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We work to ensure that patients have rapid and equitable access to innovation.

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ANSM's Director General Catherine Paugam-Burtz offers a clear view of how France's medicines agency is adapting to a fast-shifting landscape. She discusses ANSM's role within the European regulatory system, the agency's digital transformation, the pressure to accelerate clinical research, the importance of early access, and the work underway to strengthen supply resilience and prepare for advanced therapies. Her perspective reveals how a long-established institution is reshaping itself to support innovation while maintaining rigorous public-health protections.

What role does ANSM play within France's healthcare system, and how does it work alongside the broader European regulatory framework?

ANSM safeguards the safety, efficacy and quality of health products used in France. Our remit covers human medicines, medical devices, in vitro diagnostics and a broad set of biological products such as organs, tissues, cells, blood components and breast milk processed through authorised lactariums. We also oversee advanced therapy medicinal products (ATMPs). Our role spans the entire lifecycle, from authorisation and quality control to inspections, surveillance and clear communication to healthcare professionals, patients and citizens.

Two principles guide this mission. We evaluate benefit-to-risk ratio throughout a product's life, and we work to ensure that patients have rapid and equitable access to innovation. These commitments require scientific rigour, transparency and trusted dialogue with the public. At the European level, the centralised framework managed by the EMA provides a single route for authorising many human medicines. One coordinated scientific assessment, conducted through committees such as the Committee for Medicinal Products for Human Use (CHMP), leads to a decision by the European Commission that applies across all Member States. Devices and in vitro diagnostics follow other European regulations where the EMA has a more limited advisory role. National authorities like ANSM remain responsible for most aspects of their oversight.

France contributes actively to the European network by providing experts, acting as rapporteur and carrying out inspections that reinforce shared standards. Centralisation does not weaken national authority; it creates coherence across Europe while enabling each country to fulfil its own responsibilities in areas such as health technology assessment, pricing and reimbursement. In France, these evaluations are undertaken by the Haute Autorité de santé (HAS) once a European authorisation has been granted. After the EMA procedure concludes, the European Commission's decision applies across all Member States, and national differences only arise during the subsequent national phase. We believe this collaborative approach strengthens collective expertise and ensures consistent protection for patients across Europe.

How have you approached your first year at ANSM, and what priorities are shaping the agency's strategic direction?

When I arrived at ANSM, the new "Contrat d'objectifs et de performance" had just been signed. This four-year agreement with the Ministry of Health defines our strategic direction through 2028. It is the product of substantial preparatory work, including a full review of the previous plan and extensive consultation with internal teams and external stakeholders. The current framework is structured around four commitments. We protect patient safety in the use of health products. We foster innovation through a more agile regulatory approach. We remain attentive to citizens and their expectations. We operate as an efficient and accountable public health agency.

Stepping into a role with such a clear roadmap was an advantage. The plan reflects the continuity and long-standing expertise of ANSM, whose foundations extend well before its current structure was established in 2012. One year on, it is clear to me that this accumulated scientific and regulatory experience is one of the agency's strongest assets. Within this framework, I have placed

particular emphasis on engagement with our diverse stakeholders. Industrial actors, startups, hospitals, pharmacists, researchers, prescribers, patient associations and individual citizens all depend on our decisions and guidance. Maintaining steady dialogue and providing clear, transparent explanations are essential. In an environment where scientific authority is increasingly questioned, we also place great importance on precise, evidence-based and scientific communication to counter disinformation.

Another central priority is advancing ANSM’s digital transformation. We are equipping the agency with modern tools, stronger data systems and the capabilities needed to integrate real-world evidence across our scientific and regulatory activities. Our work with EPI-PHARE, the pharmacoepidemiology group created in 2018 jointly with the National Health Insurance Fund (CNAM), illustrates this evolution. Through the national health data system (SNDS), it conducts large-scale studies that provide timely insight into safety signals, treatment patterns and population outcomes, and these analyses now inform many of our regulatory decisions. Digitalisation also involves modernising information flows, automating elements of surveillance and testing new tools such as digital patient information leaflets. Together, these efforts help ANSM operate in a more agile, transparent and data-driven way.

Finally, we continue to reinforce our contribution to the European regulatory network. Active involvement in discussions on medicines, medical devices and emerging technologies strengthens coherence across Member States and supports a shared approach grounded in trust and collective efficiency. This European dimension is essential for supporting innovation and meeting the health needs of citizens in France and in the European Union.

How is ANSM working to reinforce France’s position in clinical research and support faster, more predictable access to innovative therapies?

Clinical research is essential for sustaining access to innovative therapies, so preserving Europe’s competitiveness has become a priority. International pressure is increasing, some countries can mobilise resources with notable speed, and while Europe operates under a different model, we must still improve our own predictability and efficiency to remain attractive. Our first step has been to listen carefully to the concerns raised by sponsors and academic teams. Many point out the need for clearer guidance, stronger methodological support and more consistent scientific dialogue. We have expanded our advisory activities to help applicants strengthen the quality of their submissions and address clinical judgment issues early, since these elements often determine

the pace of the authorisation process.

At the national level, we are developing what could become a structured Fast Track approach for clinical trials. This follows more than a year of work with stakeholders, including industry groups, and builds on pilot procedures tested to shorten timelines. The aim is to provide a more agile route for high-quality studies while maintaining the scientific standards and the patients' security, expected of a public health agency.

In parallel, we play an active role in the European regulatory network, in the HMA, following the upcoming Biotech Act by the European Commission. One of the central themes under discussion is procedural reduction of timelines for trial authorisations.

Recently, in collaboration with the National Commission for Research Involving Human Subjects (CNRIPH) and the National Conference of Ethics Committees (CNCP), and in coordination with French Ministry of Health and the Health Innovation Agency (AIS), we have announced the implementation—starting in the first quarter of 2026—of a new accelerated authorization process (fast-track) for certain clinical trials conducted on national territory. This initiative aims to enhance the appeal of clinical research and facilitate priority, secure access for patients to innovative treatments.

We also promote pilot actions at the European level to demonstrate that simpler and faster procedures are achievable within the existing regulatory architecture.

Industry views this initiative positively, although each stakeholder naturally interprets available data through its own lens. The underlying message remains clear: Europe and France need to streamline processes and reduce delays in authorisation and recruitment to maintain their place in global research. Our role is to support that evolution without compromising scientific rigour or patient safety.

How do you assess current access timelines in France, and what significance does early access hold during the national evaluation phase?

When we speak about access timelines, it is important to distinguish the European marketing authorisation from the national steps that follow. For innovative and orphan medicines, France benefits from a well-established Early Access pathway that helps bridge this period. A recent review by Copenhagen Economics, drawing on the work of the European Expert Group on Orphan Medicinal Products, compared access models across Europe and highlighted the French and

German schemes as among the most effective. In our case, the "*Autorisation d'accès précoce*" often allows patients to receive a treatment within three months of applying. This is particularly significant in areas of a high level of unmet need.

On the broader question of delays, we need to be precise about what the numbers actually represent. France uses all of the European authorisation routes: centralised, decentralised, mutual recognition and national procedures. Centralised and decentralised pathways remain a priority because they deliver the strongest alignment with our European partners and the greatest value for patients. We continue to receive a high volume of national marketing authorisation applications. France is among the countries with the highest numbers of these submissions, and our timelines on the national route have been longer than we would like. We are addressing this by focusing on the data, identifying the real sources of delay and improving our processes without discarding what already functions well.

The key is to understand what lies behind a delay. A delay is not the same as the regulatory timeline. It can stem from scientific issues, incomplete information or steps that require deeper clarification. Our responsibility is to analyse these situations, identify the specific bottlenecks and adapt our processes or resources where needed. At the same time, we must preserve what already works well. Improving predictability for applicants cannot come at the expense of the scientific standards and protections that underpin public health.

How is ANSM managing the rising pressure around drug and health-product shortages, and what long-term measures are being put in place to strengthen supply resilience?

Managing shortages is one of ANSM's highest priorities. Every disruption affects a patient, so our teams work on this issue daily and in close coordination with clinicians, pharmacists, patient groups, scientific societies, manufacturers and supply-chain actors. It is also important to recall that pharmaceutical companies hold primary responsibility for preventing and managing shortages. ANSM does not produce medicines, and companies have an ethical and operational duty to ensure continuity of supply.

Our approach combines immediate action with work on long-term prevention. We have strengthened the preventive framework by requiring manufacturers and supply-chain operators to maintain minimum safety stocks, develop response plans and notify us early if there are shortages of medicines of major therapeutic interest (MITMs). When a shortage occurs, we intervene to limit its impact.

A concrete example of anticipation actions is our Winter Plan, now in its third year. Introduced after the tensions of the 2022-2023 season, it anticipates demand for medicines heavily used during winter epidemics. Preparation begins in the summer through early engagement with manufacturers, followed by weekly monitoring of epidemiology, consumption and supply conditions throughout the season. This has become a key tool for avoiding or mitigating seasonal shortages.

We are also improving our digital capabilities, because full visibility across the supply chain remains limited. Today, only a small group of medicines benefits from automated monitoring, as this work is complex and resource-intensive. We are developing dedicated tools to extend real-time oversight to a broader set of critical medicines and, over time, to medical devices as well. Long-term resilience requires identifying structural vulnerabilities. We work with the Ministry of Health and the Directorate General for Enterprises (DGE) to map risks linked to active ingredients, production bottlenecks and situations with very limited alternatives. This collaborative approach helps us identify weak points early and develop targeted responses.

Finally, shortages do not stop at national borders. We work closely with our European partners, because many questions of supply security and sovereignty can only be addressed collectively. Strengthening resilience at the European level will be essential to ensuring reliable access for patients.

How is ANSM preparing for the next generation of advanced therapies, and what forms of support are you providing to innovators developing them?

Advanced Therapeutic *Medicinal Products (ATPMs)* are progressing at a remarkable pace, and we decided to prepare for this shift proactively instead of addressing it only once it materialises. Since 2020, we have built a dedicated structure within ANSM focused entirely on ATMPs, bringing together scientific, regulatory and technical expertise and working closely with French stakeholders who operate in this field. We also established the Guichet Innovation et Orientation (GIO), which serves as an early support channel for medium-sized enterprises (SMEs), academic teams and other project leaders. In its first two years alone, more than 700 innovators used this service, which means a great deal about the intensity of activity and the real need for structured guidance at the earliest stages of development.

Our effort does not stop at the national level. We contribute actively to the EMA’s Committee for Advanced Therapies (CAT) and participate in the European Innovation Network (EU-IN), which places us at the heart of how Europe is preparing for the expansion of these technologies. This dual

involvement allows us to support national innovation while ensuring full alignment with the regulatory evolution taking place across Europe.

The digitalisation of regulatory functions has become a central theme across Europe. What progress has ANSM made on this front, and what are the main challenges to integrating AI and data tools in areas such as pharmacovigilance and dossier evaluation?

Work on the digitalisation of regulatory functions is ongoing and will continue. AI and data tools are being progressively integrated into the Agency, starting with various use cases on different topics, followed by evaluation and reflections on what can be learnt.

For example, the French national pharmacovigilance (PV) database is powered with an AI module offering a decision support tool for pharmacovigilance case prioritisation (distinguishing between serious and non-serious cases) and precoding adverse reactions using the MedDRA dictionary. The AI module was developed in three stages: a regional pilot, followed by validation of the pilot, and finally validation at the national level.

We can cite many other cases, such as the field of drug shortages for analysis on drug shortages management plans or implementing a living meta-analyses tool for systematic literature search for in utero exposure to drugs and adverse pregnancy.

ANSM is also fully involved in international groups as M11 for ICH (International Council for Harmonisation) and whose objective is to build a digital protocol, namely a clinical electronic structured harmonised protocol with data directly linked to the CTIS European database. This powerful digitalised tool will highly facilitate the creation of the protocols for sponsors and will ensure harmonised, consistent data for regulators. This digitalised protocol is planned for go-live in the coming months and comes with technical specifications, guidelines and training for the stakeholders.

However, we have to keep in mind various challenges when considering integrating AI into our regulatory sciences.

The first one is about the need for a careful evaluation of the real interest of AI in this area. There is no doubt that AI will change how we work. Some applications are already there, such as supporting the completion of evaluation files or providing quick and extensive access to existing knowledge. That said, these tools must be thoroughly assessed to ensure they are used in the most effective,

efficient, and secure way possible. This means working on practical use cases that align with the day-to-day realities and needs of experts. We know these tools still need to be refined and tailored to our specific needs. Additionally, we know that we have to pay attention to the impact on our human resources.

The second point is to always keep in mind that AI integration requires data quality and system interoperability. The ANSM will lead the European Joint Action on the implementation of a common standard for medical product identification and AI capabilities across Member States. Moreover, integrating AI comes with a need for specific expertise, adequate digital infrastructures and computing power that requires dedicated financial investment.

Finally, we must ensure confidentiality and privacy of data, maintain sovereignty on our data and last but not least promote a sustainable use of the technology.

Looking toward 2026 and beyond, what strategic priorities will guide ANSM's work as it supports Europe's evolving life sciences and clinical-research ambitions?

The next phase is anchored in strengthening our data strategy and embedding AI within our scientific and regulatory workstreams. These tools will enhance the depth and speed of our analyses and help modernise how we operate across the agency. At the same time, we intend to contribute more actively to Europe's broader ambition to reinforce its competitiveness in life sciences and clinical research. Europe has now articulated a clearer strategy in this area, and regulators must help make that ambition tangible, particularly by improving predictability and efficiency in clinical research.

Alongside this, we will continue the permanent work around supply resilience. Anticipating and managing tensions in the supply of medicines and medical devices remains one of our core responsibilities. To strengthen this, we need more integrated digital tools that give us real visibility across the entire supply chain. Building these capabilities is essential if we want to move from *responding* to shortages to *preventing* them and providing patients and healthcare professionals with a more stable and reliable environment.

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