

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.

For
safe, effective,
innovative, and
accessible health
products



143/147 bd Anatole France
F-93285 Saint-Denis Cedex,
France
Tel.: +33 (0)1 55 87 30 00

 @ansm
ansm.sante.fr

The French National Agency for Medicines and Health Products Safety (ANSM) ensures the safety of medicines and other health products throughout their life cycle. It communicates in a transparent manner with healthcare professionals, manufacturers, and the general public about its actions and decisions in order to help them understand and perceive them as their own. It carries out its public service missions in the sole interest of patients.

IDENTITY

Known as the Medicines Agency from 1993 to 1999, then as the French Agency for the Safety of Health Products (Afssaps) from 1999 to 2012, the Agency became the French National Agency for Medicines and Health Products Safety (ANSM) on 1st May 2012 in application of the Act of 29 December 2011 relating to the increased safety of medicines and healthcare products.

The ANSM has an Administrative Board of Directors, a Scientific Board, and consulting commissions. It also draws support from a Committee and a Service of the Ethics of Expertise, which help to ensure that the Agency's decisions are independent and unbiased.

Relevant health products

- Medicinal products
- Vaccines and biological products
- Medicinal products derived from blood
- Medical devices, etc.

€130

Operating budget*

Almost
1,000
employees

A state-funded public administrative establishment, placed under the umbrella of the French Ministry of Health

3 sites
Saint-Denis,
Lyon, and
Montpellier-Vendargues

AMBITION

Combine quick access to innovation with continuous adaptation of benefit/risk balance of health products as therapeutic progress is made.

STRATEGIC FOCAL POINTS

- ◆ Guarantee a high level of safety for all health products throughout their life cycle
- ◆ Promote rapid, closely monitored, and broad access to all health products
- ◆ Consolidate the ANSM's relationships with stakeholders and improve their involvement
- ◆ Reinforce the ANSM's efficiency and pursue its modernisation

MISSIONS

- ◆ Evaluate and monitor the benefits and risks of health products throughout their life cycle
- ◆ Inspect manufacturing and distribution sites
- ◆ Control quality in the laboratory and monitor advertising
- ◆ Foster independent academic research
- ◆ Provide legal and regulatory expertise
- ◆ Communicate in an open and transparent manner with healthcare professionals and patients regarding its actions and decisions
- ◆ Participate in the European and international works

* 2015 budget