Annual report 2023, National Innovation Office and Scientific-Technical Advice Unit

National scientific-technical advice

- 46 national applications for scientific-technical advice for medicinal products for human and veterinary use have been submitted
- 50 national applications for scientific-technical advice for medicinal products for human and veterinary use have been closed

Simultaneous national scientific advice

- 10 submitted and closed applications for simultaneous national scientific advice (SNSA) in collaboration with other national medicines authorities in the context of the European SNSA pilot project of the EU Innovation Offices Network (EU IN)

Questions

- 189 questions and answers (including on existing regulation and guidelines, research and development, innovation and the FAMHP's services)

Meetings

- 1 portfolio meetings
- 4 project information meetings with local developers on a planned project for drug development

Consultation procedure for medical devices with a medicinal product as an integrated part of the medical device

- 1 consultation procedure submitted by a registered authority for medical devices with a medicinal product as an integrated part of the medical device

TSE consultation procedure

- 37 TSE consultation procedures for medical devices using animal tissues for their production that may cause Transmissible Spongiform Encephalopathies (TSE)

Borderline product consultation procedure

- 15 informal consultations for borderline products

European requests for scientific advice

- 88 European applications for scientific advice for medicinal products for human use handled at the level of the Scientific Advice Working Party (SAWP-H) of the EMA
- 1 European applications for scientific advice for veterinary medicinal products handled at the level of the Scientific Advice Working Party (SAWP-V) of the EMA

New

- The project information meetings and portfolio meetings with the FAMHP's National Innovation Office, which until now had only been offered to the medicinal products sector, were opened up to developers of medical devices and in-vitro diagnostics (IVDs) in 2023 in order to expand innovation support for the MedTech sector in Belgium and thus facilitate accelerated access to innovative medical technologies and IVDs for patients.

- In 2023, the FAMHP's National Innovation Office further expanded its cooperation with the Commission for International Cooperation in health "CIS Health" in order to achieve a partnership with the funding bodies in Belgium and thus support non-commercial (pre)clinical investigation in Belgium more effectively.

Trends

- After a downward trend in 2021 and 2022, more requests for advice were received again in 2023 (26% of which were related to the FAMHP vaccines spearhead). The increase is mainly visible in the number of SNSA requests. This is the result of further harmonisation of the procedure and increased awareness through active and passive communication on various channels. In addition to more support for medicinal product developers, the SNSA procedure also ensures stronger communication between different national medicines agencies.

- The significant increase in the number of TSE consultation procedures (48% compared to 2022) is due to the implementation of the Medical Device Regulation (MDR) and is an actual indication of compliance.