

OBSTRUCTING INNOVATION

By Valentin Petkantchin, Institut économique Molinari

Public debate often focuses on the profits of pharmaceutical companies, and it is hardly very popular to take positions that would seem to come to their defence. But should we stop ourselves from wondering if penalising them on a regular basis and pushing up the cost of innovation creates a risk that we would end up stifling efforts from which we are expecting tomorrow's cures? Beyond the effects that the current crisis could have on R&D investment in this sector, innovation is threatened by a number of structural factors.



ARE WE CREATING UNNECESSARY DELAYS
TO PHARMACEUTICAL INNOVATION?

© MARK CSABAI

First of all, the costs of innovation are rising, and the investment required to develop and market a new molecule has gone up sharply. These costs are spread over a period of 12 or 13 years and may amount to an average of about a billion euros.

This rise in the costs of innovation is due in large part to market access for new products being made increasingly difficult. Under the impetus of what has become known as the “precautionary principle”, innovative products face approval policies that are ever more demanding, harsh and costly. Larger sample sizes, longer time periods and more numerous administrative formalities are inevitably adding to the costs of the drug firms' innovation projects. For example, the cost of clinical trials needed to obtain approval quintupled between 1980 and 2000. And this trend does not seem to be abating.

According to a specialist with the European Organisation for Research and Treatment of Cancer, the recent European directive that was voted in 2001 may, by itself, have increased paperwork and trial costs in Europe. This has contributed to bringing down the number of trials from the 38 initiated prior to the reform to only seven after it was instituted. Declines of 25% in Sweden, 60% in Ireland and 90% in Poland have also been reported in the launch of new clinical tests after the directive came into force.

Moreover, once new treatments have managed to overcome these obstacles to market access, other policies take the relay, penalising not only their free commercial sale by innovating companies but also their prices and their use. There exist a whole panoply of measures linked to public cost containment of healthcare spending in Europe in the form of price controls, reference pricing, quantitative goals limiting prescriptions by doctors, etc. Containment of drug spending is among public authorities' priorities in this respect.

In addition to bringing in a dangerous bias wherein healthcare professionals can be pushed into favouring lower financial costs for mandatory health insurance systems at the expense of their patients' health, the inevitable result of these policies is to reduce incentives to innovate. Lower profit margins and revenues in Europe have also had a negative impact on future innovation and clearly do not encourage greater R&D investment!

Finally, drug firms' revenues are often seen as an inexhaustible reserve that governments can dip into freely in case of need. This obviously involves resources that innovating companies are deprived of and that they will be unable to devote to R&D and innovation. In Germany, for example, “discounts” are imposed on drug firms, amounting to more than 1.2 billion euros in 2007, or nearly 27% of their R&D investment!

In France, another major drug market in Europe, pharmaceutical companies are subjected to several specific taxes in addition to the general taxation common to all companies. According to a recent report from the French Senate, these taxes came to 831 million euros in 2006, more than their total industrial investments in the coun-

try (818 million euros)! These amounts have no relation to the drug firms' financial results but depend, paradoxically, on the deficits of the health insurance system: the higher the deficits go, the greater the levy on the firms' income. Despite a 2% decline in revenues, a drug firm could see its taxes rise by 42%; for another firm, the specific tax burden may have shot up by 235% in 2006 and 300% in 2007!

Is it possible to imagine that arbitrary levies and tax measures of this sort will not end up penalising the pharmaceutical industry and reducing firms' ability to innovate?

Under these conditions of structural obstacles at several levels, should anyone be surprised that the number of molecules launched by European drug firms has been cut in half during the last 20 years? This number went from an average of 97 molecules between 1988 and 1992 to 48 between 2003 and 2007.

Pharmaceutical innovation has turned increasingly in recent decades to the United States, where the drug mar-

ket and prices are traditionally less regulated. But this more innovation-friendly situation could change, and innovation in the U.S. could be penalised in turn, if healthcare policies similar to those in Europe are instituted under the Obama's presidency. Such a change across the Atlantic will make the adverse effects of current European structural obstacles felt even more deeply, with their slowing of pharmaceutical innovation.

It must not be forgotten that, despite its benefits, this innovation cannot be taken for granted. By its very nature, it is a risky activity and cannot be conducted if innovating companies find themselves penalised on a regular

basis. The danger lies in the fact that the effects of public policy on R&D and innovation are not perceived directly. It may be years, or even decades, before their negative impact becomes fully evident. It is not the role of the public authorities to ensure the future profits of drug firms, but too great a desire to tax them, ignoring the costs of these policies, risks dealing a fatal blow to tomorrow's innovation!

The cost of clinical trials needed to obtain approval quintupled between 1980 and 2000

