



ansm

Agence nationale de sécurité du médicament
et des produits de santé



SUMMARY
ACTIVITY
REPORT
2017

OUR MISSIONS

To evaluate and monitor



the risks and benefits of health products throughout their life cycle

To conduct



quality checks in laboratories

To inspect



manufacturing and distribution sites

To provide



legal and regulatory expertise

To discuss its actions and decisions in a transparent manner



with patients and healthcare professionals

To encourage



independent academic research

To monitor



advertising that promotes health products

To take an active role



in work conducted in Europe and abroad.

editorial

A YEAR WITH A STRONG FOCUS ON PERFORMANCE AND RISK MANAGEMENT

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Three commitments were defined at the beginning of 2017 to integrate the Agency into a quality and progress approach

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Catherine de Salins
Chairwoman
of the ANSM Board
of Administration



Dominique Martin
Director General
of ANSM



In 2017, ANSM continued to pursue the commitments set forth in its 2015–2018 Objectives and Performance Contract. The agency has undergone significant changes, which reflect its teams' efforts to adapt the agency's actions over the long term in order to meet new challenges in public health safety.

The agency's actions are centred on its primary missions, namely guaranteeing the safety of health products throughout their life cycle and promoting fast, controlled and widespread access to innovation for patients. These goals have led to extensive actions centred on evaluating, inspecting, and surveying health products; laboratory testing; publicising decisions; contributing to legislation and regulations; conducting pharmaco-epidemiological research; and funding research into health product safety.

At the same time, the three commitments identified in early 2017 to initiate a quality - and progress-oriented approach within the agency have started to be rolled out through concrete measures and actions.

Pursuing both public health and public service

represents the first of these commitments. Its aim is to monitor health products and make them available by offering the public high-quality, effective, adaptable, and consistent service. A few actions that demonstrate this include:

- ◆ the agency's participation in implementing the vaccine expansion policy via a vaccine supply tracking system to ensure the public's needs are being covered,
- ◆ an extensive work to ensure the supply of medicines of major therapeutic interest that are susceptible to shortages, primarily anti-infective medicines, oncology products, and blood-derived medicines,
- ◆ the control of the use of narcotic and psychotropic products for medical and scientific purposes given the importance of the fight against addictive behaviour,
- ◆ recommendations to manufacturers regarding the names and packaging of medicines to reduce the risk of confusion, error, or inappropriate use,
- ◆ the participation in the roll-out by the Health Ministry of an online reporting portal for adverse health effects in order to better monitor health products.

Implementing information sharing

The second commitment, has undergone significant developments throughout the year, especially with respect to the more systematic integration of stakeholders (patients and health professionals) into decision-making processes. Here are a few of the agency's innovative initiatives:

- ◆ live broadcast of hearings with various stakeholders as part of a commission on recommendations for naming medicines;
- ◆ hearings with patient associations as part of the Temporary Specialised Scientific Committee (TSSC) meetings on the risk/benefit ratio of the permanent sterilisation device Essure and the exception made for organ donation between HIV+ donors and recipients;
- ◆ discussions with manufacturers in 2017 regarding preparations for applying European regulations on medical devices (MD) and *in vitro* medical devices (DMDIV). Nine Interface Committee meetings were held to facilitate discussion and allow manufacturers to better understand new regulatory requirements;
- ◆ the publication of the results of pharmaco-epidemiology studies in the agency's reports and in articles in international scientific reviews. The quality and pertinence of ANSM's studies with respect to monitoring the safety of health products were the subject of two publications in 2017 in the prestigious American scientific review JAMA (Journal of the American Medical Association).

Promoting both performance and quality of life at work

The third commitment identified at the beginning of the year was to promote both performance and quality of life at work. The agency's transformation policy was continued in 2017 through priority projects and the development of adapted IT tools. Its main improvements were related to the use of a special channel to update the MAs of 5,142 proprietary medicines approved through the national procedure.

The security of the agency's IT systems was improved, and an information security charter published in April mobilised and empowered all users to protect the agency's infrastructure.

A quality policy was created in 2017. Its governance was strengthened to lay the groundwork for its roll-out in 2018 with the goal of improving its effectiveness and efficiency.

Since 1 November 2017, ANSM inspections of medicine manufacturing sites have been covered by a mutual recognition agreement with the American Food and Drug Administration (US FDA).

The agency's improved performance also led to organisational changes such as the creation in December 2017 of a unit dedicated to the examination of authorisation requests for early-phase clinical trials and significant changes to these trials. The European Strategy Steering Centre was strengthened in 2017 through the creation of three «European pilot» positions. These scientific evaluators were hired to help the agency's departments assess dossiers submitted by France to the Committee for Medicinal Products for Human Use.

The creation of jobs that support the agency's goals regarding transformation and modernisation, the development of professional career paths, and the creation of an adapted training plan strengthening the agency's approach to management have helped further these changes throughout the year. The roll-out of remote working, which concerned around 10% of the workforce at the end of 2017, illustrates this commitment to improving both performance and quality of life at work.

Making risk management the policy principle behind every decision

A culture of risk has been developed within the agency and must permeate and secure its operation and decision-making processes. It involves ensuring a high level of health safety while also constantly adapting to an environment that's extremely sensitive to public health issues.


As a result, in October 2017, the agency created a Support Centre for Emergency Situations, Health Alerts, and Risk Management (CASAR). Its mission is to coordinate the various internal departments and environment-related approaches (societal, political, and media aspects) when responding to high-risk situations and health crises.

These intense efforts to ensure the safety of health products and their availability to patients under the best possible conditions while also continuously improving the agency's performance are the result of the work of all the agency's teams against a backdrop of a limited budget and workforce and increased requirements regarding risk management, independence, traceability, and expertise sharing. Their commitment to public health and their work to further the agency's missions throughout the year deserve recognition.



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Its goal: to combine fast access to innovative developments while continuously adjusting health products' risk/benefit ratio to match therapeutic progress for the sole benefit of patients.

ANSM IN BRIEF

The French National Agency for the Safety of Medicines and Health Products (ANSM) was created on 1 May 2012 as a result of the French law of 29 December 2011 reinforcing the 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 these actions. The agency pursues its public service missions in the sole interest of patients.

ANSM has an Administrative Board, a Scientific Board, and three Advisory Commissions. It also relies on an Ethics of Expertise Committee and Department which helps guarantee the independence and impartiality of the agency's decisions.

HEALTH PRODUCTS UNDER THE RESPONSIBILITY OF ANSM

Medicines

- ◆ All medicines (pre- and post-MA) and pharmaceutical starting materials
- ◆ Blood-derived medicines
- ◆ Narcotic and psychotropic substances
- ◆ Vaccines
- ◆ Homoeopathic and plant-based medicines
- ◆ 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
- ◆ Related therapeutic products
- ◆ Breast milk collected, tested, processed, and preserved by breast milk banks

Medical devices and *in vitro* diagnostic medical devices

- ◆ Diagnostic and *in vitro* diagnostic therapeutics, technical platforms, and medical software

Cosmetic products and tattoos

SCOPE OF EXPERTISE

The ANSM conducts expert assessments and acts as a decision-making body in the field of the regulation of health products. The Agency acts on behalf of the French government to ensure patient safety.

- ◆ **A safety agency:** provides constant surveillance of product benefit/risk ratios with the help of professionals and patients.
- ◆ **An innovation agency:** secures the use of innovative medicines that have not yet received marketing authorisation (MA) [via cohort temporary use authorisations (ATUs) or temporary use recommendations (RTUs)] and promotes the proper use of medicinal products and clinical research.
- ◆ **A product safety research agency:** commissions and guides independent academic studies, conducts studies (Epidemiology Department), funds studies via research calls for proposals, assesses and controls clinical trials and cohorts (ATUs, epidemiological studies, etc.).
- ◆ **An information-sharing agency:** makes databases available (on clinical trials, on medicines, etc.), provides feedback on vigilance reports, ensures full transparency of decision-making processes, monitors the advertisement of medicines and medical devices.
- ◆ **A national public service agency:** participates in various national public health plans and programmes, develops numerous actions in partnership with other public operators (healthcare agencies, universities, etc.) and professional institutions.
- ◆ **An Agency involved at the European and international levels:** participates in European works (EMA, EDQM), cooperates and exchanges with international organisations (WHO) and medicines agencies in other countries.

KEY FIGURES in 2017



GUARANTEEING THE SAFETY OF HEALTH PRODUCTS

MEDICINES

82,077

adverse effect reports were collected and registered by regional pharmacovigilance centres, of which **31,798 were submitted by patients; 23,433 cases of serious adverse effects** were reported **by pharmaceutical laboratories**

92

pharmacovigilance surveys were underway in 2017, and eight new surveys were opened

2,234

medication error or risk of medication error reports were reported by ANSM

1,930

quality defects were reported

538

supply shortages are managed by ANSM, with search of therapeutic alternatives for essential medicines

BLOOD PRODUCTS

6,353

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

9,130

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

MEDICAL DEVICES AND *IN VITRO* DIAGNOSTIC MEDICAL DEVICES

18,208

adverse effects related to medical device vigilance were reported, **1,432 of which were received from patients and patient associations**

1,366

adverse effects related to reagent vigilance (*in vitro* diagnostic medical devices) were reported

PERFORMING LABORATORY CONTROLS AND INSPECTIONS

667

inspections were conducted in 2017, 13% of which were random and 8.5% of which were conducted abroad

4,538

test reports based on laboratory work were completed



PROMOTING PATIENTS' RAPID ACCESS TO INNOVATION

8,250

patients covered by cohort TAUs for medicines

16,621

patients covered by named-patient TAUs of which 11,390 were initiating treatment

727

clinical trials authorised for medicines and 93 for MDs and IVDMDs

92

new medications have been authorised under the centralised European procedure including 12 medications for which France was involved

92%

of national MAs updated

955

MAs, including 801 generic medication authorisations have been issued under the French national procedure, the European decentralised procedure, and the mutual recognition procedure

#1

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



REINFORCING ANSM'S EFFICIENCY AND PURSUING ITS MODERNISATION

947 FTEs

€125 M budget

129

remote-working agents

70

meetings held between management and employees



CONSOLIDATING ANSM'S RELATIONSHIPS WITH STAKEHOLDERS AND EXPANDING THEIR INVOLVEMENT

3,462

public declarations of interest (PDI) investigated as part of an internal ethics compliance report

4,083

ethics contributions and analyses

7

Temporary Specialised Scientific Committees (TSSCs) created

29

meetings organised through the Interface Committees

116

information updates added to ANSM's website

2.9 million

unique visitors to ANSM's website

11,673

followers on ANSM's Twitter account as of the end of 2017 (4,000 more followers gained in 2017)

4

non-profit projects supported (75,000 euros)

9

new research projects funded through a sixth call for projects

19

pharmacoepidemiological studies implemented by ANSM

2

ANSM publications in the *Journal of the American Medical Association* (JAMA)

HIGHLIGHTS IN 2017

JANUARY

- ◆ Publication of a report on the changes in antibiotic consumption in France between 2000 and 2015
- ◆ Launch of the 2017 call for research projects - sixth edition

FEBRUARY

- ◆ Launch of the 2017 call for projects from patient associations and users of the healthcare system - sixth edition
- ◆ Publication of the TRU for Uvestérol Vitamin ADEC

MARCH

- ◆ Update of the list of central nervous system medicines that can alter one's ability to drive
- ◆ Informational meeting for sponsors on the new regulations regarding human research and on medical devices and *in-vitro* diagnostic medical devices (MD/IVDMD)
- ◆ Participation in the 11th French Conference of General Medicine (CMGF)
- ◆ New quality governance to prepare for ISO 9001 certification on "Managing Risk"

APRIL

- ◆ Publication of a report on the assessment of benzodiazepine consumption in France
- ◆ Hearings with patient and healthcare professional associations during the TSSC created to evaluate the risk-benefit ratio of the Essure permanent sterilisation device
- ◆ New Information System Safety Charter

MAY

- ◆ Organisation of a discussion day among partners regarding the use and misuse of opiate analgesics in France
- ◆ Publication of the ANSM report on Risks Associated with the Essure Permanent Female Sterilisation Device Compared to Laparoscopic Tubal Ligation
- ◆ Publication of European MD and IVDMD regulations in the Official Journal of the European Union
- ◆ Publication of a new assessment on the use and safety of methylphenidate

JULY

- ◆ Participation in the 9th “HIV Science” conference (IAS 2017)
- ◆ Publication of the ANSM/CNAMTS report on in utero Exposure to Valproic Acid and Other Drugs for the Treatment of Epilepsy and Bipolar Disorders and the Risk of Major Congenital Malformations (MCMs) in France
- ◆ Publication of the results of a study on the new uses and safety of baclofen in France between 2009 and 2015

AUGUST

- ◆ Publication of the results of the 6th call for projects from patient and healthcare system user associations (four projects selected)
- ◆ Renewal of COFRAC accreditation (French accreditation committee) based on ISO/CEI 17020 guidelines^[1]

JUNE

- ◆ Publication of the report entitled “2012–2016: Five Years of Calls for Research Projects”
- ◆ Informational meeting for sponsors regarding new regulations for human research involving medicines
- ◆ Discussion meeting with evaluators on the safety of cosmetic products
- ◆ Publication of a recommendation regarding the ethics rules that apply to the participation of healthcare user associations in ANSM’s work
- ◆ Hearing with patient associations during the first TSSC meeting on special organ donation between HIV+ donors and recipients

SEPTEMBER

- ◆ Publication of the results of the 6th call for research projects (nine projects selected)
- ◆ Participation in the PANGEA X campaign to combat the illegal sale of medicines and health products

[1] <http://www.cofrac.fr/annexes/sect3/3-1094.pdf>

OCTOBER

- ◆ Mutual recognition between the US FDA and ANSM with respect to medicine manufacturing site inspections
- ◆ Informational meeting for stakeholders regarding the pilot phase for the European regulation on medicinal product clinical trials
- ◆ Informational meeting for stakeholders regarding toxins and microorganisms
- ◆ Implementation of the Support Centre for Emergency Situations, Health Alerts and Risk Management (CASAR)
- ◆ Informational day about ANSM, organised for manufacturers by IFIS

NOVEMBER

- ◆ Publication of a brochure on the analysis of antibiotic consumption and resistance in France in partnership with CNAMTS, ANSES, and Santé publique France
- ◆ Increased risk of lymphoma in patients treated with anti-TNF-alpha: a study led by ANSM in collaboration with AP-HP published in the Journal of the American Medical Association (JAMA)
- ◆ Participation in the 17th annual Collège National des Généralistes Enseignants (National College of Generalists in Medical Education) conference
- ◆ Informational meeting for pharmaceutical establishments on pharmaceutical starting materials
- ◆ Meeting of a joint commission between members of the initial health project risk/benefit ratio assessment commission and members of the monitoring commission, with a public hearing involving stakeholders on recommendations for the names of medicines and package labelling

DECEMBER

- ◆ Implementation of the “Pregnancy” unit. The purpose of this multidisciplinary unit is to assist in the evaluation of specific risks associated with exposure to medicines during pregnancy and to help formalise collaborations between network actors regarding this issue
- ◆ Publication of a report on antibiotic consumption in France in 2016
- ◆ Publication of a new directory for generic groups of plant-based medicines
- ◆ Publication of a report on the use of HIV pre-exposure prophylaxis (Truvada and generics) in France between January 2016 and July 2017
- ◆ Creation of the “Early Phase Clinical Trials” unit within the DPAI⁽²⁾
- ◆ Topical event, organised by the Scientific Board, on the intermediary results of research projects funded by ANSM following the 2014 and 2015 calls for projects

[2] Authorisation and Innovation Policies Division





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