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 healthcare 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 healthcare 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.

Public administrative body

€140M operating budget

1,000 employees

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

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ansm.sante.fr

ansm
The French National Agency for Medicines and Health Products Safety

ansm.sante.fr

An essential agency for ensuring the safety of medicines and healthcare products

The ANSM is entrusted with guaranteeing the safety of healthcare products for human use throughout their entire life cycle (medicines, biological products, medical devices, devices for in vitro diagnosis, cosmetic products, tattooing products, biocide products, etc.).

It assesses the safety of use, the efficacy and the quality of these products. It performs surveillance and laboratory testing of these products and conducts inspections of the manufacturing sites. It also carries out actions aimed at informing about the benefits and risks of these products.

In France, the Agency works in close collaboration with many institutional partners: other healthcare agencies, Regional Health Agencies (ARS), the French National Health Insurance Fund for Salaried Workers (Caisse nationale de l'assurance maladie des travailleurs salariés – CNAMTS), the French National Authority for Health (Haute Autorité de Santé – HAS), etc.

Finally, the ANSM is especially active on the European and international scenes. It conducts its actions by means of activities that include assessment, laboratory testing and inspection on site carried out on behalf of the European Union. It also participates actively in European standardisation and harmonisation work. It undertakes actions in the field of international cooperation and development.

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'intéret 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.