French law to make conflict-of-interest disclosure mandatory

France, still reeling from the Mediator scandal in which the diabetes drug (also known by its generic name, benfluorex) remained on the market until November 2009 despite earlier indications that it carried a risk of fatal heart valve trouble, is contemplating a revamp of its drug approval system. Lawmakers are due to discuss updates to the rules governing disclosures of conflict of interests by experts involved in the country's drug approval process when the French National Assembly reconvenes at the end of September.

As part of a draft bill reforming the drugs approval and safety system, France may soon require that conflicts are publicly disclosed by directors and experts at regulatory agencies and made available publicly. Failure to do so would now incur sanctions including fines of up to €30,000 ($43,000).

Etienne Caniard, president of Mutualité Française, a federation of most of France's nonprofit private health insurers, contends that the new rules will have a positive effect. "This proposal will help uncover the sectors where the state has given free rein to the pharmaceutical industry and where it should take its responsibility and regain control, such as continuous medical education," he says.

To gain a clean start, the new bill also suggests renaming the country's drug regulatory authority, from the French Health Products Safety Agency (AFSSAPS) to the National Agency for Medicine Safety (ANSM). The legislation would also make the renamed agency's drug approval committees smaller than before to ensure that only experts with a track record in relevant therapeutic areas are involved. These experts would not be allowed to sit on drug approval committees longer than four or five years, and the decisions made by the committees would be more transparent.

French open: Conflicts to be publicly disclosed.

But Caniard sees some complications. "The problem with this reform is that it puts too much emphasis on disclosure but not enough on limiting conflict," he says. Given that, in specific therapeutic areas, it is inevitable that experts needed by the regulatory authority would have experience of working with industry, he believes it is essential to limit the impact of existing conflicts.

"Transparency does not go well with French culture," says Guillaume de Durat, former deputy secretary general of the French pharmaceutical trade group Les Entreprises du Medicament (LEEM). "The law is not going to resolve all these problems." He suggests that awareness campaigns could help to encourage compliance with the disclosure requirements.

In parallel with the restrictions placed on drug advisors, the bill would push for more transparency on the side of industry. Pharmaceutical companies would be forced to publicly declare benefits and incentives that they provide to doctors, students, associations, hospitals, academic societies and trade publications—provisions modeled on the US Sunshine Act. France's health minister, Xavier Bertrand, was quoted on national radio as saying that "everything will need to be declared from the first euro."

Sabine Louët

Patent protection brings hope to insurers

Insurance companies are stepping up their marketing of damage-protection products to pharmaceutical and life science companies, some say in response to a June report by the US Food and Drug Administration laying out a collaborative strategy to more closely track the quality of goods globally.

In response to increasing regulatory activity, UK-based JLT Specialty, part of the Jardine Lloyd Thompson Group, has begun marketing such 'nondamage' products more aggressively this past summer—and they're dropping their prices.

The price of the insurance depends on a variety of conditions—for instance, the size of the company seeking insurance, the limits bought and the triggers chosen. However, over the past year the cost of coverage has dropped more than threefold, from approximately 5% to 1.5% of the estimated coverage. For example, previously, $5 million could have covered a company worth $100 million, whereas now it costs $1.5 million to cover the same-sized company.

This insurance product, which has been on offer for over a year, is intended to protect against the loss of revenue from shutdowns mandated by regulators, as well as from legal challenges to pharmaceutical companies' patents, product recalls caused by counterfeiting or contaminated products and cyber attacks.

"We are providing this cover to a broad range of life science companies—pharma and biotech companies being the primary focus," says James Bird, a partner in JLT's life sciences team in London. "More and more companies are outsourcing their production. The FDA, especially, [is] doing more audits, including outside of the USA. The net result is more risk on the regulatory side." The FDA has been more aggressively collaborating with its overseas counterparts to ensure drug quality following dozens of deaths in 2008 due to contaminated heparin, a blood thinner supplied to Baxter by Chinese subcontractors.

Another insurer, New Jersey–based Chubb, offers similar insurance, covering product withdrawal and crisis management expenses up to $25,000 for recalls under certain circumstances.

Christopher Bryce, an advisor in the life sciences department at the global insurer and risk adviser Marsh, based in London, is skeptical of such specialized products for the pharmaceutical industry, saying that it is no more than ordinary business risk management. But he adds that uncertainty around patents can produce real risks. "What is new and what is coming is how insurers deal with patents," Bryce says. "As large drug companies start to develop their own generics in-house, there will be a growing need for insurance. Patent protection is definitely a developing area."

Georgina Kenyon