11 December 2007: Interim measure on the medicine market

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**The Conseil de la concurrence orders Schering Plough laboratory to remind doctors and pharmacists
the exact bioequivalence of its brand name drug Subutex® with competing generic drugs**

>Version française

Following a complaint by Arrow Génériques company for practices implemented by Schering Plough laboratory, at the launching of the generic product Subutex® on the market, the Conseil de la concurrence has just ordered an interim measure before reaching its decision on the merits.

The practices concerned

Buprenorphine is a psychotropic substance, which constitutes a substitute for opiate. In 1996 Schering Plough obtained the exclusive business rights to sell this molecule, which was sold in France under the brand name Subutex®. In March 2006, Schering's patent expired and Arrow company launched its generic equivalent on the market.

Arrow denounces Schering Plough's conduct, which would have unfairly hindered the launching of the generic drug for Subutex® through two major practices: defamation against Arrow's generic drug among pharmacists, even before its entry on the market, and a significant change in Subutex® business conditions in pharmacies when the generic drug entered the market (direct selling, stock saturation, more favourable payment deadlines for pharmacies, payment for non contractual services and substantial amounts).

The Conseil de la concurrence's analysis

The Conseil observed that Arrow's generic drug had an abnormally penetration rate on the pharmacies market and more generally that the company's conduct could have generated a deterrent signal effect towards other potential entrants on the market, thus hindering the substitution process of the brand name by the generic drug. On the city market, a new generic drug gains at least 25% of market share volume in the first year and 50% the second year, and sometimes reaches 75-80% after two years. However in August 2007, i.e. 16 months after the marketing of Arrow's generic drug, its market share reached 6%, with a total market share below 13% by the two generic sellers.

The annual cost for the reimbursement of Subutex® by the social security reaches €74.6 million. The financial impact on the health insurance system of a low substitution by the generic drug is therefore significant and may cause damage to the economy.

The interim measure ordered against Schering

Since the practices linked to the specific distribution conditions set up by Schering had stopped, the Conseil de la concurrence considered that there was no need to order interim measures. However, the Conseil considered that the denounced defamation practices were likely to produce long term effects and that it was necessary to adopt measures in order to restore a certain degree of confidence towards the generic drug(s) competing with Subutex.
Therefore the Conseil ordered Schering laboratory to publish at his own costs a text reminding, on the one hand the bioequivalence of generic drugs which have been permitted on the market in two medical magazines « Le quotidien du médecin » and « Le moniteur du pharmacien », and on the other hand the possible substitution by pharmacists as soon as they are listed as generic drugs. Moreover the Conseil has taken note of Schering France's commitment presented at the hearing, that it will not stop to sell Subutex® in the case where its new drug substitute for opiate (Suboxone®) would be sold on the market.

> Decision 07-MC-06 of 11 December 2007, relative to a request for interim

measures presented by Arrow Génériques

> See decision of the Paris Court of Appeal (5th February 2008)

> See decision of the Cour de cassation (Supreme court of appeals) - (13th January 2009)