as humanitarian or non-commercial circumstances relating to CL
Notification / Publication Requirements	MoH to notify TRIPS Council of CL grant, the conditions attached to it (see para.2(c) of 2003 Decision), as well as of any modification or termination of the CL

[41] Serbia is negotiating its accession to the WTO and is therefore not legally bound by the TRIPS Agreement or any subsequent instruments, such as the 2003 Decision.

Transparency and Safeguards Against Diversion	• No product produced under CL for export to be offered for sale or put on the market in other countries, except where re-export to other RTA members takes place under the RTA waiver • Prohibition of import into Serbia, except for purpose of re-export to IC. Details for customs intervention regulated. Not applicable to imports of small quantities contained in traveller's personal luggage • Distinguishing features to be applied, unless significant price impact (see para.2(b)(ii) of 2003 Decision); packaging and literature with special marking required; characteristics to be made available to customs authorities • Licensee to post information on website (see para.2(b)(iii) of 2003 Decision) • MoH may request access to books and records kept by the licensee in order to check whether the terms of the licence have been met
Other	./.
Regulatory Approval	No specific provision
Good Faith Clause	• Explicitly only provided for non-WTO Members using the System • CL may be terminated if the System is used as an instrument to pursue industrial or commercial policy objectives
Acceptance of TRIPS Protocol	No

Singapore	
Legal Basis	Sections 2, 56, 60, 62, 66 Patents (Amendment) Act 2008
Notification to TRIPS Council	IP/N/1/SGP/4
Scope	Import
Diseases/Products/IPRs Covered	Health products referred to in para.1(a) of the 2003 Decision / Annex to 31*bis* TRIPS
Eligible Importing Countries	• LDC WTO Members • WTO Members having notified TRIPS Council of intention to use system (para.1(b) of the 2003 Decision / Annex to Article 31*bis* TRIPS)
Competent authority for CL grant	Court
Pre-Grant Conditions	National emergency / other circumstances of extreme urgency
Quantity	To be specified in notification to TRIPS Council (see reference to para.2(a) of 2003 Decision)
Duration of the Compulsory Licence	CL to be terminated by the court if the circumstances which led to the grant have ceased to exist and are unlikely to recur
Remuneration	No remuneration to be paid in respect of import and subsequent use if patentee is compensated elsewhere
Notification / Publication Requirements	• Notification to TRIPS Council pursuant to para.2(a) of 2003 Decision • Patent holder to be notified of CL as soon as reasonably practicable
Transparency and Safeguards Against Diversion	• Prohibition of export of health products imported under special CL • Prohibition of parallel imports of health products manufactured for other WTO Members qualifying as eligible members
Other	./.
Regulatory Approval	No specific provision
Good Faith Clause	No
Acceptance of TRIPS Protocol	28 September 2007 (WT/Let/594) – prior to adoption of implementing legislation

Switzerland	
Legal Basis	• Consolidated Version of Federal Law on Patents for Inventions of 25 June 1954, as amended on 1 July 2008 (Articles 40*d* and 40*e*) • Patent Regulation of 19 October 1977, as amended on 1 July 2008 (Articles 111 to 111c) • Message of the Federal Council of 23 November 2005 on the occasion of Patent Act amendment (explanatory report by the Government)
Notification to TRIPS Council	• IP/N/1/CHE/P/9 • IP/N/1/CHE/P/13
Scope	Export
Diseases/Products/IPRs Covered	• Public health problems, in particular HIV/AIDS, tuberculosis, malaria and other epidemics (see para.1 of Doha Declaration) • General reference to "patented pharmaceutical products" is further explained as including medicinal products, active ingredients, diagnostic kits and vaccines (see message of the Federal Council of 23 November 2005)
Eligible Importing Countries	• Any country with insufficient or no manufacturing capacity in pharmaceutical sector • Partial opt-out Members only in situation of public health emergency • Full opt-out Members excluded
Competent authority for CL grant	Court
Pre-Grant Conditions	• Notification made by IC to TRIPS Council, or, in the case of non-WTO Members, declaration to the Swiss IP Institute, in line with para.2(a) of 2003 Decision • Prior effort to obtain VL on reasonable commercial terms and conditions made by applicant, limited to 30 working days, not applicable in circumstances set out in Art.31(b) TRIPS • Applicant to submit: IC notification to TRIPS Council or declaration to Swiss IP Institute in the case of non-WTO Members; evidence that prior efforts to obtain VL have been made; quantity of production to be authorized under CL; if available, information about CL already obtained for the same product; distinguishing features to be applied; licensee's website address where relevant information is published
Quantity	Quantity limited to needs notified by IC (see para.2(b)(i) of 2003 Decision)
Duration of the Compulsory Licence	• Limited to the intended purpose • CL can be terminated if circumstances that led to its grant have ceased to exist
Remuneration	Adequate remuneration based on economic value of the CL to IC (see para.3 of 2003 Decision), its level of development and sanitary/humanitarian urgency. Federal Government to fix calculation method. Message of the Federal Council of 23 November 2008 provides details on a possible calculation method, based on UNHDI (see implementing legislation adopted by Canada)
Notification / Publication Requirements	• Use by WTO Members: Swiss IP Institute to notify TRIPS Council of CL and conditions attached to it (see para.2(c) of 2003 Decision) • Use by non-WTO Members: Swiss IP Institute to publish relevant data on its website

Transparency and Safeguards Against Diversion	• Distinguishing features and special marking and labelling to be applied (see para.2(b)(ii) of 2003 Decision) • Licensee to post information on website (see para.2(b)(iii) of 2003 Decision) • Entire production must be exported to IC • Reimport into Switzerland prohibited • Infringement, including by licensee, can be subject to measures under civil and criminal law (see message of the Federal Council of 23 November 2005 on the occasion of Patent Act amendment)
Other	No preliminary injunction available against special CL for export purposes
Regulatory Approval	• Licensee required to obtain manufacturing approval, to ensure respect of Good Manufacturing Practices • Marketing approval for domestic consumption not required (see message of the Federal Council of 23 November 2005 on the occasion of Patent Act amendment)
Good Faith Clause	No
Acceptance of TRIPS Protocol	13 September 2006 (WT/Let/547) – prior to adoption of implementing legislation

Chinese Taipei	
Legal Basis	Patent Act as amended in 2013 (Articles 90 and 91)
Notification to TRIPS Council	IP/N/1/TPKM/P/3 (Subsequent amendments to the Patent Act in 2013 and 2014 were notified in WTO Documents IP/N/1/TPKM/P/4 and 5, but do not affect the implementation of the Paragraph System)
Scope	Export
Diseases/Products/IPRs Covered	• HIV/AIDS, tuberculosis, malaria and other epidemics • Pharmaceutical products
Eligible Importing Countries	Countries with insufficient or no manufacturing capacities in pharmaceutical sector, including both WTO Members and non-WTO Members
Competent authority for CL grant	Patent Agency
Pre-Grant Conditions	• Prior efforts to obtain VL have not been successful within reasonable period of time; not applicable if IC has granted CL • CL applicant to submit documents providing evidence that: o in case of the IC being a WTO Member: the intention to use the System, as well as name and quantities of needed product have been notified by IC to TRIPS Council, and that the needed products are either not protected by patents in the IC or, if patented, that the IC has granted or will grant a CL; and o in case of the IC being a non-WTO Member: the name and quantities of needed products, as well as a statement agreeing to prevent re-exporting of the needed product have been notified by IC to the foreign affairs authorities of TPKM • Patent owner to be provided with an opportunity to comment on CL application within the time period specified by Patent Agency
Quantity	Not to exceed the quantity notified by the IC to the TRIPS Council or the foreign affairs authorities of TPKM
Duration of the Compulsory Licence	• The term is decided by Patent Agency and stated in the approval decision of CL • CL may be terminated if the circumstances have changed and CL is no longer necessary; licensee fails to properly exploit the patent as required or to pay the remuneration
Remuneration	• Appropriate remuneration to be paid by licensee • Amount to be determined by Patent Agency, taking into account the economic value of the patent to the IC with reference to UN human development index
Notification / Publication Requirements	• Patent owner to be notified of CL application • CL grant to be notified to patent owner
Transparency and Safeguards Against Diversion	• Special distinguishing features to be applied; marking and labelling of the product produced under CL • Licensee to post information on website (see para.2(b)(iii) of 2003 Decision) • If IC is a non-WTO Member, statement of agreement to prevent re-exportation of pharmaceutical products concerned
Other	./.

Regulatory Approval	Inspection and registration of products produced under the System not subject to Article 40ter Pharmaceutical Affairs Act (waives otherwise applicable period of five years of test data exclusivity during which no competitor can rely on data submitted by originator company)
Good Faith Clause	No
Acceptance of TRIPS Protocol	31 July 2012 (WT/Let/870) – prior to adoption of implementing legislation

The Former Yugoslav Republic of Macedonia	
Legal Basis	Law on Industrial Property of 25 February 2009 (Articles 102-115)
Notification to TRIPS Council	• No • Available on WIPO Lex
Scope	Export
Diseases/Products/IPRs Covered	• Products needed to address public health problems • Pharmaceutical products covered by patents or SPC • Includes medicinal products for human use to treat or prevent diseases, active ingredients and diagnostic kits ex vivo
Eligible Importing Countries	• LDCs appearing on UN list • WTO Members which have notified TRIPS Council of their intention to use the System as an importer • Non-WTO Members listed in the OECD Development Assistance Committee's list of low-income countries with a GDP of less than 745 USD • Excluded: WTO Members that have declared not to use the System as importers
Competent authority for CL grant	Court
Pre-Grant Conditions	• Notification of specific needs made by IC to TRIPS Council in accordance with para.2(a) of the 2003 Decision or, in the case of non-WTO Members, to the Ministry of Economy • Where patent exists in the IC: CL for import/sale/distribution has been granted • Prior effort to obtain VL made by generic manufacturer, limited to 30 days, not applicable in circumstances set out in Art.31(b) TRIPS • Applicant to provide information on: applications for CL filed in other countries for the same product, including data regarding quantities and the IC; the applicant or agent; name of the pharmaceutical product; data on the IC; the quantity required; evidence of prior negotiations with the right holder; evidence of a request by the IC, an NGO acting with the formal authorization of the IC, or UN bodies or other international health organizations acting with the formal authorization of the IC • Court to provide right holder an opportunity to comment on CL application
Quantity	• Not to exceed the quantities needed in the IC • Products produced in other countries under CL for export are to be taken into account
Duration of the Compulsory Licence	• To be determined by the reason due to which the CL has been issued • Upon notification by the IC, licensee may ask for modification of licence conditions in order to allow the manufacture and export of additional quantities; to be dealt with in expeditious proceedings by the competent court • CL may be repealed if the licensee does not comply with conditions attached to the CL
Remuneration	• Max. 4% of total price paid by IC in emergency cases • In other cases to be determined in accordance with factors in para.3 of 2003 Decision, as well as humanitarian or non-commercial circumstances relating to CL
Notification / Publication Requirements	• Court to notify right holder of CL application • Court, through the Ministry of Economy, to notify TRIPS Council of CL and conditions attached to it (see para.2(c) of 2003 Decision)

Transparency and Safeguards Against Diversion	• No product produced under CL for export to be offered for sale or put on the market in other countries, except where re-export to other RTA members takes place under the RTA waiver • Prohibition of import into FYROM, except for purpose of re-export to IC. Details for customs intervention regulated • Packaging and text must indicate that the product is produced under CL; the name of the court that has granted the CL and the number of the subject; and a clear indication that the product is intended for export only. Data to be made available to customs authorities • Products must be marked as produced under special CL in order to distinguish them from the originator product, provided that this is possible and does not have a big impact on the price • The Court may order the licensee to post information on website (see para.2(b)(iii) of 2003 Decision) and to notify the Ministries of Economy and Health
Other	• When taking a decision regarding the grant of a CL, the court shall take into consideration the 2003 Decision • CL may only be transferred together with production capacity, that is the part in which the invention subject to the CL is used
Regulatory Approval	No specific provisions
Good Faith Clause	• Explicitly only provided for non-WTO Members using the System • CL may be terminated if the System is used as an instrument to pursue industrial or commercial policy objectives
Acceptance of TRIPS Protocol	16 March 2010 (WT/Let/671) – after adoption of implementing legislation

Zanzibar/United Republic of Tanzania	
Legal Basis	The Zanzibar Industrial Property Act No. 4 of 2008 (Section 14)
Notification to TRIPS Council	• No • Available on WIPO Lex
Scope	Export and import
Diseases/Products/IPRs Covered	Reference to 2003 Decision
Eligible Importing Countries	Reference to 2003 Decision
Competent authority for CL grant	• Minister • Appeal before the Court within 60 days of the CL grant, does not suspend use of the patented invention during the process
Pre-Grant Conditions	Applicant to provide evidence that efforts to obtain a VL on reasonable commercial terms and conditions within a period of 45 days have failed. Such evidence is not required in cases of extreme urgency or public non-commercial use or to remedy anti-competitive practices.
Quantity	Reference to 2003 Decision
Duration of the Compulsory Licence	CL may be terminated if the circumstances which led to its grant have ceased to exist and are unlikely to recur
Remuneration	• In general not to exceed 4%of net sales, taking into account the value of the licence in the relevant domestic market • To be waived if the exporting country issues a CL for the same patented invention
Notification / Publication Requirements	Reference to 2003 Decision
Transparency and Safeguards Against Diversion	Reference to 2003 Decision
Other	Provisions also to be applied *mutatis mutandis* to pending patent applications
Regulatory Approval	Use is made of extended transition period for LDCs (TRIPS Council Decision of 27 June 2002, IP/C/25, due to expire on January 2016, but possibility of further extension referred to) in order to waive the otherwise applicable period of five years of exclusivity for all clinical test data submitted prior to that date for the purpose of obtaining marketing approval of pharmaceutical products
Good Faith Clause	No
Acceptance of TRIPS Protocol	No

ANNEX V

MODEL TABLE: INFORMATION COVERED BY EACH ENTRY

Country Name	
Legal Basis	Refer to domestic measure implementing the Paragraph 6 System
Notification to TRIPS Council	Refer to WTO document, if implementing measure has been notified to the TRIPS Council. If not, indicate other sources, such as WIPO Lex
Scope	Indicate whether the Paragraph 6 System has been implemented in order to allow for the grant of CL to export generic medicines and/or to import medicines from other WTO Members ➢ See paras.1(b) and (c) of 2003 Decision
Diseases/Products/IPRs Covered	Set out the application of the implementing measures, i.e. to which kind of diseases and products do they refer, if any, and whether specific reference is made to (product or process) patents ➢ See para.1(a) of 2003 Decision
Eligible Importing Countries	Explain which countries may qualify as eligible importing countries under the implementing measures. Among others, this includes clarification as to whether non-WTO Members can use the System as importer and which WTO Members are excluded from its use ➢ See para.1(b) of 2003 Decision
Competent authority for CL grant	Indicate the authority in charge of granting the CL (e.g. court, Ministry of Health, etc.)
Pre-Grant Conditions	List any conditions that apply prior to the decision regarding the grant of the CL, such as: notification of specific needs made by importing country to TRIPS Council; prior effort to obtain VL made by CL applicant, where applicable; evidence to be provided by applicant ➢ See para.2(a) of 2003 Decision, Article 31 TRIPS
Quantity	Specify whether the quantify of production authorized under CL is limited, e.g. by the needs notified by the importing country or by CL already granted in other exporting countries ➢ See para.2 (c) of 2003 Decision
Duration of the Compulsory Licence	Specify whether implementing measures specifically limit the duration of the CL, whether its validity can be extended, whether and under which circumstances the CL can be revoked, etc.
Remuneration	Set out specific rules applying to the calculation of remuneration to be paid to the right holder, if any ➢ See para.3 of 2003 Decision
Notification / Publication Requirements	Refer to any notification or publication requirements applicable under domestic implementing measures, including information to be notified to the right holder and notifications to the TRIPS Council of CL grant and the conditions attached to it, as well as of any modification or termination of the CL ➢ See paras.2(a) and (c) of 2003 Decision, Article 31 TRIPS

Transparency and Safeguards Against Diversion	Specify any measures applicable to either distinguish the products manufactured under the CL or to avoid diversion of these products ➢ See paras.2(b)(ii), 4 and 5 of 2003 Decision
Other	List any other relevant provisions, such as the non-applicability of preliminary injunctions to special CL granted under the Paragraph 6 System
Regulatory Approval	Although not mandatory under the 2003 Decision, explain if any requirements regarding regulatory approval of the medicines produced for export apply under domestic implementing measures
Good Faith Clause	Indicate whether and to what extent implementing measures reflect the key shared understandings in the Chairman's statement read out prior to the adoption of the 2003 Decision and the 2005 Protocol Amending the TRIPS Agreement. This concerns, in particular, the recognition that the System be used "in good faith to protect public health and (…) not be an instrument to pursue industrial or commercial policy objectives" ➢ See Chairman's Statement read out prior to adoption of 2003 Decision / 2005 Protocol
Acceptance of TRIPS Protocol	Indicate if and when the instrument of acceptance of the Protocol Amending the TRIPS Agreement has been formally submitted to the WTO. Where applicable, also specify whether this was done prior to or after the adoption of the relevant measures implementing the Paragraph 6 System into domestic law