EDITORIAL

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WTO agreement on medicines: a false solution

Since its November 2001 meeting in Doha, the World Trade Organisation (WTO) and industrialised nations have congratulated themselves for having introduced the necessary flexibility in patent agreements to allow poor countries access to generic drugs still covered by patents (through "compulsory licences" (a)) (1,2).

The problem is far from being resolved, however.

A last-minute agreement for countries with little pharmaceutical manufacturing capacity. In 2002 and 2003, WTO members found it hard to agree on a system that would give countries with little pharmaceutical manufacturing capacity the ability to import generics under a compulsory licence. Under strong pressure from rich countries, poor countries finally accepted an agreement on 30 August 2003 (3-6).

The WTO touted this as a "historic" agreement, claiming it showed that public health and patents were compatible (7-9). In contrast, non governmental organisations expressed strong doubts about the possibility of using such a restrictive system (b)(10,11).

Non governmental organisations considered that this system, in which drugs to be exported under compulsory licences are manufactured order by order (a given drug for a given country), would discourage producers of generic drugs, by preventing them from realizing the savings of large-scale production (12).

Many announcements... but no drugs. Canada was the first country to proudly claim that it had transposed the WTO agreement of 30 August 2003 into its national legislation, although this legislation was even more restrictive than the agreement (13,14). But even members of the Canadian government are now openly questioning whether such a system can work (15).

Similarly, France has announced in the media that it wanted to launch a "generous" solution promptly, without waiting for the European initiative (16,17). No action followed these announcements, but the media had already turned its attention elsewhere and failed to report this. The European Union patted itself on the back, first in November 2005 and again in May 2006, for having adopted a Regulation that is taken from the 2003 WTO agreement (18,19). The WTO trumpeted a new agreement signed on 6 December 2005 that simply made the "temporary" (in fact indefinite) agreement of 2003 permanent (20).

In each of these instances, the media presentation of these events gave the erroneous impression that new doors were being opened to poor countries.

In reality, as of 30 October 2006, not a single country has announced its intention to use the system, as either an importer or an exporter (21,22). And some countries, such as Morocco, have signed trade agreements with the United States that effectively prevent the provision of compulsory licences and the use of the WTO provisions (23,24).

Backed up against a wall. Before the WTO patent agreements came into effect, India was able to export three-drug antiretroviral regimens to poor countries for less than 300 dollars per year and per patient, compared to more than 10 000 dollars in rich countries (25).

A few years after the first large scale programmes for access to first-line antiretroviral drugs were launched, a growing number of patients need to be switched to second-line regimens. However, access to second-line generic antiretrovirals now requires compulsory licences and must follow the complicated system concocted by WTO. In mid-2006, no Indian manufacturers appear to be tempted by the deal.

We will soon see whether, in practice, patent law is now sufficiently flexible to ensure that the public health needs of poor countries can be met. The international community is backed up against a wall.

Prescrire

a- WTO agreements include agreements on trade related intellectual property rights (TRIPS). Compulsory licences, defined in TRIPS agreements, allow countries to authorise a third party, which is not the legal holder of a patent, to produce or import a copy of a patented drug, under certain conditions, such as payment of royalties (ref 3).

b- The most active non governmental organisations in this area were Act Up Paris, Consumer Project for Technology, Health Gap, Health Action International, Médecins sans frontières and Third World Network.

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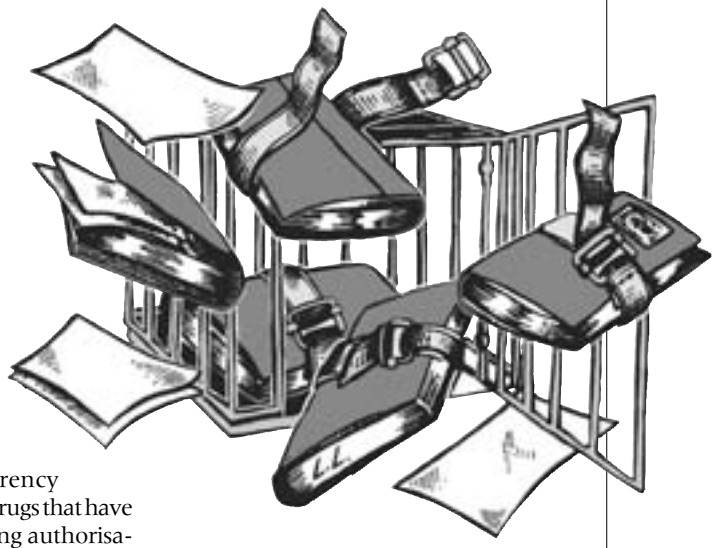
Online postings of the opinions of the French Transparency Committee: incomplete and difficult to access



The French Transparency Committee assessing medical benefits of new drugs is now overseen by the Haute Autorité de Santé. The results have been so far a mix of poor administrative performance and increased secrecy.

The French Transparency Committee evaluates drugs that have been granted marketing authorisation, in order to decide whether to include them on the list of drugs that are reimbursed in outpatient settings and/or the list of drugs approved for hospital use. The Committee also issues an opinion on the inherent value of medicines in comparison with existing treatments (**a**) (1). These opinions are not binding on ministerial reimbursement decisions. The Transparency Committee is one of seven specialised committees overseen by the French *Haute Autorité de Santé* (HAS) (2).

Until late 2004, Transparency Committee opinions were published on the website of the French regulatory agency (Afssaps) (3), but since 2005 they have been posted on the HAS site. Did this change represent an improvement in the information available to healthcare professionals?

New opinions difficult to spot. Since January 2001, Transparency Committee opinions had been posted on the Afssaps website in pdf format, both in alphabetical order by brand name and in chronological order (3). They were posted late (one or two months after being issued), but they were at least announced in the Afssaps electronic newsletter, in which new opinions were highlighted in blue.

On 14 March 2006, the last update of the HAS website (http://www.has-sante.fr/has/transparence/index.htm) was dated 6 March 2006 and mainly included opinions issued on 1 and 15 February 2006. This update also included an opinion issued by the Commitee on 16 November 2005, representing a delay of more than three months (**b**). Updates seem to be posted on a monthly basis and are announced in the HAS electronic newsletter. However, new opinions are no longer highlighted in blue, and older opinions which are placed online late, are sometimes difficult to spot, especially for those unfamiliar with the way the web site is organised. Among the Transparency Committee opinions that are actually posted online, it is still not possible to conduct a search for a particular drug by using its international nonproprietary name (INN). In searches based on a specific brand name, different opinions concerning the same medicine are not displayed in chronological order, which makes it hard to find the most recent one. ►►

a- With respect to the comparison between Prescrire's assessments of the therapeutic advantages of new products and the Transparency Committee's scores for "improvement in medical service", see reference 9.

b- This situation is far from rare. For example, the update of 7 October 2005 included opinions issued by the Committee during the first half of 2005, and even one dating back to January 2005.