Imports by and Exports to Countries with Insufficient or No Manufacturing Capacities in the Pharmaceutical Sector

Measures Required by the WTO Decision of 30 August 2003 in Relation to the TRIPS Agreement and Public Health

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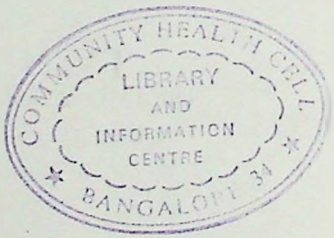
is published by
Third World Network
121-S, Jalan Utama
10450 Penang, Malaysia.

Printed by Jutaprint
2 Solok Sungei Pinang 3, Sg. Pinang
11600 Penang, Malaysia.

ISBN: 983-2729-52-1



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NOTE

This report is on the measures required by countries lacking drug manufacturing capacity and wishing to import generic drugs and measures required by countries able and willing to export generic drugs and wishing to overcome the constraints imposed by TRIPS Article 31(f) that production under compulsory licence has to be supplied predominantly for the domestic market. It is based on the Decision of 30 August 2003 adopted by the WTO General Council.

This report is a supplement updating the *Manual on Good Practices in Public-Health-Sensitive Policy Measures and Patent Laws*, published by the Third World Network.

1 Overcoming the TRIPS Restriction on Pharmaceutical Imports by and Exports to Countries with Insufficient Manufacturing Capacity

(a) Background to the "Paragraph 6" issue in the Doha Declaration on the TRIPS Agreement and Public Health

THE Doha Declaration on the TRIPS Agreement and Public Health adopted in November 2001 states that the TRIPS Agreement "does not and should not" prevent Members from taking measures to protect public health, and affirmed that the Agreement can and should be interpreted and implemented in a manner supportive of the WTO Members' right to protect public health and promote access to medicines for all.

The Declaration confirmed the right of developing countries to use compulsory licences (CLs) to override patents on medicines, in order to allow generic drug manufacturers to produce cheaper versions of patented medicines.

(b) Problem of countries with insufficient or no manufacturing capacities

However, at the Doha Ministerial meeting, there was also a recognition of a particular problem. Countries that want access to cheaper generic drugs but do not have the capacity to produce their own drugs will have to rely on imports of the generic drugs. An option for these countries is to grant a CL or a "government use" order for the import of such drugs. However these countries may find it difficult to obtain the drugs because the TRIPS Agreement limits the amount of generic versions of patented drugs that a country (that has the capacity to produce them) may export. This is because the TRIPS Agreement (Ar-

ticle 31(f)) requires that the production of generic drugs under a CL is "predominantly for the supply of the domestic market".

This restriction means that only a limited amount of the generic drugs produced under CL in a country can be exported, since a "predominant" portion of the output must be supplied to the domestic market. The portions that are allowed to be exported by the countries that can produce may not be sufficient to meet the needs of the countries wishing to import. Thus countries lacking production capacity and that would like to use compulsory licensing to import could find it difficult or impossible to obtain the required amounts of affordable medicines.

Whilst the Ministers recognized the problem, they were unable to agree to a solution, and they therefore delegated the task of finding "an expeditious solution" to the WTO's TRIPS Council.

Paragraph 6 of the Doha Declaration states: "We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002."

(c) In search of a solution

After the Doha meeting, the WTO members spent many months trying to find common ground for a solution. A few major countries suggested that they could agree to a temporary waiver to the Article 31(f) restriction for developing countries, provided the scope of diseases was limited, and that the waiver be only for national emergencies or in circumstances of extreme urgency. These conditions were unacceptable to the developing countries, which argued that they would detract from what had been achieved in the Declaration, which did not restrict the scope of diseases in its coverage, and did not restrict its application only to national emergencies.

On 16 December 2002, the Chair of the TRIPS Council produced a text containing a proposed solution, which was accepted as a compromise by almost all Members except the United States. The deadline was thus missed. Negotiations then stalled on the proposed solution, known as the December 16 text.

On 30 August 2003, the WTO General Council finally adopted the original 16 December text, together with an accompanying Statement by the Chair of the WTO General Council. The 30 August documents are known as "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Decision of 30 August 2003", and "The General Council Chairperson's Statement".

The 30 August Decision is in the nature of a "temporary solution" as it also mandates that work be carried out to amend the TRIPS Agreement, to be initiated by the end of 2003 with a view to its adoption within six months, i.e. by the end of June 2004. This deadline has been missed, and a new deadline was fixed for March 2005.

The 30 August "temporary solution" is in the form of an interim waiver to the Article 31(f) restriction, such that countries producing generic versions of patented products under CLs would be allowed to export the products to eligible importing countries, without having to limit the exported amount, as the condition that the output must be "predominantly for the domestic market" is waived.

However, the Decision also obliges importing and exporting countries that wish to make use of the waiver to undertake several measures and fulfill several conditions. It has been pointed out by some experts and NGOs that these measures and conditions are difficult for the relevant companies and governments to comply with. As a result, the Decision is hardly an "expeditious solution", as called for by paragraph 6 of the Doha Declaration.

Below is a brief explanation of the Decision and Chairperson's statement, and an outline of the measures that countries are required to follow, should they wish to import or export under the waiver. Whether the set of measures can be

implemented easily, or proves too complicated and difficult to implement remains to be seen.

(d) The Decision and Statement

The Decision of 30 August 2003 covers pharmaceutical products, active ingredients necessary for their manufacture, and diagnostic kits.

The "solution" is an interim waiver of the Article 31(f) limitation on exports. It revokes the requirement that pharmaceutical products produced under a CL shall be "predominantly for the supply of the domestic market". The waiver allows a predominant portion or even the entire quantity of output produced under a CL to be exported to countries that are "eligible" to import under the scheme.

The Decision was accompanied by a statement by the General Council Chair, which had been drawn up after intense consultations among a few members in the weeks before the end of August. The Chair's statement elaborates on some "key shared understandings" of how the Decision would be interpreted and implemented. The statement, which places more conditions in addition to those in the Decision, was an attempt to provide some language that would be acceptable to the United States, whose big pharmaceutical companies were concerned that the Decision would give be advantageous to the producers of generic drugs, which are their rivals.

The Statement states that Members recognize that the system established by the Decision "should be used in good faith to protect public health" and "not be an instrument to pursue industrial or commercial policy objectives." It also states that "all reasonable measures" should be taken to prevent diversion of medicines from the markets for which they are intended, and elaborates on the trade diversion prevention measures that are required to be taken by countries using the Decision.

2 Conditions and Measures for Implementing the Waiver to the TRIPS Restriction

(a) Countries and situations where the waiver is not required

THE special measures required to obtain a waiver to Article 31(f) of the TRIPS Agreement need not be applied in countries and situations where such a waiver is not needed. Examples of these are as follows:

(i) Countries wishing to produce and export a generic pharmaceutical product can do so without a CL if there is no patent in force on the product. In this case, there is no limit to the export.

(ii) Where a generic version of a patented pharmaceutical product is being produced under CL in a country, the generic product can be exported in amounts up to the level where the output would no longer be "predominantly supplied for the domestic market." Up to this level, the special measures required under the 30 August Decision need not apply. For amounts to be exported above this level, the special measures will have to be applied. It should be noted that the TRIPS Agreement does not define the meaning of the term "predominantly".

(iii) If a country wishes to import a generic version of the product, the importing country can do so without having to resort to the special measures required for the waiver (such as notification to the TRIPS Council) if it is able to find a foreign supplier of the generic product where:

- the product is not patented in the supplying country; or

– the product is under patent in the supplying country, and the country has issued a CL enabling production of the generic product, and the output is predominantly supplied to the domestic market (even after taking into account the new amount to be exported).

NOTE: A country wishing to import a generic product need not issue a CL to import if there is no patent in force on the product in the country. In this context, it is important to note that LDCs need not allow for drug patents until 2016. However, if a patent is in force on the product in the country, then the country is required to issue a CL in order to import. Whether the importing country requires a CL to import is a separate issue from whether the exporting country requires a waiver in order to export.

(b) General situation where the waiver is required

The objective of the Decision is to allow for countries wishing to import generic medicines to do so from a foreign generic producer, without the latter being constrained by having to produce under CL "predominantly for the domestic market."

Where a patent is in force in the importing country on the drug in question, the importing country government will have to issue a CL to enable the import of the generic version of the patented drug. In the exporting country, if a patent is in force, then the generic manufacturer would have to obtain a CL to produce the drug and export it.

Therefore, in many cases, two CLs will have to be issued. Under the TRIPS Agreement and confirmed by the Doha Declaration, WTO Members have the right to determine the grounds for the grant of CLs. The standard procedural conditions for the grant of CL are set out in the TRIPS Agreement (Article 31), which includes the condition that an application for a CL should be preceded by a failed attempt to obtain a voluntary licence from the patent holder, and the condition that the person or agency obtaining the CL payment should pay compensation to the patent holder.

The Decision modifies some of these requirements and sets out another set of procedures to be complied with, when the waiver of Article 31(f) is required to allow for generic medicines made in one country to be exported to another.

(c) Measures required by the importing country

When a developing country wishes to import a generic product, and a waiver is required by the exporting country (because it would no longer be producing predominantly for the domestic market), the importing country will have to do the following:

(i) Notify the WTO

The country has to notify the WTO's TRIPS Council of its intention to use the solution as an importer. The notification must:

- Specify the names and expected quantities of product(s) needed;
- Confirm that it has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product in question. However, LDCs need not make such a confirmation. (See Para 2 below for ways to establish this lack of capacities);
- Confirm, where the product is patented in the country, that it has granted or intends to grant a CL in accordance to TRIPS article 31 and this Decision (Decision, Para 2 (a)).

An important footnote in the Decision states that: "It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision." Thus, whilst importing countries have to notify, the notification will not be subjected to the need for approval.

(ii) Establish insufficient or no manufacturing capacities.

As part of the notification, the importing country has to establish it has insufficient or no manufacturing capacities. LDCs are automatically deemed to qualify and thus need not establish their lack of capacity. Other developing countries

have to establish either that:

- they have no manufacturing capacity in the pharmaceutical sector; or
- the capacity is currently insufficient for the purpose of meeting its needs. (Annex to the Decision).

The assessment that the country has no or insufficient manufacturing capacity is for the particular pharmaceutical product required, and not for pharmaceutical products in general. The importing country can either establish that it has no manufacturing capacity, or that it has some pharmaceutical manufacturing capacity but has found that (excluding the capacity owned or controlled by the patent holder) it is presently insufficient to meet its needs.

Under the Decision, countries are to make this determination themselves. There are no criteria or methods to establish the lack of capacity of insufficient capacity. The Chair's statement says that notification by the importing country would include information on how it has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector. However the outcome of the self-assessment cannot be challenged by other Members or be subject to review or rejected by the TRIPS Council (Correa 2004, p17).

(iii) Take measures against trade diversion

Importing countries shall take "reasonable measures within their means" to prevent re-exportation of the products that have actually been imported under the system, as "proportionate to their administrative capacities and to the risk of trade diversion". Developed countries shall provide, on request, technical and financial cooperation to countries having difficulty implementing this provision (Decision, para 4).

(iv) Grant a CL to import

Where the product is patented in the country, and there is an intention to import a generic version of it, the government has to grant a CL to import. According

to the Decision, the grant of the licence should be in accordance to TRIPS Article 31 and this Decision.

(v) Payment of compensation waived

Where a CL has been granted by the importer, and the exporting member has also issued a CL for the same product, the exporting country has to pay adequate compensation to the patent holder, but the obligation of the importing country to pay compensation under Article 31(h) shall be waived (Decision, para 3).

The ***national law*** should specify that in the case of granting a CL for import under the Doha Declaration Paragraph 6 situation (i.e. when the country does not have adequate manufacturing capacity for the particular drugs), compensation to the patent holder is waived.

NOTE: The Decision notes that 23 developed countries will not use the system set out in the Decision as importing Members. The Chairman's Statement also notes that 11 countries (Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey, United Arab Emirates) agreed they will only use the system as importers in situations of national emergency or other circumstances of extreme urgency, as will the 10 countries EU accession countries (and on joining the EU, these countries will opt out of using the system as importers).

3 Measures Required by the Exporting Country

THE importing country will need to locate a generic manufacturer that is willing and able to supply the medicines required. The generic manufacturer will require a CL if the medicine is under patent protection in its country. Any WTO members (including the developed countries) may grant a CL to its domestic generic manufacturer to produce and export to the importing country under the scheme.

The obligations of an exporting Member under Article 31(f) of TRIPS shall be waived with respect to a CL granted by it, to the extent necessary to produce pharmaceutical products and its export to an eligible importing member.

The terms and requirements include the following:

(a) Notify the WTO

When a government decides to grant a CL, it must notify the WTO's TRIPS Council of the grant of the CL and its conditions, including the name and address of the licensee, the product(s), the quantities for which it has been granted, the importing countries to which the product is to be supplied, and the duration of the CL, as well as the address of the website on which information regarding the product has been posted.

An important footnote states that this notification does not need to be approved by a WTO body in order to use the system under the Decision.

(b) Conditions of the compulsory licence

The CL issued under the Decision must be subject to the following conditions:

(i) Only the amount needed by the importing Member may be manufactured under the licence, and all of this output must be exported to the importing country.

[**Note:** The amount needed to be supplied is to be established by the importing country, which makes the order to the exporting country. To avoid transaction costs and delays in obtaining a CL, it is possible to consider the granting of an amendable CL that expands the amount to be supplied based on subsequent requests by the importing country or countries (Correa 2004, p22).]

(ii) The products produced under the licence must be clearly identified as being produced under this system through labeling or marking (e.g., special packaging and/or colouring/shaping of the products) provided such distinction is feasible and ***does not significantly impact on price***.

[**Note:** The Decision recognizes that the labeling or marking required may in some cases have a significant impact on price. The impact of price can also be assessed from the importing country's perspective, since the price would have an effect on access to the drug. The Decision does not specify who should make the assessment on whether the impact is significant. It is apparent the supplier is expected to make this judgment, taking the purchasers' interests into account (Correa 2004, p23).]

(iii) The generic manufacturer is obliged, prior to shipment, to post on a website information on the quantities supplied to each importing country and the distinguishing features of product.

(c) Payment of compensation

Where a CL is granted on a product, adequate remuneration (pursuant to Article 31(h) of TRIPS) shall be paid to the patent holder, taking into account the economic value to the importing Member of the use that has been authorized in the exporting country. (The importing country need not pay compensation for the same product).

(d) Regional arrangements

Within a regional trade agreement in which at least half the members are LDCs, a developing or least developed country shall enjoy a waiver to Article 31(f) of TRIPS to the extent needed to enable a product produced or imported under a CL to be exported to other countries in the regional trade agreement.

4 Additional Requirements under the WTO General Council Chairperson's Statement

IN addition to the conditions in the Decision, there is another set of conditions contained in the accompanying Chairperson's Statement. This may add to the hurdles that developing countries have to face when they consider making use of the system under the Decision.

Below are some of the conditions or requirements under the Chairperson's Statement and concerns that arise from them:

(a) The system should be used in good faith to protect public health, and "not be an instrument to pursue industrial or commercial policy objectives."

If this is interpreted strictly, it could prevent the use of the Decision if its use were to result in an expansion of the generic drugs industry or if the generic manufacturers were to make any profit. In any case, it adds a layer of uncertainty to how the Decision can be used.

(b) The Statement also clarifies that the obligation to label and mark the products under this scheme apply not only to formulated pharmaceuticals but also to active ingredients and finished products produced using such ingredients.

Thus the scope of the products subjected to the special labeling and marking is clarified to be wider, subjecting more products to cumbersome procedures.

(c) The Statement states the Members understand that in general special packaging, colouring or shaping should not have a significant impact on prices of the products.

This seems to suggest that generic manufacturers producing for export under the Decision will now have to comply with the requirement for special packaging, colouring or shaping, regardless of its impact on the price of the product. This to some extent dilutes the Decision, which had stated that the products should be distinguished, provided this is "feasible and does not have a significant impact on price", implying that the requirement need not be fulfilled if it is unfeasible or has a significant price effect. However, the statement can also be read to imply that generally there should not be a significant impact on price; however there also could be a significant impact in specific cases, and thus in such cases the requirement for marking or labeling need not be fulfilled.

(d) The Statement says any Member may bring matters relating to interpretation or implementation of the Decision to the TRIPS Council for expeditious review, with a view to taking "appropriate action". Members having concerns the terms are not fully complied with can use the offices of the Director General or the TRIPS Council chair to find a mutually acceptable solution.

Thus, the Statement establishes a right and mechanism for Members to challenge the validity of another Member's use of the system in the draft decision. There are concerns that these elements could have a "chill effect" on countries in their use of the Decision. However, it is also apparent that "bringing the matters" up to the TRIPS Council or to the Director General is in the nature of discussion and consultation towards a "mutually acceptable solution" and does not constitute a formal and binding dispute settlement case in the WTO.

5 Comment on the 'Dampening Effect' of the Conditions and Procedures in the Decision and Chairperson's Statement

CONCERNS have been raised that the terms and conditions in the Decision are burdensome and act as a disincentive or a barrier against the use of the Decision. This is particularly true of the obligations placed on exporting countries and the generic producers. Before embarking on an investment to produce for exports, a generic manufacturer has to be convinced that it would be economically viable and beneficial for it to apply for a CL and to make use of the system under the Decision.

If granted a CL, the generic manufacturer may face the conditions of the CL as stated above, on top of the other usual conditions for obtaining a CL.

It would appear that the requirements may have to be fulfilled anew for each batch of medicines produced under a CL, and for each and every country to which the drug will be exported. Besides this, other requirements have to be satisfied, relating to product registration and drug safety (such as proof of bioequivalence of the generic product). For these reasons, there are serious concerns that these conditions may deter a generic manufacturer, in terms of the cost implications, as well as the bureaucratic red tape.

For prices to be lowered to levels affordable to the majority of the developing country populations, it would make sense to encourage competition between as many generic manufacturers as possible. Competition from the introduction of generics would also bring down prices of patented medicines, and this has been demonstrated in many studies. However, the generic manufacturers would have to be able to achieve economies of scale or cost efficiencies to remain viable.

The producer may be dependent on large enough production runs to stay in business. The trade diversion prevention measures, in requiring each batch of medicines to be manufactured in different shapes or colours, will be obstacles to achieving this.

The Chairperson's Statement, with its "understandings", adds further to the deterrent effect that hinders countries from actually making use of the "solution." The Chairperson's Statement has been criticised by civil society organisations as another set of obstacles that restricts or limits the effectiveness of an already imperfect solution to the Paragraph 6 problem.

6 Limited Area of Applicability of the Decision

THE 30 August Decision applies only in some circumstances, and these are specific and limited.

The Decision does not reduce the affirmations of the Doha Declaration, nor does it reduce the existing flexibilities in the TRIPS Agreement. On the contrary, it does provide an addition to the flexibilities available, by giving a waiver (however cumbersome and imperfect) to the implementation of article 31.f with regard to having to produce under CL "predominantly for the domestic market." Paragraph 9 of the Decision affirms that the Decision is "without prejudice to the rights, obligations and flexibilities....under the TRIPS Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the (Doha) Declaration and to their interpretation."

The Decision does not affect whether WTO Members may issue CLs and on which grounds. The TRIPS Agreement (article 31) and the Doha Declaration are clear that WTO Members are allowed to grant CLs on any grounds, provided that certain procedural and substantive conditions are fulfilled.

The Decision thus deals only with the case of WTO members wishing to export a predominant part of their production under CL. Where a predominant part of the production under CL is provided for the domestic market, the Decision would not apply. In such cases, the limitations and conditions placed on exports under Article 31(f) is not relevant.

The Article 31(f) restriction on export does not apply (and thus the waiver under the Decision is not required) under some situations, including the following:

(a) Where production of medicines is under a CL and the portion to be exported does not constitute a "predominant" part of the output (for example, if the exported part is less than 50% of the output);

(b) Where a CL is granted on grounds that such a license is needed to correct anti-competitive behaviour on the part of the patent holder, under Article 31(k) of TRIPS.

Therefore, it would appear that where a Member seeks to export under these circumstances, it need not meet any of the terms and conditions specified under the Decision. WTO Members should therefore explore the means of using these rights and flexibilities as an alternative or in conjunction with the Decision.

In addition, the Decision does not apply and the waiver is not needed if the product is not under patent protection in the producing country.

7 Conclusions

IT remains to be seen whether and how well the developing countries will be able to make use of the "interim solution" and if it will in fact, make access to affordable medicines more of a reality. The Decision will be put to the test when developing countries attempt to make use of it. It will then be better known whether the measures and conditions contained in the Decision and the Chairperson's statement can be complied with, or whether they are an insurmountable obstacle.

Developing country governments will have to take the appropriate measures, including establishing appropriate legal provisions that enable them to exercise the best policy options, and issuing CLs for the import of generic medicines, where needed.

Generic manufacturers in other countries will have to respond to the needs of the importing countries by making applications for CLs to produce and export. In the cases where CLs are required, the governments will have to issue CLs for production and export by their generic manufacturers to produce and export, and to establish appropriate laws that also enable them to make full use of the policy flexibilities available.

When the share of production for exports rises to be so high that it almost overtakes the share of production for the domestic market, then the companies and governments concerned will have to invoke the waiver and comply with the measures required for using the 30 August Decision. Meanwhile, the devel-

oped countries can also grant CLs for export if these are applied for by their own generic manufacturers.

The Decision represents only one aspect of the broad framework that the Doha Declaration provides to safeguard against unaffordable prices for much-needed medicines. The Doha Declaration affirms the right of WTO Members to employ other measures to facilitate the protection of public health and promote access to medicines.

The implementation of these measures in developing countries is far from complete. Therefore, countries should take urgent measures to adopt and adapt their national patent laws, so as to make full use of the flexibilities in the TRIPS Agreement, as affirmed by the Doha Declaration.

The Doha Declaration also granted the right to not provide for pharmaceutical patents to least-developed WTO Members (LDCs) until 2016. Therefore, these countries do not have to enforce or provide for patents on pharmaceutical products until 2016 at the earliest. LDCs should use this flexibility to enable them to structure their patent laws and data protection rules, so as to better protect public health and promote access to affordable medicines.

The negotiations leading up to the Doha Declaration and the recent Decision have highlighted the effects of patents on the prices of, and access to, medicines. The implications of the TRIPS Agreement on public health and access to medicines are now better understood. International public opinion will judge of whether the declarations and decisions in the WTO have had a real impact on improving people's access to affordable medicines. If it is judged that these have not been effective, it may be that pressures will then begin for more far-reaching changes.

Finally, the Decision recognizes that its measures constitute only a temporary mechanism through a interim waiver. It recognizes that a permanent solution is required, involving an amendment to the TRIPS Agreement. The deadline for finding the permanent solution had been set (by the Decision) for the end of

June 2004 and this has been extended to March 2005. It is hoped that this "permanent solution", when it materializes, will be more effective and expeditious than the present "temporary solution."

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ANNEX 1

IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Decision of 30 August 2003

The General Council,

Having regard to paragraphs 1, 3 and 4 of Article IX of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");

Conducting the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;

Noting the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the "Declaration") and, in particular, the instruction of the Ministerial Conference to the Council for TRIPS contained in paragraph 6 of the Declaration to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement and to report to the General Council before the end of 2002;

Recognizing, where eligible importing Members seek to obtain supplies under the system set out in this Decision, the importance of a rapid response to those needs consistent with the provisions of this Decision;

Noting that, in the light of the foregoing, exceptional circumstances exist justifying waivers from the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products;

Decides as follows:

1. For the purposes of this Decision:

(a) "pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included[1];

(b) "eligible importing Member" means any least-developed country Member, and any other Member that has made a notification[2] to the Council for TRIPS of its intention to use the system as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system set out in this Decision as importing Members[3] and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;

(c) "exporting Member" means a Member using the system set out in this Decision to produce pharmaceutical products for, and export them to, an eligible importing Member.

2. The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below in this paragraph:

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[1] This subparagraph is without prejudice to subparagraph 1(b).

[2] It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.

[3] Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America.

(a) the eligible importing Member(s)[4] has made a notification[2] to the Council for TRIPS, that:

(i) specifies the names and expected quantities of the product(s) needed[5];

(ii) confirms that the eligible importing Member in question, other than a least-developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to this Decision; and

(iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPS Agreement and the provisions of this Decision[6];

(b) the compulsory licence issued by the exporting Member under this Decision shall contain the following conditions:

(i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;

(ii) products produced under the licence shall be clearly identified as being produced under the system set out in this Decision through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and

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[4] Joint notifications providing the information required under this subparagraph may be made by the regional organizations referred to in paragraph 6 of this Decision on behalf of eligible importing Members using the system that are parties to them, with the agreement of those parties.

[5] The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.

[6] This subparagraph is without prejudice to Article 66.1 of the TRIPS Agreement.

(iii) before shipment begins, the licensee shall post on a website the following information:
- the quantities being supplied to each destination as referred to in indent (i) above; and
- the distinguishing features of the product(s) referred to in indent (ii) above;

(c) the exporting Member shall notify[7] the Council for TRIPS of the grant of the licence, including the conditions attached to it.[8] The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

3. Where a compulsory licence is granted by an exporting Member under the system set out in this Decision, adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall be waived in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

4. In order to ensure that the products imported under the system set out in this Decision are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall pro-

[7] It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.

[8] The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.

vide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.

5. Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system set out in this Decision and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement. If any Member considers that such measures are proving insufficient for this purpose, the matter may be reviewed in the Council for TRIPS at the request of that Member.

6. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products:

(i) where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least-developed countries, the obligation of that Member under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least-developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question;

(ii) it is recognized that the development of systems providing for the grant of regional patents to be applicable in the above Members should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of the TRIPS Agreement, including in conjunction with other relevant intergovernmental organizations.

7. Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem

identified in paragraph 6 of the Declaration. To this end, eligible importing Members and exporting Members are encouraged to use the system set out in this Decision in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of the TRIPS Agreement, paragraph 7 of the Declaration and any other relevant work of the Council for TRIPS.

8. The Council for TRIPS shall review annually the functioning of the system set out in this Decision with a view to ensuring its effective operation and shall annually report on its operation to the General Council. This review shall be deemed to fulfil the review requirements of Article IX:4 of the WTO Agreement.

9. This Decision is without prejudice to the rights, obligations and flexibilities that Members have under the provisions of the TRIPS Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration, and to their interpretation. It is also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the present provisions of Article 31(f) of the TRIPS Agreement.

10. Members shall not challenge any measures taken in conformity with the provisions of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.

11. This Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member. The TRIPS Council shall initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, on the understanding that the amendment will be based, where appropriate, on this Decision and on the further understanding that it will not be part of the negotiations referred to in paragraph 45 of the Doha Ministerial Declaration (WT/MIN(01)/DEC/1).

ANNEX 2

ASSESSMENT OF MANUFACTURING CAPACITIES IN THE PHARMACEUTICAL SECTOR

Least-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector.

For other eligible importing Members insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways:

(i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector;

OR

(i) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply.

ANNEX 3

THE GENERAL COUNCIL CHAIRPERSON'S STATEMENT 30 AUGUST 2003

The General Council has been presented with a draft Decision contained in document IP/C/W/405 to implement paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. This Decision is part of the wider national and international action to address problems as recognized in paragraph 1 of the Declaration. Before adopting this Decision, I would like to place on the record this Statement which represents several key shared understandings of Members regarding the Decision to be taken and the way in which it will be interpreted and implemented. I would like to emphasize that this Statement is limited in its implications to paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.

First, Members recognize that the system that will be established by the Decision should be used in good faith to protect public health and, without prejudice to paragraph 6 of the Decision, not be an instrument to pursue industrial or commercial policy objectives.

Second, Members recognize that the purpose of the Decision would be defeated if products supplied under this Decision are diverted from the markets for which they are intended. Therefore, all reasonable measures should be taken to prevent such diversion in accordance with the relevant paragraphs of the Decision. In this regard, the provisions of paragraph 2(b)(ii) apply not only to formulated pharmaceuticals produced and supplied under the system but also to active ingredients produced and supplied under the system and to finished products produced using such active ingredients. It is the understanding of

Members that in general special packaging and/or special colouring or shaping should not have a significant impact on the price of pharmaceuticals.

In the past, companies have developed procedures to prevent diversion of products that are, for example, provided through donor programmes. "Best practices" guidelines that draw upon the experiences of companies are attached to this statement for illustrative purposes. Members and producers are encouraged to draw from and use these practices, and to share information on their experiences in preventing diversion.

Third, it is important that Members seek to resolve any issues arising from the use and implementation of the Decision expeditiously and amicably:

- To promote transparency and avoid controversy, notifications under paragraph 2(a)(ii) of the Decision would include information on how the Member in question had established, in accordance with the Annex, that it has insufficient or no manufacturing capacities in the pharmaceutical sector.

- In accordance with the normal practice of the TRIPS Council, notifications made under the system shall be brought to the attention of its next meeting.

- Any Member may bring any matter related to the interpretation or implementation of the Decision, including issues related to diversion, to the TRIPS Council for expeditious review, with a view to taking appropriate action.

- If any Member has concerns that the terms of the Decision have not been fully complied with, the Member may also utilise the good offices of the Director General or Chair of the TRIPS Council, with a view to finding a mutually acceptable solution.

Fourth, all information gathered on the implementation of the Decision shall be brought to the attention of the TRIPS Council in its annual review as set out in paragraph 8 of the Decision.

In addition, as stated in footnote 3 to paragraph 1(b) of the Decision, the following Members have agreed to opt out of using the system as importers: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America.

Until their accession to the European Union, Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic and Slovenia agree that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency. These countries further agree that upon their accession to the European Union, they will opt out of using the system as importers.

As we have heard today, and as the Secretariat has been informed in certain communications, some other Members have agreed that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency: Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey, United Arab Emirates.

ANNEX 4

"BEST PRACTICES" GUIDELINES

Companies have often used special labelling, colouring, shaping, sizing, etc. to differentiate products supplied through donor or discounted pricing programmes from products supplied to other markets. Examples of such measures include the following:

- Bristol Myers Squibb used different markings/imprints on capsules supplied to sub Saharan Africa.

- Novartis has used different trademark names, one (Riamet®) for an anti-malarial drug provided to developed countries, the other (Coartem®) for the same products supplied to developing countries. Novartis further differentiated the products through distinctive packaging.

- GlaxoSmithKline (GSK) used different outer packaging for its HIV/AIDS medications Combivir, Epivir and Trizivir supplied to developing countries. GSK further differentiated the products by embossing the tablets with a different number than tablets supplied to developed countries, and plans to further differentiate the products by using different colours.

- Merck differentiated its HIV/AIDS antiretroviral medicine CRIXIVAN through special packaging and labelling, i.e., gold-ink printing on the capsule, dark green bottle cap and a bottle label with a light-green background.

- Pfizer used different colouring and shaping for Diflucan pills supplied to South Africa.

Producers have further minimized diversion by entering into contractual arrangements with importers/distributors to ensure delivery of products to the intended markets.

To help ensure use of the most effective anti-diversion measures, Members may share their experiences and practices in preventing diversion either informally or through the TRIPS Council. It would be beneficial for Members and industry to work together to further refine anti-diversion practices and enhance the sharing of information related to identifying, remedying or preventing specific occurrences of diversion.

IMPORTS BY AND EXPORTS TO COUNTRIES WITH INSUFFICIENT OR NO MANUFACTURING CAPACITIES IN THE PHARMACEUTICAL SECTOR

Measures Required by the WTO Decision of 30 August 2003 in Relation to the TRIPS Agreement and Public Health

This TWN report is on the measures required by countries lacking drug manufacturing capacity and wishing to import generic drugs and measures required by countries able and willing to export generic drugs and wishing to overcome the constraints imposed by TRIPS Article 31(f) that production under compulsory licence has to be supplied predominantly for the domestic market. It is based on the Decision of 30 August 2003 adopted by the WTO General Council.

This report is a supplement updating the *Manual on Good Practices in Public-Health-Sensitive Policy Measures and Patent Laws*, published by the Third World Network.

TWN INTELLECTUAL PROPERTY RIGHTS SERIES

is a series of papers published by the **Third World Network** to provide a critical analysis of intellectual property rights protection from a Third World perspective. A particular focus is given to the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and its implications for developing countries.