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A weakening in the fabric of France's pharmaceutical industry

Leem calls for urgent consolidation of France's position to ensure industrial growth going forward

Two unpublished studies commissioned by Leem have undertaken a detailed and forward-looking review of the pharmaceutical industry's manufacturing base in France The country continues to rank among the world's largest manufacturers of medicinal products, but its position now needs strengthening. Declining investments, an ageing product portfolio, difficulty tapping into new products ... Leem calls on the government to act.

Against a backdrop of pervasive erosion of the French productive base, maintaining a world class industrial capability in the pharmaceutical sector presents a major challenge. This challenge impacts not only on jobs, but also on access to innovative therapies and on the country's strategic independence in healthcare. More than providing a detailed snapshot of France's production system, the two surveys published today analyse the dynamics of investment in pharmaceutical and biotechnology manufacturing in France, and investigate ways to revive the production of medicines in the country.

Produced by the consultancy firms Arthur D. Little and Roland Berger, these studies form part of a symposium organised by Leem and Polepharma in Paris under the title: *"Pharmaceutical Manufacturing: France faces its responsibilities! ".*

A decline in manufacturing investment

The first study, conducted by Arthur D. Little consultants and commissioned by Leem and Polepharma, focuses on the level and type of investment in the means of production in medicines and vaccines across France. It reveals that in 2013, all 224 pharmaceutical and biotechnology sites across France invested EUR 810 million, representing a fall of € 120 million compared with the previous survey, which covered 2010.

Most of these investments (60%) were concentrated on the production of chemical-based drugs, products that are often mature and exposed in the short or medium term to competition from generics. These relatively small investments (averaging between EUR 1 to 5 million per site) are not generally intended to develop production capacity or to expand into new markets, but to adapt the means of production to regulatory changes.

Investments made in biological sites (primarily vaccines) account for 40% of investments recorded over the period. Less dispersed since spread over only thirty sites, these investments are often larger and support the transition to biological agents. Designed to expand capacity and develop exports, most investments in biological sites were decided 4 or 5 years years ago, and have now reached the end of their cycle.

By and large, the decline in investment in the past three years now raises questions about the future growth of France's industrial production. *"Manufacturing sites, especially French ones that are not Big Pharma players, have invested relatively little in their attempt to seek export growth outside Europe",* the authors of the study report. As a result, more than two-thirds of sites in France are not approved to export to the United States, despite it being the world's largest market for health products. As for sites dependent on laboratories based outside of France, site managers are all too often (in 80% of cases) excluded from the investment decision. Yet the view from international headquarters of France's complex and unpredictable system is not counterbalanced by a more refined perception of French assets, and is often regarded as off-putting.

Predominantly European competition

This slow evaporation of investments is compounded by a weakening of the production system. Roland Berger consultants were commissioned by Leem to map the pharmaceutical industrial base and to analyse its strengths and weaknesses. In terms of strengths, France remains a major power in the pharmaceuticals industry, making a major contribution to the trade balance (+ EUR 8.8 billion in 2013), ranked second in Europe for industry jobs (as many as in aeronautics) and societal value (providing social security contributions, taxes and duties for the country) of around EUR 7.2 billion.

However, despite the significant advantages offered by French sites, the warning signs are mounting in terms of know-how, equipment, productivity. The instability of political decisions, the burden of taxation, the complexity of French employment law and the impact of price changes in France all play an important role in investment decisions.

More worryingly, of the 40,800 jobs directly involved in pharmaceutical manufacturing, 85% are generated by chemical-based products and 75% by chemical-based products that have reached maturity. These jobs are especially vulnerable since the products on which they depend are poorly funded, modestly priced, and exposed in the short or medium term to competition from generics.

Despite its leadership in the production of vaccines, France's performance in the manufacture of biological medicines (manufacturing only 3% of the monoclonal antibodies consumed locally) and new medicines is disappointing. *"France is struggling to launch medicines and renew its industrial base"* according to the study. *The competition is predominantly European".* Of the 130 new molecules licensed in Europe in 2012-2014, only 8 will be produced in France. By comparison, Germany will produce 32, the UK 28, and Ireland and Italy 13 each.

Emergency measures to sustain and revive French manufacturing

The studies conducted by Roland Berger and Arthur D. Little largely confirm the projections made in 2012 - likewise commissioned by Leem - and have set out a number of recommendations, some of which have already been defended by the industry:

- **Maintain production volumes of traditional medicines and their associated jobs**. The two firms recommend fostering investment and location in France by introducing fiscal measures (tax credit on pharmaceutical taxes), by promoting local production through price setting or by recognition of a "Label Europe" in public procurement procedures. They urge the encouragement in France of generic medicines by simplifying the early production of bioequivalent generics by the originator patent holders and the promotion of their production in France/Europe through price setting. As regards exports, they recommend the streamlining of export procedures and support (in the form of credit) regarding site approvals.

- **Foster investment in future manufacturing (including biomanufacturing)**. Both consulting firms advocate improving the conditions for market access, most notably by reducing the time required for marketing authorisations, for assessments of benefit provided and for price setting. They recommend greater consistency in price regulation, primarily by achieving price stability for highly innovative products or by developing a multi-year vision of price levels. Finally, on the issue of biomanufacturing capacity, the authors of both studies recommend the establishment of a single hub in which biomanufacturing capacity and training provision converge.

"Our major European neighbours have understood the need to act proactively in terms of regulation, taxation, market access and social standards, if they are to attract investment in health. They have understood that the conditions for forward visibility, clarity and predictability must be met, and companies offered the prospect of stability over a three- to five-year horizon, **according to Patrick ERRARD, Chairman of Leem.** *Our country has long been held up as a benchmark for pharmaceutical research, production and access to innovation. In all these areas, that image is now becoming tarnished. Let's get back on track and develop a real industrial policy for our country. Entrepreneurship leads to a thriving manufacturing base."*

The Roland Berger and Arthur D. Little studies can be downloaded fromwww.leem.org

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