



Press conference

The French Drug Companies Association New Year Address

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New challenges, new dialogue, new Leem: A year of reorganization

Presentation by Patrick Errard, Chairman of Leem

Ladies and Gentlemen,

Thank you for taking up the invitation from Leem.

My first words will, of course, be to wish you, your families and the publications you represent an excellent year in 2015.

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2015 brings with it an unprecedented number of promises and challenges for the healthcare system in France.

- **The promises include** a very significant acceleration in the speed at which we are seeing innovative new therapies emerge, bringing with them new hope of recovery for patients
- **The challenges include** the emergence of a fundamental debate on how to modernise the healthcare system and, against a background of falling social security contributions, question marks over our country's ability to adapt its healthcare funding model.

This will be a pivotal year for our industry. After four years of fast-tracked accounting regulation, legal instability, downturn in sales and a general weakening of the industry, **2015 must see a complete departure from the models of the past.**

As chairman of Leem, I cannot bring myself to stand by and watch this country accelerate the downgrading of its drug industry on the world stage.

As the representative of an international group that has chosen to invest in France, I cannot accept that the commitment of our people, our projects and our partnerships are not sufficiently appreciated for what they are: opportunities for national growth.

Alongside all its members, committee chairmen and directors here this morning, Leem will continue to promote its belief in essential reforms with force and conviction.

In 2014, we saw the first signs of the major trends that will become the most important challenges to our environment in the months ahead:

- **The challenge of innovation**, and the way in which our country intends to ensure that patients have fast and equal access to the drugs they need
- **The challenge of the efficiency** offered by healthcare technologies, and the ability of our healthcare system to plough back the savings generated as a result of innovations in therapy
- **The challenge of national appeal** in terms of attracting inward investment in production, clinical research and scientific expertise

All these challenges are decisive for the future.

They demand every stakeholder in the healthcare system to consider **a fundamental review and overhaul of their current positions.**

Before I go any further, I'd like you to listen to what five pharmaceutical manufacturers had to say when asked about their expectations for 2015.

[VIDEO]

As we've heard, the heads of drug companies - French and international - are united in underlining the need **for urgency in addressing important concerns.**

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In recent years, we've seen nothing less than a chasm open up between an ambitious industrial policy - based on universal recognition of the strategic importance of our industry - and a short-termist policy of expenditure control.

The downward spiral that is reducing the appeal of France is a reality:

- A continuing pattern of disproportionate economic regulation targeting our industry
- One of the slowest drug market access rates in Europe
- The most onerous general and industry-specific taxation burden of any major EU country
- Increasingly alarming scientific and industrial indicators

Leem now has three important questions for government:

- How will France embrace tomorrow's innovations in therapy, and will it continue to guarantee access to healthcare for its population?
- Will it dare to put in place the fundamental reforms required to ensure that savings generated by new technologies and progress in therapeutic care are ploughed back into the healthcare system?
- Lastly, is France determined to regain its former appeal for inward investment in science, manufacturing and business?

In addressing these key questions, we have some proposals for government.

Given the fact that the old models of consultation are running out of steam, we believe that what is required is a **profoundly different and new dialogue with the State.**

United around a clear policy line, and with a brand new governance and operating structure, **Leem is ready and eager to take on these major challenges.**

1. New challenges for the drug industry.

What precisely are these challenges?

- **The first challenge: to embrace innovation and provide guaranteed access to healthcare within a redesigned framework**

Yes, innovation is back!

At the cost of enormous industrial, financial, organisational and cultural effort, **the healthcare industries have succeeded in bringing a new impetus to progress in therapeutic care.**

Nowhere is this truer than in pharmaceuticals, with the arrival of major innovative breakthroughs that have already, or will soon, **radically transform patient care**, especially in hepatitis and cancer.

182 drugs are already scheduled for market launch in 2015, and many of those are new anti-infectives, antivirals or products for use in cancer treatment and the neurosciences.

462 medicinal products will arrive in the market by 2017 in the same therapeutic areas, with 1,423 other drugs currently in phase II clinical trials that will be with us by 2018.

They bring with them a challenge to our healthcare policy, because this wave of new treatments raises questions about the ability of our social system to incorporate such innovations in its healthcare provision.

The debate over the cost of innovation is clearly a legitimate one to have. But it is equally legitimate to ask ourselves collectively about the inability of our system to plough back the efficiency gains generated by the drug industry.

The challenges are equally fundamental in terms of product evaluation and patient access.

The **medical and scientific landscape** has changed dramatically in just a few years, impacting significantly on therapy strategies and evaluation methods.

But what are we actually seeing in parallel with these changes?

The rules governing which drugs will be funded have become increasingly inappropriate, with growing confusion between MA and transparency evaluation, and between the concepts of SMR (medical benefit provided) and ASMR (improvement in medical benefit provided).

We are also seeing longer time to access to innovative products, especially since 2012.

"The maximum period of 180 days set by the European directive has been complied with in France for only two drugs since 2009! Even for products subject to the FDA priority procedure because they are considered vital, the 180-day period is never complied with: the median period (between 2009 and mid-2014) is 360 days.

Consequently, the gradual accumulation of regulatory changes has meant that the system has become **illegible** to drug companies, **hard to comprehend** for healthcare professionals and **puzzling** for the public.

For all these reasons, Leem is now advocating practical proposals to modernise assessment criteria and enable rapid access to innovative therapies:

- ✓ Linking reimbursement to the severity of the illness
- ✓ Basing evaluation of the added value on the overall benefit delivered by the drug concerned to the patient, rather than on the risk/benefit ratio alone
- ✓ Building a transparent, high-quality evaluation process using procedures involving both parties
- ✓ Enabling immediate and controlled access via hospital and non-hospital pharmacies as soon as the MA is granted, with a pilot phase for patients with no further therapeutic options
- ✓ Taking account of the special status of orphan drugs

➤ **The second challenge: betting on efficiencies offered by healthcare technologies and their impact on the healthcare system**

Once again this year, the government has ignored another opportunity to introduce genuinely structural reforms. It has avoided choosing efficiency.

The system has finally given birth to its own contradictions:

- How is it possible simultaneously to claim to be attractive to inward investment by healthcare manufacturers, and yet impose on those very manufacturers - often in an authoritarian manner - increasingly high levels of price reductions and a forward trend in drugs expenditure of more than -1% under threat of a levy payable to the Health Insurance system?
- How is it possible to talk about requiring greater responsibility from all healthcare system stakeholders (especially hospitals), and yet demand that 50% of the savings effort is made by the drug industry, which accounts for only 15% of Health Insurance expenditure?

[Subject to the actual content of the speech]

- How is it possible to praise the efficiency of agreement-based economic management and at the same time introduce a legally binding regulatory provision that targets a specific category of drugs?
- Lastly, how is it possible to promote the fair and reasonable use of drugs, at the same time as passing legislation that - purely for economic reasons - introduces a system that permits the use of drugs outside their indications?

There can be no genuine - that is to say effective, consistent and legible - regulation policy without an analysis that takes full account of innovation and the way healthcare is organised.

That is why we will be forceful in promoting and advocating **structural reforms to the healthcare system and a health policy based on efficiency.**

We have submitted many concrete examples to the Health Minister: here are just a few of them:

- The optimisation and rationalisation of care pathways, preventing hospitalisation by providing hospitalisation at home and the impact of oral chemotherapy options on the organisation of healthcare: **all offer obviously effective ways of improving healthcare, but they also offer effective ways of reducing costs**
- The same applies to telemedicine, the development of preventive procedures, early-stage screening and biological indicator monitoring, **all of which would prevent or delay the onset of illness in many patients.**
- In terms of combating drug-related illnesses and developing self-medication as part of a care pathway, **the system has reserves of efficiency that should be leveraged intelligently.**

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In the context of this approach, care quality and safety must always act as the compass for our member companies.

That is why drug companies are committed to promoting real objectives for public health (the prevention of drug-related illnesses in elderly patients).

- **The third challenge: to restore the parameters for attracting inward investment to France**

The declining appeal of France as a target for inward investment impacts on all our activities, and its effects on manufacturing are now widely documented.

Investment is falling:

- Over the last three years, investment in production has fallen by €120 million to €810 million.

- 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.

Production capacity is weakening:

- Today, the great majority of the 40,800 direct jobs in pharmaceutical production depend on products that are poorly funded, modestly priced, and exposed in the short or medium term to competition from generics
- 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

Our manufacturing base faces twin problems:

1. On the one hand, our production facilities are ageing.

A very large proportion (around 80%) of the 40,800 direct jobs in pharmaceutical production relate to chemical molecules and/or high-maturity products. 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.

Leem is therefore calling for concrete measures to protect the production volumes of traditional drugs and the jobs that go with them: tax incentives to promote local production, bringing the fact of production in France/Europe visibly to the attention of patient and public-sector buyers, facilitating international approval of production sites, etc.

2. On the other hand, we are failing to attract new production capacity.

Despite its leadership in the production of vaccines, France's performance in the manufacture of biological drugs and new drugs is disappointing: for example, it manufactures only 3% of the monoclonal antibodies consumed locally.

To boost investment in future manufacturing (including biomanufacturing), Leem is proposing better forward visibility of prices for locally produced original drugs.

2. A new dialogue with the State

I've talked about innovation, benefiting from the savings delivered by new healthcare technologies, and the conditions required to reinstate France as an attractive target for inward investment.

But if we want France to meet these challenges aggressively, we must work with the public sector to define and introduce a new form of dialogue.

The old consultation models belong in the past. Too many, too confined and too focused on the specific to the detriment of the general.

We have to return to a holistic vision of our challenges.

Indeed, every report (Gallois, Lauvergeon, Rocard, etc.) stresses the strategic nature of the healthcare industries... **and yet, that very strategic dimension has never suffered as much as in the last five years!**

That's why, in accordance with the mandate granted to me by the directors of Leem at their seminar on 19 December last year, I have recently written to the Prime Minister to suggest a dialogue based on two fundamental principles:

1. Principle 1: A Strategic Council for the Healthcare Industries (CSIS) that will provide the effective backbone for dialogue between State and manufacturers.

The new CSIS must not become a directory of piecemeal measures picked out of successive French Social Security Finance Acts.

It must now rediscover its role alongside the CSF (Sectoral Strategic Committee) for the operational implementation of short-term measures.

Reporting directly to the Prime Minister, it must act as **guarantor for the consistency and forward visibility of public policy** on manufacturing, economic regulation and public health.

Naturally, this process is pointless unless every aspect of drug-related public policy aligns with the directions set by the CSIS.

I'm thinking here particularly of regulation policies, which is why we have also suggested to the Prime Minister that parliamentary representation should have a closer relationship with the work of the CSIS.

Lastly, it should be refocused on shared strategic challenges. I defined these as follows:

- **The attractiveness of France** (in terms of original and generic drug production, exporting and, of course, research)
- **Innovation**
- **The efficiency** offered by healthcare technologies and its impact on the healthcare system

The CSIS must also play an instrumental role in multi-year budget transparency.

Britain and Germany understood that to attract investment in healthcare, they had to put in place the conditions required to provide the openness, forward visibility and predictability needed by the industry and offer companies the prospect of stability over a three- to five-year horizon.

We cannot wait until all our competitors have made their moves before we in France make the same correct choices!

Refocused on its original goals and reinvested with its full authority, this restructured CSIS would be able to rely on the active participation of drug companies.

This summer would be a desirable deadline for bringing this new Strategic Council for Healthcare Industries together.

2. Principle 2: the contractual policy, as interpreted in the Leem-CEPS framework agreement, must return to playing its full role

For twenty years, the framework agreement between Leem and CEPS (the Economic Committee for Health Products) has governed interactions between State and industry in areas as essential as market access, price setting, economic regulation and industrial policy.

Yet we have seen the scope of the agreement eroded year after year in favour of legislation

The most recent Social Security Finance Act contains flagrant examples of this permanent short-circuiting of the contractual channel:

- A prior agreement procedure applied to a hypercholesterolemia drug
- Temporary recommendation for use authorising off-label prescription of an anti-cancer drug
- Introduction of a special tax on hepatitis C treatments

Although the policy of regulation by agreement has, until now, provided a welcome competitive edge in international competition, **an increasing proportion of the economic regulations targeting our industry is now being introduced through other legislative and regulatory channels.**

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At a time when the process of renegotiating the Leem-CEPS framework agreement is due to begin, **the principle of agreement must be confirmed and strengthened as a matter of urgency.**

The framework agreement will expire at the end of 2015. **We aim to bring forward proposals before the spring by introducing a number of new priorities into the consideration process:**

- Identifying innovative funding methods for breakthrough innovations
- Defining alternatives to the policy of systematic price reductions by focusing particularly on structural initiatives

What we are proposing to the Prime Minister today is the **introduction of a 'primacy principle' under which the agreement-based route** – and therefore the framework agreement – would be the first choice for any decision with the potential to have an economic impact on drug companies.

In the same spirit, Leem succeeded last spring in securing the involvement of drug companies in **an interministerial consultation process prior to the PLFSS (French Social Security Finance Bill)** .

The principle of this - previously unprecedented - dialogue must be maintained in order to ensure a minimum level of consistency between the strategic priorities of CSIS-CSF, Leem-CEPS agreements and the regulation measures contained in the Social Security Finance Acts.

I would like to take this opportunity of reminding you that the measures voted on annually by Parliament in respect of healthcare products are the only ones whose effective performance is achieved in full and measurably. We are demanding that all those provisions voted on annually in respect of Health Insurance expenditure should be the subject of a subsequent **impact measurement study** so that the degree to which the savings voted on by Parliament are achieved becomes public knowledge.

Lastly, I cannot leave this subject of the urgent need for dialogue without mentioning the increasingly productive discussions that Leem is having with **associated industries**, whether through Féfis (the French Federation of Healthcare Industries) or MEDEF (the French Business Confederation), which is currently showing a great deal of interest in the issues facing us.

We also commend this ambition to establish a new dialogue to our **partners in the drugs supply chain** – through structured discussions with dispensing pharmacists and distributors – **as well as with physicians and patients.**

3. A refocused Leem

Our companies are changing, and so is their industry organisation.

With a single ambition: to reflect the diversity of our 270 members and their businesses, whilst promoting the principles we all share.

This work began with restructuring the **governance** of Leem to provide the full diversity of its member companies with a clearer voice, but without compromising the operational efficiency of the structure.

A broad range of different views is now better represented in the executive bodies of Leem.

The role of the **committees** has been enhanced in order to gain maximum benefit from the ideas and expertise of our members and return real power to the membership in terms of day-to-day preparation of industry policy.

This restructuring exercise has been extended to include the development and adoption of a **new policy line** that is clearly defined around three priorities:

- Creating an ecosystem that encourages innovation
- Supporting a proactive manufacturing policy that goes hand in hand with changes in the industry:
- Promoting the principle of a strategic industry that behaves responsibly and ethically in its dedication to making therapeutic progress

At a more operational - and perhaps less visible - level, we also have a role to play in improving **the service we offer our members:**

- The imminent launch (in early April) of an ambitious SME Hub - a one-stop shop to provide guidance for small and midsize companies needing advice and services
- The hosting of information meetings targeting the interests of our members

[Subject to the actual content of the speech]

- The imminent upgrade of the jobs forum on our leem.org website
- Enhancement of the Careers and Skills Observatory

The restructuring of Leem has also been driven by a **quest for greater efficiency**, improved focusing of initiatives and resources and greater cross-disciplinary interaction of expertise. The outcome of this commitment has been increasingly multidisciplinary formats for interaction and redesigned working methods.

The restructuring exercise will also involve LEEM in relocating to new premises this summer. Our traditional base in the Rue de la Faisanderie is no longer suited to the operation and needs of a modern organisation, and so we plan to start a new chapter of our history by bringing everyone together in a single location: Porte Maillot. This will allow us to relocate some satellite operations of Leem, promote greater cross-disciplinary interaction between departments and teams, modernise our working methods, welcome our members collectively and individually, and give Leem a more modern and welcoming image.

Lastly, this commitment to greater openness is also demonstrated by **communication** that targets the general public more directly to provide a clearer explanation of the challenges facing the drug industry and the complex machinations of the system. We understand that the issues surrounding our industry are not easy to understand, but it is our duty to make them more accessible and to report on our own activities.

In conclusion

In concluding, I would like to return to the essentials.

The very purpose of our companies is to offer patients new hope of recovery.

That hope is already being, and will increasingly be, fulfilled, because breakthrough innovations like those recently rumoured so widely in the press are only the first in a long succession.

With biotechnologies, the increasingly productive alliance of drugs, diagnostics, imagery and medical devices, and the dramatic increase in treatment-related services, an entirely new world of healthcare is now emerging.

It is now the responsibility of society, politicians, administrative authorities and health agencies to envisage how this change can be embraced.

Along with drug companies, patients and the medical community, it is up to them to rethink how the system can and should evolve to ensure universal access to healthcare within a sustainable framework.

For ourselves, we are also committed to becoming more closely involved in clarifying our challenges, our missions and our responsibilities.

We are fully aware of the sometimes irrational debate with which we are confronted and that what we say is not always perceived as legitimate or sincere.

[Subject to the actual content of the speech]

Although French confidence in the drugs industry remains high (75%), this confidence in the 'product' does not extend to the 'producer'. Only 55% of French people have confidence in drug companies.

This result is abnormally low for an industry that saves lives. It results from a lack of knowledge amongst the French population regarding the reality of this industry, which can seem remote and complex.

Our companies have for several years been engaged in a process of **reviewing and updating their practices**. This is a necessary step, but it is not sufficient in itself if we wish for greater understanding and recognition.

It is up to us to put in the necessary work, communicate more effectively about the issues that concern us, and do a better job of 'embodying' our member companies. This presupposes, of course, that we are attentive to the expectations of society.

Let's hope that in 2015 the healthcare debate is conducted in a spirit of mutual attentiveness in which every part of the landscape can have its views heard and respected.

Thank you.