



ansm

French National Agency for
Medicines and Health Products Safety

SUMMARY ACTIVITY REPORT 2018

OUR MISSIONS

To evaluate and monitor



the risks and benefits of health products throughout their life cycle

To discuss its actions and decisions in a transparent manner



with patients and healthcare professionals

To provide



legal and regulatory expertise

To conduct



quality checks in laboratories

To encourage



independent academic research

To take an active role



in work conducted in Europe and abroad.

To inspect



manufacturing and distribution sites

The agency places risk management firmly at the heart of its missions



Catherine DE SALINS
Chair of the Board of Directors



Dominique MARTIN
Director General of ANSM



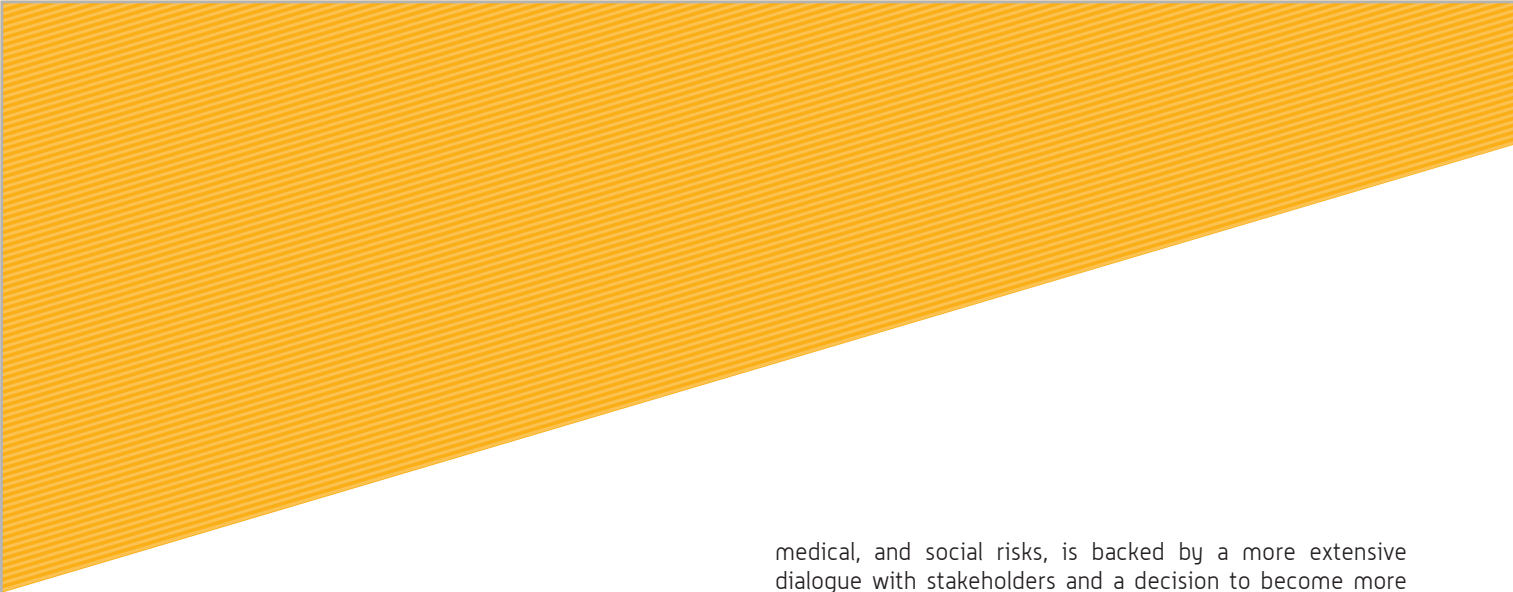
ANSM is determined to fulfil its health product safety missions in order to better protect the safety of the patients using these products ”

The year 2018 was marked by a number of important transformations that improved ANSM's ability to carry out all of its public health missions. These changes are a product of the agency's push to become more open and increase stakeholder involvement in order to make its services more relevant and effective for users.

The year 2018 thus saw the rise of a new internal structure, CASAR, which is designed to increase the agency's ability to respond to emergency situations, health alerts, and risk mana-

gement needs with help from a team whose sole purpose is to anticipate and coordinate all events that could turn into high-risk situations.

The creation of this body is part of the agency's risk management-centred approach, which underpinned all of its activities in 2018. This step demonstrates that ANSM is determined to fulfil its health product safety missions in order to better protect the safety of the patients using these products. This approach, which includes the analysis of all pharmacological,

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medical, and social risks, is backed by a more extensive dialogue with stakeholders and a decision to become more open to the rest of society.

It is in this context that the agency hosted several public consultations, including an event dedicated to raising awareness among patients and healthcare professionals about the liver toxicity risk associated with the misuse of paracetamol, and another regarding the implementation of new mandatory vaccines, with a focus on the safety data for vaccines that are mandatory for children under the age of two. It is also with this goal in mind that the agency organised public hearings featuring expert committees that were broadcasted live online.

ANSM also developed a strategy to publicise its data on health products and its processes that will be rolled out in 2019. This is part of a broader governmental policy aimed at the effective use of data.

Among its many interactions with healthcare professionals, the agency worked with general practitioners to reduce private practice medication errors and met with representatives of proprietary medicines to resolve supply shortages.

This push to become more open and increase the involvement of stakeholders was also seen in the agency's reform of its scientific advisory bodies, which began at the end of 2018. ANSM issued a call for applicants to recruit external experts from all fields within its purview as well as human and social science experts. The call was also opened to representatives of regionally and nationally certified user and patient associations that, starting in 2019, will become full members of all the agency's governing bodies.

In order to better meet the needs of stakeholders with respect to providing faster access to innovative treatments, the agency implemented new processing methods for named-patient TAUs and fast-track systems for authorising clinical trials involving medicines to reduce the time to process these applications. A Strategy and European Activity Piloting Centre was created to boost France's participation in the centralised procedure, which serves as the main gateway for pharmaceutical innovation.

In addition, to better meet the growing need for health product epidemiology expertise, ANSM and CNAM pooled their pharmaco-epidemiology teams in a single scientific interest group (SIG) founded in December 2018 known as EPI-PHARE. This structure will result in enhanced epidemiological expertise to help monitor health products in real time.

The agency's Quality Policy, which supports all of these changes, was adopted in March. In December, it helped ANSM earn ISO 9001 certification for its risk management. This certification recognises the agency's ability to secure its processes and enables it to reach the main objectives listed in its 2015-2018 Objectives and Performance Contract. It also provides a powerful boost to the agency's transformation process and will empower it to better protect public health and respond to the needs of civil society.

These significant advancements serve as the foundation for the strategic guidelines included in the next Objectives and Performance Contract for 2019-2023, which the agency has been working on in collaboration with its partners and regulatory authorities throughout the year, and were implemented even as the agency continued to work diligently every day to ensure that health products are safe and that patients can access them under optimum conditions. The agency issued over 84,000 decisions in 2018. This work was possible thanks to the efforts of all of the agency's teams, whose commitment and dedication in the interest of better serving users must be recognised and commended.

**ANSM's goal:
to combine rapid access
to innovative developments
with the continued
adjustment of health
products' risk/benefit ratio
to match therapeutic
progress for the sole
benefit of patients.**

ANSM in brief

The French National Agency for Medicines and Health Products [ANSM] was created on 1 May 2012 as a result of the French law of 29 December 2011 concerning the increased safety of medicines and health products.

The agency ensures the safety of medicines and other health products throughout their life cycle. It transparently shares its decisions and actions regarding health products with all healthcare stakeholders, manufacturers, and members of the public to enable them to understand and take ownership of said actions. The agency pursues its public service missions in the sole interest of patients.

ANSM has a Board of Directors, a scientific Board, and Advisory Commissions.

It also relies on an Ethics of Expertise Committee and Department which help to guarantee the independence and impartiality of the agency's decisions.

A STRATEGY INCLUDED IN 2019-2023 OBJECTIVES AND PERFORMANCE CONTRACT

The 2019-2023 Objectives and Performance Contract was signed on 23 May 2019 with the Minister of Health and Solidarity. It is built on 4 strategic areas:

- ♦ **Area 1:** Developing the Agency's openness to stakeholders and enhancing transparency in its work
- ♦ **Area 2:** Establishing risk management as a principle of action common to all the Agency's missions
- ♦ **Area 3:** Strengthening and stabilising the Agency's positioning in terms of access to innovation in the European environment
- ♦ **Area 4:** Stabilising the establishment's performance and efficiency

AN ISO 9001, 2015 VERSION, CERTIFIED AGENCY

This certification, issued by AFNOR Certification in January 2019, concerns:

- ♦ health product surveillance activities,
- ♦ the treatment of high-risk situations,
- ♦ the control of health products,
- ♦ inspection.



HEALTH PRODUCTS UNDER THE RESPONSIBILITY OF ANSM

Medicines

- ♦ All medicines (pre- and post-MA)⁽¹⁾ and pharmaceutical starting materials
- ♦ Blood-derived medicines
- ♦ Narcotic and psychotropic substances
- ♦ Vaccines
- ♦ Homoeopathic and herbal medicines
- ♦ Compounded pharmacy and hospital preparations

Biological products

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

Medical devices and *in vitro* diagnostic medical devices

- ♦ Diagnostic and *in vitro* diagnostics therapeutics, technical platforms, and medical softwares

Cosmetics and tattoos

⁽¹⁾ MA: Marketing Authorisation.

Key figures in 2018



GUARANTEEING THE SAFETY OF HEALTH PRODUCTS

MEDICINES

71,130 cases of adverse effects were collected and registered by the RPCs⁽¹⁾, including **20,192** adverse effects reported by patients

59,371 cases of serious adverse effects were reported through pharmaceutical laboratories

98 pharmacovigilance studies were in progress in 2018, and **17** new studies were begun

17 pharmacoepidemiological studies were implemented by ANSM

2,197 medication errors or risks of medication error were reported to ANSM

1,987 quality defect reports were submitted

871 reports of shortage or risks of shortage were managed by ANSM, as were strategies for finding medicinal alternatives for critical products

BLOOD PRODUCTS

6,587 adverse effects related to haemovigilance were reported among donors of labile blood products

8,611 adverse effects related to haemovigilance were reported among recipients of labile blood products

MEDICAL DEVICES AND *IN VITRO* DIAGNOSTIC MEDICAL DEVICES

18,838 adverse effects related to medical device vigilance were reported, **682** of which were received from patients and patient associations

1,344 adverse effects related to reagent vigilance (*in vitro*) diagnostic medical devices

LABORATORY TESTS AND INSPECTIONS

677 inspections were conducted in 2018, including **11%** random and **6%** conducted abroad

4,225 test reports based on laboratory studies were completed



PROMOTING PATIENTS' RAPID ACCESS TO INNOVATION

5,642 patients covered by cohort TAUs⁽²⁾ for medicines

15,987 patients covered by named-patient TAUs, of which **11,342** were starting treatment

741 clinical trials authorised for medicines and **83** for MDs and IVDMDs⁽³⁾

16 centralised-procedure MA⁽⁴⁾ applications attributed to France

18,671 MA updates⁽⁵⁾

1,162 MAs, including **932** generic medication authorisations have been issued under the French national procedure, the European decentralised procedure, and the mutual recognition procedure

1st France, by way of ANSM control laboratories, releases more vaccines to French and European markets than any other member state



CONSOLIDATING ANSM'S RELATIONSHIPS WITH STAKEHOLDERS AND INCREASING THEIR INVOLVEMENT

1,265 conflicts of interest investigated as part of an internal ethics compliance report

1,872 ethics contributions and analyses

10 Temporary Specialised Scientific Committees (TSSCs) created

32 meetings organised through the interface committees

129 information updates added to the ANSM's website

2.9M unique visitors to ANSM's website

16,617 followers on ANSM's Twitter account as of the end of 2018 (5,000 more followers gained during 2018)

+23M visits to the Public Medicine Database

2 NGO projects funded through a seventh call for proposals

2 new research projects funded through a seventh call for proposals



REINFORCING ANSM'S EFFICIENCY AND PURSUING ITS MODERNISATION

927.2 WFTEs⁽⁶⁾

€123.5 million budget

58 meetings held between management and employees

[1] RPCs: Regional pharmacovigilance centres. [2] TAUs: Temporary Authorisations for Use. [3] MDs and IVDMDs: Medical devices / In-vitro diagnostic medical devices.

[4] MA: Marketing authorisation. [5] Granted through national procedure and European decentralised and mutual recognition procedures. [6] WFTEs: Worked full-time equivalents



Highlights in 2018

**Application of new
treatment methods**
for named-patient TAU's

**Creation of two
fast-track channels**
for authorisations
for medicinal clinical
trials

Paracetamol:
public consultation to
raise awareness among
patients and healthcare
professionals regarding
the risk of liver injury
due to misuse



Issuance of market authorisation for the use of baclofen in the treatment of alcohol addiction

Favourable opinion issued by the TSSC regarding the use of cannabis for therapeutic purposes in France

Organisation of an ANSM-College of General Practitioners **discussion day** on medication errors in high-street pharmacies

Creation of the scientific interest group (SIG) EPI-PHARE between ANSM and CNAM's health product epidemiology teams

AFNOR certification audit on "Risk Management"

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