Product quality control

Consultez la version française

For the purposes of obtaining independent expertise and enhancing the safety of health products for patients, it is important for France to have substantial laboratory testing capacity, in particular to counter market globalisation, the emergence of falsifications, and the appearance of new infectious agents.

For this reason, ANSM has set up testing laboratories for health product quality control, for both products that have already been released to market and those undergoing the authorisation process.

ANSM performs a variety of controls (biochemical, immunological, physicochemical, biological, microbiological, immuno-haematological) on all health products. They are organised according to an annual work programme or urgently in response to a suspected quality defects reported via inspections, referrals from judicial authorities or reports by healthcare professionals or patients.

They are intended to:

- verify and confirm the quality of finished products and of their components;
- detect quality defects, assess the potential danger that they pose, and undertake corrective or preventive actions;
- detect, where applicable, falsified health products and undertake enforcement actions;

In addition, and alongside the controls performed by manufacturers, ANSM performs controls on batches of vaccines and blood-derived medicines before they are released to market in countries of the European Union, in order to ensure their quality prior to their sale.

Strong european involvement

The substantial investments and work to ensure compliance with European or even international quality standards have helped validate the reliability of the results from the work conducted at ANSM’s laboratories, and has placed them in the top tier of the European Official Medicines Control Laboratories (OMCL) network, led by the European Directorate for the Quality of Medicines and HealthCare (EDQM) of the Council of Europe.

This network particularly enables mutual recognition between different competent laboratory control authorities, governed by a common quality standard (ISO 17025). It also ensures that control programmes are coordinated, particularly for European biological, biotechnological and chemical product market surveillance.

Laboratory health product control

Medicinal products and biological products are subject to scheduled controls, based on a risk analysis accounting for multiple criteria including the probability of the occurrence of a quality defect, the nature of potentially associated adverse reactions, or the level of exposure for the population, etc. This risk analysis is conducted using a framework developed by the European OMCL network and used by European countries.

The samples primarily come directly from pharmaceutical companies at ANSM's request or are taken by ANSM inspectors at the premises of a finished product or starting material manufacturer (in France or outside France).

The controls concern both medicines authorised on a European level (in which case the results are shared between European countries) and medicines only authorised in France.

Controls are also performed on medical devices and in vitro diagnostic medical devices.

ANSM’s laboratories play an active role in the quality control of state health product supplies, alongside the General Directorate for Health and Santé Publique France.

Release of batches of vaccines and blood-derived medicines

Vaccines and medicinal products derived from human blood are sensitive biological products since their production uses starting materials of human or animal origin, as well as a complex process, subject to variability. While they meet the same requirements as other medicines in terms of approval, safety of use and surveillance, their marketing conditions are enhanced via a national authority batch release process.

This system requires 100% control of vaccine and blood-derived medicine batches before they are marketed. Batches released may then circulate freely within the European area.

This release, conducted by ANSM in its capacity as the national official control laboratory, involves a documentary review and controls carried out in independent laboratories relating to the identity, efficacy and safety of vaccine and blood-derived medicinal product batches. An exhaustive assessment of the manufacturer’s production and control data is also performed. For each batch, the critical parameters to be controlled are defined jointly by all the European laboratories within the European Directorate for the Quality of Medicines and Health Care in Strasbourg (EDQM - Council of Europe). This harmonisation work also enables mutual recognition between the Member States and avoids unnecessary duplication of tests.

ANSM is the No. 1 vaccine batch release centre, and the No. 4 blood-derived medicine (BDM) batch release centre in Europe.