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The FAMHP publishes its annual report for 2021: all figures and results, trends, activities related to COVID-19 and testimonials from our staff

2021 was the year we gradually returned to our normal way of working at the FAMHP. The high workload caused by the pandemic remained present, but numerous other important projects awaited us, such as the implementation of several European legislations. In addition to the traditional facts and figures, the 2021 annual report includes testimonials that demonstrate the commitment and professionalism of our staff.

## Some key figures

- 43 354 reports of adverse reactions received of medicinal products for human use, many of which were about the COVID-19 vaccines. About three-quarters of the reports came from patients.
- 2 112 reports of unavailability of medicinal products received. The main causes are a slowdown in production or increased demand. The average duration of an unavailability was 57 days.
- 332 investigations into illegal medicines and medical devices were conducted by our Special Investigation Unit.
- 565 marketing authorisation files for medicines were processed.
- 609 clinical trial applications were processed.
- 257 licenses for raw materials used in magistral and officinal preparations were granted.
- 705 laboratory analyses of products on the market were performed.
- 3 613 postal packages containing non-compliant products from outside the EEA were blocked.

#### Coronavirus health crisis and European legislation

The fight against COVID-19 continued to require a great deal of time and resources from our agency in 2021. For example, our inspectors and controllers supported the training and inspection of vaccination centres and the amendment to the legislation, we also processed applications for clinical trials of medicinal products against COVID-19 and assessed the many reports of adverse reactions to the COVID-19 vaccines.

But there were many other projects waiting for us. In 2021, we were fully committed to finalising the implementation of several new European legislations on veterinary medicines, clinical trials, medical devices and in vitro diagnostics. We were ready to assist our stakeholders with our expertise and support and worked closely with other national and European institutions.

#### A word from our experts

In the annual report, our experts provide a unique look behind the scenes and talk about their approach and experiences with a number of major projects within the FAMHP. In addition to our activities related to the coronavirus pandemic, we find out how the agency cooperates with other medicines authorities at European level and how the new legislation on veterinary medicines, clinical trials and medical devices was prepared. You will also get more details on how the relocation of more than five hundred employees was carried out and how we innovate in our internal communication and complaint management. Each



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interview shows the commitment and professionalism of our experts who sometimes worked on these complex projects for several years.

A few quotes from the interviews

- "We have always been careful to ensure that the vaccination campaign could be conducted in a
  qualitative way. That was our biggest concern. We have been pragmatic, yet the quality always had to
  be 100 %"
- "The market for medicines for veterinary use is evolving rapidly and is very different from the market for medicines for human use, so it was urgent to review the legislation. The new legislation encourages innovation so that more new products come onto market and the availability of medicines for veterinary use increases"
- "All the materials we have chosen for our new building are reusable. We want to work together on public health in a sustainable and healthy environment"
- "The cooperation between European competent authorities is essential to ensure the quality, safety and efficacy of medicines and health products"

Discover all achievements of 2021 in digital annual report of the FAMHP. We want to improve our annual report every year, so we invite you to give your opinion on the annual report through an online survey.

A message from Xavier De Cuyper, Chief Executive Officer of the FAMHP:

"I would like to thank all the FAMHP's colleagues for their unconditional support and commitment they are making to tackle the health crisis for over two years now. Our efforts have resulted in real solutions in many complex issues and for our fellow citizens who faced difficult situations. You can certainly be proud of the results achieved. I would also like to thank all external FAMHP's partners for their support and trust. Let us all continue to work together to safeguard the health of people and animals."

### More information

The 2021 annual report of the FAMHP

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