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Ensuring access to treatments today while preparing for those of tomorrow

Fewer medicine shortages, stronger dialogue with patients and support for innovation: in 2025, the Federal Agency for Medicines and Health Products once again demonstrated the diversity of its responsibilities in the service of public health. The year 2025 was also marked by the management of the case involving a sperm donor carrying a TP53 gene mutation. This case affected many families, mobilised numerous teams within the agency and led to a profound analysis and reflection.

As every year, the Federal Agency for Medicines and Health Products (FAMHP) publishes its [annual report](#). This document provides an overview of the FAMHP's activities and achievements in support of public health, as well as the challenges encountered during the year.

The annual report highlights some of the measures taken to ensure that patients have access to safe, effective and high-quality medicines and healthcare products, while supporting innovation and addressing emerging public health challenges.

2025 key figures

- 654 staff members working in the service of public health.
- 1 126 Narcoreg dossiers (narcotics order forms) were opened, compared to 492 in 2024.
- 387 inspections of medical device distributors were carried out, compared to 221 in 2024.
- 537 notifications were received concerning reproductive cells and tissues, compared to 277 in 2024.
- 30 rapid alerts relating to quality or safety issues concerning reproductive cells and tissues, compared to 13 in 2024.
- a 10.44 % increase in hemovigilance notifications.
- 395 press enquiries were dealt with, representing a 36 % increase compared with 2024.

Innovation and access to treatment

The FAMHP continued its efforts to ensure that patients have access to safe, effective and high-quality treatments. The number of unavailable medicines continued to decline thanks to measures taken at both national and European levels to prevent shortages and limit their impact. At the same time, the agency has continued to support innovation, particularly in the field of clinical trials and advanced therapy medicinal products (ATMPs), while maintaining high standards of quality, safety and patient protection.

The TP53 case: an exceptional mobilisation

The past year was marked by the management of the case involving a sperm donor carrying a TP53 gene mutation. This exceptional situation had a profound impact on the families concerned and required the sustained involvement of numerous teams across the agency over several months. This case also had a significant personal impact on many of the agency's experts. In addition to dealing with the immediate aspects of the case, the agency carried out a major analysis to identify improvements that could be implemented to further strengthen the protection of public health.

Patients at the heart of our mission

Strengthening dialogue with patients and improving access to information were once again among the FAMHP's goals. These ambitions resulted in the organisation of Patients' Day in November and in the launch of the agency's Instagram account in March, designed to provide reliable information that is accessible to everyone.

“The challenges we faced in 2025 once again demonstrated the commitment, expertise and professionalism of the FAMHP's staff. Whether it involves supporting innovation, ensuring the availability of medicines, strengthening dialogue with patients or managing exceptional situations such as the TP53 case, we once again demonstrated that protecting public health remains our highest priority.”



Hugues Malonne, FAMHP Chief Executive Officer

More information

Discover all the FAMHP's achievements and projects in 2025 in our [digital annual report](#). We would love to hear your feedback, so please do not hesitate to share your views with us via the [feedback form](#).

Would you like to stay informed about the latest news from the FAMHP and receive our press releases and related communications materials? Send an email to comm@fagg-afmps.be and follow the FAMHP on social media.

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