The French National Agency for Medicines and Health Products Safety (Agence nationale de sécurité du médicament et des produits de santé – ANSM), was created by the Act of 29 December 2011 relating to the increased safety of medicines and health care products. It was implemented on 1 May 2012 following the publication of Decree no. 2012–597 on 27 April 2012. As a public body under the supervision of the Ministry of Health, the ANSM has taken over the tasks of the Afssaps and has been entrusted with new responsibilities. It is funded by a State subsidy.

The ANSM conducts expert assessment of health care products and acts as a decision-making body in the field of sanitary regulation. Every year, its Director General takes tens of thousands of decisions on behalf of the State. Their aim is to reconcile patient safety with access to therapeutic developments.
New monitoring, transparency and information responsibilities

- Regularly measuring variations in the benefit-risk ratio of medicines on the market
  Three major medicine categories have been identified: medicines recently identified for pharmacovigilance or as having lost efficacy, medicines pending renewal of their authorisation, old medicines, authorised in France before 2005.

- Promoting quick access to therapeutic innovation before receiving Marketing Authorisation (MA):
  renewal of the premarket approvals scheme (PMA) and supervision of prescriptions without MA by means of issuing recommendations for temporary use (RTU).

- Guaranteeing transparency in the work of the commissions and task forces: publishing their agendas, their reports and/or video extracts.

- Promoting academic research on medicine safety:
  - calls for projects aimed at public research bodies, non-profit private research bodies and healthcare institutions in order to develop a high-level scientific research strategy.
  - access to the CNAMTS databases for surveillance and epidemiology studies, in particular in the context of a public interest group (groupement d’intérêt publique – GIP) between the State, the HAS, the French Institute for Public Health Surveillance (Institut de veille sanitaire – InVS), the CNAMTS and the ANSM.

- Improving the management of conflicts of interest: creation of an ethics department and committee, publication of the individual declarations of currently appointed experts.

- Developing information and distributing it to patients, healthcare professionals, professional intermediaries and learned societies, the press, etc., using suitable tools.

- Improving relations with healthcare professionals and patients: setting up task forces that bring together healthcare professionals, calls for projects to promote associative initiatives aimed at encouraging correct use of healthcare products and reducing the risks linked to usage, participation of associations of patients and users of the healthcare system in the Board of Directors and committees of the Agency, etc.

- Better supervision of advertising:
  - prior authorisation for all advertising materials of medicines aimed at healthcare professionals;
  - ban on advertising for all medicines pending reassessment of their benefit-risk ratio after receiving a pharmacovigilance request;
  - prior authorisation of advertising for medical devices that pose a serious risk for human health and for medical devices for in vitro diagnosis, in which a defect could cause serious health risks.