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ActionAid Alliance

TRIPS and health

The 30 August 2003 decision: will it improve access to affordable medicines in poor countries?

Summary

This paper examines the recent WTO decision on TRIPS and health. A short background on the decision is given followed by an analysis of its implications and discussion of related concerns. An illustrative example of how the agreement may work in practice is also given.

The 30 August 2003 WTO decision
On 30 August 2003 the TRIPS Council of the WTO reached a decision that seemingly brings to an end a two-year standoff on access to medicines in poor countries.

Several solutions had been proposed and rejected at various stages during this time. In December 2002, when it appeared consensus on the issue was within reach, the USA alone vetoed the proposed solution. The USA wanted the agreement to a) specify countries that could benefit from the proposed solution, b) limit the scope of diseases that would be covered by the solution, c) make provisions for an opt-out clause that would allow developed and some developing countries to state that they would not resort to the use of the compulsory licence solution and d) limit the use of the solution to humanitarian crises or emergencies.

What does the decision offer?
Technically, the decision allows countries lacking adequate pharmaceutical manufacturing capacity to issue a compulsory licence and import generic drugs from countries that do have such capacity and have issued a compulsory license themselves. The decision reflects a compromise by the USA and its allies (EU and Japan) in two key areas: a) there is no restriction to emergencies or circumstances of extreme urgency and b) there is no restriction to a set of diseases or specific countries. The USA did manage to retain the opt-out clause in the final decision. Twenty-three developed countries have used this clause to state that they will not use the system set out in the decision as importers, while some others (largely developing countries) have stated they will only use the system in national emergencies or other circumstances of extreme urgency.

Any interpretation of the decision and implications needs to recognise that there are currently 3 potential categories of generic drugs; those whose patents have been exhausted, those produced under compulsory licence and those patented before patent laws were enacted or made compliant with WTO requirements. An example of the third category would be all the generic HIV/AIDS drugs produced in Brazil and India.

Key concerns on the decision:
1) **Although the role of generic drugs in lowering the cost of medicines is acknowledged, the decision ignores competition as the very factor that results in such price reductions.** By requiring that licences specify quantities and that manufactured quantities must be for specific markets where compulsory licences must be issued, the decision limits the number of potential actors in a particular market, and therefore competition. The small size of individual markets would make any one market unattractive for a firm to enter into production of generic drugs for. The issue of economies of scale is addressed in paragraph 6 of the decision; but the solution suggested places the onus on securing such economies of scale on governments using compulsory licences rather than leaving the responsibility with the suppliers of generic medicines.

2) **While generic drugs have the effect of lowering prices, the majority of generic drug manufacturers will have to await the exhaustion of patents** (unless granted a compulsory licence) before they can begin manufacturing such drugs and yielding lower prices for consumers. This will remain true for many drugs that are currently on the market as well as any new drugs.

3) **Drugs produced under compulsory licence will not necessarily translate into the lowest possible cost.** The drugs patented before the enactment of WTO compliant national patent laws will be subject to restrictions unless the necessary compulsory licenses are issued. The issuing of the licences will restrict the size of the market for the drugs and require that they be for public non-commercial use. Thus, in the medium to long-term the decision does not guarantee low prices, especially for newer medicines.

4) **The decision places the onus to foster technology transfer and capacity building in the pharmaceutical sector on importing and exporting countries.** Paragraph 7 of the decision reinforces the need to facilitate technology transfer and capacity building in the pharmaceutical sector, though places no responsibility on the WTO to foster the implementation of this part of the agreement. This implies that such capacity building will occur without a defined plan and without WTO support.

5) **The lack of research and development on diseases that primarily affect poor countries is not addressed in any way.** While focusing on the 'desirability of promoting the transfer of technology and capacity building' the TRIPS Council makes no specific reference to diseases that afflict mainly poor countries. The current provisions may, in the short-term, make available in poor countries drugs that have been developed to address health problems that are shared in common with developed countries.

6) **The decision places the management and monitoring of the system with the WTO.** The WTO will now need to receive information on intended use of compulsory licences, with details on product type, distinguishing features, quantities, and licensees, amongst other information. This provision of the decision places a huge administrative burden on the WTO that hitherto, has dealt only with complaints brought by individual members rather than the administration of contracts.

7) **Many LDCs already lack capacity to develop and implement legislation that makes use of the flexibility allowed under the TRIPS Agreement, and are unlikely to be able to do so without increased technical support.** While this constraint is recognised, the decision again does not make a firm commitment to provide such support, leaving the onus on developing countries to negotiate with and seek the support of developed countries. This implies that enforcing the rules and regulations of the system is seen to be more important than ensuring that poor countries can actually use it to address public health concerns.

Illustrative example on how the TRIPS Agreement will stand in the way of access to new life-saving medicines:

Scenario

Company X develops a drug that can treat a new strain of HIV found only in Southern Africa. The drug is patented globally in 2003 with patent protection until 2023. The company sells it at US$3,600 for a year's supply. The government of country A lacks manufacturing capacity and decides to issue a compulsory licence for the manufacture of the drug, notifies the WTO of its intention, and issues the compulsory licence. At this point country A must specify the product and its distinguishing features, quantity and identify the licensee.

Problems that will be encountered:

- Difficulty in finding a generic manufacturer. In the USA a generic manufacturer has to wait five years after the registration of the patent before they can access data, test and begin registration of a generic version of the drug. In the European Union, following the extension of the data

exclusivity period from 8 to 10 years, the wait is longer.

- If a generic manufacturer can be found, country A must ask country B to issue a compulsory licence for the drug to be produced on its territory. Country B must specify the manufacturer, product quantities and the destination for which the licence has been issued.
- The generic manufacturer, who would like to produce the drug after the data exclusivity period ends, finds that investing in the production of the drug is costly when the market to be supplied is small.
- In the meantime, the patent holder also lowers their prices to country A thereby increasing the potential loss and risk for the generic manufacturer.

Outcome:
Country A will find that the system is restrictive for access to new drugs, thereby finding itself at the mercy of monopolies held by patent holders. Country A also finds the system appeared to have worked in its favour initially, as many of the drugs that were previously supplied by generic manufacturers had been patented before countries developed TRIPS compliant legislation and today would require a compulsory licence for a few producers to make them. The alternative would be to await the exhaustion of the patent for more suppliers to emerge.

Concluding comment
The TRIPS Council decision does very little to make affordable medicines available in poor countries in the long-term. While acknowledging the value of generic competition in lowering drug prices, the TRIPS Council decision does little to foster such competition. Fostering competition would require a large number of suppliers as well as free entry and exit from the market by such suppliers. Such conditions will in effect only exist upon the expiration of a patent. Newer medicines will remain unaffordable and again people from poor countries will be excluded from the benefits of scientific progress.

The HIV/AIDS epidemic has created a potentially large market in poor countries, but the economic potential of this market is constrained by the inability of people in such countries to pay for the medicines they need. The TRIPS Agreement provides extended protection only to rich governments and pharmaceutical giants. Any concessions given serve only to open up small fractions of the market and moreover, only the least-lucrative sections of the market, thereby ensuring new competitors do not pose any real threats. Developed countries will, under the provisions of the TRIPS Agreement, be able to effectively keep out competition from generic drugs made by developing countries. The right to health continues to play second fiddle to commercial interests.

The TRIPS Council decision of 30 August 2003 will be reviewed next year when the WTO TRIPS Agreement is amended. ActionAid believes that there is a need to continue advocating for a more viable and workable solution, as the 30 August 2003 decision will likely prove inadequate in ensuring that medicines reach those most in need in poor countries. For recommendations on the development of such a solution, please see ActionAid's discussion paper *Access to Medicines: Ensuring People's Rights*.