

Early-phase drug development support by the Innovation Office of the National Institute of Pharmacy and Nutrition

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Our mission



Innovation Office

The Innovation Office of the National Institute of Pharmacy and Nutrition of Hungary (OGYÉI) was established to provide efficient and tailored support to drug developers working for disease prevention and care. In accordance with the mission of OGYÉI, we aim to facilitate that Hungarian patients get timely access to safe and effective new medicines.

How can we help?

- Regulatory and scientific advice
- Health-economic assistance
- International relations



The service profile

Early
development

Scientific
advice



EMA
resources

Methodological
center

Early-phase drug development

- The Innovation Office is committed to support national drug development efforts.
- Face-to-face meeting
- Well-defined questions
- Review of related regulatory requirements and available EMA resources
- Giving help to the interpretation of relevant guidelines

Scientific and regulatory advice

- New drug development
- Pharmacovigilance issues
- Marketing Authorisation
- Quality assurance systems
- Health-economical issues
- Medical devices
- Consultancy on issues dedicated to the Chief Pharmaceutical Division

EMA Tools and Resources

- Innovation Task Force (ITF)
- PRIME
- Adaptive Pathways
- Compassionate Use
- Accelerated Assessment
- Conditional MA
- STAMP



How to apply?

- innovacio@ogyei.gov.hu
- Application form
- Background documentation (Briefing document)

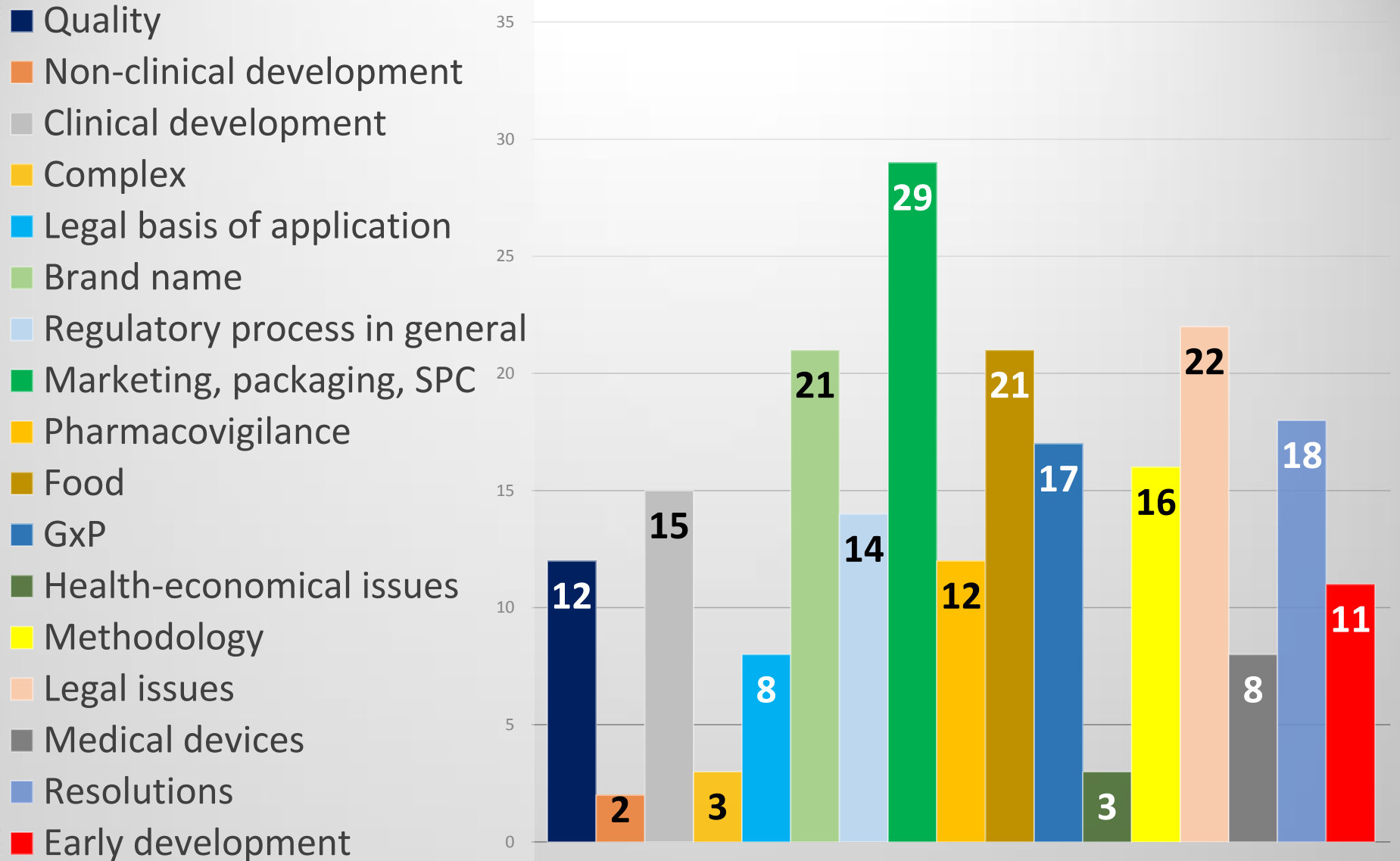


Behind the scenes

1. Validation
2. Choosing experts
3. Consultation
4. Internal discussion
5. Reply to the questions



Scientific advice in 2018



Thank you for your attention



Take your chance!
Your success is everyone's interest!