ansm

French National Agency for
Medicines and Health Products Safety

ANNUAL REPORT 2021

EDITORIAL

An agency even closer to its publics

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.

Valérie DELAHAYE-GUILLOCHEAU
Chair of ANSM's Board of Directors

Christelle RATIGNIER-CARBONNEIL
Director General of ANSM

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.

ANSM in brief

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

For more information about ANSM

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 tatoo 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

Temps forts 2021

January

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

February

New organisational structure

March

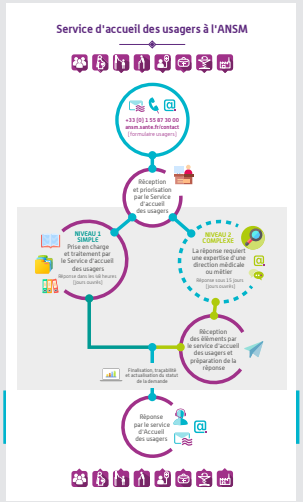
New website

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

December

Stock Decree

September

Key figures in 2021

ENSURING

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

THE SAFETY OF PATIENTS EXPOSED TO MEDICINES AND HEALTH 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

MEDICAL DEVICES (MDS) AND *IN VITRO* DIAGNOSTIC MEDICAL DEVICES (IVDMDS)

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

LABORATORY TESTS AND INSPECTIONS

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

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** et **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

855
clinical trials authorised for medicines and **80** for MDs and IVDDs

636
marketing authorisations (MAs) and registrations issued by ANSM (national procedure and decentralised European and mutual recognition procedures)

18
MA applications under a centralised procedure assigned to France

France Rapporteur or Co-Rapporteur for
100 PIP (Paediatric Investigation Plans) (3rd place)

France is the
1st Member State
to release batches of vaccines to French and European markets

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

corresponding to a total of
more than 123 million
injections in France, with **128,510** pharmacovigilance cases recorded

*Full time equivalents

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