

1. A TECHNOLOGICAL REVOLUTION UNDER WAY: AN OPPORTUNITY TO MEET THE HEALTH NEEDS OF THE FUTURE

1. Changing health needs

➤ Living longer... and healthier!

Progress in medical treatment has pushed back the boundaries of time. Life expectancy has increased from around 45 years of age in 1950 to 85.6 years for women and 79.7 years for men in 2019. According to the scenarios envisaged by the INSEE (French National Institute of Statistics and Economic Studies), by 2070 women could live to between 90 and 96 years, and men to between 87 and 93 years. In 2019, there were 22 000 centenarians in France, i.e. 32.6 per 100 000 inhabitants, the highest number in Europe.

The main development we should focus on is **population ageing**. There are 15 million people aged 60 and over today. This will rise to 20 million in 2030, and to almost 24 million in 2060. The number of people over the age of 85 will increase from 1.4 million today to 5 million in 2060. This long-term trend has a budgetary cost that needs to be assessed and anticipated. Moreover, some thought should be given to the way we organise our society (in particular, changes to living arrangements) and healthcare, which needs to be redesigned¹. Prevention is also key to reducing age-related illnesses such as Alzheimer's disease. One weakness in the French healthcare system is the approach to prevention, on which France currently spends only 2% of its current health budget (compared to an EU average of 3%). Paying more attention to prevention by means of cross-cutting action (since this issue goes far beyond health matters) could lead to substantial savings in the long run.

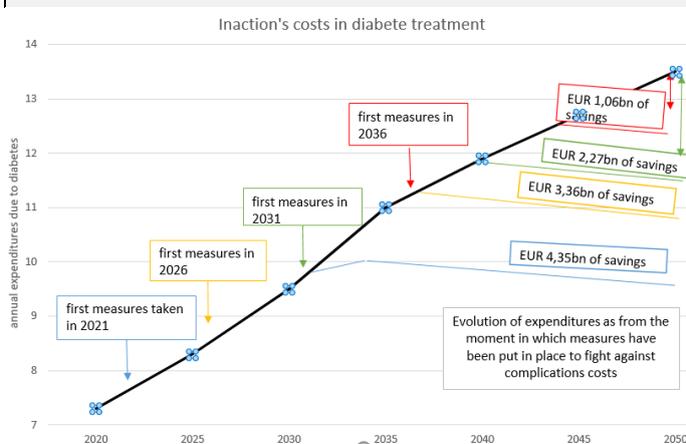
Living longer while retaining full possession of one's capacities means efforts are needed to deal with **chronic diseases and multiple chronic diseases**, the number of which is expected to increase, especially in a context where prevention has often been neglected in order to treat COVID-related infections as a matter of priority. At the moment, chronic diseases and treatments account for over 60% of healthcare costs covered by health insurance and concern 35% of the population². The risks representing the largest share of expenditure are: mental health (EUR 23 billion), cancer (EUR 20 billion) and neuro-cardiovascular diseases (EUR 17 billion). What is needed is an assessment of long-term needs and the introduction of multi-annual tools.

¹ 8% of the over-60s and 1 out of every 5 in the over-85 age group (20%) are dependent. The average age of loss of autonomy is 83 years.

² CNAM (French health insurance system) 2021 report on income and expenditure.

Diabetes: the cost of failure to act

- Diabetes is a major item in health insurance expenditure, **accounting for EUR 7.2 billion of associated expenses in 2018 out of a total of EUR 142 billion**. Given the **ageing population**, which is expected to rise steadily until 2035 and to increase at a more moderate rate thereafter, the number of diabetics in France, which currently stands at 3 million, is expected to shoot up, **leading to a spiralling of associated expenditure, which could amount to EUR 13 billion each year by around 2050**.
- **As half of these costs are due to complications** [1], various measures could be taken to halve them: early detection, in particular; more effective monitoring based on better knowledge of the genes responsible for diabetes and technological solutions to obtain a better understanding of patient metabolism, for instance using artificial intelligence, and allowing doctors to check remotely that patients are complying with prescribed treatments.
- **Since complications occur on average ten to fifteen years after the triggering of diabetes** (which does not in general coincide with screening), the effects of



the measures to limit complications are by necessity delayed. Hence, **the cost of failure to act can be very high**. While in the short term these measures will raise expenditure (as an investment), they will procure substantial savings in the long term: **action taken now could potentially save EUR 4.35 billion each year up to 2050, compared to the (worst-case) scenario of taking no**

measures at all.

[1] *The direct medical cost of diabetes: a study for the canton of Vaud, 2012*: https://www.diabetevaud.ch/wp-content/uploads/2016/08/Couts_directs.pdf
 Figures in EUR dating from 2018. The cost of the measures is not taken into account in this estimate.

Nor should we ignore the increase in **antibiotic resistance**. This could become one of the main causes of mortality in the world, undermining our ability to treat even the most common infections in community healthcare, hospital treatment and veterinary medicine. In Europe, France is the 6th country most affected by antibiotic resistance, with 125 000 infections and over 5 000 deaths caused by it³.

If no action is taken, infectious diseases of bacterial origin could become one of the world's leading causes of mortality by 2050, causing up to 10 million deaths⁴. In addition to the human cost, the financial cost of healthcare for society would amount to over EUR 1.5 billion in Europe. Curbing this trend is all the more difficult since, as a market does not yet exist, the pharmaceutical industry is reluctant to invest in this domain.

³ <https://www.irdes.fr/>

⁴ <https://solidarites-sante.gouv.fr/>

➤ **Greater awareness of the impact on health of climate and environmental risks**

Public opinion is becoming increasingly aware of **the effects of climate change on health**, which may or may not be exacerbated depending on the corrective action taken. This is one of the biggest risks to public health in the world. The impact on health is wide-ranging: emergence or re-emergence of infectious diseases, more frequent and intense extreme weather events such as heatwaves, and changes in the environment generating new risks. The need to take mitigation and adaptation measures, mindful of the different potential scenarios (global warming of + 1.5°C/+ 2°C), will become increasingly important.

Some thought should also be given to exposure to **environmental risks**⁵ as this can be reduced if clearly identified. According to the World Health Organisation (WHO), environmental factors account for 15% of deaths in the European Union. In France, for instance, **air pollution** apparently causes some 48 000-67 000 premature deaths every year (this represents an economic cost of 4.4% of the EU's GDP⁶). Other sources of environmental pollution include: **exposure to chemicals** via food and everyday objects (cosmetics, toys, clothing, household products, etc.); **indoor air pollution** caused in some cases by insufficient ventilation which may lead to mould, and also by emissions from construction materials; **soil pollution** (around 250 000 sites in Europe have contaminated soil); **exposure to electromagnetic fields** (high voltage lines, mobile phones, wifi, microwave ovens, medical equipment, etc.), although the health effects are still under discussion; **exposure to noise**, particularly from transport (road and air traffic, etc.), the impact of which is estimated at 10 000 premature deaths per year in Europe.

More broadly, in an increasingly interconnected and urban world, **the risks of new pandemics**⁷ are not negligible. Combating deforestation could be a way of preventing the emergence of zoonoses. The US Centre for Disease Control and Prevention (CDC) in Atlanta and the World Organisation for Animal Health estimate that 75% of emerging diseases originate in (mainly wild) animal species. The destruction of ecosystems due to human activity increases contact between wildlife and humans, increasing the risk of transmission of pathogens to humans and the emergence of new diseases.

➤ **Societal developments: towards faster, safer and more individualised medicine**

In the modern era, we are less and less willing to travel long distances to consult a doctor and to wait for results, put up with invasive medical practices, and entertain doubts about a diagnosis. Generally speaking, there may well be a greater drive towards individual treatment. This involves reshaping the world through a process of personalisation, by diversifying supply in order to widen the

⁵ *Futuribles, Rapport de vigie 2018 (monitoring report).*

⁶ *Health at a glance 2020 - OECD indicators.*

⁷ *Report by IPBES (Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services) -29 October 2020.*

choices available to individuals. Paradoxically, this movement towards individual treatment could be accompanied by increasing control by society, exercised in particular through digital technologies.

2. The technologies of the future: the scope of possibilities

➤ A paradigm shift in medicine

In the current paradigm shift, **digital therapies**⁸, which are key in '5P' medicine (personalised, preventive, predictive, participatory and proven) involving a move from a product-based approach to a service-based approach⁹, should play an increasingly important role. This is a real revolution in the sense that it is no longer a matter of making a centralised system available to all patients, but rather of putting the patient at the centre of the mechanism and offering a combination of different therapeutic options as part of a healthcare pathway. In particular, **remote medical consultations** could meet the needs of an ageing population who find it difficult to travel and whose healthcare is part of a complex pathway; it could also benefit an active population with less and less time on their hands, who would welcome the convenience of digital technologies.

➤ It will be based on promising technologies, including:

- **Microfluidic chips**: this medical device filters plasma from a drop of blood in order to detect, very far upstream, various diseases from the markers it contains (cancer, diabetes, etc.). Used regularly by the patients themselves, the device could become a kind of 'health report';
- **gene therapy**, which introduces functional genes into the body to correct an abnormality and combat severely disabling genetic diseases;
- **regenerative medicine**: bio-printing could make it possible to reconstruct damaged human organs and tissues;
- **the creation of digital duplicates using artificial intelligence**, which permits less invasive examinations as they are carried out beforehand on the digital duplicate, producing a much more accurate diagnosis based on data that is not visible to the naked eye, such as blood flow;
- **molecular medicine**, which adapts treatments to each individual, making it possible to act in a very localised way using 'molecular scissors' on a specific bacterium;
- **connected devices to monitor diabetic patients remotely**¹⁰ and to regulate insulin for type I diabetes;

⁸ Report by PIPAME (interministerial centre for foresight and anticipation of economic change), *Industries of the future: challenges and opportunities for the health industries and technologies sector* — 2019.

⁹ Report by the National Council for the Future of Health Insurance: *'Innovation and the health system* — 2016.

¹⁰ <https://www.leem.org/publication/sante-2030-une-analyse-prospective-de-linnovation-en-sante>.

- **smart prostheses** that use artificial intelligence to anticipate patient movements, in a bid to bridge the gap between the control of the prosthesis and the patient's intention.

3. A revolution to be anticipated in a context of public finance constraints

➤ **Technological innovations presenting major transformational challenges**

Despite the therapeutic value of these forward-looking technologies, there are **significant financial challenges**. The digital transformation of the health sector is accelerating with estimated growth in the global e-health market between 2019 and 2023 of around 160%, worth a total of USD 90 billion in 2019 and possibly USD 235 billion in 2023¹¹. **To meet this challenge, France must start preparing for the investments to be made in digital infrastructure¹², set aside storage areas in hospitals, and also ensure digital coverage throughout its territory** (there are significant disparities at the moment).

Older patients not always familiar with digital technologies, and all care workers generally, **will need to be trained** in these new technologies (bio-printing, robotic surgery and use of new medical devices). **Provision must be made for these training needs.**

Some thought must also be given to the **ethical, democratic¹³ and environmental challenges** arising from these new treatments. The use of connected devices and digital simulation raises ethical questions about the use of personal data and freedom of decision over one's own body.

Lastly, we cannot ignore **the question of reconciling our digital health ambitions with our environmental ambitions** (the 2050 carbon neutrality requirement). To date, digital health is responsible for the following: energy consumption (3 million tonnes oil equivalent each year or 35 billion KWh), significant waste (700 000 tonnes per year, 20% of which is difficult to process), and high-tech raw materials containing rare metals amounting to 35 million tonnes CO² equivalent per year, or 5% of France's carbon footprint.

➤ **Provision must be made for public finance constraints**

According to OECD forecasts, health expenditure is expected to exceed GDP growth over the next 15 years in almost every OECD country. It is estimated that per capita health expenditure will increase at an average annual rate of 2.7% in the OECD, rising to 10.2% of GDP by 2030 compared with 8.8% in 2018.

¹¹ Source: *Global Digital Health Outlook, Artificial Intelligence, Care Coordination, Cybersecurity, Data Analytics, Digital Therapeutics, and Telehealth Will Drive the Market*, Frost & Sullivan, 2020.

¹² Rapport « e-santé : augmentons la dose ! (E-Health report: let's increase the dose!) Institut Montaigne, June 2020.

¹³ Maxime des Gayets, Jérémie Peltier, «La santé numérique demain: démocratique, sur-mesure, experte, préventive » - (Digital health in the future: democratic, tailor-made, specialist, preventive' — Jaurès Foundation — September 2020.

Given this, we need **to anticipate our health needs** in order to support the innovations that can meet them, and also possibly revise the overall funding strategy accordingly, the challenge being to **ensure the sustainability of the health system in the long run.**

To take up the global challenges posed by health innovations, we must propose coherent long-term strategies covering at least the management of predictable risks and creating a favourable framework for the development of the most promising therapies.

2. PREPARING FOR THE CHALLENGES OF THE FUTURE — PRESENTATION OF THE 2030 INNOVATION STRATEGY

In order to prepare for these future challenges, the French President presented a strategy on 30 June 2021 entitled 'Health Innovation 2030', based on the work of the Strategic Council of Health Industries (CSIS), comprising seven pillars:

1 — EUR 1 billion to strengthen our biomedical research capacity

Excellent biomedical research is a key first step in sustaining a continuous flow of health innovations. France already has major biomedical research led especially by INSERM and supported by large research centres - the CNRS, the CEA, etc. - and universities. The Research Law, which provides for EUR 25 billion worth of investment in the coming years, will result in massive reinvestment in research. However, our health research still suffers all too often from a division between research and care at a time when the development of personalised medicine requires two-way information flows between the laboratory bench and the patient's bed, as well as between academic and industrial actors. Although technological developments are very often the driving force behind major scientific advances, in relation to biomedical research there is a lack of investment in research infrastructures available to academic and biotech teams. Lastly, there are still difficulties in persuading young talent to spend their careers in France. The measures selected aim to transform the French biomedical research landscape by bringing healthcare, research and innovation together within centres of excellence. This will ensure funding for integrated health research projects involving clinical practitioners, researchers and entrepreneurs. It will strengthen our main research facilities, providing our researchers with the best technology and state-of-the-art equipment, and will restore the attractiveness of the national scene by means of a policy of hosting very high-level young researchers. A training component will underpin the changes in research and health industries, particularly in the digital sector.

Main measures

- Relaunching and consolidating biomedical research site policy by supporting the creation of centres of excellence (IHU) and international clusters.
- Supporting integrated research projects in health. Developing biomedical research infrastructure, cohorts and biobanks.
- Underpinning France's sovereignty in pre-clinical research.

→ Attracting and maintaining very high level researchers.

→ Developing new training courses to support changes in research and health industries.

2 — Investing in three forward-looking health areas: biotherapy and bioproduction of innovative therapies, digital health, emerging infectious diseases and CBRN threats

The health industries sector is now undergoing a real revolution with the arrival of medicines whose active ingredients are produced from living organisms and from the most fundamental research into biotechnology. The rise of these biotherapies has facilitated the development of so-called personalised medicine through therapeutic solutions that have proved their worth in many fields (oncology, immunology, virology, rare diseases, etc.); these biomedicines currently account for 50% of ongoing clinical trials. **The development of biotherapies and bioproduction of these therapies is promising, but also involves major challenges for our country: for our healthcare system, for our economy and for our sovereignty.**

In relation to digital health, the transformation must benefit the general population and patients. In particular, the aim is to improve the quality of life and the organisation of healthcare, and to prevent further inequalities in access to healthcare by adding a digital divide to the social divide.

The COVID-19 crisis illustrates the major health, economic and social effects that the emergence of new pathogens can have. **The accelerated strategy for emerging infectious diseases and CBRN threats is intended to strengthen our preparedness to cope with the risks of a major new health crisis (involving emerging diseases or CBRN threats)** in the coming years and our capacity to respond at national level, in conjunction with the European level. To limit the impact of such crises, it will be necessary to define prevention strategies and anticipate the needs of our societies from now on to meet them, be they conceptual, organisational or material.

Main measures

→ EUR 800 million to support the development of biotherapies and the industrial fabric needed to cut our 95% dependence on foreign biotherapies.

→ EUR 650 million to move to 5P medicine (preventive, personalised, predictive, participatory and proven) thanks to digital technology and the emergence of leaders.

→ EUR 750 million to prepare for pandemics and have the means to respond to them on our territory.

3 — Being at the forefront of clinical trials

In order for patients to benefit from innovation, the first step is to host key clinical trials to offer our patients new therapeutic arrangements. There is international competition to attract these clinical developments. European regulations on clinical trials came into force at the end of May 2021 for medical devices, and will apply from January 2022 for medicinal products. They will harmonise the maximum time limits for investigations in each country. We need in France to increase the number of clinical trials and the number of patients included by significantly reducing authorisation deadlines, while at the same time maintaining a high level of quality and stricter management of national calls for projects.

Main measures

- Simplification and acceleration of the authorisation system for clinical trials, including committees for the protection of individuals.
- Recognition of and enhanced status for experts involved in the ethical evaluation of clinical trials.
- Strengthening national management and mobilising the ecosystem around health institutions to improve coordination and speed up inclusions.
- Developing our methodological and operational expertise in new types of clinical trials.

4 — Ensuring fair access to healthcare for patients and providing an accelerated and simplified market access framework for innovations

Access to innovations and therapies that are costly for patients must be regulated to ensure that it is in the interests of the community to cover these apparently innovative treatments (medicines, medical devices, medical intervention, etc.), and to guarantee that they are safe. Over the years, the regulatory processes have lengthened; some hospitals do not have access to expensive therapies, and it takes several years to obtain funding for some medical acts. Moreover, after several years of experimentation, the digital health ecosystem wants to see a wider deployment of remote monitoring, which would mean cover for the technological approach and payment for the health professionals who carry out these activities. The challenge is to improve the provision of expensive therapies to patients while speeding up coverage of all these treatments (including medical intervention) so that patients and healthcare institutions can benefit more widely from innovative remote monitoring solutions, making the system as a whole much more dynamic, mindful of the lifespan of an innovation.

Main measures

- The introduction of a mechanism to provide immediate market access for medicines scoring 1 to 4 in terms of 'improvement of the clinical benefit' (ASMR), following the approval of the *Haute autorité de santé* (National Health Authority), comparable to the German market access system, with a two-year pilot phase.
- Greater access to costly medicines and medical devices in hospitals: broader criteria for covering medicinal products and medical devices, in addition to hospital fees, where an improvement in the medical service is recognised by the National Health Authority and an important medical service is authorised.
- Simplified access to innovative procedures: reform of the 'reference framework of non-classified innovative procedures' (RIHN) eligible for reimbursement in order to provide dynamic and fluid support for innovative medical biology and pathology.
- Generalised access to remote monitoring and associated medical devices, ensuring that this benefits patients, professionals and the health system.
- Reduction of market access deadlines so that they are shorter than the statutory deadlines.

5 — Providing a predictable economic framework consistent with the objective of health and industrial sovereignty

The purchasing policy of health institutions plays an important role in ensuring security of supply and enabling the development of small and medium-sized enterprises and start-ups. In recent years, bulk purchases have led to vital savings but may also have had collateral effects on companies with a significant industrial impact in France or Europe, and even on start-ups in the process of expansion. Moreover, in order to ensure our health sovereignty, greater attention must be paid to investments and our industrial footprint, in the case of both medicines and medical devices, when it comes to setting the price of health products. Lastly, all companies big and small must be given visibility over the coming years, something that has been missing in the last ten years. This visibility will involve greater understanding of the budget for health products and also the ability to anticipate and comply with sector regulation.

Main measures

- Introduction of a hospital procurement policy in line with the objective of health sovereignty, fostering innovation and SMEs.
- Provide visibility as regards expenditure on medicines and health products.
- Ensure increased attention is paid to our industrial footprint when setting the price of medicines and investments in France, raising the CSIS (Strategic Health Industry Council) medicine credits and extending them to medical devices.

6 — Health Innovation 2030 — Supporting the industrialisation of health products in France and underpinning the growth of enterprises in the sector

The resilience of the production tools and supply chains of the health industries, which posed a problem during the health crisis, and the ability of French companies in the sector to reach a critical size, are key elements of France's health sovereignty. Under the Recovery Plan and in response to the COVID-19 crisis, industrialisation support schemes (AAP Resilience and AMI Capacity Building) have made it possible for a number of companies to relocate and have provided substantial support for investment in France (up to 123 projects supported, an investment worth over EUR 1 billion). Continuing along the same lines, support for investment and relocation will be extended with the aim of promoting European industrial projects that will underpin therapeutic innovations, strengthen our strategic autonomy by means of innovative production processes and develop crisis response tools. The President of the European Commission, the German Chancellor and the President of France have announced the launching of an IPCEI (important project of common European interest) in the field of health in order to make it a strategic area of investment for Europe, like batteries and hydrogen. To boost innovation and the growth of companies in the sector, access to finance for the risky and capital-intensive phases is crucial. Tools for funding health undertakings engaged in producing medicines, medical devices or *in vitro* diagnostic tools will be strengthened.

Main measures

- Ensure long-term support for investment and relocation of health industries with an additional EUR 1.5 billion as part of a European approach.
- Increase the health investment of Bpifrance (French public investment bank) by EUR 2 billion in five years.
- Step up the action of the French Tech Sovereignty fund in relation to health, and encourage health investors to participate in the Tibi initiative (to finance tech companies).

7 — Creating a structure to drive and steer health innovation: the Health Innovation Agency

In the health sector and most other areas, while innovation comes from the actors themselves — researchers, health professionals and manufacturers — development of innovation is partly driven by political impetus, a strategic vision and an innovation-friendly public policy. The way in which the current organisation of the State can promote this policy is highly fragmented and hampers the dynamics of health innovation in France. In this context, it seems more necessary than ever to promote understanding of risk, multidisciplinary, understanding and trust among all actors within the French health system, i.e. a real cultural transformation in health innovation.

Main measures

- Develop a national health innovation strategy and ensure its implementation, including short-term anticipation and responsiveness and a strategic vision for 2030, in line with the research challenges France wants to invest in and in order to anticipate future health crises.
- Simplify and clarify existing processes to speed them up by identifying cases of priority uses together with the ecosystem, where appropriate proposing to the Government changes in the organisation of the State.
- Act as the main and trusted contact point with health innovation stakeholders, promote synergy between them, and guide and support innovators.
- Ensure the implementation of the 2030 Health Innovation Plan and report to the Government on the proper implementation of all measures; if necessary, propose adjustments.

⇒ **A total of EUR 7 billion will be mobilised for the ‘2030 Health Innovation’ strategy.**