In 2021, at the service of citizens, at the heart of life and health policy, the Agency demonstrated its proactive approach in anticipating major issues and its operational efficiency in responding to multiple complex situations. Once again, the year was rich and intense. We honoured our commitment to continue our activities and accomplish our missions, while meeting the requirements directly linked to the pandemic, which was still very present in 2021.

The ANSM teams worked constantly to guarantee the safety of users of health products and to ensure their availability in our territory, both by promoting access to therapeutic innovations in a controlled manner, and by anticipating and managing the risk of stock shortages; a risk whose importance we have fully appreciated in the light of the health crisis. 2021 was also characterised by innovation and the Agency’s adaptability to society, as demonstrated in the launch of the experimentation of medical cannabis and major regulatory reforms, as well as the implementation of our project aimed at “opening up to users and health professionals” through our new organisation, our reception desk and our proactive and committed communication, as shown by our first information and prevention campaign on the theme of “Medicines and Pregnancy”, for instance.

In addition, as part of our commitment to all issues related to Covid, we were particularly active in supporting the arrival and deployment of treatments and vaccines in France, with great care and perseverance, in constant contact with our European counterparts and our highly effective French pharmacovigilance network. An exceptional job was done in managing this crisis, at all levels of the Agency, thanks to everyone’s efforts in the evaluation, monitoring, controls, inspection and information of users.

We were also able to observe that the dynamic transformation of our working and communication methods initiated before the pandemic, in close cooperation with all our stakeholders, was accelerated and amplified by Covid. As a catalyst for change, this crisis has undeniably allowed us to further consolidate our expertise and the essential nature of our missions, which are deeply rooted in the daily lives of citizens and healthcare professionals. By acting on the basis of scientific facts, by upholding our commitments, through providing systematic information on our actions with transparency and the desire to educate, we have demonstrated that we are up to the challenge.
Thus, overall, throughout the year and in constant consultation with our stakeholders, ANSM has acted at all stages of the life of health products to ensure that they are safe, effective, accessible and used appropriately by patients and health professionals. This annual report allows us to fully appreciate the wideness and diversity of our fields of intervention and the unfailing commitment of all our teams, to whom we extend our warmest thanks.

On the strength of our achievements, which encourage us to make further progress every day, we are already experiencing and will continue to experience several highlights in 2022, starting with the Presidency of the European Union, which France has the honour of holding from January to June. This is a great challenge that we are taking up with agility. As part of this exceptional event, the Agency is organising 20 meetings of technical working groups and European strategic committees. At each of these meetings with our European counterparts, we measure the degree to which France’s voice and presence count; how essential it is to strengthen collaboration between European agencies and to facilitate the exchange of information in order to work together for the safe use of health products.

Our 2022 work programme, which has already been launched, will enable us to implement many projects. A few examples: medical cannabis, the fight against drug misuse, risk management, Covid-19, implementation of European regulations, user reception, ISO 9001 certification, among others. This is an illustration of what makes the Agency so strong and rich: the diversity of its expertise and professions.

Once again, it is the mobilisation of our teams that will enable us to deal with the situations we are facing in the context of the ongoing Covid-19 epidemic and the current geopolitical tensions in Europe.

Finally, we are going to initiate in-depth discussions on our next Objectives and Performance Contract (COP) between our Board of Directors, ANSM staff and all our stakeholders. The new contract will be in line with the current COP, which has greatly increased the openness of our Agency as a public service, serving the public. This openness is now our primary strategic focus; it embodies our DNA, our main spring: at the service of users and health professionals and, more broadly, of the general public, always capitalising on collegiality because, together, we can resolutely go further.

This report provides a snapshot of the road we have travelled, and illustrates once again this year the evolution of the Agency at the service of our fellow citizens thanks to the commitment of ANSM staff who work every day for the benefit of public health.
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, it is responsible for the safety of health products and promotes access to therapeutic innovation. It acts on behalf of patients, alongside health professionals and in consultation with their respective representatives in all the Agency’s bodies.

Through its evaluation, expertise and monitoring policy, ANSM ensures that the health products available in France are safe, effective, accessible and properly used.

It has the following missions:

- **enabling** early and rapid access to innovative products,
- **authorizing** clinical trials,
- **authorizing** the marketing of medicines and biological products,
- **monitoring** all health products throughout their life cycle,
- **collecting** and analyzing adverse effect reports,
- **studying** the impacts of their use,
- **ensuring** the availability of “essential” health products,
- **controlling** product quality in its laboratories,
- **inspecting** manufacturing and distribution sites.

Its priorities for actions are set out in the Objective and Performance Contract signed with the State through the Ministry of Health.

ANSM is actively involved in European and international activities. Its activities are carried out in coordination with the European Medicines Agency, the European Commission and the other national agencies of the European Union. It also collaborates with international health organisations.

ANSM has a Management board, a Scientific Board and Advisory Commissions. It is also backed by an Ethics of Expertise Department and an Ethics Advisor who help guarantee the independence and impartiality of the agency’s decisions.

It is based on three sites: in Saint-Denis (headquarters), Lyon and Vendargues (laboratories).
An ISO 9001-certified agency for the following activities:

- Monitoring health products
- Dealing with high-risk situations
- Testing health products
- Inspecting
- Tackling shortages of medicinal products
- Organising the quality control of medical devices and *in vitro* diagnosis devices
- Processing user’s requests

**Our scope**

**Medicines**
- All medicinal products (pre- and post-MA) and pharmaceutical raw materials
- Blood-derived medicinal products
- Narcotic and psychotropic substances
- Vaccines
- Homoeopathic and herbal medicinal products
- Compounded pharmacy and hospital preparations

**Biological products**
- Labile blood products
- Cell and gene therapy products
- Organs, tissues, and cells used for therapeutic use
- Microorganisms and toxins
- Breast milk collected, tested, processed and preserved by breast milk banks

**Medical devices (MD) and *in vitro* diagnosis devices (IVDD)**
- Therapeutic diagnostic and *in vitro* diagnosis devices, technical platforms, and medical software

**Cosmetics and tattoo products**
Our role in the health system

Under the authority of the French Ministry of Health, the ANSM works closely with all health stakeholders.

**[FRANCE]**
- Patients, users, and their representatives
- Health professionals and their representatives
- Public health agencies: ABM, ANSES, ARF, SPF
- Health authorities: ANS, CEPS, CNAM, HAS, HCSP, IRSN
- Vigilance networks
- Other public bodies: DGCCRF, EFS, INCA, INSERM
- Manufacturers

**[EUROPE]**
- European Commission (EC)
- European Medicines Agency (EMA)
- European Directorate for the Quality of Medicines (EDQM)
- Group of Competent Authorities for Medical Devices (CAMD)
- Heads of Medicine Agencies (HMA)

**[WORLDWIDE]**
- World Health Organisation (WHO)
- Organisation for Economic Co-operation and Development (OECD)
- Counterparts in other national health agencies
- International Coalition of Medicines Regulatory Authorities (ICMRA)

**ABM:** Biomedicines Agency
**ANS:** Digital Healthcare Agency
**Anses:** French Agency for Food, Environmental and Occupational Health Safety
**ARS:** Regional Health Agency
**CNAM:** National Health Insurance Fund
**DGCCRF:** Directorate General for Fair Trade, Consumer Affairs, and Fraud Controls
**EFS:** French National Blood Service
**HAS:** French National Health Authority
**HCSP:** French High Council for Public Health
**INCa:** National Cancer Institute
**Inserm:** French National Institute of Health and Medical Research
**IRSN:** Institute for Radiation Protection and Nuclear Safety
**SPF:** French National Public Health Agency
January

- Covid-19: Launch of the enhanced surveillance system for Covid-19 vaccines

February

- New organisational structure

March

- New website
- Launch of the medical cannabis trial
- Covid-19: the first cases of early access to treatment

April

- Implementation of the User Reception Department
May
The new European Medical Devices Regulation

June
- Medicines and Pregnancy prevention campaign
- Entry into force of the early and compassionate access reform

July
- Covid-19: arrival of treatments

September
- Stock Decree

December
Key figures in 2021

**ACTING IN COMPLETE TRANSPARENCY THROUGH DIALOGUE AND OPENNESS**

- 89 Standing Scientific Committee meetings
- 1,262 ethical contributions and analyses
- 5,115,289 unique visitors to the ANSM website
- 4,335 requests submitted to the User Reception Department
- 623 public conflict-of-interest statements checked
- 162 news and updates and 10 press releases published
- 88,067 subscribers on LinkedIn and 40,800 on Twitter
- 4 information and discussion webinars with health professionals and patient associations, and 5 with operators and manufacturers

**MEDICINAL PRODUCTS**

- 169,336 cases of adverse effects were collected and registered by the Regional Pharmacovigilance Centres (Centres Régionaux de Pharmacovigilance - CRPVs) 34,822 of which were not related to Covid-19 vaccines
- 40,999 cases of adverse effects were reported through pharmaceutical companies, of which 38,343 were not related to Covid-19 vaccines
- 70 pharmacovigilance studies were in progress in 2021, and 5 new studies were begun
- France acted as Rapporteur for 186 entered on PRAC agendas
- 5,159 spontaneous notifications concerning cases of abuse, drug dependence and misuse were collected and recorded by the Centres for Evaluation and Information on Pharmaceutical Drug Dependence–Addiction Vigilance (CEIP-A)

**BLOOD PRODUCTS**

- 6,281 adverse effects related to haemovigilance were reported among donors of labile blood products
25 new high-risk situations (HRS) with an average of 40 HRS in progress

30 pharmacovigilance studies were in progress in 2021, and 6 new studies were begun

1,815 medication error or risk-of-medication-error reports were transmitted to ANSM

2,160 reports of shortages or risks of shortages were managed by ANSM, as were strategies for finding medicinal alternatives for critical products

1,798 quality defect reports were submitted

9,568 adverse effects related to haemovigilance were reported among recipients of labile blood products

20,492 adverse effects related to medical device vigilance were reported, 776 of which were received from patients and patient associations

2,012 adverse effects were reported in reagent vigilance

623 inspections were carried out, of which:
- 6% were documentary inspections,
- 3% were random inspections,
- 2% were inspections conducted outside France.

4,249 test reports based on laboratory studies were produced

LABORATORY TESTS AND INSPECTIONS

MEDICAL DEVICES (MDS) AND IN VITRO DIAGNOSTIC MEDICAL DEVICES (IVDMDS)
### FACILITATING PATIENT ACCESS TO INNOVATIVE TREATMENTS

- **277**
  - Scientific or regulatory support missions via the Innovation and Referral Service managed

- **73**
  - European scientific opinions attributed to France

- **51,096**
  - Named-patient temporary authorisations for use (ATU) or compassionate-access authorisations (AAC) granted, and **28,876** patients included

- **27**
  - New cohort temporary authorisations for use granted and **7** positive opinions on early access authorisations issued

- **1,098**
  - Patients included in the medical cannabis trial

### MOVING FORWARD WITH OUR RESOURCES

- **129,9 M€**
  - Budget

- **915** FTEs* under ceiling authorised in the initial budget increased to **935** FTEs under ceiling in the amending budget and **36** FTEs over the ceiling

- **94%** of staff teleworking

- **more than 148** applications used each day across **320** servers

### SPECIAL REPORT ON COVID-19

- **more than 18,000** early-access approvals for monoclonal antibodies used for the curative or preventive treatment of Covid-19 were validated

- **more than 123 million** injections in France, with **128,510** pharmacovigilance cases recorded

*Full time equivalents