

## **Annual report 2022, National Innovation Office and Scientific-Technical Advice Unit**

### **National scientific-technical advice**

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

### **Simultaneous national scientific advice**

- 4 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**

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

### **Meetings**

- 5 portfolio meetings
- 6 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**

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

### **European requests for scientific advice**

- 136 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
- 4 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

- **Pilot project on patient involvement in national scientific-technical advice**

In 2022, six national scientific advice files have been handled in close collaboration with representatives of a disease-specific patient organisation as part of the FAMHP's pilot project on patient involvement in national scientific-technical advice.

- **Pilot project about repurposing of medicines**

In 2022, a national scientific advice has been provided in the scope of the European pilot project for the repurposing of medicines for new therapeutic indications. The project was launched at the end of 2021 by the expert group Safe and Timely Access to Medicines for Patients (STAMP) of the European Commission. Our service also follows the projects for repurposing REMEDI4ALL and REPO4EU in close collaboration with the European workgroup RePog-EU-IN of the STAMP. The aim is to maximise the facilitation of repurposing research of the non-profit sector through scientific-technical advice.

## Trend

- The number of questions treated yearly by the National Innovation Office and Scientific-Technical Advice Unit keeps increasing. Questions come from the pharmaceutical and medical device industries as well as citizens and healthcare practitioners. We see an increase of 12,8 % compared to 2011. This shows that more stakeholders are finding their way to our service. The recent significant regulatory changes at national and European level also raise many questions.