

Speech by Frédéric Collet at the Annual Press Conference

“Transforming France's drug policy to ensure that everyone has access to today's treatments and those of tomorrow”

Introduction:

- Good morning everyone. I'd like to begin by wishing all of you a very happy New Year. I wish you a 2020 full of family fulfilment, success in your career plans and, not the least, very good health.
- Health is by no means the least, because health affects us all.
- We are all patients.
- You will no doubt be familiar with the *Leem Parole de Patients* literary prize awarded annually to the best account written by a patient about his or her illness
- In *Et vivre encore*, this year's winner Pierre de Cabissole recounts his experience and talks very accurately about the long wait the patients suffer. I quote:
- *“My life has been on hold for a long time. For the last ten years, in fact. It went on hold when I was diagnosed with multiple sclerosis. I took a deep breath, and I'm still holding it. For ten years, I've been waiting for a miraculous something that will give me my life back (...)”*
- The decade now beginning should allow us to bring that waiting to an end as quickly as possible, not by producing a “miraculous something” to borrow the words of Pierre de Cabissole, but by some very impressive prospects of real therapeutic progress
- As you know from previous years, this annual New Year conference is usually an opportunity for the Chairman of LEEM to take stock of the previous year and outline the prospects for the year ahead
- It is also an opportunity to give voice to the demands of our organisation
- Nevertheless, I should like to take a slightly different direction this year:
 - Firstly, because the past year was impacted by very significant social unrest, from the *gilets jaunes* crisis to pension reform, to say nothing about the world of healthcare. **In these unusual circumstances, our role as healthcare companies is primarily to seek out avenues for constructive dialogue and possible solutions rather than to pile demands on top of demands**

- Secondly, because the equation facing not only our industry, but also our wider healthcare system, requires us more than at any other time to engage in a different kind of thought process and discussion that undoubtedly extends beyond the litany of grievances
- **I will, of course, leave plenty of time for questions and answers** so that we - in conjunction with my fellow chairmen whose presence I am grateful for - and the team from Leem address the major issues of the moment about which you may wish to have information, clarification and comment. It will therefore be an opportunity for us to discuss a current situation that is, as so often, particularly complex

- So what precisely is this new equation I just referred to? (*Mathematical terminology refers to “unknowns”. But we are lucky enough to know the constituent elements of this equation...*)
 - **Element 1: the resurgence of therapeutic innovation.** In the decade between 2010 and 2020, we saw the resurgence of therapeutic innovation. As a result, the number of new drugs registered with the FDA rose from around 40 in the mid-2010s to 60 or so in 2018. Nevertheless, we must all be aware that **this resurgence is nothing compared with the revolution that began in 2019 and will continue throughout the coming decade**
 - **Element 2: the renewed attractiveness and competitiveness of the industry in France.** A recent EY survey (*published on 13 January this year*) positions France as European leader in terms of attractiveness for foreign direct investment. This result echoes that of another survey, this time conducted by Business France in early 2019, which indicated that 85% of the foreign company executives surveyed associated France with industry, creativity, competitiveness, innovation and the startup mindset. **France has therefore returned to the closed circle of the most attractive nations, which is something we are delighted to celebrate**
 - **The third element is the continually rising level of societal demand.** Healthcare has become the top priority for the French population (46%), ahead of employment (40%), national education (34%) and the environment (31%), according to the Kantar barometer survey conducted last December for the Institut Paul Delouvrier. This emergence undoubtedly has a lot to do with the hospital crisis and the malaise of general practice and the healthcare professions in general, but also with drug-specific issues, from access to innovative new therapies to discontinuities of supply. **It is clear that our fellow citizens are now voicing concerns about the future of our healthcare system**
- So this year’s conference is - as you will already have realised - unusual, not to say exceptional: as one decade closes behind us, another opens ahead of us, which holds out an astonishing level of promise for the health of the French population

Part 1: the challenge of innovation is our ability to identify, prevent and cure disease, at the same time as improving patient health:

- Gene therapies, cell therapies, immunotherapies, nano-medicine, vaccines... The period we are now entering is full of hope for patients waiting for new therapeutic solutions, a better quality of life and/or the opportunity to take a more active role in managing their illness and their health
- We see these promises every day in our companies
- Let me give you some examples:
 - **In the next five years - in other words, tomorrow - gene therapies will open up the prospect of a cure for diseases as serious as multiple myeloma, beta thalassemia, sickle cell disease, Duchène muscular dystrophy and haemophilia.** Cellular therapies will then take up the challenge to offer effective treatment of solid tumours, for example
 - Today's new cancer therapies mean that 2 out of every 3 patients diagnosed with cancer will survive at least five years. **By 2030, progress in patient care should make it possible to cure 3 out of 4 patients and 9 out of 10 children**
 - It is now possible to stop the progression of multiple sclerosis using monoclonal antibodies. **By 2030, diagnosis and monitoring of this disease will have improved as a result of advances in MRI technology and the introduction of reliable blood biomarkers**
 - **And we could carry on adding further examples ad infinitum: in the field of vaccines, immunotherapy, rare diseases, and so on.**
- These innovations will redesign care pathways and, more broadly, the way our healthcare system is organised and structured. They also require us to work together on rethinking the issues around patient access to new treatments
- **LEEM has drawn these future opportunities together in a collective work called *Santé 2030*** in conjunction with the Think Tank Futuribles and more than 30 respected experts. *Santé 2030* - (copies of which will be available in this room at the end of our discussions) - is our industry contribution to tomorrow's healthcare. It is also our way of stepping back from the urgent imperatives of everyday life to think about longer-term prospects

Because therapeutic innovation is primarily a challenge for the future:

- The challenge of diagnosing, preventing and screening for illnesses at the earliest-possible stage
- The challenge of facilitating the fastest-possible recovery
- The challenge of delivering the most effective, least painful, care to the patient
- And also the challenges of the post-illness phase of reconstruction and the return to an active life

- **However, like any challenge, innovation inevitably comes with risks and uncertainties, which are reflected in its financial model**
- **Every innovation is a promise for the future.** A promise accompanied by a presumption of cure, the value of which must be substantiated by 'real-life data'. We must never lose sight of the fact that although it is our vocation to provide a constant stream of new therapeutic solutions to doctors and their patients, our industry is characterised by:
 - **A permanent commitment to risk-taking, with high research and development attrition rates**
 - For example, 400 international studies into Alzheimer's disease have been stopped in the last 20 years or so. And of the 117 molecules for the treatment of Alzheimer's still at the clinical trial stage, only 12% are at an advanced stage of development
 - **By massive capital investment** (it costs between 1.5 and 2 billion to develop a new drug today) **over the long term** (it takes twice as long to develop a new drug as it does to develop a new aircraft)
 - **By an R&D model that is undergoing major changes with the emergence of startups and the transformation of professions... For example, the gene and cell therapy business model is cutting R&D lead times, while industrial production costs are becoming preeminent**

Can France win the innovation challenge? Does France have the resources needed to achieve its ambitions?

Part 2: Turning our strengths into competitive advantages

The answer is yes! Let me restate the strategic importance of our industry. The fact is that our pharmaceutical companies have what it takes!

- **Economic growth: we have what it takes!** France's pharmaceutical companies report total annual revenue of €54 billion, half of which is generated from exports (making us the third-largest French exporter after aerospace and automotive. Drugs remain the fourth-largest contributor to our balance of trade, contributing €6.8 billion in 2017)
- **Production: we have what it takes! With 270 production facilities in France,** leadership in vaccines, a strong presence across the broad spectrum of mature products, and a growing presence in the production of innovative therapy drugs, our industry is very significant in strategic terms. We are also strategic on the basis of our regional footprint => **we are an essential facilitator of regional development, since our production facilities are not concentrated in major urban centres: they inject wealth into all regions of France.** The *gilets jaunes* crisis is partly a crisis of de-

industrialisation that originates in former working class regions that have experienced the negative effects of progressive factory closures. Nevertheless, where others have faded away, we have managed to remain, and we have no doubt that we can be part of the answer if we are given the resources to do so

- **Employment: we have what it takes! With nearly 100,000 direct jobs** - 3% of all French industrial jobs - 7,000 people recruited every year, 4,000 work/study contracts and an industry of experts, our industry is a generator of jobs => 45% of our employees work in production, 14% in R&D, 25% in sales and distribution, and 17% in administration. We are also engaged in transforming careers and integrating digital technologies into our businesses!
- **R&D: we have what it takes!** The pharmaceutical industry base in France invests 10% of its annual revenue in R&D; a figure that rises to around 15% in research-only laboratories, making us France's third-largest business sector in terms of R&D investment as a percentage of revenue
- **Clinical research: we have what it takes!** France takes part in 19% of oncology trials worldwide and in 45% of industry trials opened for this condition in France. Rare diseases are also a recognised area of excellence, with 14% of trials performed.
- **VSEs/SMEs: we have what it takes!** I would also like to remind you of one obvious fact: the French pharmaceutical industry does not comprise solely major international pharmaceutical corporations. The dynamism of our industry in France is driven not only by companies of international stature, but also by many SMEs and midcaps, specialist biotechnology companies and startups that are driving innovation in digital uses and solutions for patients and healthcare professionals. So it is absolutely key that the links that already exist between innovative biotech companies and major pharmaceutical companies are strengthened further, since biotechs are often the scene of tomorrow's innovations.
- **Public/private partnerships: we have what it takes!** We are proud of our ability to take a discovery made as a result of French publicly funded research and develop it at the global scale, and equally proud of the competitive advantage we have in France thanks to one of world's most attractive research tax credit (CIR) schemes. But it is equally vital that public research in France should benefit from funding provided by our industry and have access to therapeutic innovations via major clinical research programmes, when our companies choose France as their research base. What I am calling for here is a strengthening of this virtuous mechanism of skills pooling and cross-fertilisation, and I hope that we will go beyond the condemnatory rhetoric we have heard far too much of recently, even in Parliament

- So as you can see, our industry has all the aces we need to take on the challenges of tomorrow
- We are experts not only in drug development and manufacture, but also in employment, R&D, production and clinical research
- But we cannot transform the healthcare system by ourselves. In the years to come, innovation in drugs - and more generally in all healthcare products - will be a telling indicator of the weaknesses

in our healthcare system (slow to adapt, unable to capitalise on higher efficiency, increasing duplication, inflexibility in transforming professions and skills, etc.)

- It is obvious that the only way we will solve the equation is in conjunction with other stakeholders in the system

Part 3: rebuilding, resuming and enhancing dialogue with all our stakeholders

Beginning with the process of rebuilding dialogue with our public authorities

- I want to add new strength to this spirit of constructive and permanent dialogue with our public authorities, perhaps the most telling illustration of which was the CSIS meeting of July 2018
- Rarely since its creation in 2004 has the only forum devoted solely for interactive dialogue between central government and the healthcare industry resulted in such operational measures
- But the work done at this CSIS meeting must be completed as quickly as possible, particularly in terms of access to innovation, industrial transformation, the attractiveness of France for clinical research, and economic competitiveness
- I am very well aware that the French President and Prime Minister have called for a new CSIS meeting to be held early in 2021. We will of course be there, but with two central concerns:
 - The first is the need to reassert together the shared strategic goals around the four major challenges, which are: **1/ guaranteeing patient access to innovation in the shortest-possible time, 2/ building increasingly effective research ecosystems that allow us to stay in the race for therapeutic progress 3/ supporting employment, the transformation of professions and manufacturing policy 4/ and lastly, renewing and strengthening the agreement-based policy.**
 - The second is the adoption of new measures to boost the attractiveness of France; measures that I would like to see more focused around a number of strategic priorities. Ambitious, clearly understandable measures that give substance to the Government's stated commitment to research, innovation and industrial policy.
- **I referred earlier to the renewal of the agreement-based policy. The other major area of work to be tackled alongside the public authorities in 2020 will be the renewal of the Framework Agreement** that forms the backbone of France's drug policy
- The use of framework agreements concluded every three years between LEEM and CEPS has provided the standard structure for drug pricing in France ever since their introduction in 1994.

- It is this structure that has formed the basis for controlling drug expenditure for more than 20 years.
- I am absolutely convinced that this agreement-based policy remains the method best suited to the innovations that are now in the pipeline:
 - It provides the flexibility needed to find funding solutions to the complex and varied challenges posed by innovation.
 - It allows the partners to be proactive;
 - It remains the best method for achieving ownership of decisions by all stakeholders through a process of dialogue.
- **This framework agreement will have to embrace the practical consequences of the arrival of new therapeutic solutions, which will require innovative funding mechanisms.**
- **It must also provide active support for more ambitious attractiveness policies.**
- **We will therefore suggest to Government that any issue impacting on drug pricing should be addressed in a discussion around agreement-based policy before any unilateral measures are adopted.**
- As we look forward to the coming decade, France no longer has a choice: if it wants to provide its people with a guaranteed right to access therapeutic advances within acceptable lead times, if it wants to retain its strategically important independence, if it wants to maintain the quality of its research and the competitiveness of the healthcare companies that operate here, it will have to adapt its drug budget to address the challenges of the revolutions in therapy that are now in sight. In common with education, security and defence, innovation - particularly in healthcare - must be central to public policy-making
- The latest opinion polls show - and I touched on this briefly earlier - that health has become the absolute number one concern for our fellow citizens. The resources allocated to innovation in healthcare, and more generally to drugs, must reflect this level of concern. But make no mistake: the worsening situation around discontinuities of supply - a major concern for our pharmaceuticals companies - and the increasing difficulty of accessing innovative therapies are two sides of the same coin. These are the first indications of an excessively Malthusian regulatory policy, whose restrictions we are urgently calling for to be relaxed. **We cannot remain attractive for long with the lowest growth rate of any major European country, as has been the case for several years**

The second issue we face is the way we work alongside healthcare professionals. Far from the controversies around suspicions of conflicts of interest, it is crucial that we reassert the value of the working relationship we have with them:

The number of initiatives brought forward by LEEM in recent years is undeniable (Collectif Bon Usage, Lab M&S, and the Impact group, for example), but we must go further.

- **Beginning with pharmacists**, because we are both links in a chain of responsibility, and we must work together to improve the image of the pharmaceutical industry and those who manufacture and dispense drugs.
- **But especially with doctors.** I am always surprised at the biased view some doctors take of drugs, which are, after all, the ultimate tools of their profession. Doctors - and especially the younger ones - must be aware of the explosion of fake news and downright lies about health issues that feeds public suspicion and tends to pit healthcare professionals and pharmaceuticals companies against each other, despite the fact that they are united in their fight against disease. Scientific truth is a long-fought struggle, but we will show no weakness in continuing that fight. We owe it not only to patients and doctors, but also our employees.

Rebuilding trust with patients and all our stakeholders:

- I believe we need to become better at integrating patient concerns into the way our industry operates.
- Patients who are expert, autonomous, participative, informed, connected... Whatever you want to call it. The concerns of patients and their carers must be taken onboard and integrated into the decision-making processes of our companies. That is the direction of travel. Patients are already playing an increasingly 'formal' role in the healthcare system (HAS, ANSM, CEPS, etc.). So including them in our governance structures is simply a logical next step.
- As you realise, patients have a strategic dimension in the necessary reconstruction of our healthcare system.
- But let's stop thinking for them. We need to be working with them. Their feedback is essential for developing new drugs and analysing their effects in real life, but it provides equally essential input for redesigning the care pathway, building bridges between hospital and community care, involving carers, improving information, and so on...
- Their expectations are fair and reasonable, and we must put ourselves in a position where we can listen to them more attentively (*mention the assignment of Alexis Vandier, Company Secretary to the LEEM Board, to integrate patients more closely into the organisation*). The consultation process around this issue will form the basis of recommendations to be issued between now and April
- I would also like to remind you of the missions of the M&S Lab, an agile and collaborative space created to build shared stakeholder recommendations on issues related to drugs and society => initiation of a discussion cycle on 'fake news in healthcare'

- Lastly, I would like to highlight the fact that our social commitment is expressed through organisations such as CYCLAMED, DASTRI and TULIPE

Reasserting our collaborative relationships with SMEs and VSEs:

- These small and very small businesses are the future of our industry, so we are increasing their presence in our governance structure to better address their specific features.
- There is no conflict between the world of big pharma companies and SMEs/VSEs, because they all operate in the same ecosystem. Big companies cannot grow without a dense fabric of small companies, just as SMEs can only grow with the help of larger companies. **And it would be a major strategic mistake to think that either can prosper independently of the other.**
- The LEEM mission is therefore also to support the growth of innovative small and midsize companies, some of which will become the world leaders of tomorrow, and to support exporting SMEs, which make a major contribution to our national trade surplus in drugs.

Rethinking our relationship with society in its greatest diversity.

- We have challenges around our reputation and the responsibility we take for the way we operate.
- Not surprisingly, drugs and the pharmaceutical industry are still extensively trusted by the population of France. According to our latest Ipsos barometer survey conducted last November, 8 out of 10 French people trust drugs. As a nation, we believe that drugs relieve pain, cure and heal. They improve the patient quality of life and save lives
- However, the results of the Ipsos survey also show us that, despite the progress made in recent years, there is still considerable room for improvement in terms of our behaviour, ethics and transparency. 52% of French people trust pharmaceutical companies. That is a better result than in 2018 (up 3 points), but it is still not enough...
- **The gulf between French public perceptions and the reality of our companies' commitment to therapeutic progress and combating disease requires us to redouble our efforts in terms of explanation and transparency.** We have an educational role to play in explaining how our companies operate and how they are supervised at every stage of everything they do (from the development of drugs to price setting and real-life patient access to those drugs) in order to answer the legitimate questions of French citizens
- **This is the reason why LEEM has just initiated a new survey designed precisely to measure the quantitative and qualitative long-term societal contribution made by pharmaceutical companies and the industry as a whole**

- How many people know that pharmaceuticals is now the only industry that recruits every young person who successfully completes its training programmes?
- How many people know that tens of millions of euros were saved between 2015 and 2016 as a direct result of the *Bon Usage du Médicament* collective to which Leem contributes, and which has implemented many initiatives to combat iatrogenesis in over 65s?
- How many people know that in March last year, Tulipe provided 2.5 tonnes of medical products free of charge in the form of emergency humanitarian aid for southern Africa following the disaster caused by Cyclone Idai in Mozambique, Zimbabwe and Malawi?
- How many people know that 10,452 tonnes of unused drugs were collected in 2018 by the environmental organisation Cyclamed, and that this initiative reclaimed sufficient energy to light and heat 7,000 homes for a year?
- This unprecedented approach should help us to bolster and amplify the commitment of our industry to corporate responsibility and long-term sustainability. As you will have appreciated, this project is not about ideological statements, nor is it about self-promotion of our own industry; it is about being recognised as public health partners committed to delivering overall improvements in the health of individuals

This new initiative and commitment also involve every one of you journalists here in this room right now. We are conscious that we have sometimes failed in our duty to explain, educate and simplify. You are our direct link to the general public. So we need to work more closely and more effectively with you in order to raise the profile of the contribution we make to therapeutic progress.

Conclusion

- As I have focused on throughout the morning, we have considerable potential to drive innovation, but we must boost that potential tenfold by encouraging closer collaboration between private-sector and public-sector research, between pharmaceutical companies and the medical profession, between university faculties and our innovation hubs, and between our production sites and local politicians...
- We must also open doors and mindsets, and break down the barriers between outdated silo structures. The fact is that in today's world, we must unite, work together and achieve a new reconciliation.
- **I must tell you that in this context, I absolutely agree with the Chairman of the French Hospital Federation when he calls for a conference of national consensus spanning our entire health system.**
- The fact that we are social and economic stakeholders based in the regions of France means that we are well aware of social realities, and the daily challenges encountered by many French people

- That is precisely why I want to breathe new life into our healthcare system, so that it becomes more supportive, more shareable and - in a word - more humane
- I am convinced that exchanging views, understanding what divides us and what unites us, and pooling our expertise in a more cross-disciplinary way, is the way forward to successfully meeting tomorrow's health challenges together
- We can prepare today to address the challenges of tomorrow:
 - By completing the work of the CSIS
 - By committing to a new framework agreement that facilitates access to innovation
 - And by working closely and in good faith on the next Social Security Finance Bill to ensure that it is consistent with these two projects
- As we begin the New Year, we are preparing for these challenges by introducing a new, more close-knit, more transparent and more effective governance structure focused on 6 priorities supported by 6 strategy committees. These priorities are:
 - 1. To make France the most attractive country in Europe in which to conduct the research and development needed to deliver therapeutic innovations that directly benefit patients;**
 - 2. To create the conditions that will facilitate rapid patient access to innovative therapies within a clear and predictable framework;**
 - 3. To provide conditions that will enable the fair and sustainable growth of our companies, ensure that regulations do not compromise our attractiveness as a country, and guarantee absolute compliance with commitments negotiated and agreed;**
 - 4. To adapt the manufacturing base of our industry to capture future production and secure existing investment;**
 - 5. To accurately forecast employment trends as the basis for appropriate adaptation of our training initiatives, support changing career profiles within companies, attract new talent, and strengthen and coordinate our regional network;**
 - 6. To be recognised as trusted partners and build our reputation on responsible practices and our commitment to patients and stakeholders.**
- Winning the innovation challenge means ensuring that the therapeutic innovations now on the horizon are available and accessible to as many people as possible
- This is a major challenge for France today, and our duty to the patients of tomorrow.