

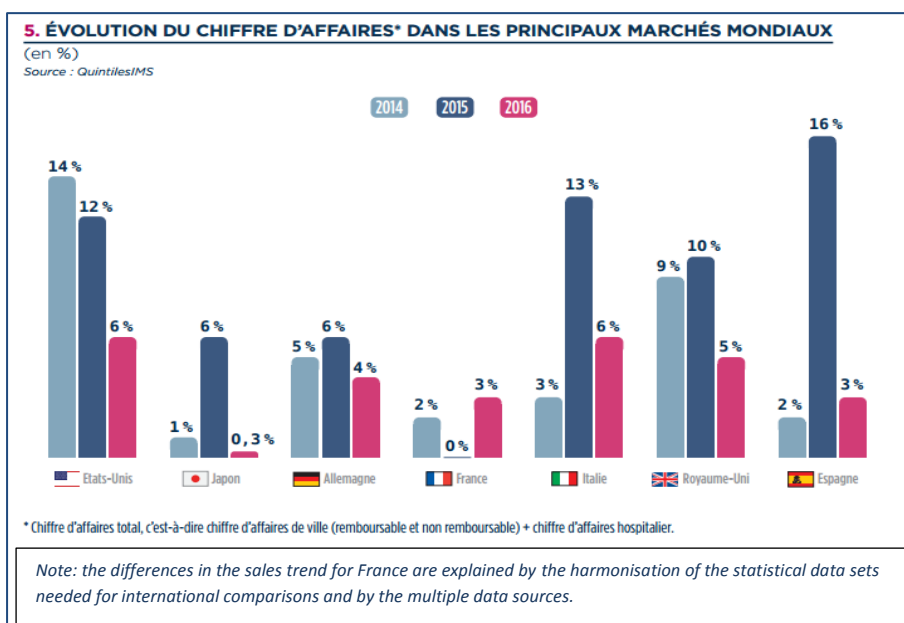
Economic Review of Pharmaceutical Companies

It is imperative that we jettison an economic regulation that is both short-termist and ill-suited to innovation in therapy

The publication of Leem's economic review for 2017 once again highlights a stark contrast in France between a strong pharmaceutical industry and an accounting regulation that is short-termist in nature and undermines the buoyancy of the economy. Pharmaceuticals, one of the country's most strategic sectors of industry, have emerged sluggish after years of implementing regulatory and pricing mechanisms that have hindered innovation. France, not long ago hailed as the benchmark for research, manufacturing and access to innovation, is now lagging far behind its European neighbours in these three areas. Leem is convinced of the urgent need to undertake structural reforms in order for France to reclaim its place among the community of innovative nations.

An illusory return to growth

This is what can only be called false good news. In 2016, the French pharmaceutical market (retail pharmacy, hospital, reimbursable and non-reimbursable medicines - excluding exports) once again showed positive growth (+3%). Yet, despite this slight upturn, France is unable to catch up with its European neighbours. The French pharmaceutical market remains, with Spain, at the bottom of the league table behind Germany (+4%), the United Kingdom (+5%) and Italy (+6%). And it is worth noting that once the rebates paid by manufacturers are deducted, the growth in sales of reimbursed medicines falls to a mere 0.9% according to the Bipe-Gers survey.



The French share of the global pharmaceuticals market has also shrunk significantly: from 5.6 % in 2006 to 3.9% in 2014 and just 3.4 % in 2016. In 2016, France was still the world's fifth largest market behind the United States, China, Japan and Germany, and the second largest market in Europe behind Germany, but its market share has seen a decline of 2.2 percentage points in ten years. A study published in December 2016 by QuintilesIMS confirms this trend: by 2021, France will have dropped a further two places in the ranking, overtaken by Italy and the United Kingdom (Outlook for Global Medicine Through 2021).

Fighting common misconceptions

The findings of the economic review are dispelling a number of common misconceptions surrounding pharmaceuticals in France.

➤ First common misconception: **"Sales of medicines are constantly on the rise"**

False. In 2016, the growth in revenue from pharmacy medicines was marginal (+0.1%). This slight upturn comes after four consecutive years of decline. Growth in revenue from the hospital market was certainly higher (+7.5%), but it was driven solely by medicines granted ATU (temporary authorisation for use) and post-ATU status, for which manufacturers pay very high rebates. Across the hospital and non-hospital pharmacy markets as a whole, after deducting all the rebates paid by manufacturers, the latest BIPE-GERS survey shows that the regulated pharmaceuticals market was the same (EUR 22.9 billion) in 2016 as it was in 2011 (EUR 23.1 billion). Despite this sluggish growth, the pharmaceuticals industry has had to cope with the increasing number of patients treated (due to the combined impact of demographic and epidemiological changes), an ageing population, and two big waves of innovation in therapeutics (new treatments for hepatitis C in 2013 and more recently immunotherapies to combat cancer).

➤ Second common misconception: **"Expenditure on medicines is responsible for the rise in healthcare spending"**

False. The reverse is true! Since 2011, expenditure on medicines has risen far less rapidly than the other health insurance costs and the National Healthcare Spending Target (ONDAM). Proof that medicines are unfortunately being treated as a budgetary adjustment variable in order for the ONDAM target to be met.

➤ Third common misconception: **"The price of medicines is always on the rise"**

False. The price of retail pharmacy medicines continues to decline as the cost of living is steadily increasing. Between 1990 and 2015, the cost-of-living index increased by 48.4% while that of public prices for medicines (refundable and non-refundable) fell by 27.9% over the same period. At European level, a study carried out by CEPS (French Economic Committee for Health Products) and published in its 2014 – 2015 activity report shows that French prices are, in half of all cases, lower than the lowest prices in Europe's five comparable markets. And prices are below the average of the five countries for 93% of products.

➤ Fourth common misconception: **"The French pharmaceutical market enjoys particularly attractive tax advantages"**

False. Despite various tax incentives - the Research Tax Credit (CIR) and the Tax Credit for Competitiveness and Employment (CICE) - France still has the highest tax burden in Europe. A survey of French and European pharmaceutical industry taxation conducted by the firm PwC Société d'Avocats on behalf of Leem found that France consistently trails behind the seven countries included in the survey (France, Germany, Italy, United Kingdom, Ireland, Spain and Switzerland), with tax rates well above the European average. Despite a slight narrowing of the gap with its European

neighbours - due in particular to the repeal of the additional corporation tax levy - France remains the top taxing country with no fewer than five industry-specific taxes while the other European countries have only three (Spain and Italy), only one (Germany) or none (United Kingdom, Switzerland and Ireland).

➤ Fifth common misconception: **"France is still a major host market for innovative products"**

False. France, traditionally a leading host market for innovative products, has experienced a deterioration in recent years:

- In terms of industrial manufacturing: of the 282 medicinal products authorised by the European Medicines Agency (EMA) between 2012 and 2016 (excluding generic and biosimilar medicines), only 21 are produced in France, whereas 86 are produced in Germany, 68 in the United Kingdom and 39 in Ireland.
- In terms of patient access: France has the sad honour of having one of the slowest market access rates in Europe. It takes more than 400 days on average before a medicine is placed on the market after being given marketing authorisation, instead of the 180 days required under European regulations. Even the fast-track access procedure (ATU), through which patients are eligible for restricted access to highly innovative agents once the MA is granted, is delayed by assessment and pricing periods of up to 335 days.

➤ Sixth common misconception: **"The pharmaceutical industry is experiencing a decline in workforce numbers"**

False. In spite of economic regulation and taxation mechanisms which are weighing heavily on the sector, the pharmaceutical industry has managed, temporarily, to avoid a reduction in its workforce. With employee numbers of 98,690 at the end of 2015, i.e. down just 0.1% compared to 2014, pharmaceutical companies have managed to stem the erosion of their workforce through forward-planning, support and job transformation measures. This slight downturn runs counter to the decline observed in manufacturing as a whole (-1.0%).

After four years of short-termist accounting regulation, Leem is expecting the new government to make a clean policy break. Tradeoffs will have to be made in the French Social Security Finance Act 2018 to restore growth margins to the sector, revive the tradition of hosting innovative products, and make innovations in therapy available to all.

"Despite being strategic to employment, growth and the balance of trade, the pharmaceutical industry has been wrung dry after three years of drug regulation" according to Patrick Errard, Chairman of Leem. The pressure on the price of medicines, the regulation-driven inflationary environment and the burden on general and sector-specific taxation all act as brakes on manufacturing investment. What's more, they jeopardise early access by patients to innovative therapies. Jettisoning this erosive regulatory policy is no longer merely desirable, but imperative. Faced with the challenge of innovation against a backdrop of increased international competition, for our industry to develop, we need an ambitious, reforming health policy that is prepared to regard therapeutic innovation no longer as a cost but as an investment, an opportunity to improve the health of our fellow citizens and our economy. "

The 2017 edition of Leem's Economic Review is available at: www.leem.org

Video of key figures: <http://dai.ly/k60v39Wns8sWFTnNS4h>

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