ansm

Summary
2022 Annual Report

Summary

The French National Agency for Medicines and Health Products Safety (ANSM) is a public establishment under the authority of the French Ministry of Health.

On behalf of the French State, we are responsible for the safety of health products and promote access to therapeutic innovation. We act on behalf of patients, alongside healthcare professionals and in consultation with their respective representatives in all the Agency's bodies.

Through our evaluation, expertise and monitoring policy, we ensure that health products available in France are safe, effective, accessible and properly used.

Our priorities for action are set out in the Objectives and Performance Contract that we sign with the State.

The Agency is also actively involved in European and international activities. Our activities are very much in line with European procedures and our activities are carried out in coordination with the European Medicines Agency, the European Commission and the other national agencies of the European Union. We also collaborate with international health organisations.

ANSM has a Management Board, a Scientific Board and advisory bodies. We are also supported by an Ethics Department and an Ethics Advisor who help guarantee the independence and impartiality of our decisions.

We are based at three sites: in Saint-Denis (headquarters and laboratories), Lyon and Vendargues (laboratories).

Our main missions are to:

- Enable early and rapid access to innovative products;
- Authorise clinical trials;
- Authorise the marketing of medicines and biological products;
- Monitor all health products throughout their life cycle;
- Collect and analyse adverse effect reports;
- Study the impact of using health products;
- Ensure the availability of "essential" health products;
- Control their quality in our laboratories;
- Inspect manufacturing and distribution sites.

EDITORIAL

In 2022, ANSM steadfastly pursued its role of protecting citizens.

In the wake of the multiple crises related to the Covid-19 pandemic, supply tensions have affected numerous health products worldwide. In constant dialogue with patient representatives and healthcare professionals, ANSM has worked hard to identify practical solutions in order to address real needs on the ground. Working with its counterparts within the European Medicines Agency, ANSM seized on the French Presidency of the Council of the European Union in 2022 as an opportunity to make progress on major issues of common interest. In a globalised world where health is an increasingly complex challenge, ANSM is reasserting, through each of its actions, its role as a public health agency in tune with the needs of the citizens it serves.

VALÉRIE DELAHAYE-GUILLOCHEAU
Chair of the ANSM Management Board

JEAN-PHILIPPE PLANÇON
Vice-Chair of the ANSM Management Board

CHRISTELLE RATIGNIER-CARBONNEIL
Director General of ANSM

Watch
the full editorial

→ 2022 Key dates

JANUARY

Clinical trials on medicinal products: entry into force of the new European regulation

FEBRUARY

French Presidency of the Council of the European Union: ANSM organises 20 meetings of European working groups and committees

MARCH

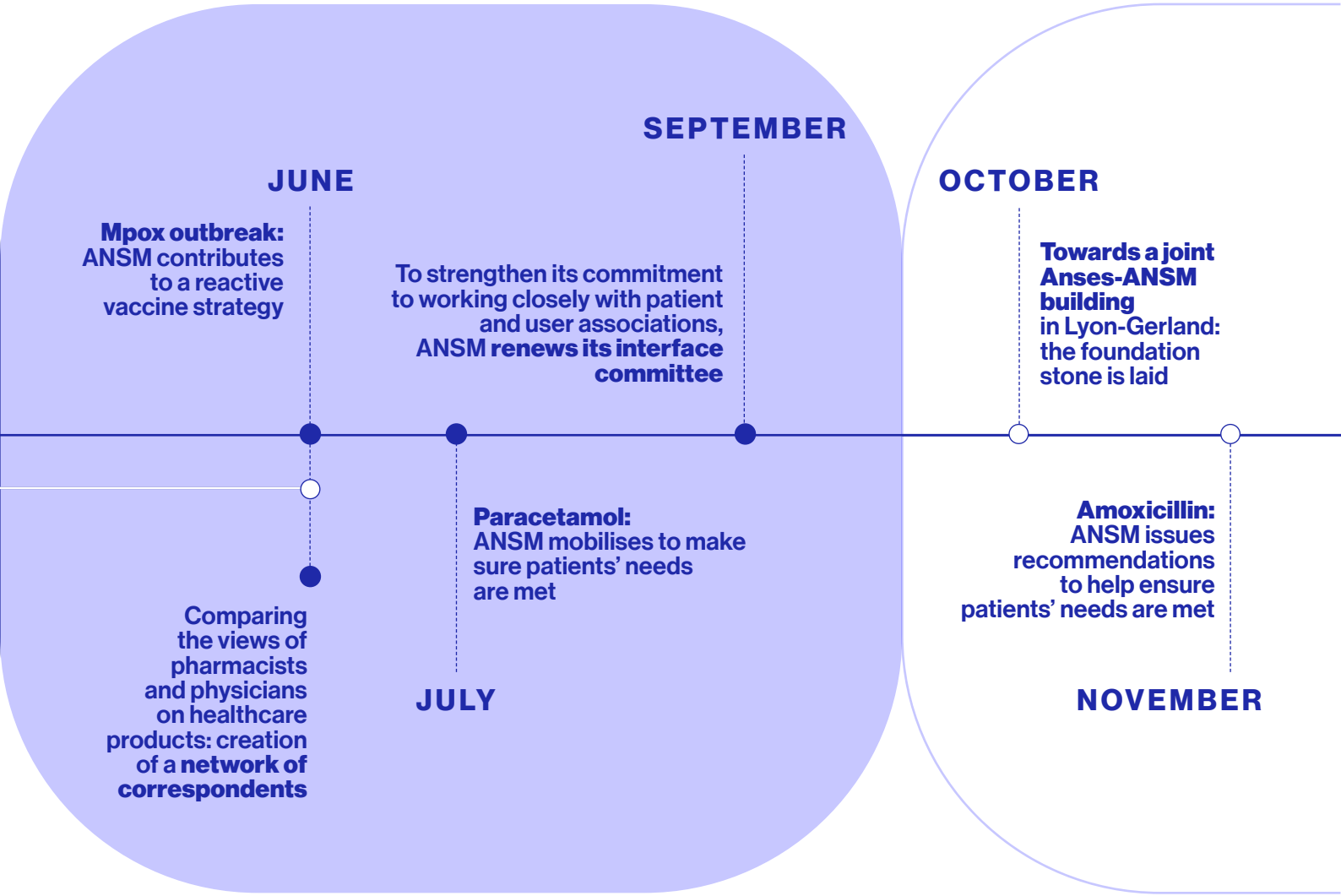
The Chair of the ANSM Management Board is renewed

In vitro diagnostic medical devices (IVDMD): entry into force of the **new European regulation**

MAY

"ANSM reasserts its role as a public health agency in tune with the needs of the citizens it serves. It is an active player in a dynamic drive for innovation, commitment and performance, for the benefit of the population as a whole."

JEAN-PHILIPPE PLANÇON
Vice-Chair of the ANSM Management Board



→ Working together to build the Europe of health

European cooperation is essential to ensure that patients have access to high-quality, safe and effective medicines, medical devices and IVDMDs*. ANSM is closely involved in this process, bringing France's expertise and position to bear on discussions and decisions. In 2022, the Agency hosted its European counterparts during the French Presidency of the Council of the European Union (FPEU) and supported the implementation of two new European regulations.

Greater coordination, harmonisation and transparency between Member States

France has always contributed to European activities, particularly the work of the European Medicines Agency (EMA). The FPEU was a unique opportunity to promote the country's strong position on a European level, particularly as regards health products. Recent crises such as the Covid-19 pandemic and drug shortages have highlighted the need for a shared strategy designed to support innovation and foster the development of complex technologies for the benefit of French and European citizens.

Clinical trials, MDs and IVDMDs: new European regulations for ever greater safety

In 2022, ANSM supported the implementation of:

• The new European Regulation for the authorisation and monitoring of clinical trials on medicinal products. There is now a common framework for the assessment of such clinical trials via a single portal – the Clinical Trials Information system

"International leadership crucial to innovation for French patients"

→ **Read the interview with Pierre Démolis, Scientific Advisor, and Valérie Denux, Director of the European and Innovation Division.**

Spotlight

In 2022, ANSM organised 20 meetings for the French Presidency of the Council of the European Union. One of these, launched at the Agency's initiative, concerned "real-world" evidence throughout the life cycle of a medicinal product. Real-world evidence optimises the assessment of the efficacy and safety of innovative health products available to patients through early access. It accelerates the development of new, even more reliable therapeutic solutions.**

→ For more information about the French Presidency

"Participating in the construction of a 'Europe of Health' has become a key issue for our country. Against a backdrop of potential new pandemics and the globalisation of production, we have every interest in developing a certain level of harmonisation and cooperation with other continents [...]."

VALÉRIE DENUX
Director of the European and Innovation Division

(CTIS) – enabling Member States to work together with a harmonised approach. This new regulation gives patients access to clinical trials under optimum safety conditions. The Agency supports sponsors in the transition from national procedures towards a coordinated European assessment process, by promoting, informing and exchanging information about the changes involved.

New European Clinical Trials Regulation: one year on, a first positive assessment

→ **Read the interview with Sophie Accadebled, Clinical Trials Project Officer, and Corinne Kiger, Clinical Trials Advisor, within the Authorisation Division.**

• The new European regulation relative to performance studies (**PS**) on **MDs/IVDMDs**, one year after the regulation relative to clinical investigations (**CI**) on medical devices. Introduction of risk classes, requirements for demonstrating conformity and performance, structuring of clinical follow-up... This major change in European regulations reinforces the safety of medical devices, for the benefit of patients.

→ For more information about **new European regulations**

Key figures

146
number of cases recorded in the agendas of the European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC) for which France was the reporting Member State

19
marketing authorisation (MA) applications under a centralised procedure assigned to France

101
European scientific opinions were attributed to France

107
France appointed rapporteur or co-rapporteur for 107 Paediatric Investigation Plans (PIPs)

Understand

MD/IVDMD
A medical device (MD) is an instrument, material, device or piece of equipment that is used for medical purposes: dressings, breast implants, pacemakers, etc. An in vitro diagnostic medical device (IVDMD) is a product or instrument intended for the examination of samples from the human body, such as tests (Covid-19, pregnancy, etc.) or reagents used in a medical biology laboratory.

Real-World Evidence
Data that is not collected as part of an experimental research project, but is derived from the usual management of patients, for example routine care.

PS
Performance studies to establish or confirm the performance of a device.

CI
Clinical investigations involving one or more human participants and intended to evaluate the safety or performance of a device

→ Securing the supply of health products

In 2022, a large number of health products, including some very widely-used medicines such as paracetamol and amoxicillin, were subject to severe supply tensions, leading to stockouts in some cases. Working closely with the players involved at national and European level, ANSM mobilised to provide practical solutions to address real needs on the ground.

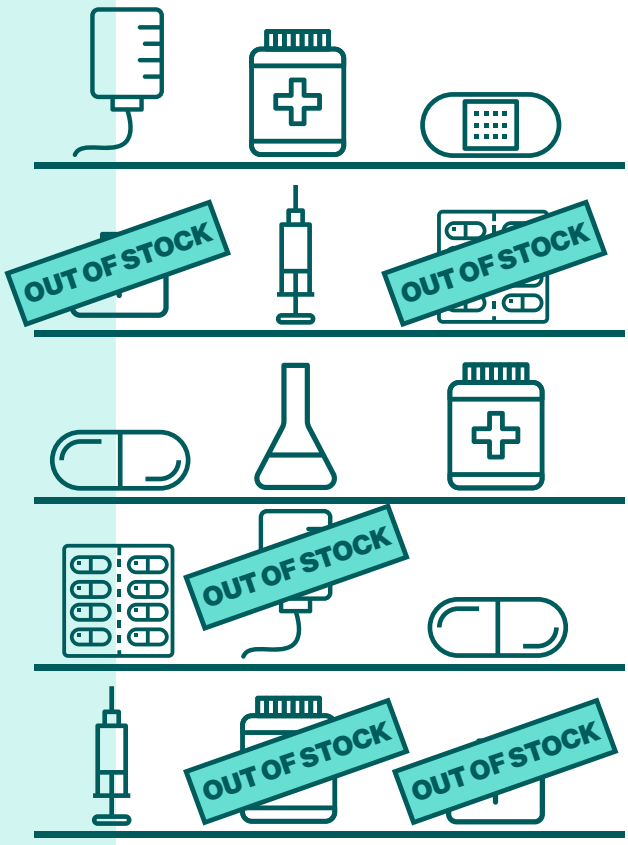
Amoxicillin and paracetamol under pressure: ANSM mobilised on every front

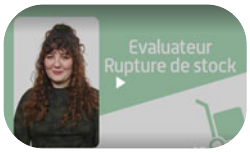
In 2022, seasonal epidemics of influenza and bronchiolitis returned, with Covid-19 also still present. This contributed to a sharp rise in demand for medicines containing amoxicillin and paracetamol, especially in paediatric forms (oral or suppositories), which pharmaceutical companies were unable to meet.

In response to reports of shortages or stockouts, ANSM worked together with pharmaceutical companies to find solutions and supply routes. It implemented a variety of measures to guarantee fair access to these medicines for patients: **quotas** in the community medicine setting, a ban on direct sales by pharmaceutical companies to pharmacies and on exports by wholesaler-distributors, securing of supplies for healthcare facilities, etc. Throughout the year, the Agency monitored consumption, stocks and supplies using data from pharmaceutical companies, wholesaler-distributors and pharmacies. It exchanged information regularly with institutional players, representatives of healthcare professionals (physicians, pharmacists, etc.) and patient associations, in particular France Assos Santé, in order to adjust its actions in line with the evolving situation.

ANSM also published recommendations drawn up with learned societies and aimed at healthcare professionals and the general public. For instance, the amount of paracetamol that could be dispensed without a prescription was limited to two packs per patient. In another example, pharmacists were provided with support for the preparation of pharmacy-compounded amoxicillin preparations for children.

→ For more information about
Amoxicillin and paracetamol under pressure





Discover the job of stock shortage assessor

"Our monitoring system does not prevent shortages, but it does play a mitigating role in the management of shortages and tensions, and in the proper use of medicines."

CHRISTELLE RATIGNIER-CARBONNEIL
Director General of ANSM,
Senate hearing of 15 February 2023

Ozempic: misuse for weight loss purposes

Ozempic, a medicinal product for type 2 diabetes (semaglutide), experienced supply tensions following inappropriate prescriptions for weight loss purposes. In addition to a quota system in the community medicine setting, and in consultation with the *Société francophone du diabète* [French-language Diabetes Society] and the *Fédération française des diabétiques* [French Diabetics Federation], ANSM published recommendations for prescribers to ensure that diabetic patients could have access to their treatment.

→ For more information about **Ozempic**

Medical devices and in vitro diagnostic medical devices: optimised stockout management

ANSM manages supply tensions for medical devices (MDs) and in vitro diagnostic medical devices (IVDMDs). With a working group bringing together manufacturers, users and hospital buyers, the Agency implemented the pilot phase of a process for optimised management of MD and IVDMD shortages and stockouts, based on the early exchange of information, but also on the responsibility of manufacturers, importers and distributors. Following an initial review, the system was simplified and made operational using a risk analysis grid based on the MD and IVDMD and the specific situation. In parallel, ANSM was involved in the drafting of legislation making the stockout management process compulsory.

→ Browse the list of **MDs and IVDMDs under tension**

Understand

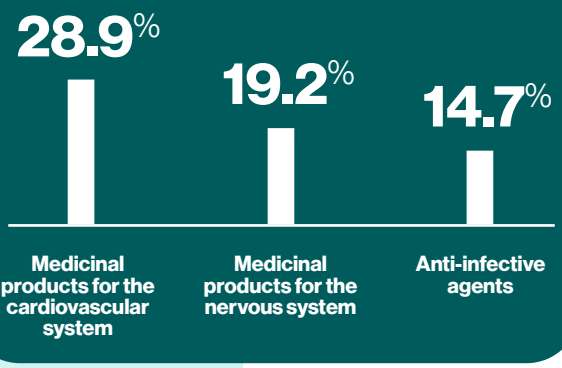
Quantitative quota
The maximum number of packs delivered periodically by manufacturers to pharmacies is limited to ensure the continuous and fair distribution of available stocks.

Medicines of major therapeutic value (MITM)
medicinal products for which interrupting treatment could be life-threatening for the patient in the short or medium term or represent a significant loss of opportunity for the patient.

Key figures

3761 reports of risks of shortages and stockouts managed by ANSM,

of which: :



→ Find out all about **the risks of shortages and MTIM stockouts: regulations, medicines concerned, causes, role of ANSM, etc.:**

→ Talking to healthcare professionals and patients

Ever more committed to open and transparent communication with its various publics, ANSM took another step forward in 2022 with the creation of a network of correspondents designed to facilitate dialogue with healthcare professionals on the ground. It also renewed its interface committee liaising with patient associations.

Reinforcing the link with patients

In 2022, ANSM renewed its interface committee liaising with patient and healthcare system users. Created in 2013, this committee ensures regular, constructive dialogue with associations on cross-cutting issues of common interest. Associations have been represented in all the Agency's other bodies, including scientific committees, since 2019. The France Assos Santé association, a major player when it comes to representing the interests of patients and healthcare system users, coordinates the members of the committee and helps to run it. The renewal of this committee reaffirms the Agency's determination to ensure constant dialogue with patients and to really listen to their concerns.

→ For more information about **the new Interface Committee** with Patient and Healthcare User Associations

Launch of the Correspondents' Network

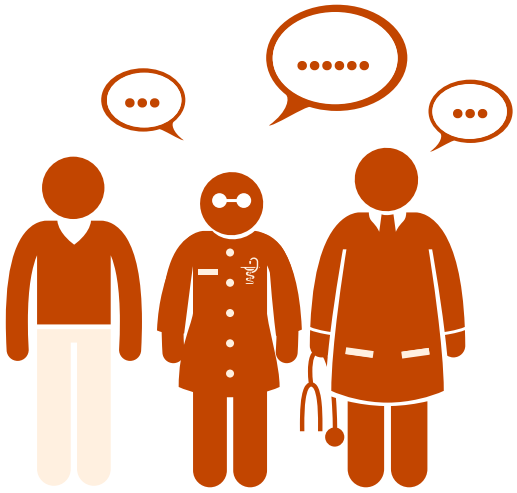
In partnership with the French College of General Practitioners (CMG), the Federation of French Pharmaceutical Unions (FSPF) and the Association of Dispensing Pharmacists' Unions (USPO), ANSM created a "Correspondents' Network", composed of pairs of general practitioners and dispensing pharmacists working throughout France.

The Agency will consult this network periodically via short surveys. The four partners will decide on the content of these surveys (medicinal products, medical devices, regulations, etc.). Conversely, the pairs can inform ANSM of any issues, ideas or initiatives arising from their day-to-day work. By taking into account the points of view of local healthcare professionals and, indirectly, patients, ANSM can assess the impact of its decisions more effectively and draw on experience from the field to inform its reflection processes. For this pilot phase, which will run until the end of 2023, the network is made up of 100 correspondents, i.e. 50 physician and pharmacist pairs.

→ For more information about **the Correspondents' Network**

"Our aim is to create an ANSM reflex, and we will continue to work towards this goal. Our ability to interact with our stakeholders and to incorporate them in our decisions is recognised as a model to be followed."

ROSE-MARIE TUNIER
Head of the Communication and Information Division



"Listening to our publics, to keep moving forward".

→ **Read the interview with Annie Dumortier, Quality Manager, and Rose-Marie Tunier, Director of the Communication and Information**

Key figures

4 209.711
unique visitors to the ANSM website

99.216
LinkedIn subscribers

42.510
Twitter subscribers

12 information and discussion webinars with health professionals, patient associations, and operators and manufacturers

Spotlight

The Agency is determined to be ever more attentive to its stakeholders and is reinforcing the educational value of its information by multiplying its formats and media. It also has a stronger social media presence to help it reach its publics in a different way.

→ Controlling, inspecting and monitoring health products

ANSM constantly oversees the accessibility, safety and proper use of the health products available in France. In 2022, it contributed to a reactive vaccination strategy during the mpox outbreak and managed an alert relative to implantable pacemakers.

Key figures

26 new high-risk situations (HRS) with an average of 43 HRS in progress simultaneously

562 component or site inspections

3.879 laboratory tests

Understand

HRS
Occurrence of an emerging event or a series of unusual and/or obscure events identified during the everyday management of alerts and ongoing cases on the basis of the magnitude, seriousness, or treatment of the event(s) in the media.

Mpox outbreak: close monitoring of treatments and vaccines

In 2022, mpox virus (Monkeypox) infections were reported worldwide, outside endemic African zones. As soon as the first cases were confirmed in France, ANSM worked with the French High Council for Public Health (HCSP) and the French National Health Authority (HAS) to recommend pre- or post-exposure smallpox vaccination for high-risk individuals. An antiviral treatment (tecovirimat) was recommended in people at risk of serious forms of the disease. At the same time, ANSM facilitated access to specialist therapies for the patients concerned, and closely monitored adverse reactions to vaccines and treatments for mpox.

→ For more information about **ANSM's contribution**

360° management of the consequences of a manufacturing defect with a highly sensitive medical device

Pharmaceutical company Abbott informed ANSM about a manufacturing defect with some of its implantable pacemakers. The defect affected around 16,300 pacemakers in France. In September 2022, reports of failures that could be linked to this problem had been received for 0.3% of these medical devices. In this context, working in liaison with learned societies in the field of cardiology, ANSM drew up and disseminated recommendations on measures to be taken aimed at patients and healthcare professionals. By February 2023, some 9,500 patients had been placed under remote monitoring and almost 2,700 had had their pacemakers removed.

→ For more information about **Abott pacemaker monitoring**

Facilitating access to innovative treatments

ANSM provides oversight and support in order to facilitate early, safe and fair access to innovative health products for patients. In 2022, it submitted its assessment of the medical cannabis trial and continued its involvement in the SACHA study on new drug substances in paediatric oncology.

Medical cannabis trial: a first positive assessment

En 2021, ANSM launched a trial on the use of medical cannabis. 2022 saw the submission of the assessment reports concerning the trial to the Ministry of Health. These reports give a positive assessment of the trial, taking us a step closer to the possibility of widespread use: feasibility and safety of access to medical cannabis, acceptable safety profile, encouraging efficacy, patient satisfaction. This trial has been extended for a one-year period by the Ministry of Health, until March 2024. In parallel with the trial, ANSM issued a technical opinion on the feasibility of a medical cannabis production chain in France, an essential step towards the creation of a French medical cannabis production industry.

For more information about
the Medical cannabis trial

Innovative treatments for young cancer patients

ANSM is actively involved in the SACHA project, initiated by the French Society for childhood and teenage cancers and leukaemias (SFCE) and promoted by the Gustave Roussy centre. The study draws primarily on data concerning compassionate access authorisations* (AACs) granted by ANSM in the field of paediatric cancers. It makes access to innovative therapies for young cancer patients safer by reporting any adverse effects. SACHA also collects efficacy data concerning these innovative treatments. This helps to identify the most promising therapies and promote clinical trials on these treatments.

Key figures

337 requests for regulatory and scientific support received via the Innovation and Referral Service

63.340 compassionate access authorisations granted (27,427 patients treated)

30 favourable opinions issued for early access authorisations

Spotlight

"Exceptional" access to medicines allows certain patients - for example those with serious diseases with no available treatment - to have access to innovative medicines not marketed in France, either before they are placed on the market (early access) or when there are no plans to place them on the market but they meet an unmet therapeutic need (compassionate access).

For more information about
the different procedures to oversee and support innovative products

→ Drawing on our resources to move forward

In 2022, ANSM included a raft of actions in favour of quality of work life and the environment in its sustainable development plan. Its ISO 9001* certification was also renewed.

The sustainable development plan covers all work-related issues: quality of life and conviviality, gender equality, parenthood, prevention of psychosocial risks. ANSM has added a component dedicated to "sustainable management" to its employment policy, focusing on improving working relations and conditions. It is continuing its efforts to limit waste, achieve greater energy and digital sobriety and green its outdoor spaces.

A work/life balance charter in the teleworking age

ANSM aims to reconcile performance and quality of work life for everyone, at every level of its organisation. In 2022, in the wake of the health crisis, the Agency demonstrated its commitment to this approach to quality of life at work and outside work by adopting a work/life balance charter. Hinged around nine commitments, this charter covers aspects such as the right to disconnect, improvement of communication methods and the organisation of work meetings. It fits squarely with a broader societal trend in which the Agency is an active participant, where working methods are evolving and hybridising, shifting from purely on-site or face-to-face work to partial remote working.

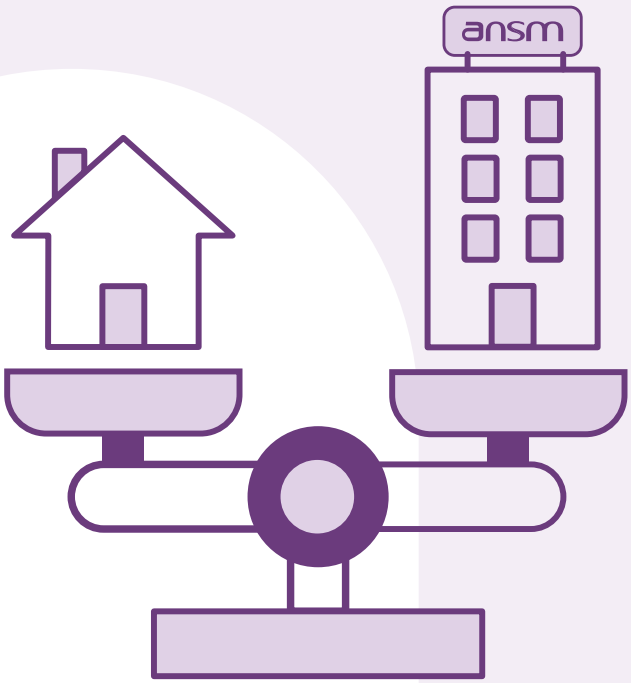
→ For more information about **the Work/Life Balance Charter**

Renewal of ANSM's ISO 9001 certification

On the basis of a firmly established quality culture, ANSM saw the **ISO 9001** certification of its Quality Management System (QMS) renewed in 2022. The processes concerned fall within the scope of risk management: monitoring and controlling health products, managing high-risk situations (HRS,) inspecting, combating medicine shortages, organising the quality control of MDs/IVDMDs and examining user requests.

Understand

ISO 9001
Quality management standard.



"We are committed to constantly improving the quality of work life for every ANSM employee, in order to offer them the best possible environment and work/life balance."

VALÉRIE DELAHAYE-GUILLOCHEAU
Chair of the ANSM Management Board

"Responsible and committed employees",

→ **Read the interview with Bérangère Barrau and Didier Leuridan, responsible for General Services in the Administration and Finance Division, Patricia Logghe-Jewkes, Head of Internal Communications in the Communication and Information Division, and Amélie Picard, Head of the Workplace Environment and Social Dialogue Unit in the Human Resources Division.**

Key figures

€126.85 M
budget

940 and **37**
worked full-time equivalents (WFTE) under ceiling authorised in the initial budget

WTFE over the ceiling

94%
of staff teleworking

Have a look at our information and awareness campaign to promote the correct use of medicines (in French).

lesmedicamentsetmoi.fr

→ Read the interview about the Public health policy on preventing misuse of medicines

143/147, boulevard Anatole France
F-93285 Saint-Denis Cedex
Tél. : +33 (0) 1 55 87 30 00
@ansm
ansm.sante.fr