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

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

Non-Paper from Switzerland

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## Introduction

At the informal session of the TRIPS Council of 24-25 July 2002, which was dedicated exclusively to the discussion on paragraph 6 of the separate Doha Declaration on TRIPS and Public Health (hereafter: 'the Declaration'), the Chairman of the TRIPS Council encouraged Members, in view of the formal session in September, to present and submit in writing their substantive views and positions on the list of issues contained in the Secretariat's thematic compilation as circulated in Document IP/C/W/363, which summarizes Members' statements and written communications in the discussion on paragraph 6 so far. Switzerland is committed to contribute actively and constructively to find a balanced solution for the paragraph 6 issue. A clarification of views and positions of Members on the elements of a solution to the problem addressed by paragraph 6 of the Declaration seems a necessary prerequisite for the TRIPS Council to enter into the final stage of the process of finding a mutually agreeable solution for a TRIPS Council recommendation to the General Council before the end of 2002.

In the following, Switzerland responds to the Chairman's request and briefly outlines its view on the key elements listed in the thematic compilation in Document IP/C/W/363. The individual elements are treated according to the chronological order as listed in the Secretariat's compilation.

## A. SCOPE AND COVERAGE

### 1. Scope and product coverage

As regards the scope of the solution, Switzerland shares the view expressed by many Members that the Declaration and the context in which it was elaborated and agreed give clear guidance. According to paragraph 1, the Declaration deals with "public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics." Paragraph 6 and paragraph 1 need to be read together in this respect. They are complementary in nature and mutually supportive. Any solution to the paragraph 6 issue should therefore cover *diseases causing public health problems* afflicting many developing and least-developed countries (LDCs), especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

As for the products covered, they should also be those the Declaration refers to and aims at facilitating access to, i.e., *patented pharmaceutical products and pharmaceutical products manufactured through a patented process, which are required by a WTO member while dealing with public health problems* (see paras. 3 and 4 of the Declaration). The focus of the product coverage of a paragraph 6 solution should, of course, be on pharmaceutical products for those diseases falling within the scope as outlined above. Still to be discussed is the question whether diagnostic kits which fall within the scope of paragraph 1, such as AIDS test kits, should be covered, too, by a paragraph 6 solution.

**2. Beneficiary importing Members**

In order to determine who should benefit from a paragraph 6 solution, again, the Doha Declaration is the source to turn to for a response. While paragraph 1 clearly puts the emphasis on developing and least-developed country Members facing a public health problem, paragraph 6 adds the element of "insufficient or no manufacturing capacity in the pharmaceutical sector."

As a matter of fact, LDC Members are most likely not to have sufficient manufacturing capacity in the pharmaceutical sector. This is why Switzerland proposes that *all LDC Members of WTO should qualify as potential recipient countries without any further examination* as to their manufacturing capacity.

As for the remaining WTO Members, Switzerland considers *a case by case examination* to be appropriate in order to determine whether a Member in a given case has sufficient manufacturing capacity or not. This examination should be done *by the individual Member on the basis of clear and transparent objective criteria* on what constitutes 'sufficient manufacturing capacities.' Such criteria should be worked out by the TRIPS Council within the paragraph 6 solution, guided by the data provided in the Secretariat's Document IP/C/W/345. Such criteria will assist Members' own appreciation whether they qualify for a paragraph 6 solution in a particular case. Recognizing that the paragraph 6 solution is intended to help poor countries without production capacity and without any other means to ensure "fair" negotiations with suppliers, Switzerland suggests that *OECD countries should refrain from using any paragraph 6 measures*.

In the view of Switzerland, a paragraph 6 solution, including the modalities and safeguards, should also apply in case the required medicine is not under patent protection in the territory of an eligible recipient Member, but in the territory of a potential and eligible exporting country to which the beneficiary country has made a request.

**3. Eligible supplying Members**

Switzerland has no final view on this element at this point of the discussion, but reserves its right to come back to it in the Council's ongoing discussion.

B. CONDITIONS

**1. General considerations**

*Whatever legal mechanism the TRIPS Council will eventually opt for, clear and adequate safeguards will need to accompany any paragraph 6 solution* in order to keep the mechanism transparent and workable. Since the key conditions and safeguards will apply to any mechanism, it seems important that the Council comes to an agreement on these conditions first. However, the choice of the mechanism plays a relevant role in this context. The number and ambit of modalities and safeguards will have to correspond to the scope of the solution and the kind of legal mechanism chosen. The broader the scope and product coverage and the more open the legal mechanism

eventually chosen, the more modalities and safeguards need to be worked out and agreed by the Council in order to reach the goals of efficiency and workability of a solution.

In the course of the TRIPS Council's discussion, the argument was made by some delegations that the safeguards provided in Article 31 of the TRIPS Agreement are sufficient and that therefore, no additional safeguards would need to be considered by the Council for a paragraph 6 solution. Switzerland does not share this view. First, by working out a solution to paragraph 6, the TRIPS Council creates a new possibility of granting a compulsory licence which was not contemplated by Members under Article 31 in the Uruguay Round. Specific conditions therefore need to accompany such a paragraph 6 solution in order to ensure a rule-based mechanism. Secondly, it is recalled that many WTO Members who might want to make use of a paragraph 6 mechanism are benefiting from a transitional period with respect to the obligation of the TRIPS Agreement relating to pharmaceutical products. Therefore, the establishment of an adequate framework and guidelines is necessary.

## 2. Safeguards against diversion

It is necessary to prevent diversion of the products delivered under a paragraph 6 solution in order to keep any solution workable and is, therefore, first of all, in the very interest of the recipient countries. If products are diverted from those recipient countries by exportation to higher income countries for the sake of economic benefits, the goal of facilitating access to medicines in countries with insufficient or no manufacturing capacities cannot be reached. Safeguards against product diversion are also in the interest of the research-based industry which is producing the patented products. If products sent at heavily reduced prices to developing countries are eventually (re-)exported to industrialized country markets, the R&D based industry will be deprived of the return on investment made when researching and developing these products. Consequently, there is an obvious risk that, eventually, less R&D will be done by the R&D based industry with regard to those medicines or disease conditions.

For the solution to be found to paragraph 6 of the Declaration, *all Members should* therefore *agree* in particular *to the following conditions:*

- It seems evident that the supplying country must exercise control such that a manufacturer producing the medicines under the legal mechanism of paragraph 6 solution may *only manufacture the quantity actually needed by the recipient countries*.

- The *entirety of products manufactured in the context of a paragraph 6 solution shall be exported to the recipient countries*. The safeguards provided by Article 31 of the TRIPS Agreement are not sufficient in this respect, since Article 31 does not address the situation where products under a compulsory licence are exported, but covers only the case of compulsory licenses granted for the supply of the domestic market. If the exporting country is in need of a particular medicine for its domestic market too, and if that medicine is or cannot be made available by another channel, a separate compulsory licence, according to the procedure of Article 31 TRIPS, will have to be initiated, since the grounds for the production of pharmaceutical products in the context of the paragraph 6 situation are different from the ones for the supply of the domestic market.

- Finally, in the course of the export of such pharmaceutical products and the import and distribution in the recipient country, pharmaceutical products produced under a paragraph 6 solution must be prevented from being diverted from the recipient countries and, within each importing country, from being diverted from those in need and for whom these products were destined . The responsibility to take the necessary measures to prevent diversion should be on both the exporting and importing country. To assist Members in complying with this obligation, a

*specific labeling requirement for products* produced under a paragraph 6 solution could be helpful. In order to prove easy and efficient, this could include special packaging, coloring and shaping of such products. This requirement should be agreed by Members and implemented in a manner so as not to result in additional costs for recipient countries.

## 3. Transparency

Transparency requirements in any paragraph 6 mechanism are also key to ensuring its efficiency and effectiveness. Transparency, a general principle and concern of WTO, is addressed in Article 63 of the TRIPS Agreement in the context of dispute prevention and settlement, but needs to be reflected by the TRIPS Council in the paragraph 6 solution too. Transparency will not only allow the TRIPS Council to monitor and review the efficiency and effectiveness of any paragraph 6 mechanism. It will also benefit the countries in need by helping to identify and inform potential suppliers, thereby increasing competition and ensuring more and better offers to potential recipient countries. Transparency is, therefore, also helpful and in the interest of eligible Members making use of the paragraph 6 in whose territory there is no patent in force for that medicine yet. Transparency should therefore apply throughout the procedures of any paragraph 6 mechanism, without making them unnecessarily heavy or burdensome.

*An eligible beneficiary Member* in a paragraph 6 situation *should notify its need of a product to the WTO.* That way, the holder of the patent right is enabled to offer the medicine at reasonable conditions to the country in need in the first place. Direct delivery by the right holder at affordable price will always be more expeditious than any compulsory licence procedure, whether under Article 31 of the TRIPS Agreement or a paragraph 6 solution.

*An exporting Member should notify to WTO any decision with regard to the export of a pharmaceutical product under a paragraph 6 situation.* This notification should include information on the supplier, delivered pharmaceutical product, place of destination, quantity, required labeling as well as special packaging, coloring and shaping of the pharmaceutical products produced under the paragraph 6 mechanism.

## 4. Involvement of the right holder

The delegation of Switzerland strongly believes that the most expeditious way of making patented pharmaceutical products accessible to an eligible country in a paragraph 6 situation is by direct delivery of the product by the right holder at preferential prices. Also a voluntary licence negotiated between the right holder and a country in need of a specific medicine is much more expeditious than any paragraph 6 solution will ever be.

*It seems, therefore, important that the right holder is closely involved and regularly notified whenever a paragraph 6 situation occurs*, in order to find a solution according to regular commercial arrangements, the legal mechanism under paragraph 6, just as any compulsory licence under Article 31 of the TRIPS Agreement, is only the last resort.

In a case where resort needs to be taken to a paragraph 6 mechanism, the right holder needs to be able to participate in the respective legal procedure eventually chosen for a paragraph 6 situation and shall, in a paragraph 6 solution, have the same rights and obligations as all other potential suppliers. In the case of the grant of a compulsory licence to a supplier other than the right holder, adequate remuneration shall be paid by this supplier to the right holder; a double remuneration (from the recipient *and* the exporting country), however, should be excluded.

**5. Import duties**

Since import duties can constitute an important obstacle to the affordable access to pharmaceutical products, Member States which need to import those products under a paragraph 6 mechanism should lift, or at least lower, significantly tariffs on the import of the required pharmaceutical products. This measure should apply irrespective of the legal mechanism eventually chosen by the TRIPS Council, of the identity of the supplier and of its origin.

C. LEGAL MECHANISMS

Several legal mechanisms for a paragraph 6 solution have been proposed by Members so far. Each needs to be analyzed as to its aptitude to offer an efficient and expeditious solution to the paragraph 6 problem. An excessively burdensome and heavy mechanism must be avoided. At the same time, the stimulus for research and development of new and more effective medicines to combat or even eradicate the diseases addressed in the Doha Declaration on TRIPS and Public Health must not be impaired. If the paragraph 6 solution eventually recommended by the TRIPS Council will prejudice the latter, more damage than good will have been done to our common cause of improving access to medicines for the poor.

The problem addressed in paragraph 6 of the Declaration is one arising in the context of Article 31(f) of the TRIPS Agreement. Systemically, it seems therefore obvious to *look for a mechanism which is based in the context of Article 31*. Further, the mechanism eventually chosen must make it possible, in a legally safe manner, to *focus* a paragraph 6 *solution precisely on patented pharmaceutical products and pharmaceutical products manufactured through a patented process as covered by the scope* without affecting patented pharmaceutical products which are out of the scope or even patented products of other fields of technology.

Taking into consideration the valuable information provided by the Secretariat in document IP/C/W/363/Add.1, Switzerland will further analyze the various mechanisms proposed as to their suitability to provide for a legally secure, transparent, long term, economically viable and practical solution which is pinpointed to assist those eligible Members that are really in need of a paragraph 6 mechanism to provide affordable access to a specific medicine.

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