

Ladies and Gentlemen,

After an unprecedented year, and at a time when we are preparing for an important phase in our national political life, I would like to begin today by extending my very best wishes to you and your loved ones. More particularly, I wish you good health, especially since we have recently become aware just how close we are to being patients ourselves! But we have also realised that health is a collective good that we must protect by working together.

So it is fair to say that my messages and wishes for 2022 are set against a very unusual and challenging background.

I say this for three reasons:

- The COVID crisis which - unfortunately - we still cannot predict the end of, and which means we have to meet in this remote way;
- The intensity of commitments, work and reforms undertaken in 2021
- And, of course, the major electoral deadline by which our nation must choose its next President and the parliamentary majority.

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So let me begin with the COVID crisis.

When I spoke to you at this time last year, the first vaccination campaign had just begun. Many observers were sceptical about whether the targets set by government could be met, and even whether the vaccine would work.

So what is the situation a year later?

90% of our fellow citizens over the age of 12¹ have now been fully vaccinated, and we are seeing on a daily basis how this high vaccination coverage - one of the highest in the world, in fact - is limiting the most serious forms of the disease, and therefore avoiding our healthcare system reaching saturation point. **It is the vaccine that has allowed us to return to near-normality after a very intense year, and now allows us to face the threat of new variants with greater optimism and confidence.**

¹ <https://solidarites-sante.gouv.fr/grands-dossiers/vaccin-covid-19/article/le-tableau-de-bord-de-la-vaccination>

Our pharmaceutical companies responded immediately in terms of readiness to develop the new vaccines that may be required to treat mutations of the COVID virus.

Better still, new and promising treatments are being regularly and rapidly made available to patients, testifying to the exceptional level of commitment and involvement shown by all our research teams and, in the broader sense, by every part of the industry.

We are all fully aware that this is a global pandemic and that ensuring universal access to treatment is a key issue. Which is why I would like to remind you that every production capacity worldwide is working to meet this need. Vaccine manufacturers have now put in place more than 300 production and manufacturing partnerships around the world, and total vaccine production is expected to exceed 24 billion doses by June 2022! To give you an idea of the tremendous resilience of our industry, this means that overall vaccine production capacity will have increased by a factor of six in less than two years!

Pharmaceutical companies are committed to responsible and reasonable pricing (at cost price or on a scale of prices tailored to the purchasing power of the poorest countries), and continue to deliver on the commitments they made in May and September 2021 to work with governments and partners - including the COVAX scheme - to support the efforts underway to help all countries achieve their immunisation targets. So far, COVAX has shipped more than 700 million doses to 144 countries with healthcare systems less well developed than our own, although we remain fully aware that much more remains to be done².

In this context, allow me once again to pay tribute to the extraordinary commitment shown by every employee in our industry, because they have all worked tirelessly regardless of circumstances to ensure the provision and availability of treatment.

I sincerely believe that our pharmaceutical companies have demonstrated exceptional levels of responsiveness, commitment, innovation, risk taking and resilience, and that we can be particularly proud of this achievement given the enormous size of the challenge.

² [Microsoft Power BI](#)

So it is perfectly logical that the way our industry is viewed by others has changed dramatically; that much is clear from the reputational survey conducted by Ipsos in partnership with Leem last September and October.

2021 put the spotlight firmly on pharmaceutical companies, whose image has been enhanced by the leading role they have played in combating the pandemic. **On the basis of these indicators, it is clear that confidence in pharmaceutical products and vaccines is at an all-time high.**

But this crisis has also brought new concerns to the forefront of public opinion. None more so than the health sovereignty of France. Despite the many alarm signals flagged up by LEEM, this issue was virtually ignored before the crisis, but is now a very real concern among the general public: only 28% of the French population believes that France is investing enough in the pharmaceutical industry to be able to deal effectively with any future health crisis.

If I had to take one lesson away from 2021, it would be the - now widely shared - awareness of the strategic importance of our industry as an actor in the health of the nation, of course, but also as an economic force, and the fact that today, **no country can justifiably claim to be a major economic power if it does not possess a strong health research and manufacturing industry.** Competitiveness and attractiveness - these are our two key challenges.

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2021 will also have been a landmark year in terms of the unprecedented succession of long anticipated and coherent measures to transform the industry, which extend even beyond the COVID crisis.

I would particularly like to draw your attention to this issue of coherence, which has so often been lacking in the way government has approached pharmaceutical industry policy. Research and development ecosystems, industrial incentives for investment, market access and growth conditions, and the clarity and predictability of the industry's operating environment together constitute a coherent whole, from which no single element can be disassociated, especially at a time of heightened international competition. Ensuring the attractiveness and competitiveness of France demands an holistic response, which is what I believe was achieved in 2021.

In this context, 2021 was primarily the year of a breakthrough CSIS. Renamed 'Healthcare innovation 2030', this platform reflects the new perspective from which the powers that be are now viewing our industry, with spectacular announcements on investment in academic and fundamental research, the

revitalisation of clinical research and industrial policy, and the radical transformation of market access mechanisms.

All these announcements are reflected in the LFSS for 2022, but perhaps most importantly the new - direct - access mechanism, which will enable certain innovative products with ASMR I to IV ratings to be made available to patients as soon as the HAS Transparency Commission has delivered its opinion, without having to wait for the outcome of price-setting discussions.

This reform of direct access complements the previous reform of early access introduced in the previous year's Social Security Finance Act - the implementing legislation for which was published in the first half of the year after an exemplary level of consultation - and the reform of the 'liste en sus' supplementary list for which the implementing decree appeared as recently as December.

The bottom line is that the trio of reforms to the supplementary list + early access + direct access will transform the entire landscape of access to innovative treatments in France, with patients as the primary beneficiaries.

Last year was also marked by **the return of manufacturing policy in France and the wider Europe as a result of pressure primarily applied by France**, with the launch of a series of structural initiatives, including a call for expressions of interest to repatriate production of active ingredients and strategically important pharmaceutical products, the launch of an action strategy on bio-production, the launch of an IPCEI (Important Project of Common European Interest) for the development of health innovations, an increase in CSIS credits, and greater importance placed on levels of investment in industry negotiations with the CEPS. There was no shortage of initiatives in 2021, to which I must, of course, add the reduction in manufacturing-related taxation!

The second building block is the framework agreement. **2021 saw the signature of a new framework agreement - the agreement that provides the basis for our agreement-based negotiations - and to which you know we are closely committed.** A framework agreement in which - I think - we were able to learn from what hadn't worked in the previous agreement, but which allowed us to make adaptations to address some future challenges.

Lastly, with the continued introduction of the multi-year research programming law, the emergence of new projects to create international clusters in several areas of excellence, the creation of a health innovation agency, the development of a national digital health strategy, the structuring of the Health Data Hub, and other measures, **2021 also saw significant additional initiatives introduced to our research environment.**

And these changes in France are being noticed by the senior executives of our companies!

Even before the CSIS, and on the basis of measures adopted following the 2018 CSIS, our industry had already begun to respond positively with, for example, 17% growth in (production and R&D) investment in 2020, the gain of one place in the European rankings for clinical research in 2021, putting us back ahead of Great Britain once more, and the increase in jobs in the industry, particularly through apprenticeship contracts, which will have more than doubled since the beginning of this five-year period. And how can I fail to remind you that all the young people we train find jobs on completion of their training, and that even more pertinently, we are now struggling to fill vacancies in certain specialist areas!

We are confident that the announcements made in 2021 will allow us to consolidate this positive trend.

But despite this undeniable progress, which we absolutely welcome, we realise that there is still a great deal to be done.

More specifically, net growth in the pharmaceutical product market remains too low to protect and develop our manufacturing base, at the same time as enabling the widest-possible access to innovative products. While we understand the constraints that govern the policy of keeping tight controls on social expenditure, we remain closely focused on ensuring that the contribution we make is not disproportionate to the influence we have on the National Healthcare Spending Target (ONDAM). Furthermore, in elevating the pharmaceutical industry to the level of a strategic sector, the powers that be must also ensure that they allow our companies room to achieve the growth necessary for innovation and investment.

This is why one of the challenges facing our sector in the next presidential term of office will be understanding how we deal with the unprecedented wave of innovation we can expect to arrive over the next few years, at which time the shrinkage in the pharmaceutical products budget we have seen over the last dozen years will no longer be appropriate.

Lastly, and in addition to that, I am particularly pleased that LEEM has scored some important successes on a number of issues to which I committed myself when I took up this appointment: the first being the ambitious and very practical roadmap for member corporate social responsibility, the second to take an extremely proactive approach to the issue of supply disruptions - particularly through introduction of the TRACStocks platform, and the third in the shape of

the upcoming launch of our Digital Health Academy to improve the acculturation of our industry to all these issues and facilitate transformational change in our core businesses and careers.

The achievements of the year were therefore truly exceptional, and I would like to take this opportunity of thanking all the teams here at Leem for the tremendous work undertaken and completed over the last twelve months, all the member companies who contribute to our collective effort, and above all, my colleagues on the Board of Directors. During this period, I have paid close attention to ensuring coherence across our industry; something I saw as absolutely essential, and which I believe will not have escaped our external audiences.

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Let's now turn the page on 2021, and look forward to 2022 together.

There can be no doubt that it will be a year unlike any other, since it will be an election year, not only to elect a new President, but also a new legislature.

We want to adopt a constructive position during the campaign period by building on everything achieved during the last five years, and - most importantly - going further still with even higher ambitions.

This is the reason why we intend to formulate around twenty proposals for 2022, structured around four major complementary and coherent priorities.

Goal 1: To make France the European leader in pharmaceuticals by providing massive support for research and innovation

The health crisis has highlighted just how much ground France needs to make up in research and innovation. We therefore need to uprate the capabilities and capacities of France in research and innovation by transforming these strengths into competitive advantages.

1/ By setting clear ambition and guidance for research: new resources have been made available, although the amounts involved still remain below the Lisbon target of 3% of GDP dedicated to research. These public-sector efforts must be further improved if we are to catch up with our European neighbours led by Germany. We also look forward to the creation in 2022 of the Health Innovation Agency, which should have the authority to set clear priorities for medical research and improve our ability to anticipate and implement therapeutic progress.

2/ We must also assess the new digital and technological challenges we face, and develop an aggressive biotechnology strategy by supporting the funding and growth of French HealthTechs, and creating an attractive framework to encourage companies to invest in digital. We also have the ability to make France a pioneer in integrating health data for the benefit of patients, provided that we accelerate the rollout of the Health Data Hub to include private operators.

3/ Developing more attractive ecosystems for investment in research is the third challenge faced by research and innovation. This is why LEEM proposes that savings should be directed more decisively towards funding the intelligence economy, and that the research tax credit scheme should be made more attractive, because this regime - already the touchstone of France's attractiveness in terms of R&D - has lost some of its appeal over time.

Lastly, and still on the subject of research, we must all learn the lessons of the COVID crisis: it is clear to me that those countries that have led the way in terms of research and innovation around this emerging pathology are those that have successfully broken down barriers between academic research and industrial research.

Goal 2: To make the pharmaceutical industry the spearhead for re-industrialisation

At a time when France and Europe are becoming more aware of how much autonomy they have lost in terms of health products, pharmaceutical products are an even greater strategic challenge, and one that is central to national ambitions for a recovery in manufacturing industry. This industrial policy is underpinned by a number of priorities:

1/ Consolidating the existing industrial fabric. This was introduced in the wake of the COVID crisis. It deserves to be amplified by the implementation of a fiscal policy appropriate to the challenges involved in improving the health autonomy of France, and by developing a strategy to reshore the production of raw materials and strategically important pharmaceutical products within a framework that must be Europe-wide.

At this point, I must stress that special attention must be focused on the situation of the SMEs and VSEs that represent more than one-third of the companies in

our industry. These are the businesses that work in our regions: subcontractors, mature product manufacturers, etc. They are the ones that suffer most from the excessive regulatory policies to which our industry has been subjected for more than a decade. Let me put it as clearly as I can: an entire industrial fabric of small and medium-sized health companies is now threatened with nothing short of extinction. The special nature and value of these businesses must be officially recognised, and public-sector policies adapted to take account of their specific vulnerability. This is why we are asking that the next government of France commits to an action strategy specifically tailored to the needs of this sector, which include a very significant level of simplification in terms of administration and taxation.

2/ Boosting regional competitiveness. Maintaining our manufacturing capacities and reshoring the production of mature products will not be enough; far from it, in fact. We must also attract research, development and production of new pharmaceutical products, including biopharmaceuticals at regional level to regenerate our industrial fabric and accelerate the deployment of future pharmaceutical production technologies as part of updating our manufacturing base. Alongside the general policy of reducing tax liabilities, extending the RTC scheme to include the production of pre-production batches contributes to achieving this goal, as does the ability to match price levels with our main competitors, shorter lead times for patients to access innovative pharmaceutical products and a reduction in the rate of industry-specific taxation.

3/ Lastly, the process of accelerating the transformation of jobs in the industry by expanding work/study training opportunities to meet the needs of talented people and attract them into the industry must be continued. Our industry is changing on an extraordinary scale, and we now offer more than 150 different career options, so the issue of training is strategically essential, and must be treated as such. This is why we will be launching a large-scale communication campaign about careers in our industry by the summer to attract new talent, focusing particularly on attracting young people from priority urban communities.

Goal 3: To make France the European champion for patient access to pharmaceutical products

The technological revolutions that are about to take place hold out great hope. Pharmaceuticals account for a significant proportion of healthcare expenditure,

but also represent a major investment that generates jobs, inward investment and therapeutic progress that benefits patients. Some of our European neighbours are doing better than us in terms of patient access to pharmaceutical products.

1/ We must make innovative treatments available to French patients more quickly: the early and/or direct access mechanisms are now in place, at least on paper. We must now implement them as effectively as possible so that French patients become the first in Europe to have access to major therapeutic innovations.

2/ The pharmaceutical product budget is inadequate: we must set a budget for health products that actually meets health needs, is sufficient to fund innovation, and acts on the desire to reshore manufacturing in France.

I cannot stress it strongly enough: we cannot succeed in the twin challenges of disruptive innovation and industrial recovery without a significant effort to recapitalise the pharmaceutical product budget, which has all but bled out after more than a decade of totally disproportionate regulation. A survey recently conducted by EY on our behalf clearly shows that France is the only one of Europe's 5 leading countries to experience a recession in its market between 2016 and 2019. With the lowest net prices in these five major markets and the longest access times, how can we possibly convince parent companies to choose France?

3/ Clearly, such a goal - and I am well aware of just how ambitious it is - must be accompanied by a series of fundamental reforms: the introduction of enlightened management of French health expenditure and strategy over a period of several years to provide the health sector with the visibility and stability needed for long-term investment, the revision of our economic assessment mechanisms within a framework that must be Europe-wide, the adaptation of the legal and agreement-based framework to facilitate the development of pricing methods better suited to the challenges of tomorrow's innovations, and the modernisation of care pathways to facilitate access to screening and preventive care as the basis for improving primary care provision.

Goal 4: To be possible, all of these require a simplified governance structure for pharmaceutical products; a structure that takes full account of the strategic status of our industry.

To give concrete expression to the political will of government and/or parliamentarians, it is now essential to provide France with a pharmaceutical product policy supported by an agile and better coordinated administrative structure. Let me be clear: the excessive number of administrative bodies in the field of pharmaceuticals and their lack of effective coordination result in a lack of decision-making, and therefore chronic inefficiency.

1/ The pharmaceutical products policy must be an absolute government priority based on coherent goals. With impetus provided by the Prime Minister, this policy must be built on the principle of overall coherence by asserting the primacy of public health, scientific and manufacturing goals, and by making economic regulation the result of this choice.

2/ Governance must be tightened through the creation of a major ministry with responsibility for pharmaceutical research, manufacturing and innovation to bring the upstream and downstream sections of the value chain closer together, and the creation of a sovereign health ministry with a broader remit, which does not necessarily need to include management of social expenditure, and which can act as a strong advocate for our sector.

We will soon get the measure of the next government's will and determination to do so. That will be revealed in the LFSS for 2023, which must carry forward, implement and expand the recovery efforts made by central government in 2021.

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We will have the opportunity to debate all these subjects and our proposals with the presidential candidates and their campaign teams, and we would encourage you to visit our 'health candidate' website, which many of you very much enjoyed during the last election campaign, and which we will continue to run going forward. It contains the first comparison of the health programmes of the declared (and potential) candidates for the 2022 Presidential election. With a few clicks, web users can read the health-related proposals of all candidates and the latest statements on health issues. They can also compare competing programmes, and like or share the proposals of each candidate via their own

social media accounts. Our proposal platform mirrors this comparator. And we will soon be extending it to include a fact check section (the 'Leem Scan').

During previous elections, we have often regretted the absence of health as a major strand of political debate. The last two years have changed that situation completely.

Health has now become the most important concern for our fellow citizens.

Beyond the pressure on hospitals or the weaknesses of our public health policy, we should not forget that the way out of the crisis relies on pharmaceuticals, whether vaccines or treatments for the care of patients suffering from the effects of the virus.

The USA and China have already made the pharmaceutical industry one of the spearheads of their industrial and research policies. Closer to home, Germany, Italy and Switzerland have all done the same.

This fact should encourage all our presidential candidates to prioritise our industry and treat it more seriously than ever before as a sector of national strategic importance. In terms of health, of course, but also in terms of innovation, investment, employment and economic development.

I would like to end by once again sending my best wishes to each and every one of you for this new year, which is so important - not only for our industry, of course - but for France as a nation.