ANSES and the ANSM strengthen their partnership

On 12 June, ANSES and the ANSM signed a new framework agreement to reinforce their partnership across the entire field of human and veterinary medicinal products. This new agreement between the two health agencies also provides for cooperation to be extended to all possible synergies according to the "One Health" approach.

Responsible for human and veterinary medicines, respectively, the ANSM and ANSES (through its French Agency for Veterinary Medicinal Products, ANMV) have a long history of dialogue and collaboration in this field.

The new framework agreement signed on 12 June will enable them to continue this collaboration and consider cooperative exchanges between them in other shared areas. In particular, it takes into account the continuation of discussions on cosmetics and tattoos, since responsibility for cosmetovigilance and tattoovigilance was transferred from the ANSM to ANSES in January 2024.

Human and veterinary medicines: extending and deepening cooperation

Annexed to the framework agreement is a specific partnership agreement covering a number of areas of common interest, such as prescription of human therapies in veterinary medicine, herbal medicines, innovative therapies and antibiotics.

In the new agreement, the two agencies also reaffirm their commitment to working together on regulatory and ethical developments in the entire field of medicinal products. Seeking to align their operating benchmarks with the highest standards, they will also be stepping up their exchanges on practices relating to inspection and monitoring of pharmaceutical establishments and testing facilities, as well as quality control of medicines and active substances, and pharmacovigilance.

Representing France on the Management Board of the European Medicines Agency (EMA) and involved in numerous European and international working groups of common interest, the ANSM and ANSES, through the ANMV, are now validating the close links between their representations at supra-national level.

Cooperation on medicines derived from biotechnologies

To harmonise their practices in the assessment of medicinal products, the two health agencies have committed to developing technical cooperation, with a particular focus on the environmental toxicity of residues. Their new framework agreement also includes an annex

devoted to risk assessment in the specific case of medicinal products falling within the regulatory scope of GMOs, when they are used outside research laboratories.

This follows the dissolution of the High Council for Biotechnology, and the extension of ANSES's remit for assessing the public health risks of biotechnology to include environmental risks for all non-confined uses ("deliberate release") of organisms derived thereof, including human medicines. Assessments with a view to placing products on the market, early access, compassionate use: since 2022, the ANSM has been relying on ANSES for French and European procedures relating to medicinal products consisting of or containing GMOs, which require an assessment of the potential impacts on human health (excluding patients) and the environment.

A shared building in Lyon from 2025

The new framework agreement provides for the creation of specific agreements on all the topics that will enable the two agencies to further develop their "One health" approach to benefit the health of humans, animals and the environment.

It also involves the pooling of material and human resources, particularly at the Lyon-Gerland Biodistrict site, where teams from both agencies will move into a shared building in 2025. Entirely dedicated to the "One Health" approach, this building will combine cutting-edge technological facilities with laboratories ensuring a high level of biosafety in human, animal and plant health.

Pharmacovigilance and the use of massive databases are also areas in which the ANSES and ANSM departments will be seeking closer dialogue, in order to better identify health signals and ultimately better protect health.

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market. Through its assessments, expert appraisals and surveillance policy, it ensures that the healthcare products available in France are safe, effective, accessible and used for their intended purpose.