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In an exclusive interview,

Dominique Le Guludec, president of the French National Authority for Health (Haute Autorité de Santé (HAS)), offers her insider comments on the changes in French healthcare policy under President Emmanuel Macron.

With the 2018 integration of the Agence Nationale de l'Évaluation et de la Qualité des Établissements et Services Sociaux et Médico-Sociaux (Anesm), the HAS is more than ever a central administration to France's health sector. How has this integration benefited the HAS, and how has it modified the role of the HAS in France's health sector?

As you know, we have three missions centred on healthcare quality: the evaluation of health products and medical procedures, insofar as reimbursement is concerned; the recommendation of best practices; and the certification of medical facilities and the accreditation of high-risk specialty professionals. These are the three big tasks that our organization is in charge of completing. The integration of all of the social and medical sectors impact two of the aforementioned missions that we have, recommending best practices and the evaluation and certification of medical facilities and professionals. Naturally, the integration of this entire sector completely resonates with our vision of a comprehensive health pathway that is not limited to healthcare alone. Therefore, this integration is very important for us in delivering the best available care to patients.

In France, we tend to be somewhat compartmentalized. This integration helps to abate that problem, as it lets us now work directly alongside more actors that influence the approved healthcare pathway in France. All the while, we have been able to maintain the key tenets of our organization: independence, commitment to transparency for our citizens, scientific expertise and excellence.

You have compared France's healthcare system to an elastic band that could snap at any time. What are, in your eyes, the systemic issues faced by the system and the necessary reforms?

In February of this year, PM Edouard Philippe announced France would be working on a profound transformation of the healthcare system, which was officially disclosed by President Emmanuel Macron on September 18th, as the "Strategy for the Transformation of the French Healthcare System". The President's announcement truly outlines all the issues we face and shares the result of a thorough diagnostic workup of our healthcare system, itself enriched by a number of consultations involving patient associations, health professionals, and think tanks. Over the past few months, a lot of work and progress has already been made with the discussion of legislative reforms that shall allow for transformative change to take place. With one of the main leads of the reform being quality improvement and appropriate care (relevance) HAS, France Assos Santé (National Union of Registered Associations of Health System Users) and CNAMTS (National Health Insurance Fund for Salaried Workers) have been tasked with its co-development and piloting.

But before addressing all of the changes that are coming in our healthcare system, I would like to underline how beneficial the diagnostic workup was in allowing a number of solutions to surface. Contribution was widespread and the outcome incredibly rich. While we are considered to have an excellent system here in France, many circumstances in the very nature of healthcare have evolved over the decades. Namely, there have been profound changes in the needs of the French people. The population has grown and is ageing rapidly (for instance, in the last ten years, the percentage of our population that is over 60 years old has increased by 25%). This poses certain challenges for us. The pathological conditions under which we used to work have changed, as an increasingly elderly

population inherently has an increasing incidence of multiple chronic diseases (otherwise known as polypathology). This trend has challenged us to place a stronger impetus on outpatient care, while our current system was founded on an era centred on inpatient needs. Our medical resources have simply not evolved at the same rate as the changing needs of the population. Firstly, our method of selecting doctors has probably prevented the acquisition of a sufficient number to keep pace with the ageing population. Secondly, we have placed too much of an emphasis on producing specialists, rather than GPs. In the past ten years, we have had more than an eight percent reduction in the number of GPs in France while there has been a six percent increase in specialists. The problem, here, is that the specialists are heterogeneous and heavily clustered in various regions. In some regions, you have too many specialists, while in others, you do not have enough.

There are two additional factors that are important to address. First, the ever-increasing fast-paced innovation that applies not only to health technologies but to organizational issues as well. Take e-health for instance – this is a tool that will greatly impact organization and delivery of care. But there are many others, like CAR-T and the management of vascular and cerebral accidents with thrombectomy, among many others, which will have impacts on how the healthcare system is organized, regardless of care setting. Lastly, there are significant societal changes happening in France that determine how the healthcare system is structured. French citizens have shown a strong desire to participate and hold higher expectations for transparency. Our young health workforce has a stronger desire to work in teams to address the growing complexity of medicine. In search of a more satisfying work-life balance, young health professionals no longer want to work excessively long hours as previously seen and done.

It should also be noted that in the future medical group practice (or health centres) will become the norm with regards to delivering primary care services. The restructuring of our primary care services via hospital decentralization will allow us to better respond to patient needs.

On that note, why do you think that the public's desire to engage with the system has grown in recent years?

I think that it is a question of civic maturity. Of course, the people are the recipients of this service; it is only natural that they wish to become engaged in the public decision-making processes and the choices made for our country. Though they sometimes wish to become involved out of dissatisfaction with the service, I think that the main reason behind this trend is the maturity of a democratic, social healthcare system. Moreover, I believe that people are becoming engaged out of an interest in equality. In a resource-constrained context, France spends a great deal of money on its healthcare sector. Spending is considered fair in France with low out-of-pocket healthcare spending for households (less than 8% – the lowest of the OECD countries). There is no limit to how many times one can access treatment, irrespective of revenue, and regardless if they are having an expensive treatment like an organ transplant or CAR-T.

France is a country that strives to ensure budgetary fairness. Despite our efforts to make the system as fair as possible, we may find an unfortunate inequity among regions, with a lack of access to certain procedures, due to an imbalance between offer and demand. Furthermore, under the effects of medical progress and an ageing population, France has seen its healthcare spending growth exceed 4% per year and this in the presence of slow economic growth. Thus, as a measure to regulate annual health expenditures, parliament is required to set the estimated healthcare spending rate – generally set above the country's GDP growth rate (set at 2.5% for 2019). These annual forecasts are intended to encourage key organizational changes which in turn are expected to result in efficiency gains and sustain budgetary fairness and equity. This measure forces the French

people and its government to rethink the way that its system functions – for instance, we may need to consider emphasizing prevention, rather than treatment and ensuring that our current facilities are equipped for modernity. We also need to focus more on providing quality outpatient care rather than inpatient care.

Overall, the President of the Republic and our government are rethinking the way that the entire system is structured to accelerate our country’s move towards an integrative approach to healthcare, the only way forward today.

How has this restructuring of the French healthcare system impacted the HAS?

It has impacted us profoundly. Above all else, the underlying focus behind each change that we consider is our commitment to quality. The second element that we consider as very important is the relevance (pertinence) of patient care. These are the two foremost aspects that we account for when we institute any change, whether we are talking about the coordination between healthcare professionals or shifting the very nature of our healthcare professionals’ job descriptions (for instance, we are now considering shifting some of a doctor’s traditional tasks to nurses).

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We have had to take a serious look at patient security with the putting in place of a national accreditation program for practising high-risk specialty professionals. Our institution is equally tasked with the collecting and analysis of reported serious adverse events (SAE) at the national level. The recent launching of a systemic analysis of SAEs in France, together with the elaboration of an annual SAE report, will allow identification of the very safety issues that require attention and thoughtful elaboration of best practices. Other ways that we are specifically addressing safety is by revamping our continuing education programs, ensuring that our professionals become recertified and constantly learn the new, best practices that we approve. Moreover, all efforts in the area of safety will also minimize unnecessary healthcare expenditures.

We are additionally developing quality indicators to ensure that patients receive the best care possible throughout the entire approved healthcare pathway – not just throughout the treatment process. We have decided to start implementing said quality indicators among cases of certain chronic diseases such as chronic obstructive pulmonary disease (COPD), chronic kidney failure and stable coronary insufficiency. We are essentially trying to streamline the entire approved healthcare pathway for patients with certain conditions, removing barriers that may exist between different actors and institutions that are involved. For instance, our recommendations are more frequently being elaborated as care pathways be it from prevention to chronic ambulatory care, with the expansion of quality metrics that go well beyond hospital care. These are some of the steps we are taking as we move towards an integrative approach to care. In order to reinforce these measures, President Macron has decided to implement financial incentives that reward the facilities that score highest according to quality indicators. With this measure, we can reward those that provide the best care and encourage those that are operating insufficiently to do better.

Furthermore, we have been tasked with collecting patient satisfaction and experience from a wider range of services. The HAS has always done so with inpatient acute care – requiring at least 48 hours of hospitalization (say for medicine, surgery or obstetrics). But now, the current administration has asked us to collect feedback from our nursing home programs, our rehab facilities, and our outpatient healthcare programs, among others. Another way that the HAS is working on bettering

patient satisfaction is by encouraging the healthcare professionals to work better among themselves, a skill we believe must be learned. We have therefore instituted a national program called the Continuous Teamwork Improvement Programme (Pacte), which aims to increase effective communication and cooperation among the workers in our healthcare organizations.

Overall, all of these progressive and transformative changes have caused a systemic reorientation of the HAS. Today, we are focusing more and more on the development of result-oriented indicators (both physician and patient-reported), when in the past our metrics generally aimed to appreciate structures and processes. We are primarily concerned with how our healthcare system impacts the French household. We are taking a holistic approach in improving the healthcare system's quality, encompassing all procedures and all facets of care. We are equipping our professionals and government institutions for success, engaging patients, encouraging innovation, and collaborating better with international organizations like the European Commission; and all parallel to working on the streamlining of HAS's own in-house efficiency.

How is the HAS working to encourage new medical technologies and innovation?

We work in approving a wide variety of medical software packages that help our doctors and pharmacists in the field. These programs improve diagnostic procedures and monitor patient care. We also work on connected medical devices, AI, and "telemedicine," providing standards for best practices and ensuring a high quality of care even when frontier technologies are involved. While we are working hard to incorporate these technologies into our guidelines (such as with the recent publication of a guide on how to evaluate connected devices), the impact e-health shall have on practices leaves us feeling that we have not yet pieced together the puzzle. For instance, I feel that there are ways in which we could use more of big data to make our analysis and recommendations more efficient. But, as I have said, all of the pieces are there; we have one of the best systems in the world with lots of data available and a very high level of human capital. We just have yet to find a way to harness the HAS's potential of using big data to provide a better service.

Overall, the implications of AI on HAS's mission also remain a challenge for now. How will it be used in diagnostics and devices? How can our organization monitor and evaluate the effectiveness of ever-changing algorithms? These types of challenges pose questions for which answers remain thoroughly incomplete. But, rest assured that we are working on them!

Do you have any comments on how general world events, such as the US-China trade war and Brexit, will impact the French healthcare system?

These are problems that are worrying every organization in the French healthcare system. As you know, each year, the HAS has to conduct a prospective analysis of the future of the healthcare system in France. We have issued a report on the economic situations surrounding our healthcare, and we recommended that the government create an institutionalized, public debate surrounding the national healthcare system. This debate should encompass a wide array of topics so that the government understands the needs and wants of the people. It will help the system be more efficient with its budget and it will increase the "civic maturity" that I mentioned earlier. This forum will help information transfer between the government and the voters.

Would you like to offer our readers any concluding thoughts?

I would like to conclude by expressing my pride at being at the helm of such an incredible organization, especially in this day and age. I am passionate about healthcare, and being able to help this institution change for the better is quite an honour.

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