

ansm

French National Agency for
Medicines and Health Products Safety



SUMMARY
ANNUAL
REPORT
2019

The ANSM in brief

The French National Agency for Medicines and Health Products (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, the ANSM ensures that 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 action are set out in the Objectives and Performance Contracts that it enters into with the State.

The ANSM is actively involved in European and international activities. Its activities are very much in line with European procedures and 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.

The 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 THE ANSM



Medicines

- All medicines (pre- and post-MA) 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
- 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* diagnostic devices, technical platforms, and medical software



Cosmetic and tattoo products

**An ISO 9001:
2015-certified Agency
since January 2019
for the following activities**

- Monitoring Health Products
- Dealing with high-risk situations
- Testing health products
- Inspecting
- Tackling shortages of medicines



editorial



Catherine DE SALINS
Chair of the Board
of Directors



Dominique MARTIN
Director General
of ANSM

A committed Agency attentive to its users' needs

2019 was the first year of the Agency's new Objectives and Performance Contract (COP), signed with the Minister for Solidarity and Health in May 2019. It sets out the Agency's strategic areas of focus up to 2023, the most important of which include openness to stakeholders and increased transparency.

The continuation and acceleration of this outreach strategy designed to address society's expectations had a very concrete impact on the Agency's activity and operations throughout the year.

The reform of the ANSM's advisory bodies is the cornerstone of this commitment, aimed at taking into account the plurality of expertise and, in particular, the patient experience, in a more systematic and integrated way. Health system users are now an integral part of the 15 permanent scientific committees created in

July 2019 and whose work began in September 2019. Of the 291 members appointed, 40 represent user associations. The same applies to the "healthcare products information" committee, specifically dedicated to information and communication issues and which held its first meeting in October 2019.

Other initiatives testify to the Agency's openness towards informed decision-making based on a plurality of perspectives: for example, seven public consultation processes were organised in 2019 on topics that strongly mobilise public opinion, such as textured breast implants, as well as numerous consultation meetings with stakeholders. The very close partnership with the College of General Medicine (CMG), hinged around regular meetings, has also made it possible to get general practitioners involved in the Agency's actions and decisions and for the Agency to address practitioners at the French Congress of General Medicine (CMGF). The advice and expertise of pharmacists is also

sought whenever a recommendation impacts their practices and their relationship with patients. There are therefore frequent discussions between the Agency, the French National College of the Board of Pharmacists and pharmacists' union representatives.

This open approach ties in very closely with the Agency's communication and information policy and the dissemination of the risk management (RM) culture. Supported by the COP, this approach focuses all the ANSM's actions and decisions on the safety of the patients who use healthcare products and not only on the safety of healthcare products themselves. It is gradually permeating all of the Agency's activities.

The outreach strategy also reflects the Agency's development plan launched in 2019, which aims to implement an organisation that is even more open to the outside world in order to better integrate professionals and users in its activities. In-house, conferences led by sociologists and philosophers throughout the year aimed to more effectively share with teams the issues at stake in this major change within the Agency, to provide objectivity and help employees better understand the transformations under way within the Agency's environment and in the public health landscape as a whole.

In addition to its «traditional» activities, the Agency is increasingly involved in public health priorities. An example of this in 2019 concerned the issue of medication errors, approached in an innovative way through the first Hackathon dedicated to the topic, in partnership with the CMG, the University of Paris-Est Créteil, the Regional Pharmacovigilance Centres and ASIP-Santé.

At the same time, a shift towards a proactive policy with respect to publication of the Agency's data began in 2019. This policy is largely reflected in the Information and Data Systems Master Plan (SDSID), appended to the COP 2019-2023. The ultimate objective is to put the Agency's data and documents online proactively and progressively, in accordance with what is legally allowed to be divulged, in order to raise awareness of the Agency's actions, promote its expertise and encourage the use of its data. To enable them to be understood by all publics, the data are accompanied by educational information. Hence more than 100 releasable documents were published between April and December 2019 and preparatory work for the publication of raw pharmacovigilance, haemovigilance, medication error and clinical trial data was carried out in 2019.

Access to innovation is also one of the Agency's major focuses, mainly through its European activities, which have been further strengthened, both in terms of human resources and the

improvement of procedures. The Agency is developing a proactive policy that is both quantitative (the number of European dossiers examined by the Agency) and qualitative (the weight of our opinions in the European debate). The ANSM is the first European agency to have set up a pilot phase concerning the initial application for authorisation for clinical investigations relating to medical devices.

In order to improve the service provided to users and, in particular, reduce the time taken to process applications, the ANSM has made changes to some of its procedures. For example, 2019 saw the arrival of new «fast track» procedures for clinical trial authorisations, the e-saturne system for named-patient temporary authorisations for use (ATUs) and the implementation of a «simplified procedures» platform for pharmaceutical sites.

With a view to further optimising its services and responsiveness to stakeholders, the ANSM has once again demonstrated its commitment to its Quality approach and obtained renewal of its ISO 9001 certification in January 2020 for «Risk Management».

The wide-scale roll-out of teleworking processes in 2019 has had a significant impact on the Agency's ability to ensure the continuity of its missions in the recent situations facing the country, including the public transport strike at the end of 2019.

2019 was also marked by the Médiateur trial at the Paris High Court, held from 23 September 2019 to 6 July 2020. Through its Director General, the ANSM participated in the judicial debates throughout the trial with the utmost transparency, helping to uncover the truth and assuming its responsibility as a public institution.

The ANSM and its employees demonstrate a constant and ongoing commitment to ensuring patient safety. The high level of expertise of the Agency's teams and their ability to deal with crisis situations that often generate new expectations, while continuing to fulfil all of the ANSM's missions, must be applauded. These teams are key players in the far-reaching changes under way designed to open up the Agency to different publics and adapt to new challenges related to public health and the safety of healthcare products

Highlights

in 2019



ISO 9001 certification
for the scope of risk management
[January]



Implementation of the e-Saturne application
for the computerised processing of requests for personal temporary authorisations for use (TAUs)
[March]

Withdrawal of textured-shell breast implants from the market
[April]



Signature of the 2019-2023 Objectives and Performance Contract
[May]

2019
2023



Medical cannabis: the Agency endorsed the recommendations of the Temporary Scientific Committee (July)

The authorisation of medical use of cannabis was written into law
[Article 43 of Law n°2019-1446 on financing social security]



Reform of bodies:

establishment of the new scientific committees and the Healthcare Products Information Committee
[July and September]

Organization of a hackathon on medication errors with the CMG (College of General Medicine) and UPEC
[September]



Proper use of paracetamol and non-steroidal anti-inflammatory drugs (NSAIDs):
end of free access
[December]

**HACKATHON
"E-MED"**

EDITION 2019

Key figures

in 2019

OUR INTERACTIONS WITH OUR ENVIRONMENT



1,537 conflicts of interest investigated as part of an internal ethics compliance report



2,394 ethics contributions and analyses



11 Temporary Specialised Scientific Committees (CSSTs) created



3.7 million unique visitors to the ANSM website



138 updates and **13** press releases published



40,085 LinkedIn subscribers and **22,722** Twitter subscribers

ENSURING THE SAFETY OF HEALTH PRODUCTS

37 new high-risk risk situations (HRS) dealt with in 2019, with an average of 42 HRS in progress

MEDICINES



59,177 cases of adverse effects were collected and registered by the Centres Régionaux de Pharmacovigilance (Regional Pharmacovigilance Centres - RPCs), including **7,802** adverse effects reported by patients



51,807 cases of adverse effects were reported through pharmaceutical companies



86 pharmacovigilance studies were in progress in 2019, and **6** new studies were begun



2,180 medication error or risk of medication error reports were transmitted to the ANSM



1,504 reports of shortages or risks of shortages were managed by the ANSM, as were strategies for finding medicinal alternatives for critical products



2,102 quality defect reports were submitted

BLOOD PRODUCTS



6,838 adverse effects related to haemovigilance were reported among donors of labile blood products



7,700 adverse effects related to haemovigilance were reported among recipients of labile blood products

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



18,994 adverse effects related to medical device vigilance were reported, **553** of which were received from patients and patient associations



1,628 adverse effects were reported in reagent vigilance

LABORATORY TESTS AND INSPECTIONS



660 inspections were carried out in 2019, of which **10%** were random inspections and **6%** were inspections conducted outside France.



4,387 test reports based on laboratory studies were produced

FACILITATING ACCESS TO THERAPEUTIC INNOVATION



813 clinical trials authorised for medicines and **99** for MDs and IVDMDs



19 MA applications under a centralised procedure assigned to France



20 new cohort TAUs granted and **3,766** patients newly included in the scheme



• France rapporteur or co-rapporteur for **88** PIPs (Paediatric Investigation Plans)



26,528 registered TAUs granted



#1 France releases more batches of vaccines to French and European markets than any other Member State



1,016 MAs and registrations issued by the ANSM in 2019 (national procedure and decentralised European and mutual recognition procedures)

OUR RESSOURCES



912 WFTEs



120.55 M€ budget



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