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Press conference The French Pharmaceutical Companies Association New Year Address



Date: Wednesday 8 January 2014 – 09:30 **Venue:** Le 8 Valois – 8 rue de Valois – 75001 Paris

Speech by Patrick Errard Chairman of LEEM

Ladies and Gentlemen,

I am delighted to welcome you here at the start of 2014, and to wish you, your families and the media organisations you represent a very Happy New Year on behalf of pharmaceutical companies operating in France.

This meeting has a particular significance for me, because it is the first time I have spoken to you as the association's permanent chairman. On completion of my four-month temporary appointment, the newly elected LEEM Board of Directors voted unanimously to appoint me as chairman of our industry organisation for the next two years.

Coming at the beginning of my chairmanship, this press conference provides me with the opportunity to set out my analysis of the current situation in our industry, but also, and perhaps more importantly, to set out a longer term vision of future key events.

LEEM will approach these key events in a spirit of collective commitment and unity. That is why, for this press conference, we wanted to involve three of our directors in sharing the presentation with me. Shortly, they will tell you about the initiatives we intend to promote collectively this year; initiatives on issues as important as the healthcare economy, patient access to innovation and the social aspects of our industry going forward.

Long-term vision and initiative are hardly new concepts, and the policy commitments of LEEM have for many years reflected our willingness to engage with new ideas. I would like to take this opportunity to reaffirm our legitimate role as a contributor to the major debates surrounding healthcare, which directly affect patients and all those involved in patient care and recovery.

Our first priority:

To promote a macroeconomic and structural approach to what we do

In ten years of involvement in the struggles conducted by the Leem, I have all too often regretted that we are analysed by others from a 'micro' perspective: micro-sectoral, microeconomic, micro-scientific, and so on.

The same applies to the way in which our key events are managed: the 'tragic repetition' that is the annual discussion over the social security finance bill, with levels of taxation that have cost our industry €1.5 billion every year for the past three years; it locks into a thought process that is increasingly short-term and consistently more financially draining on businesses. The burden and instability of the tax regime imposed on our industry put us way behind all other European countries in terms of the fiscal appeal, and simply strengthen this lack of forward visibility.

The contribution our industry makes to healthcare, the balance of the system and the economic vitality of the country puts it at the top of the national social and economic debate: a fact that no one can deny.

There is therefore an urgent need to 'release' our companies from captivity, to 'liberate' them and to free them from this conceptual rut in which some would like the pharmaceutical industry to remain.

There is an urgent need to change mindsets, and to stop seeing our companies as accounting units, as disembodied entities, and as a variable factor in adjusting the social security budget.

There is an urgent need to bring perspective, power and depth to our thinking, and to define ourselves fully as stakeholders in healthcare.

And there is an urgent need to dare to assert the medical credentials of our companies, and explain that the entrepreneurial aspects of our businesses are not incompatible with a humanist vision of our mission to serve patients.

Throughout my period as chairman, we want to focus on achieving a profound and substantial reconstruction of the relationship between pharmaceutical companies and their environment.

We want to rethink our position in the debate surrounding how the healthcare system should be structured.

With the support of all the strands within LEEM, I intend to bring forward a new 'social and political contract' between our industry and the nation.

We no longer want to be seen as a problem; we are determined to be seen as a solution

- A solution in terms of healthcare, of course, with an obvious contribution to be made by our industry to combating illness and disease, and all the more so given the promise of new treatments and therapies on which our companies are working tirelessly and to which they devote €5 billion in R&D investment every year in France.
- A solution in terms of care system efficiency, because as everyone agrees correct prescription of medication can avoid hundreds of thousands of hospital admissions, and because our industry returns more productivity gains to the system than any other area of healthcare expenditure.
- An economic and industrial solution, because against today's background of intense international competition, nearly half of our national production is exported (€25 billion out of a total of €52 billion), and because every additional €1 generated by the industry generates €3 of additional value for the rest of the economy.

Our second priority:

To unite our companies around a political line that positions LEEM as a persuasively proactive force for change

Whether French or international, the 270 company members of LEEM range from researchers and industrial manufacturers to generics and OTC laboratories, start-ups and biotechnology companies, SMEs and VSEs: they all contribute to building and maintaining the global reputation of our country, and they all deserve to contribute to this plan.

LEEM has a responsibility to bring this rich diversity of market players together around a single political line. An ambitious, modern political line focused clearly on the future of our healthcare system. A political line that is a proactive force for change: an agitator of ideas that challenges the political system and politicians on the basis of choices rather than demands.

A political line that will convince others:

- **Convince** others that we constitute a major macroeconomic lever with the ability to generate sustainable growth that will undoubtedly be more effective than the suicidal policy focused entirely on levies and taxation.

- Convince others of our determination to contribute to national economic recovery through enhanced dialogue conducted in the spirit of the CSIS (Strategic Council for Healthcare Industries), the CSF (Sectoral Strategic Committee) and policy by agreement.
- **Convince** others that patient access to innovation is not only a public health priority, but also a key element in France's ability to attract inward investment.
- Convince others that we have solutions that will support the necessary change in our economic model, and that we can offer a scientific and economic evaluation model capable of responding effectively to this new paradigm.
- **Convince** others that there is a genuine level of quality accreditation that exists in both research and production especially in France and that a fair price should be paid for that.
- **Convince** others that fiscal clarity and simplification work better than headline-grabbing hype, and put forward solutions that take account of national budgetary constraints.
- **Convince** others that there are efficiency measures yet to be explored, such as self-medication, improvements to the healthcare network, especially in hospitals, and the development of a genuine screening and disease prevention policy.

In establishing this political line, we must base our decisions on the same approach as that applied to patients by the medical profession: analysing the symptoms, making the diagnosis and prescribing the treatment. Making a statement is all well and good! But if that statement is not supported by concrete solutions, we will never get more than halfway towards our goal.

The start of my chairmanship coincides with the end of the LEEM strategy plan for the period 2010-2013. Beginning this January, we will determine the methodology and timetable for defining the political line regarding this new period, and our conclusions will be presented to our directors before the spring.

Our ambition:

To reconcile the industrial and scientific ambitions of France with the necessary rebalancing of the social security budget

Of course, this period of consideration and discussion does not mean that we should in any way avoid taking action now to learn the lessons of recent months, and attempt proactively to gain a clearer understanding of future key dates.

I am thinking particularly of preparations for the forthcoming PLFSS (French Social Security Finance Bill) - yes, already! - and the risk of once again having the strategic ambitions pursued through the Strategic Council for the Healthcare Industries and the Industry-wide Agreement competing with the regulatory measures at work in the Social Security Finance Bill.

Pharmaceutical companies are already making a major contribution to reducing social budget deficits. Thanks to the effective nature of policy-by-agreement, the national bill for medicines is totally under control. As evidence, I would point to how closely the ONDAM (National Healthcare Spending Target) for medicines has been achieved, despite the inclusion of new and more costly treatments. But the extent of the additional tax burden placed on our industry over the last three years now threatens the ability of the French life sciences industry to compete effectively.

The annual PLFSS exercise encourages a constant stream of short-term adjustment measures to the detriment of any meaningful policy to restructure healthcare in overall terms. The Finance Bill is an obsolete and inappropriate tool, not only in terms of controlling healthcare expenditure, but also when it comes to the future development for our healthcare system. We must therefore change the way the system works. As companies whose businesses are structured around long-term cycles, we need forward visibility beyond a simple one-year horizon.

What is preventing us from moving to multi-year scheduling of expenditure on medicines, which would enable us to make a far better case for attracting the international head offices of our members to France? This is the proposal I make here and now to the Minister of Health and the Minister for Industrial Recovery.

There is an urgent need to strengthen our ability to compete and our ability to attract inward investment, because there are already signs that we are losing out on both:

Firstly economically (the recession in the French pharmaceuticals market, with reimbursement sales in general practice down by 2.5% in 2013, 27 controlled redundancy plans resulting in 2.1% fewer jobs in 2013, bringing the total number of employees below 100,000, and the fact that France is losing touch with innovative product development).

Then scientifically (the collapse of clinical trials in some therapeutic areas, the reconstruction of the evaluation system, and the slowdown in access to innovation).

Even more concerning (because they occur against a background of rapid national deindustrialisation) are the increasing signs of disengagement in <u>manufacturing</u>. The French pharmaceutical production machine, which employs nearly 40,000 people, has to cope with fierce international competition from within Europe and from emerging countries, at the same time as it continues to be engaged in a phase of profound structural change that has been further complicated by the global economic crisis.

Maintaining and developing the ability of France to attract inward investment requires the use of industrial levers that pharmaceutical companies have already begun to act upon... But how can we possibly maintain or increase national production when, for the third year running, the French

government is extracting nearly one and a half billion euros in taxation from an industry in recession?

This industry demands consistency and clear choices: an industry recognised by government as strategically important can no longer be treated as a variable factor in adjusting the social security budget.

It is for this reason that LEEM - and indeed my predecessors in this role - have always promoted a process of dialogue with government built around shared goals and mutual commitments. It is also why we continue to be committed to a policy of regulation <u>by agreement</u> in reconciling the public need for budgetary control with the needs of the industry for openness, forward visibility and predictability.

For this reason, and because decisions to invest in the future must be taken today, we have submitted a proposal to the Minister of Health for the formation of a Government/Industry contact group in preparation for the next PLFSS. We believe that this group should have three goals:

- **Goal 1:** To reach agreement on key industry macroeconomic data. It cannot be right that we have such diverging figures on revenue trends, reimbursement amounts and market trends
- Goal 2: To test the essential macroeconomic assumptions on which the PLFSS figures for expenditure on medicines are based
- Goal 3: To prevent any risk of contradiction between CSIS or CSF medium- and long-term commitments on the one hand, and short- or medium-term regulatory measures on the other

By working together openly at this preliminary stage, the stakeholders in healthcare expenditure and its associated financial compromises can assert themselves as responsible and proactive contributors to the process. Within the system, there are pockets of productivity that have yet to be explored; within our companies, there is the ability to enter into contractual agreements regarding public health and expenditure targets. It is up to us to identify them.

CONCLUSION

The New Year press conference is traditionally a time to assess the past. But as you now appreciate, we prefer to talk about the future.

Our companies are not making demands; they are simply asking questions and making proposals. They are waiting for a consistent regulatory and governmental environment, they want a rapid reconstruction of this country's ability to compete long-term, and they hope to put in place the

conditions required to rebuild confidence in the medical treatment system, medical research and the entrepreneurial aspects of their businesses.

Our leading European neighbours - the British through their agreement on a Pharmaceutical Price Regulation System (PPRS) and the Germans with the revision of their five-year re-evaluation procedures - have put in place powerful initiatives that increase their ability to attract inward investment from the healthcare industries. Both understand that to attract such investment, they must 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 to give our pharmaceutical companies forward vision over a period of years in terms of regulation, taxation, market access and social standards. Our country has long been held up as a European and global benchmark for pharmaceutical research, production and access to innovation. In all these areas, that image is now becoming tarnished.

We want to see France regain that leadership so that we are no longer seen as an exception in Europe, but rather as its model.

Thank you.		

As I said at the beginning of my speech, I would now like to hand over to

Philippe Tcheng, *Chairman of the Economic Affairs Committee*, who will tell us about the economic challenges and the challenges we face nationally in attracting inward investment.

Cyril Titeux, Secretary to the Board of LEEM, who will talk about the scientific challenges and patient access to innovation.

And lastly, Frédéric Soubeyrand, Chairman of the Employment Issues Committee, who will present our employment challenges.

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