

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.

Selected references from Prescrire's document watch.

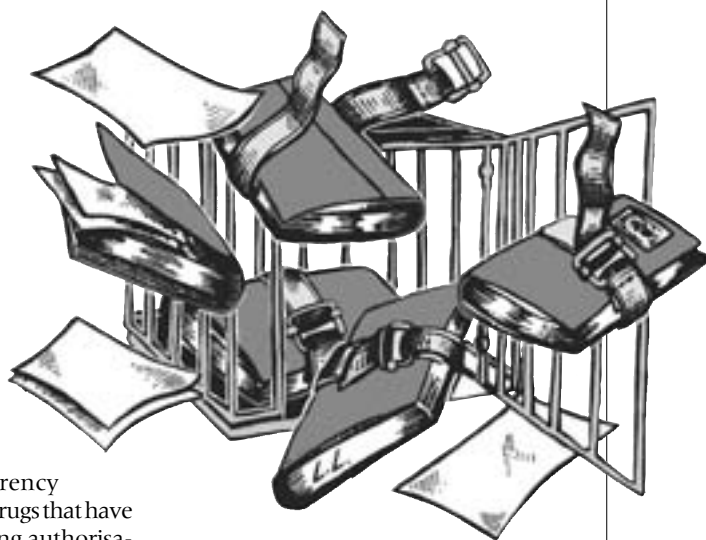
- 1- World Trade Organization "Declaration on the TRIPS agreement and public health adopted on 14 November 2001" Website <http://www.wto.int> accessed 15 Mai 2006: 2 pages.
- 2- Prescrire Rédaction "La fable du charbon et de l'OMC" *Rev Prescrire* 2002; **22** (225): 149.
- 3- Prescrire Rédaction "Accord de l'OMC sur les médicaments: une fausse solution" *Rev Prescrire* 2004; **24** (251): 459-461.
- 4- Siringi S "Kenya rejects drugs deal" *Lancet Infect Dis* 2003; **3**: 320.
- 5- Fleck F "Foot dragging" by the West threatens drugs deal for poorer countries" *BMJ* 2002; **325**: 10.
- 6- Fleck F "US given more time to consider cheap drugs deal for poor nations" *BMJ* 2003; **326**: 353.
- 7- World Trade Organization "Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health" Website <http://www.wto.int> accessed 15 May 2006: 8 pages.
- 8- World Trade Organization "The General Council Chairperson's statement" Website <http://www.wto.int> accessed 15 Mai 2006: 5 pages.
- 9- World Trade Organization "Decision removes final patent obstacle to cheap drug imports" Website <http://www.wto.int> accessed 15 May 2006: 4 pages.
- 10- Pollock AM et Price D "New deal from the World Trade Organisation - May not provide essential medicines for poor countries" *BMJ* 2003; **327**: 517-572.
- 11- Fleck F "World Trade Organisation finally agrees cheap drugs deal" *BMJ* 2003; **327**: 517.
- 12- Médecins sans frontières "Amendment to WTO Trips agreement makes access to affordable medicines even more bleak" Website <http://www.accessmed-msf.org> accessed 8 June 2006: 2 pages.
- 13- Spurgeon D "Canada decides to lead the way in exempting AIDS drugs from patent laws" *BMJ* 2003; **327**: 832.
- 14- Spurgeon D "Canada's plan to sell generic drugs to developing countries is threatened" *BMJ* 2004; **328**: 728.
- 15- Smith G et Galloway G "Chrétien's drug program ineffective. Clement says" *Globe and Mail* 28-04-06. Website <http://www.globeandmail.com> accessed 2 Mai 2006: 2 pages.
- 16- Jakubyszyn C "Au Brésil, M. Douste-Blazy promet de nouveaux génériques antisida" *Le Monde* 11 October 2004.
- 17- Latrive F "À Dakar, Douste-Blazy annonce une loi qui permettra la libre exportation vers le Sud - Génériques antisida: la France s'y met" *Libération* 23 November 2004.
- 18- "Commission welcomes changes to EU law to allow export of patented medicine to countries in need" Website <http://www.europa.eu.int> accessed 16 May 2006: 2 pages.
- 19- "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" *Official Journal of the European Union* n° L157 du 9 June 2006: 7 pages.
- 20- World Trade Organization "Members OK amendment to make health flexibility permanent" Website <http://www.wto.int> accessed 16 May 2006: 4 pages.
- 21- World Trade Organization "Notifications by importing WTO Members" Website <http://www.wto.int> accessed 30 July 2006: 2 pages.
- 22- World Trade Organization "Notifications by exporting WTO Members" Website <http://www.wto.int> accessed 30 July 2006: 2 pages.
- 23- Ahmad K "USA-Morocco deal may extend drug patents to 30 years" *Lancet* 2003; **362**: 1904.
- 24- Replégé J "Central American trade pact may limit access to generics" *Lancet* 2004; **363**: 1612-1613.
- 25- Prescrire Rédaction "Des antirétroviraux génériques cassent les prix" *Rev Prescrire* 2001; **21** (218): 467.

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Translated from *Rev Prescrire* June 2006; **26** (273): 466-467

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 (Afsaps) (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 Afsaps 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 Afsaps 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/>

<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 Committee 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 website 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.

► **Half the opinions are missing.** Not all opinions are posted online. In 2003, the Transparency Committee issued 592 opinions, including 267 relating to initial reimbursement decisions, approval for hospital use, or licence extensions (4). On 14 March 2006, only 154 of the opinions released in 2003 were available on the HAS website; in other words, 74% of the opinions issued in 2003 were missing. In 2004 the Committee issued 570 opinions, yet on 14 March 2006, only 294 of these opinions were available on the website. In other words 48% of 2004 opinions were missing (5). A September 2005 HAS press release provided the following data: for the period from 1 January to 31 August 2005, 199 opinions out of a total of 371 were available on the website (6). In other words, 46% of opinions were missing.

Re-evaluations of "medical service": the good and the not so good. The Transparency Committee regularly re-evaluates therapeutic value of medicines it reimburses, or the "medical service rendered". Results of these re-evaluations are posted online. In September 2005, on the basis of re-evaluations carried out during two different time periods, 1999-2001 and 2004-2005, HAS recommended removing 221 drugs, corresponding to 364 products, from the list of reimbursed medicines.

A ministerial decree issued on 17 January 2006 announced that as of 1 March 2006, 282 products would no longer be reimbursed (7). For the first time in France, the government also provided explanatory notes for patients. They were posted on the HAS website, with a direct link from the Transparency Committee's own site (8).

On 14 March 2006, "transparency files" intended to help caregivers choose the cheapest drug within a given therapeutic class were posted online. But with the exception of the files on anti-infectives, dating from 2004, none of the files has been updated since 1999 or 2000.

Transparency please! The Transparency Committee's internal regulations, adopted on 22 June 2005, have been available online since November 2005 (1,2), while the Transparency Committee's 2004 activity report was only posted online in March 2006 (5).

A list of the conflicts of interest declared by Commission members and experts is posted on the HAS website, but with no direct link to the Transparency Committee's website.

The procedure for selecting Committee opinions to be published online is not described, nor is the policy for updating the

Committee's web pages. The timetable, minutes and transcripts of meetings are not openly available online. Opinions that are challenged by manufacturers, during the phase in which a manufacturer may respond to the Transparency Committee's evaluation of its product, are not clearly distinguished from other opinions (c), something that would be facilitated by highlighting in colour opinions that are newly placed online.

No summary of the studies that the Transparency Committee requires from a company when issuing its opinion is provided, nor is there a precise description of companies' responses (d).

It would be very useful to be able to search for opinions based on multiple search criteria, such as the INN, the therapeutic class, the type of innovation (new substance, licence extension, range extension, generic, etc.) or the type of intervention by the Transparency Committee (initial or renewal opinions, reimbursement for hospital use). Summaries would be particularly useful, especially for unfavourable opinions.

The home page indicates that the Transparency Committee is intending, for some new drugs, to issue "product files" that will contain "useful summary information for prescribers on the therapeutic value of specific drugs" (editor's note: our translation) (5). As of 14 March 2006, these files had not yet been posted on the Transparency Committee's site, but two "Good Drug Usage" files were recently placed online under "Publications" on the HAS website (5).

Even if certain limitations already existed when opinions were posted on the French regulatory agency's website (9), new Transparency Committee opinions are less visible on the HAS website.

We hope the *Haute Autorité de Santé* will become more transparent and improve the service it offers healthcare professionals and patients alike.

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Selected references from Prescrire's literature search

1- Haute autorité de santé "Règlement intérieur de la Commission de la transparence (version du 22 juin 2005)" *Bulletin Officiel Santé* 2005/9 15 October 2005: 24-28.

2- Haute autorité de santé "Rapport d'activité au Parlement et au Gouvernement" 1 July 2005. Website <http://www.has-sante.fr> accessed 14 October 2005.

3- Prescrire Rédaction "Agence française de sécurité sanitaire des produits de santé (Afssaps). Website" *Rev Prescrire* 2003; **23** (suppl. 245): 920-921.

4- Commission de la transparence "Rapport d'activité de la Commission de la transparence 2003" 11 December 2004. Website <http://www.has-sante.fr> accessed 14 October 2005.

5- Commission de la transparence "Rapport d'activité de la Commission de la transparence 2004" 10 October 2005. Website <http://www.has-sante.fr> accessed 14 March 2006.

6- Haute autorité de santé "Dossier de presse. La Haute autorité de santé de janvier à septembre 2005. Bilan d'activité et perspectives" 27 September 2005. Website <http://www.has-sante.fr> accessed 14 October 2005.

7- Prescrire Rédaction "Sécurité sociale. Déremboursements post-réévaluation" *Rev Prescrire* 2006; **26** (271): 258-260.

8- Haute autorité de santé "Réévaluation des médicaments à service médical rendu insuffisant (2ème phase) - Liste des médicaments déremboursés - Éléments de réponses aux questions posées par les patients". Website www.has-sante.fr accessed 14 March 2006.

9- Prescrire Editorial Staff "Comparative advantages of new drugs: French authorities are not sufficiently demanding" *Prescrire Int* 2005; **14** (76): 75-79.

10- Prescrire Rédaction "Fiches de transparence 1999" *Rev Prescrire* 1999; **19** (197): 547-548.

c- According to article R. 163-16 of the Social Security Code, opinions issued by the Transparency Committee for new products are communicated to the companies concerned. The company may, within eight days after receiving this opinion, either ask to be heard by the Committee, or submit written comments. The Committee can then, if it feels necessary, modify its initial opinion. The opinion then becomes final (refs 1,2,9). Communication of the final opinion to the company terminates the "contradictory procedure". According to the 2005 version of the internal regulations of the Transparency Committee, final opinions are to be posted on the HAS website within one month (ref 1). The 2001 version stated that opinions should be placed on the Afssaps website within 15 days (ref 5).

d- The Transparency Committee requested supplementary studies for 21 products in 2004. These were mainly studies of prescribing conditions and conditions of use, the benefit of treatment for the patient, adverse effects, and impacts on the healthcare system (ref 5).