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Lionel Collet, president of France's Haute Autorité de Santé (HAS), explains the role of the independent public authority, which extends beyond health technology assessment (HTA) to clinical practice guidelines and certifying hospitals, and its unique position as a separate body outside of the Ministry of Health. He describes France's early access procedure under which HAS has evaluated 200 products during the past two years, accepting 80 percent; weighs in on the move to introduce EU-wide HTA legislation in 2025, and outlines HAS's goal of addressing the complexities of mental health in its next strategic plan leading up to 2030.

Could you elaborate on the unique role and responsibilities of the Haute Autorité de Santé (HAS) compared to similar bodies in other countries?

When I stepped into my role at the HAS one year ago, it became apparent that the agency’s scope and functions are quite distinct from other healthcare assessment bodies, particularly in comparison to traditional health technology assessment (HTA) agencies. Not solely focusing on HTA, HAS encompasses a broader spectrum of responsibilities. Yes, evaluating healthcare technologies for regulatory purposes, particularly for reimbursement, is a significant aspect of our work, but it is not the only facet. For example, we also engage in developing clinical practice guidelines and certifying healthcare facilities.

These core missions were established back in 2004 through legislation governing healthcare insurance. HAS holds a unique institutional setup in France as a public independent authority, distinct from being just another health agency, while my role as president is directly appointed by the President of the Republic. This means that once appointed, the president and members of the institution, including myself, operate independently from executive authority. Each member of the college, which comprises eight members including the president, is appointed, and our six-year mandates are irrevocable, ensuring our autonomy in decision-making.

This setup is vital to safeguarding the impartiality and integrity of our decisions. Moreover, in France, laws dictate that members of such independent authorities cannot seek or receive instructions from any other authority, including the government ministry. Thus, our status remains entirely separate from the Ministry of Health, ensuring autonomy and impartiality in our assessments and recommendations. It is crucial to understand this distinction, as in France, there are only eight such independent public authorities, with HAS being the sole representative within the healthcare sector. This aspect of HAS's institutional framework was certainly surprising and noteworthy to me upon assuming my role.

Why is it essential for organisations like yours to maintain independence in carrying out your tasks?

Maintaining independence is paramount because we must never be beholden, in any way, to either industry interests or governmental influence. When our primary goal is determining reimbursement, we must ensure that our assessments, particularly regarding a medication's therapeutic value, remain unassailable against anything other than scientific criteria.

Independence ensures that our focus remains steadfastly scientific in assessing technologies and medications for the benefit of all. Here, scientific integrity is one of our core values. Upon my arrival, I witnessed first-hand the calibre of individuals within the institution. While our team of 450 staff members is substantial, it is not extensive considering the scope of responsibilities, especially concerning hospital visits and the diverse array of tasks we undertake. Despite this, our institution remains remarkably efficient.

An important observation is that many French citizens are unaware of the significant contributions we make to their lives. When someone takes a reimbursed medication or benefits from early access to an innovative treatment, it is because of our evaluations. Similarly, when a patient receives optimal care from their physician, it is often guided by our clinical practice

recommendations. We directly impact the daily lives of French citizens; a responsibility we take very seriously.

As HAS's 2024 strategic plan draws to a close, what are the main aims of the organisation's next strategic plan up to 2030?

Upon assuming my role, one of our primary focuses has been developing a strategic plan for the upcoming five years. While the specifics are still in development, one certainty is our commitment to fostering innovation and maintaining our capacity to assess emerging technologies. However, I hope that within this strategic plan, we can pinpoint a particular area where France, and by extension HAS, must take a stance.

In our current deliberations, a central focus is on the state of mental health and psychiatry within France's healthcare system. It is striking to note that mental health surpasses even cancer and cardiovascular diseases combined in terms of healthcare insurance expenditure, highlighting the critical need to address mental health issues. Despite its significant impact, mental health remains somewhat taboo, contributing to disparities in healthcare outcomes. Individuals with mental illness face a shortened life expectancy, partly due to delayed diagnoses.

Addressing these complexities is a key priority for HAS, entailing the development of clinical guidelines, promoting appropriate medication usage, and evaluating mental health care across healthcare and social service settings. However, mental health faces unique challenges, including the absence of biomarkers and the type of ground-breaking therapeutic advancements seen in other medical fields. While there have been some advancements, such as serotonin reuptake inhibitors, significant innovation has been lacking for decades. This poses a challenge for HAS in evaluating truly innovative medications in psychiatry. Nevertheless, there is optimism regarding the evolving landscape, with discussions underway about potential biomarkers for bipolar depression, hinting at the possibility of future therapeutic progress in the field.

French patients must wait an average of 443 days between a drug achieving regulatory approval and being made available, according to IQVIA's WAIT Indicator. This puts it far behind not only the likes of Germany (47 days) and Switzerland (148) but also Bosnia (262), North Macedonia (305), and Albania (376). What do you see as the root cause of this issue and how can stakeholders come together to improve it?

We must be clear here; the WAIT Indicator alludes to the time elapsed between a product receiving market authorization and its subsequent reimbursement. Essentially, it signifies the duration of the evaluation process. Regarding this, France stands out positively within Europe.

If we analyse the time from market authorization to completion of HTA, France typically takes around 187 days, whereas Germany requires 221 days. If we looking at the time taken for early access, the same is true: the average assessment takes around 77 days in France, which is faster than the legal requirement of 90 days.

Even when considering all medications and not just innovations, France tends to evaluate medications swiftly. It is crucial to note that the mere issuance of market authorization does not guarantee a product's availability in the market. There are instances where despite having authorization, products are not introduced due to various reasons.

Firstly, the medication's therapeutic value might be deemed insufficient by our assessment. Secondly, there could be prolonged negotiations regarding pricing between pharmaceutical companies and the relevant authorities, which may delay or even prevent the product's market entry.

Therefore, when interpreting French data, it is essential to focus on the moment when HAS provides its evaluation. Subsequently, market availability depends significantly on the actions and decisions of pharmaceutical companies.

What is your view on the gap between the assessments conducted by HTA bodies in Europe and the availability of those medicines under conditional reimbursement?

In France, we have a procedure called "early access to medicines." This law has been in place since 2021, but previously, there was another mechanism known as Temporary Authorization for Use (ATU), to simplify matters. Over the past two years, we have evaluated over 200 products under the early access scheme, which are presumed to be true innovations. We have accepted 80 percent of these products. The remaining 20 percent were not accepted because they did not meet all the criteria. The criteria are very precise. Therefore, if a pharmaceutical company has a genuine innovation and applies for early access in France, meeting the criteria four out of five times, it means that immediately afterward, the product can be available at the industry's price, as pricing negotiations occur later. This is crucial to remember.

So, firstly, HTAs do not hinder innovation. Secondly, they expedite patient access to innovation. I am not critical at all. I believe our American friends have other reasons for not wanting to adopt similar measures.

How do you handle the growing complexity of new medicines based on advanced scientific modalities such as CAR-T and mRNA? How useful do you find methods like "horizon scanning" to assess the impact of current and upcoming innovations?

With early access, we presume that the product is innovative. It meets certain criteria, but there is uncertainty. So, there is a gamble involved. We take that gamble, but ultimately, it is the patient who decides whether to take that medication or not. That is our way of handling uncertainties.

Now, your question is more general, particularly from an industry standpoint. However, for us at the HTA, that is not our focus. Our job is simple: we are provided with a product, and we evaluate it. That is what we were created for—to assess the quality of the healthcare system.

We regularly meet with industries; they provide us with horizon scanning because what interests us is having a vision of what is coming and, more importantly, preparing quantitatively. For instance, will there be many new therapies based on messenger RNA? Will there be a surge in vaccine development? Hence, we need to strengthen the vaccine evaluation sector. Additionally, we need to contemplate potential advancements in treating diseases like Alzheimer's, or certain types of cancers that still pose significant challenges. The same applies to psychiatry. This allows us to gain clarity and anticipate various developments.

When assessing medication efficacy, how do you address the challenge of conducting studies with real-world data?

Real-world data is an area of significant focus, particularly in post-approval studies conducted after drugs have been evaluated. One of our primary concerns with real-world data studies is their often-inadequate scientific robustness. These data lack the comparative purpose we seek, which poses limitations. However, the evaluation doctrine, known as the transparency committee doctrine, evolved in February 2023 to allow for departures from traditional protocols, such as randomized studies, to permit indirect comparisons.

Quality remains a crucial criterion in these evaluations, and many studies lack the necessary standards. The quality of real-world data, often derived from cohorts or registries, presents challenges. However, last year, the HAS and the transparency commission addressed these concerns, clarifying their position on alternative study designs. Subsequently, a case involving a drug prompted a re-evaluation, resulting in a shift from a ASMR5 to a ASMR4 rating, Essentially, the drug was re-evaluated positively based on real-world data, this underscores the ongoing importance of robust evaluation practices amidst evolving methodologies.

What is your perspective on the assertion that European healthcare systems have an advantage due to their unified nature for data capture, despite industry claims to the contrary regarding their effectiveness in this regard?

In France, indeed, there exists the Health Data Hub. There is also the national health data system, although its data is not yet integrated. What I understand is that there is access for industries. However, they often complain about the lengthy process of obtaining the data. Nonetheless, according to regulations, it is entirely feasible.

The move to EU-wide HTA legislation in 2025 has been described as positive for the bloc's smaller countries that were short of capabilities in this area, but potentially an added layer of bureaucracy for larger countries with well-established frameworks like France. What is HAS's take on the challenges and opportunities of this new legislation?

The 2021 European Regulation, effective from January 1st, particularly focuses on oncology medications and innovative therapies, raising questions about potential duplications in evaluation processes. While the regulation explicitly states that the Common Clinical Assessment (CCA) at the European level should not be replicated by individual countries, exceptions may arise if additional compelling data surfaces between the CCA and national evaluations, warranting supplementary analysis rather than a complete redo. However, our involvement may be necessary for medical-economic evaluations, though we will not duplicate the entire process. France is expected to participate in assessing these submissions, each requiring two evaluators to draft the document.

Although the evaluation criteria, currently undergoing public consultation, may delve deeper than our current practices, concerns linger about the need for increased resources and potential delays in other areas, particularly routine medication evaluations. Despite these challenges, the European

regulation offers a positive step towards standardizing scientific review processes across member states, while ensuring each country maintains autonomy over reimbursement decisions based on its own evaluation criteria.

Also, I strongly believe France has a crucial role to play in shaping the future of European healthcare, especially in ensuring a comprehensive and holistic approach to healthcare evaluation and regulation. At the heart of this endeavour lies our agency's commitment to providing expertise that promotes patient-centricity, transparency, and excellence in healthcare standards.

Within the framework of European regulations, such as the coordination group outlined in the recent legislation, our agency actively participates to ensure that France's perspectives and priorities are represented. This includes involvement in sub-groups focusing on critical aspects like common clinical evaluation methods, where our agency contributes expertise and insights.

The overarching goal is to foster a unified vision of health technology assessment across Europe, recognizing that health challenges transcend national borders. While advocating for a Europe-wide approach, we remain mindful of maintaining the sovereignty of national healthcare systems, allowing for flexibility tailored to each country's unique needs and circumstances.

When we interviewed your predecessor, she discussed some of the strains on the French healthcare system. What are your thoughts on this matter?

Like many countries worldwide, we are grappling with a shortage of healthcare professionals. However, our challenges extend beyond staffing issues. The escalating costs of healthcare, a trend mirrored in France since the establishment of health insurance post-World War II, underscore the financial strain on our system. In France, safeguarding health is enshrined as a constitutional principle, reflecting our commitment to national solidarity. Yet, this solidarity comes with a price tag, as the expenses associated with medical products and treatments continue to soar.

In this context, the sustainability of our healthcare system is a pressing concern for the future. As an indirect player in this arena, our evaluations play a crucial role in determining the scope of coverage provided by our system of national solidarity. Through rigorous assessments, we strive to navigate the complexities of healthcare expenditure, ensuring that our resources are allocated effectively to support the health needs of our population.

When you mention certification of hospitals, do you evaluate the public and private sectors? And how do these evaluations differ between the public and private healthcare sectors?

Our evaluations are grounded in a comprehensive set of criteria aimed at assessing the quality of healthcare services and ensuring patient safety and dignity. These criteria, numbering over 130 in our reference framework, cover three main domains: patient-centred, healthcare professional-centred, and facility-centred aspects. Regardless of whether the institution is public or private, the evaluation process remains consistent, emphasizing uniform standards across the healthcare landscape.

Upon evaluation, institutions are certified based on their fulfilment of these criteria, with the possibility of receiving commendations or recommendations for improvement. However, the ultimate decision regarding certification status lies with the public authorities, who determine the allocation of resources based on the evaluation outcomes.

While certification may confer certain benefits, the exact implications may vary and are subject to government policies and priorities. Ideally, certification serves as an incentive for institutions to strive for excellence and continuous improvement in healthcare delivery.

Many perceive France as having one of the finest healthcare systems worldwide. It is often seen as a model where everything is covered. Where do you believe France stands today?

In my view, the French are fortunate to have such an excellent healthcare system. Unlike Americans or some British citizens who may struggle to afford treatments, in France, accessibility is relatively high. Even medications priced at EUR 300,000-400,000, are accessible if needed.

However, despite occasional complaints from the French about the system, it is imperative to maintain its quality. This entails ensuring well-equipped facilities and trained professionals. While optimism exists about overcoming challenges, securing adequate financial resources is crucial. With a considerable budget, our role is not to drive down prices for industry, but to discern what deserves funding.

Is there any message you would like to convey to your colleagues in Europe, the United States, and worldwide regarding your work, considering the emerging interest in HTA and healthcare system reforms?

Firstly, at the European level, it us essential to highlight the valuable collaboration within the Head Agency Groups (HAG), where presidents of HAS and others HTAs from across Europe convene. As the co-chairman, alongside the Portuguese president and Swedish co-chairman, we engage in monthly video meetings, fostering continuous communication and exchange. Strengthening ties among all HTAs across Europe while maintaining independence is crucial, especially with upcoming regulations. We must enhance understanding of each other’s practices and initiatives.

Regarding countries in the South, we have a unique opportunity to assist in the implementation of HTA frameworks. Collaborating with Southern and Middle Eastern countries, we aim to support their HTA efforts, recognizing the global significance of this endeavour. This is not solely a French concern but of global interest.

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