18 May 2010: Marketing of Plavix® generic medications

Published on May 31, 2010

The Autorité de la concurrence does not declare emergency measures against Sanofi-Aventis but continues its investigation on the merits regarding the complaint by Teva Santé

> Version française

Generic drug manufacturer Teva Santé applied to the Autorité de la concurrence relative to the practices used by the company Sanofi-Aventis France (hereinafter Sanofi-Aventis) in an effort, according to Teva Santé, to drive from the market the generic medications that compete with one of its flagship products, Plavix®. Its complaint also included a request for interim measures.

In a decision that it has just issued, the Autorité de la concurrence rejects the request for interim measures, considering that the conditions have not been met for such measures to be applied, but it will be continuing its investigation on the merits of the case.

Plavix®: blockbuster of the pharmaceutical industry

Plavix® is a medication than is prescribed to prevent complications related to arterial thrombosis, an illness resulting in lesions on artery walls and the formation of thromboses on the level of the arteries that can result in serious cardiovascular accidents, such as cerebrovascular accidents and heart attacks. Its active substance is clopidogrel, present in the form of a salt.

Launched in 1998, Plavix® is a blockbuster of the pharmaceutical industry: 4th most widely sold medication in the world, it is the leading product for medication reimbursements by the Health insurance plan in France. In 2008, almost all of

the patents entered the public domain and some 15 laboratories, including Teva Santé and Sanofi-Aventis, launched their generics in 2009.

As two patents still protect certain of the medication's pharmaceutical data, most Plavix® generics, other than the manufacturer's own brand, are distinguished from the original by the usage of a different clopidogrel salt. Also, the patent protecting the indication of Plavix® in the treatment of acute coronary syndrome, together with aspirin, is still valid.

The Teva Santé complaint: Sanofi-Aventis is denigrating Plavix® generics

In its referral, Teva Santé complains of the usage by Sanofi-Aventis of these differences in order to denigrate competing generic medications amongst physicians and pharmacists.

In its commercial presentations to physicians and pharmacists, Sanofi-Aventis emphasizes the differences that exist between its reference and competing generics (other than its own), without indicating that their total bioequivalence has been recognised by health authorities and that these differences are of no therapeutic relevance. By letting it be understood, in an implicit but necessary manner, that these differences have an impact on the product's safety and efficiency, and therefore on the patient's health, the Sanofi-Aventis laboratory is encouraging health care professionals not to prescribe or replace the original with anything other than the laboratory's own generic.

The Autorité de la concurrence will not declare emergency measures, but will continue to investigate the merits of the complaint.

The investigation on the merits will strive to determine if the practices claimed against Sanofi-Aventis can be considered a legitimate commercial effort to defend the laboratory's commercial interests or, on the contrary, could be viewed as abusive.

For this reason, the Autorité de la concurrence has decided to continue the investigation on the merits of the complaint but without declaring interim measures, given that the conditions for interim measures have not been met

(situation of the applicant and of the sector not jeopardised by these practices and absence of damages for the Health insurance plan, since the substitution rate of the original by generics, including the laboratory's own generic, is already significant).

> For more details, consult the full text of the decision 10-D-16 relative to the practices implemented by the Sanofi-Aventis France company