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French Industry Chief On How To Encourage Innovation & Avoid Drug Shortages

by **Ian Schofield**

Pricing challenges, high taxes and the growing problem of drug shortages have led the pharmaceutical industry body Leem to come forward with a set of proposals that it says should inform future government policy towards the sector.

The French pharmaceutical industry is facing two major challenges that are either caused or exacerbated by government policy and that risk deterring investment in innovation in France and jeopardizing patient access to medicines, according to the pharmaceutical industry body, Leem.

One of these challenges is a financing and regulation model that does not take account of future innovation in medicine. The other is the threat of drug shortages caused not only by global factors such as increased demand and supply chain problems, but also by low domestic drug prices that discourage investment and spur parallel exports of medicines to higher-priced countries.

Government policy towards the industry took a turn for the worse last year, but Leem wants to take a constructive approach and is preparing an action plan and a set of proposals that could be incorporated into future government policy, Leem president Thierry Hulot told a press conference this week.

He said he had been told by the prime minister, Elisabeth Borne, that a “ministerial mission” would be put in place shortly to look at how to balance support for the industry with the government’s budgetary considerations and patients’ need to access new drugs.

Change In Government Policy

Key among the industry’s concerns are some provisions of the social security financing law (LFSS) for 2023, which was passed in December and includes a ceiling on drug spending that is

lower than actual spending in 2022, a raft of price cuts, and an escalation of what Leem calls a “confiscatory” tax on sales (the so-called “safeguard clause”). (Also see “[*Total Disconnect’ Between French Drug Spending Plans And Reality*](#)” - Pink Sheet, 9 Nov, 2022.)

A year ago, it had seemed that things were looking up for the pharma industry in France, with improvements to the early access system, and a “new dynamic” in terms of clinical research, investment and employment in the sector, Hulot noted. Reforms to the early access mechanisms had allowed “thousands of patients” access to the latest medical innovations before marketing authorization.

Moreover, the COVID-19 pandemic had shown the “strategic role” of the industry, and the health innovation plan 2030 set out a “clear roadmap” for France to become the leading European country in terms of innovation in health care.

But the LFSS changed all that, marking a “return to a system of financial regulation based on repeated price cuts and a sectoral taxation without limits,” Hulot declared. The safeguard clause “confiscated most of our [sales] growth in the context of hyperinflation,” he said. “We have returned to a purely financial-based and short-termist approach to medicines policy.”

This approach, he continued, sent “a harmful message about the attractiveness of France for research, industrial presence, employment and, eventually, access to innovation.” But Hulot stressed that the industry wanted to take a “constructive approach” to these problems and to work with the authorities and other stakeholders on a medicines policy that was “in the service of our citizens.”

New Approach Needed

The need for a new system of drug financing and regulation was taken up by Leem board member Corinne Blachier-Poisson, president of Amgen France, who referred to novel therapies such as immunology and gene and cell therapy and said the system must be adapted to funding such innovations.

Changes such as improvements to the early access system were welcome, she said, with “thousands” of patients getting access to new innovative drugs. But she added that since the last LFSS, France had again become “unreadable and unpredictable” for the industry.

Tackling Medicine Shortages

France, like most other European countries, is experiencing frequent shortages of certain medicines. Hulot noted that more than 600 shortages were recorded in the first half of 2022, compared with 900 for the whole of 2021.

The reasons are generally the same as those seen in other countries: a resurgence in winter

infections following COVID-19 lockdowns, an increase in global demand for medicines that is outstripping increases in manufacturing capacity, the concentration of suppliers of raw materials and excipients, and supply chain problems.

But Hulot argued that France was more exposed to shortages than neighboring countries, partly because drug prices were “among the lowest in Europe,” which encouraged parallel exporting to higher-priced countries. Moreover, as drug prices are controlled in France, companies cannot pass on the current increases in the costs of production, packaging, energy, labor and so on.

Leem’s Proposals

Leem has put together a number of recommendations for improving the situation, Hulot noted. They included a “realistic medicines budget that takes account of the actual needs of patients, the aging of the population, growth in chronic diseases, and recognizes innovation.” Leem also wants continued efforts to speed up the approval of innovative clinical trials.

On the shortages front, Hulot said it was up to all stakeholders to respond to the problem “as an absolute priority.” He said that by the end of this quarter, Leem would present the authorities with a “plan of action and recommendations” for tackling supply chain issues.

The recommendations would include wider sharing of information on shortages, and a clear focus on products of strategic interest, ie, 200-300 products where shortages would have “immediate consequences” for the health of patients.

'Access Barometer'

Leem has also decided to put in place an “access barometer” to evaluate access to medicines and “the dynamics of the industry” in France on an ongoing basis. This will include data on the performance of the medicines sector as well as international comparisons wherever the data were available. It will cover supply chain issues in France and elsewhere, including marketing cessations, availability of innovative drugs in France and elsewhere, any economic difficulties experienced by companies, and data on investment, trade and the workforce.