

The economy, innovation, jobs... **Our analyses and proposals**

Economic challenges: restructuring healthcare expenditure regulation

Presentation by *Philippe Tcheng*, Chairman of the LEEM Economic Affairs Committee

ANALYSES:

Analysis 1: For the 10th consecutive year, medicines remain the main variable used to adjust the system

- Medicines are the focus for €960 million in price reductions and €300 million in cost-cutting measures in the LFSS 2014 social security finance bill
- Medicines, which represent 15% of compulsory health insurance expenditure, contribute more than 50% of the savings
- New savings made on medicines by the Assurance Maladie health insurance fund have totalled €10.2 billion in 9 years: more than €1.1 billion per year, rising to more than €1.5 billion in 2012 and 2013 (*'Bilan de 9 ans de régulation sur les différents postes de soins 2005-2013' (9 years of regulation and its effect on aspects of healthcare 2005- 2013) – BIPE survey – May 2013*)

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Analysis 2: Many of the major measures included in the new PLFSS social security finance bill contradict measures approved by the Strategic Council for Healthcare Industries (CSIS) and Sectoral Strategic Committee (CSF) on 5 July last year. Especially:

- **Biosimilars:** although CSIS/CSF recommended the formation of a working group to develop a legal framework that would reflect the manufacturing, economic and public health challenges of biosimilar medicines, the 2014 LFSS acts in advance of any such findings to create a reference list and authorise substitution by pharmacists.
- **Taxation of wholesale sales:** in contravention of the fiscal stability commitments given by the CSIS, the LFSS plans to transfer wholesaler-distributor taxation to pharmaceutical laboratories, despite the fact that the latter are already subject to the highest tax burden of any European country (11 industry-specific taxes, as well as the normal tax regime).

PROPOSALS:

- Manufacturers wish to contribute to a global discussion on the opportunity for **all healthcare stakeholders to contribute to the regulatory process.**

- This process must be based on **data that are up-to-date, acknowledged as accurate and shared by all stakeholders**. What is the actual consumption of medicines in France? How do French medicine prices compare with those in other European countries?
- **Manufacturers want to contribute as a persuasively proactive force for change and commitment** to alternative economic regulatory measures that are not restricted exclusively to the price of medicines.
- **A number of options are worthy of exploration**, especially the development of responsible self-medication, the streamlining of care pathways and the avoidance of hospitalisation (day surgery, hospital care at home, etc.).

Scientific challenges: stimulating innovation

Presentation by **Cyril Titeux**, Secretary to the Board of LEEM

ANALYSES:

- **The place of France in clinical research**

The fact that clinical research is declining in Europe (25% less than five years ago) has led to a revision of the 2001 Directive.

France is left behind by Germany: 6.5% of patients recruited worldwide, compared with 8.9% for Germany.

France ranks no higher than 4th in the list of European countries attracting clinical research, behind Germany, Holland and the UK.

- **Early-stage access to innovation**

ATUs (temporary authorisations for use) enable access to medicines prior to them being granted Marketing Authorisation (MA). This is particularly important for French patients, because there is currently a difference of around one year between the time taken for an American MA and a European MA. Cohort ATU evaluation and acceptance procedures must be simplified to maintain this advantage.

- **Recognition of innovation**

The French post-MA evaluation system is neither very clear nor predictable.

The 180-day period specified in the European Transparency Directive is not respected (236 days on average for an initial registration between the submission of the transparency documentation and publication in the Official Journal (*OSCARS database - August 2013*)).

- **Real-world monitoring of medicines**

The process of evaluating medicines does not stop with the MA, but continues in the real world. Efficacy evaluation is an essential part of assessing medicines within the care pathway.

PROPOSALS:

- **To develop innovation in France**

- **By encouraging clinical research**, which enables faster patient access to innovations:

Simpler administration: One of the reasons why France lags behind is the time taken to sign contracts, which averages 111 days in hospitals (compared with 2 days in England and 7 days in Germany in certain areas).

LEEM manufacturers propose a **single contract for all hospitals**. This is CSIS measure 19, which should be implemented this February.

- **By retaining the temporary authorisation for use (ATU) system** which has made France one of those countries in which patients gain the earliest access to innovations (e.g. those in cancer and HIV treatment):

Manufacturers are committed to giving the submission of cohort ATU requests **priority** over named ATU requests.

They also want to see the time taken by the ANSM to evaluate cohort ATU requests **shortened** from the current average of 5 months (*OSCARS database - August 2013*), which can result in a real lack of opportunity for patients.

- **To encourage the recognition of innovation**

Manufacturers want to see a **revision to the criteria** applied to the reimbursement and added-value evaluation of medicines, and propose that the evaluation methods be reconsidered in public debates attended by patients. Compliance with the times specified by the Transparency Directive is a necessity. **More** early-stage meetings and easier **preliminary** submissions could contribute to this.

- **To monitor medicines in the real world**

If they are to monitor medicines in the real world, manufacturers must have **easier access to administrative databases** based on research protocols and independent scientific committees.

Employment challenges: anticipation and support

Presentation by Frédéric Soubeyrand, Chairman of the LEEM Employment Issues Committee

ANALYSES:

Pharmaceutical companies together form an efficient industry that is subject to **fierce international competition** and is currently engaged in a phase of **profound structural change** further complicated by the global economic crisis.

- ✓ The days of blockbuster drugs - most of them from the chemicals industry - are behind us, and the consequence is restructuring exercises that are impacting essentially on sales/marketing and administration/support roles (**11,500 jobs** have been lost in these areas (including with service providers) over the last five years).
- ✓ The R&D model is changing to an **increasingly outsourced model**. Many more research contracts are being outsourced to the public and/or private sectors. 2013 saw the first-ever **reduction in R&D jobs: 2.9% fewer** than in 2012.
- ✓ **Production is also facing new challenges in France:** maintaining and increasing production volumes that are based essentially on products averaging 18 years old. Coping with production cost inflation. Attracting production of generics and biomedicines to France.

For the time being, these new challenges are having only a very small impact on production jobs (-1.1%, compared with 2012). **Nevertheless, this reduction in numbers, which also affects production subcontractor workforces, marks a disturbing trend reversal.**

These data have allowed us to identify those factors that could impact on jobs, and to identify the levers available for maintaining the overall level of employment in the industry.

The proactive scenario, which requires the implementation of initiatives, would enable the level of employment to be maintained between now and 2020. Nevertheless, **the figures for 2013 confirm the downward trend in the workforce, with industry employee numbers dipping below the 100,000 level.** The declining trend seen since 2008 has the effect of returning the industry to an employment level last seen in 2004.

PROPOSALS

- **Priority 1: To continue anticipating and preparing for change through initiatives that help to retain jobs.**
 - ✓ Introduction of the initiatives set out in the Forecasting Studies Contract (Contrat d'Etudes Prospectives or CEP)
 - **Develop youth employment** via work/study schemes offered by a network of leading companies and SMEs
 - **Prepare for the job mobility and reskilling of employees in jobs that are changing dramatically or are in declining demand**
 - **Prepare now for the skills demanded by emerging technologies** (e-health/telemedicine)
 - ✓ **Use industry agreements to introduce a jobs forecasting policy:** Generation succession contract, in-service training and forward management of jobs and skills (GPEC), and increased employment of disabled people (+21.6% of new recruitment in 2012)
 - ✓ **Introduce CSIS/CSF job creation/retention measures**
 - Single research contract: simpler implementation of public/private research and intellectual property management contracts
 - Promote transparency of medicine production facilities via the use of a symbol
 - Promote bioproduction in France (tap into the production of development products by French biotechnology SMEs)
- **Priority 2: Support change in medicine promotion and enhance quality policies**
 - Revision of the pharmaceutical representative calls charter now being negotiated with CEPS to improve the quality of medical information provided by companies