

PRESS RELEASE

Diffusion: 13 June 2006

HIDDEN DEFECTS IN THE AUTHORISATION PROCEDURE OF PLACING DRUGS ON THE MARKET

The French Agency for the medical safety of health products (AFSSAPS or, *Agence française de sécurité sanitaire des produits de santé*) requires pharmaceutical laboratories to carry out a series of safety and effectiveness tests for every new product, before authorising them to be placed on the market. It thus poses as guardian of French health. The task is complex because trades-off between safety, effectiveness and the time necessary to ensure itself of these are in any event necessary.

According to the latest report of the *Institut économique Molinari* published today, Hidden defects in the authorisation procedure of placing drugs on the market, the AFSSAPS tends to ignore an essential dimension for patients of trades-off which it makes on their behalf. The current procedure of authorisation neglects the disadvantages of a late placement on the market compared to patients' priorities between the search for safety, the effectiveness of products and their more or less fast public availability. It would however be advisable not to forget the suffering and the deaths that are not avoided because of delays imposed by the procedure.

For Xavier Méra, author of the Economic Note, the source of this bias lies in the operation of the agency: "The signals revealing a bad choice are limited to the large media scandals. That hardly constitutes a criterion to judge the adequacy of its decisions with the best compromises between effectiveness, product safety and waiting costs. On the one hand, it is fundamental, for the agency wishing to preserve or increase its budget, to avoid any media scandal related to the introduction of a drug onto the market. On the other hand, when a drug reduces a death rate from 40 to 30%, the 10% of people who would otherwise have died remain unidentified. Nothing spectacular there. Consequently, the agency is encouraged to neglect the problem of delay compared to considerations of effectiveness and safety."

The author recommends exploring a new route to circumvent this bias: "The regulation agency of health products exerts a certification job and many other products are the subject of a certification of their conformities to standards without the existence of a legal monopoly of certification. Within a competitive framework, losses and profits oblige the certification specialists to adopt standards of safety, product effectiveness and waiting costs according to the priorities of end-buyers, without neglecting any of these dimensions. "

Taking into account the noted effectiveness of such practices, the author concludes in calling a debate on allowing competition between the regulation agency and private certification organisations.

The economic note is available on the website of the IEM:

French version : <http://institutmolinari.org/pubs/note20064fr.pdf>

English version : <http://institutmolinari.org/pubs/note20064.pdf>

Contacts : Cécile Philippe on +33 (0) 1 40 95 01 59

Xavier Méra on +32 (0) 2/506 40 04

Institut économique Molinari www.institutmolinari.org

Rue du Luxembourg, 23, bte 1 1000 Bruxelles Belgique