ANNUAL REPORT 2020

ansm
French National Agency for Medicines and Health Products Safety

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:

- **authorising the marketing** of medicines and biological products,
- **monitoring all health products** throughout their life cycle,
- **studying the impacts** of their use,
- **collecting and analysing** adverse effect reports,
- 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 Board of Directors, a Scientific Board and Advisory Commissions. It is also backed by an Ethics of Expertise Committee and Department, which help guarantee the independence and impartiality of the agency's decisions.

It has three sites: in Saint-Denis (headquarters), Lyon and Vendargues (laboratories).

HEALTH PRODUCTS UNDER THE RESPONSIBILITY OF ANSM

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
- Micro-organisms and toxins
- Breast milk collected, tested, processed and preserved by breast milk banks

Medical devices (MD) and *in vitro* diagnostic medical devices (IVDMD)

Therapeutic diagnostic and *in vitro* diagnosis devices, technical platforms, and medical software

Cosmetic and tattoo products

afaq ISO 9001 Quality AFNOR CERTIFICATION

An ISO 9001:2015-certified agency for the following activities

- Monitoring health products
- Dealing with high-risk situations
- Testing health products
- Inspecting
- Tackling shortages of medicinal products

ANSM's role in the health system

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

EDITORIAL

A committed Agency mindful of the patients' needs

Catherine DE SALINS
Chair of the Board of Directors

Christelle RATIGNIER-CARBONNEIL
Director General of ANSM

2020 **was a most unusual year for the ANSM as a result of the COVID-19 health crisis, to which this activity report devotes a special section.**

Throughout this period, the Agency was able to adapt and evolve. Thanks to the **day-to-day mobilisation of all its personnel,** working closely with the Ministry of Solidarity and Health, government departments and all health stakeholders, **the ANSM was able to both maintain its activities and its essential public service missions, and address the needs directly related to the global and national context of the pandemic**, in order to guarantee the safety of both the patients and its staff.

From the very start of the crisis, ANSM teams anticipated the impacts of COVID-19 on the availability of medicinal products and medical devices. They took action to ensure the continuity and quality of care delivered to all patients. The ANSM supported healthcare professionals and adapted certain clinical research conditions to the constraints of the health situation, such as fast-track assessment procedures. It put into place temporary authorisation for use and waiver mechanisms in order to promote early access to medicines and medical devices used in the treatment of COVID-19. Alongside its European counterparts, the Agency was also fully involved in the assessment of vaccines and, since the launch of the vaccination campaign, it has reinforced monitoring of adverse events to ensure their safe use in the

population groups concerned. Throughout the year, the ANSM promoted access to good information for its stakeholders and the general public, by communicating about its actions and decisions in this unprecedented context.

In 2020, the ANSM also continued to adapt, while preparing its new organisation, as the second step in the "Opening up to users and healthcare professionals" project launched at the start of 2019, with the reform of its various bodies, which now include representatives from the society. **Based on collegiality, dialogue and a simplification of exchanges with our public and stakeholders, this new organisation is aimed at optimising the way we approach our public health and health product safety missions, with efficiency, commitment, transparency and agility.** It is part of an evolutionary process that reflects the commitment made by the ANSM in its Objectives and Performance Contract (COP 2019-2023) signed with the State to work diligently every day to safeguard patients' interests and ensure that health products are safe to use.

ANSM anticipated the impacts of COVID-19 to ensure the continuity and quality of care delivered to all patients.

Throughout 2020, **we co-constructed the new ANSM website with our stakeholders through workshops and exchanges,** for roll-out in early 2021. The new website was designed specifically to be more accessible and easier to read. This information site offers a clearer and more user-friendly interface for easier navigation, more accessible information on health products, as well as access to simplified procedures for patients, healthcare professionals, researchers or the health industries in the context of their administrative procedures.

The ANSM teams deserve special praise. They have demonstrated their ability to adapt and reinvent themselves, the quality of their expertise, their mobilisation, their resilience as well as their responsiveness in all their missions, in order to cope with an unprecedented situation while continuing to ensure the safety of patients and the population as a whole.

Highlights in 2020

January

- Strengthening of information about the use of vasoconstrictors (January and October)

February

- COVID-19 : mobilisation to ensure the availability of medicines and health products
- Establishment of the College of Advisors *(Collège des conseillers)*

March

- COVID -19 : acceleration of clinical trial evaluation procedures for COVID-19 treatments

April

- COVID-19 : setting up of an enhanced adverse drug reaction monitoring scheme for drugs used in patients with COVID-19
- COVID-19 : support and guidance for operators offering innovative solutions for the manufacture of medical devices

July

End of the Médiator trial

September

Guichet innovation et orientation

Creation of the Innovation Service *(Guichet Innovation)* at ANSM

Appointment of the new Scientific Board

October

Medical cannabis: call for applications from suppliers

Cannabis médical

November

Public consultation on Lutenyl/Luteran

COVID-19 : setting up of the enhanced surveillance system for the COVID-19 vaccination campaign

December

Appointment of a new Director General

Key figures in 2020

OUR INTERACTIONS WITH OUR ENVIRONMENT

83
meetings of the Standing Scientific Committees

394
ethics contributions and analyses

4.3 million
unique visitors
to ANSM's website

175
public conflict-of-interest statements (DPIs) checked

101
news and updates and 13 press releases published

67,209
subscribers on LinkedIn
and **31,822** on Twitter

11 high-risk situations *(situations à risque élevé –*

MEDICINES

49,758
cases of adverse effects
were collected and registered by the Regional Pharmacovigilance Centres *(Centres Régionaux de Pharmacovigilance - RPCs)*, including **6,492** adverse effects reported by patients

40,258
cases of adverse effects
were reported through pharmaceutical companies

76
pharmacovigilance studies
were in progress in 2020, and **11** new studies were begun

7,275
spontaneous notifications
concerning cases of abuse, drug dependence and misuse

BLOOD PRODUCTS

6 443
adverse effects
related to haemovigilance were reported among donors of labile blood products

ENSURING THE SAFETY OF HEALTH PRODUCTS

SREs) including the "COVID-19 Pandemic" exceptional health situation (SSE) "Pandémie COVID-19", with an average of **36** SREs in progress

43
pharmacovigilance studies
were in progress in 2020, and **20** new studies were begun

2,365
medication error
or risk of medication error reports were transmitted to ANSM

2,446
reports of shortages
or risks of shortages were managed by ANSM, as were strategies for finding medicinal alternatives for critical products

1,854
quality defect reports were submitted

9,060
adverse effects
related to haemovigilance were reported among recipients of labile blood products

MEDICAL DEVICES (MD) AND *IN VITRO* DIAGNOSTIC MEDICAL DEVICES (IVDMD)

19,871
adverse effects
related to medical device vigilance were reported, **794** of which were received from patients and patient associations

1,554
adverse effects
were reported in reagent vigilance

LABORATORY TESTS AND INSPECTIONS

441
inspections
were carried out in 2020, of which:
- 15% were documentary inspections,
- 3% were random inspections,
- 2% were inspections conducted outside France.

4,395
test reports
based on laboratory studies were produced

FACILITATING ACCESS TO THERAPEUTIC INNOVATION

809
clinical trials
authorised for medicines and **83** for MDs and IVDMDs

37
new cohort temporary authorisations for use granted and **7,300** patients newly included in the scheme

40,437
registered temporary authorisations for use granted

973
marketing authorisations (MAs)
and registrations issued by ANSM (national procedure and decentralised European and mutual recognition procedures)

19
MA applications under a centralised procedure assigned to France: **the 3rd-largest number** for a Member State after the Netherlands (29) and Germany (25)

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

79
scientific or regulatory support missions
handled *via* the Innovation and Referral Service

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

OUR RESOURCES

€116.83 millon budget

912
WFTEs* authorised

2,076
training days
and **64%** of staff received training

more than 145
applications
used each day across 330 servers

* Worked full-time equivalents

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