Federal agency for medicines and health products

Results from the famhp's national survey for SMEs, academic research centres and affiliated partners

Karolina Szlufcik – 1/12/2016

General Disclaimer

The results of the national survey are the ownership of famhp and cannot be distributed, reproduced or published without former permission of famhp.

Introduction

Purpose of the questionnaire:

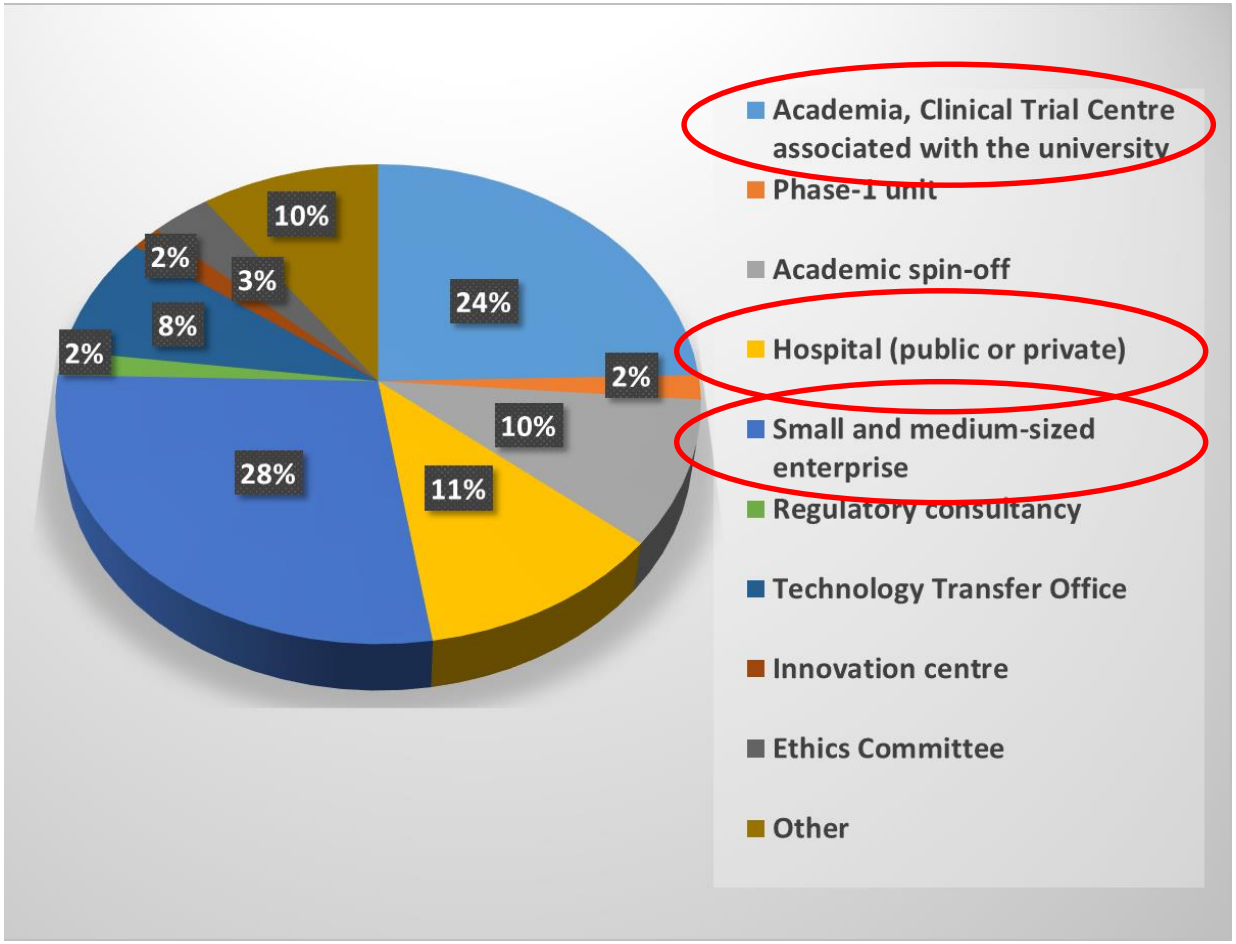
- to capture responder's awareness about the current key activities from the famhp relevant to academics and SMEs
- to identify current and future challenges faced by SMEs and academia
- to determine specific (future) needs for establishing an SME/academia innovation friendly policy and support at Agency's level

Methodology:

- Questionnaire with multiple choice – open questions
    - 3 parts:
        - Responder's profile
        - Section about the current and potential future services foreseen at Agency's level
        - Section about scientific-technical advice (STA) (national – EMA)
- Sent per e-mail to about 400 stakeholders
- Response rate: ~10 %

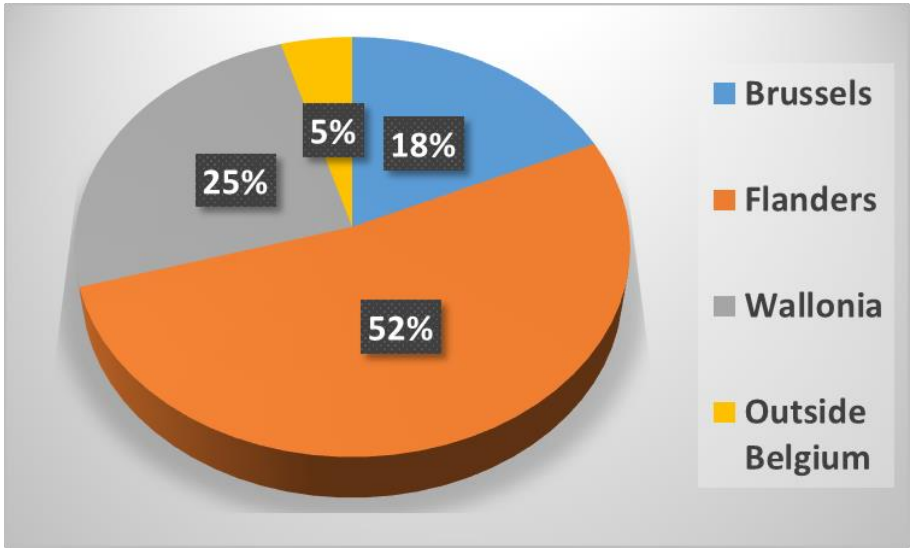
Results – Responder's profile

Results – Responder's profile

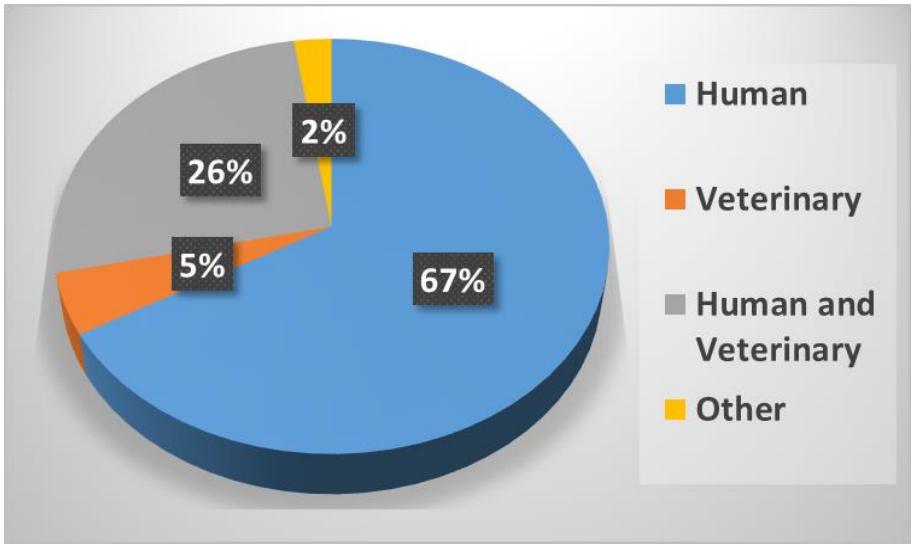


Results – Responder's profile

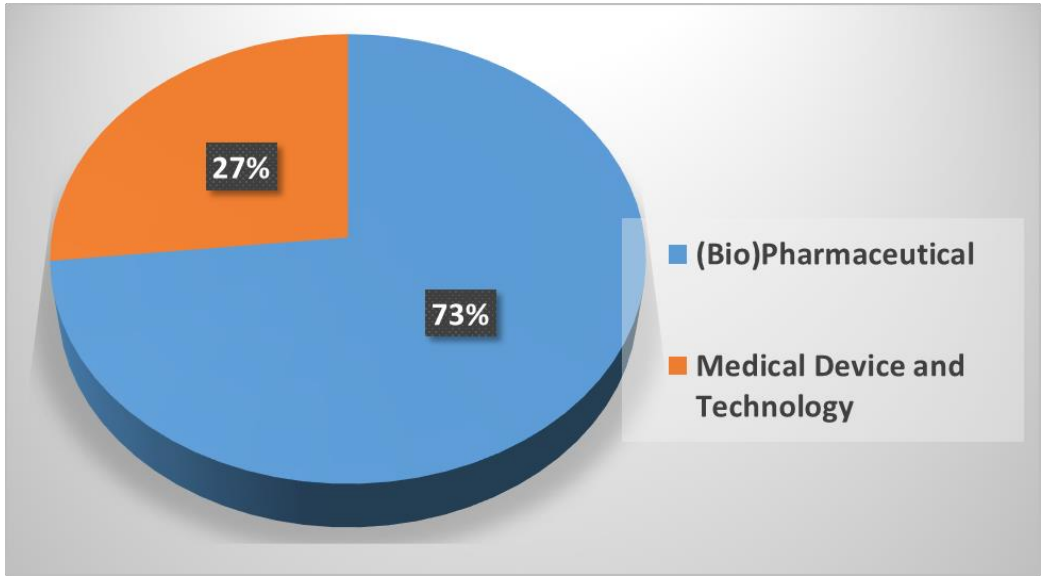
Location



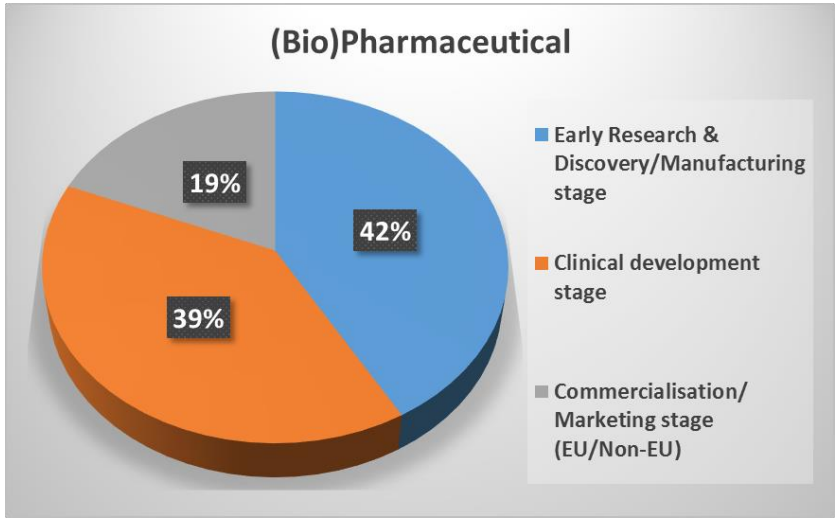
Field of activity

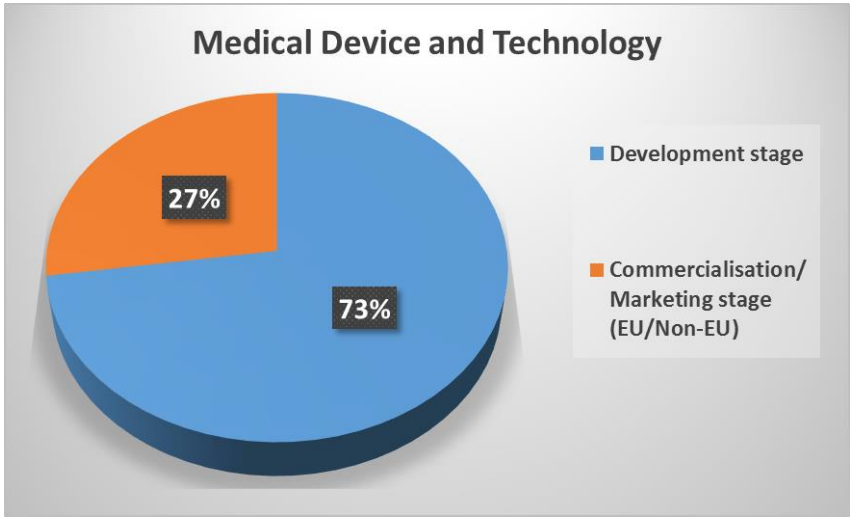


Results – Responder's profile



Sector





Results – Section about the current and potential future services (to be) foreseen at Agency's level to promote innovation and development of new medicinal products

Results - Section about the current and potential future services foreseen at Agency's level

What are the top 3 specific difficulties/hurdles and challenges you are presently faced with R&D or/and translation of basic academic research to clinical research?

- GMP requirements

  Stimulate access to GMP facilities/providers
- Clinical trials

- Regulatory knowledge
  - Difficult to gather sufficient regulatory knowledge – no budget for consultancy or scientific-technical advice
  - Regulatory process of drug development is difficult to understand (ATMP, human cell & tissue, classification of borderline products – veterinary medicine vs feed additive)

  Early stage regulatory guidance to be provided by famhp
  Stimulate partnerships between academia/SME and regulatory consultancy
  Workshops – regulatory update newsletter
  Database with experts in the field of CMC – non-clinical - clinical
  Famhp: user-friendly website

Results - Section about the current and potential future services foreseen at Agency's level

- Gap between academic early stage development and further clinical development

  CREATE NETWORKS:
  Academic – industrial partnerships
  Academic – academic partnerships
  Famhp should be involved from the beginning of the development

- Famhp: challenging to find information – provided information is difficult to understand – demanding and complicated procedures – lack of uniformity

  Dedicated website combined central innovation office email address to access the famhp

- Access to sufficient high quality human samples and biological material to support R&D and clinical trials

  Solid, reliable and flexible legal framework - support and stimulate cooperation between clinical centers, academia, patients & patient organizations and industry – organize virtual tissue bank involving all hospitals, banks and diagnostic centers

Results - Section about the current and potential future services foreseen at Agency's level

What are the hurdles and challenges that are considered as emerging ones within the next 3-5 years?

The current challenges will remain

BUT:

- Big uncertainty about the impact of the new CT Regulation

  Workshop/training needed

- Regulatory requirements will become more and more demanding and complicated

  E-mail advice/informal advice – regulatory update newsletter

- For companies working on the development of allogenic ATMPs – the obligation to work with an accredited bank to get the Human Body Material will block the development of cell therapy products

- Small molecules development under pressure because of the climate to support the biological therapies

Results - Section about the current and potential future services foreseen at Agency's level

To what extent are you aware of the following famhp's core services?

- National scientific-technical advice
- Joint scientific-HTA advice
- European scientific advice
- Clinical trial applications
- Compasionate Use – Medical Need
- Portfolio meetings
- Marketing authorization application
- Variation procedures
- GxP inspections
- Domains of Excellence
- EMA representation

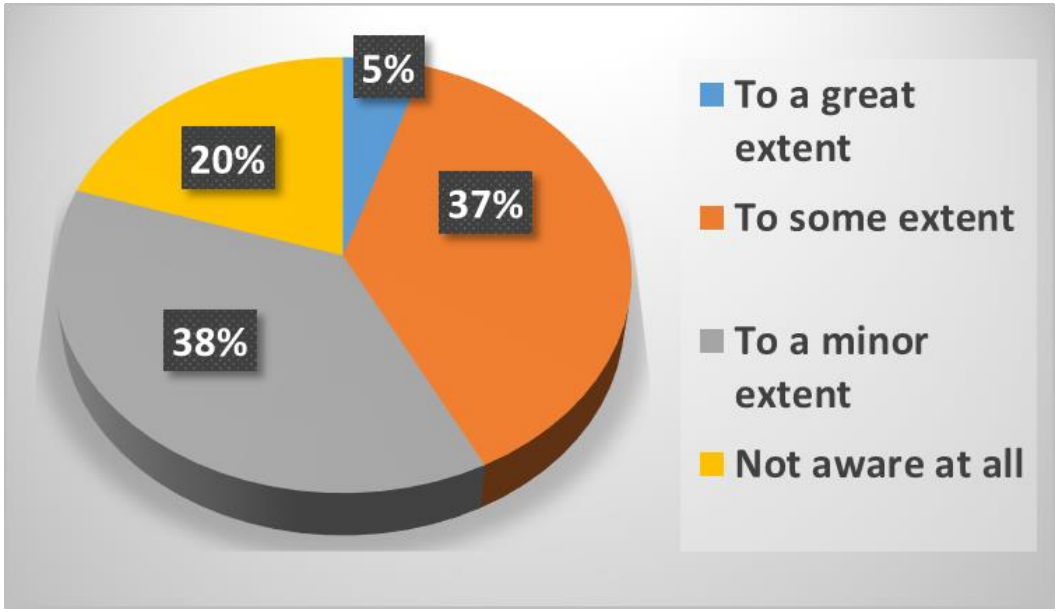
Results - Section about the current and potential future services foreseen at Agency's level

To what extent are you aware of the following famhp's core services?

	to a great extent / to a some extent
Portfolio meetings	**7 %**
Joint scientific-HTA advice	**22 %**
Variation procedures	**22 % (14% AC/H – 44% SME)**
Domains of Excellence	**36 % (42% AC/H – 29% SME)**
Compasionate Use – Medical Need	**41 % (64% AC/H – 31% SME)**
European scientific advice	**47 % (35% AC/H – 69% SME)**
EMA representation	**46 %**
National scientific-technical advice	**55 %**
Marketing authorization application	**60 %**
Clinical Trials Applications	**63 %**
GxP Inspections	**73 %**

Results - Section about the current and potential future services foreseen at Agency's level

To what extent are you aware which department is responsible for the coordination of those core activities?



58% is « not aware at all » or « to a minor extent »

Results - Section about the current and potential future services foreseen at Agency's level

How relevant are the following support activities to your organization?

	Very relevant/Relevant
Workshops and trainings	**97 %**
Innovation office	**92 %**
Dedicated website	**92 %**
Collaboration platforms	**86 %**
Newsletter	**84 %**
Project Kick-off Meetings	**84 %**
Designation for innovative products	**71 % (82 % AC/H – 63% SME)**
Innovation Office membership	**63 % (56 % AC/H – 90% SME)**

Results - Section about the current and potential future services foreseen at Agency's level

Any other suggestion for support and guidance?

Also a designation for innovative veterinary products

What about diagnostics and medical devices?

Present situation – (EU) incentives mainly for SMEs – broaden to academia

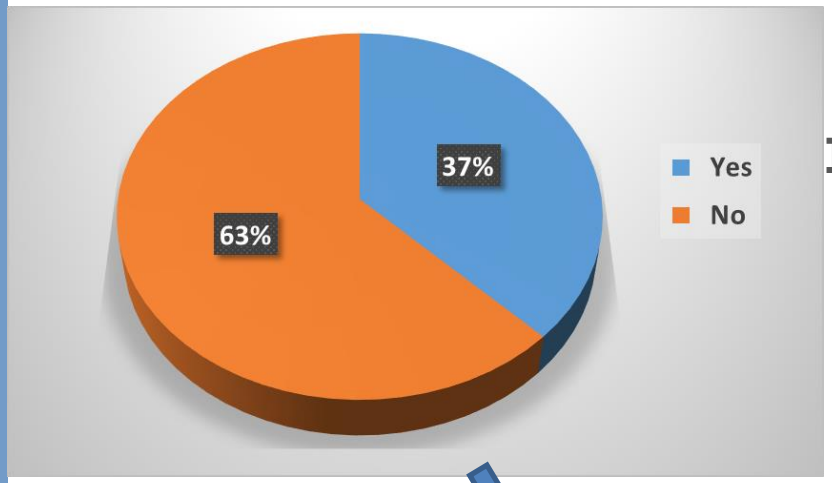
Integrate EU/EMA – famhp – national – other countries' incentives (no duplication, competition, scattering…)

Overview of high-quality providers (GMP-lab/GMP-CMO/CRO/regulatory consultants) with accreditations and QC

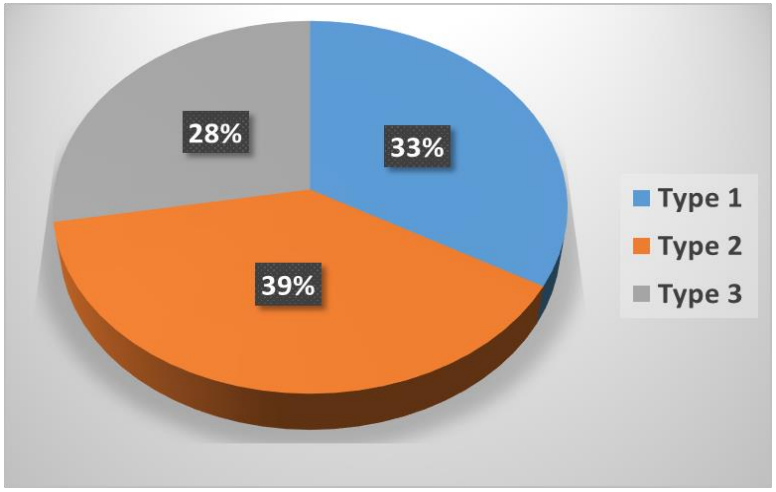
Results – Section about the current knowledge of the national and European scientific advice and future initiatives to be foreseen to stimulate innovation

Results - Section about scientific-technical advice (STA) (national – EMA)

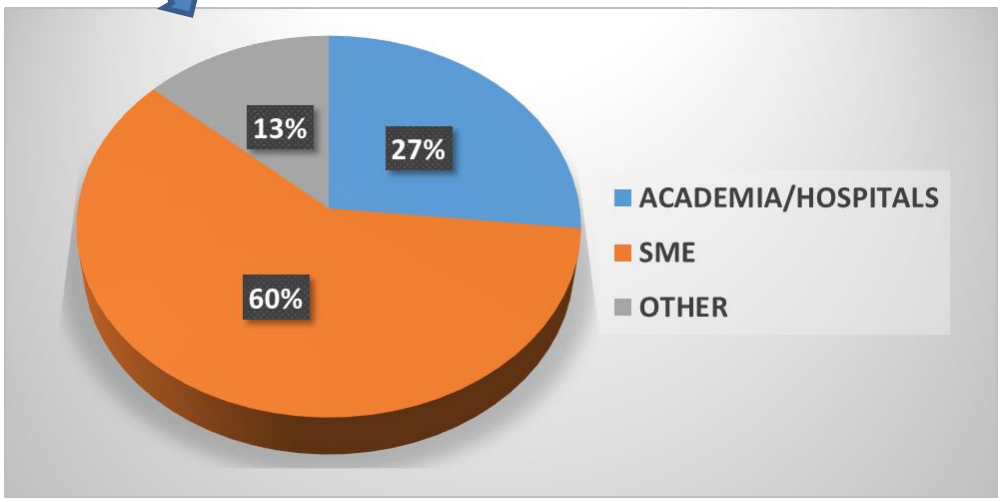
Have you already requested a national scientific-technical advice?



IF YES

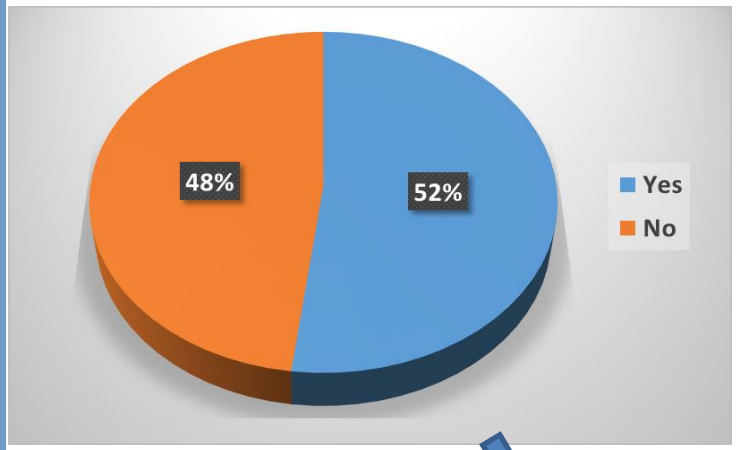


IF YES

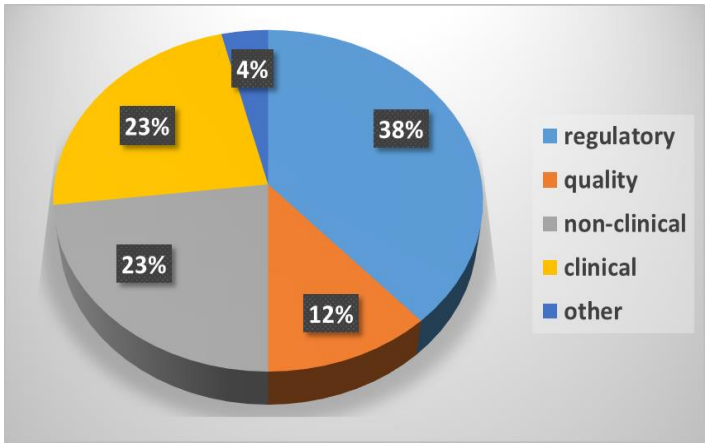


Results - Section about scientific-technical advice (STA) (national – EMA)

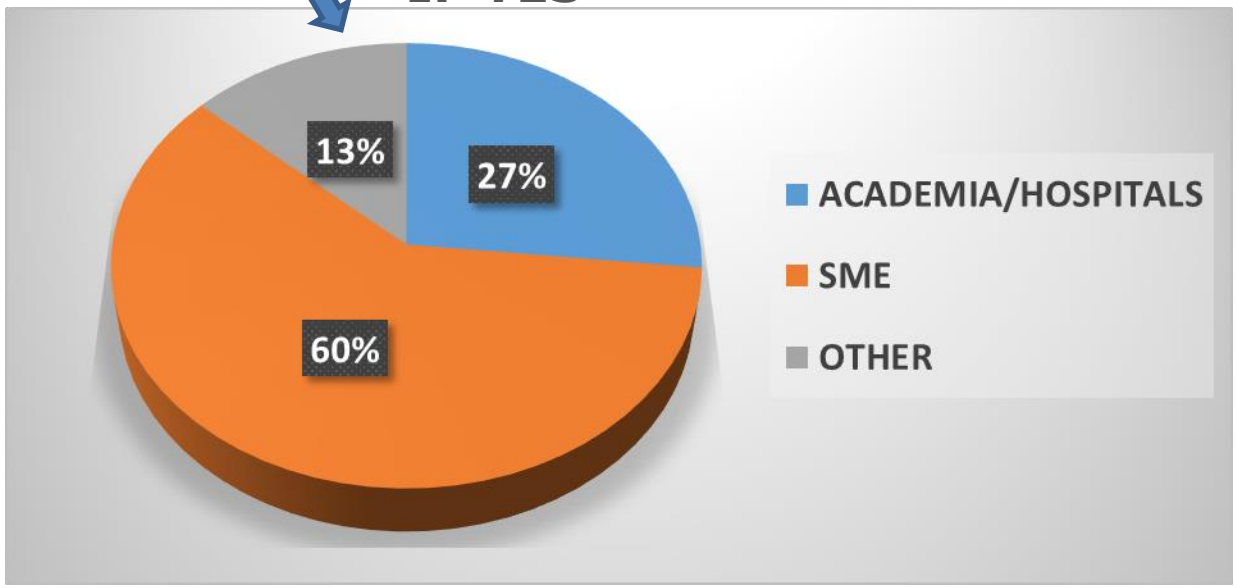
Are you in need to request a national scientific-technical advice?



IF YES

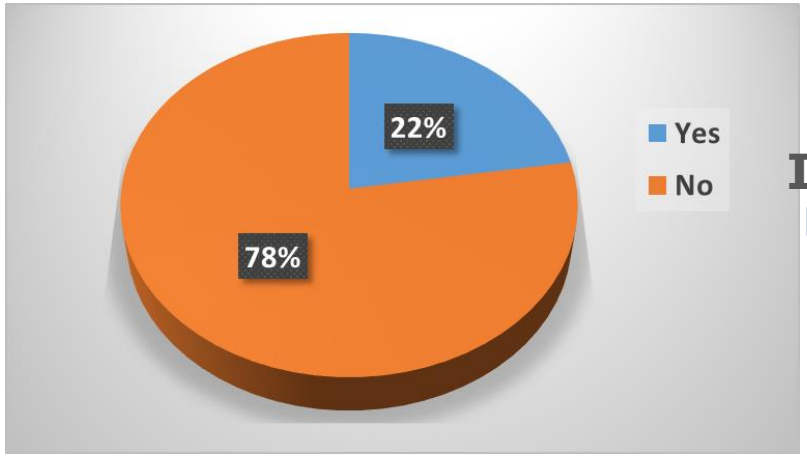


IF YES

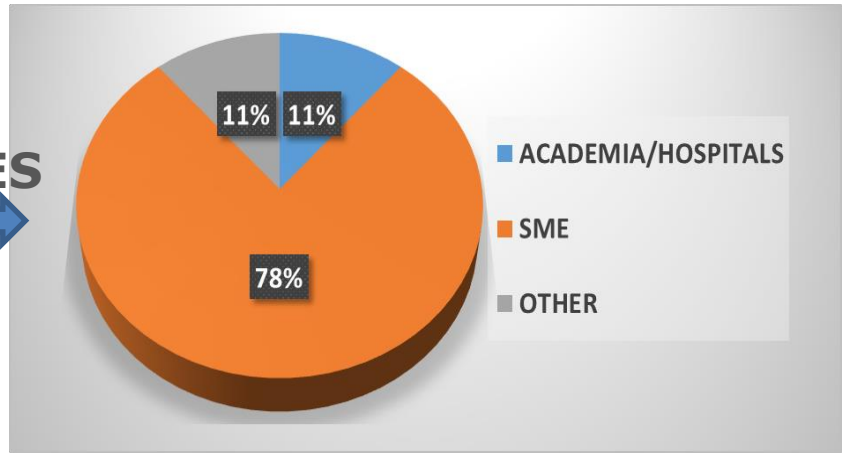


Results - Section about scientific-technical advice (national – EMA)

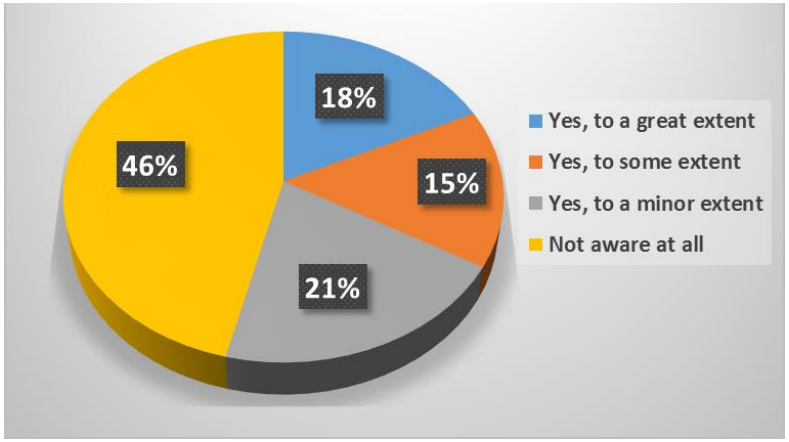
Have you already requested an European scientific advice (SAWP)?



IF YES



Are you aware of the existing EMA incentives for recognized SMEs relevant to SAWP procedure?



Results - Section about scientific-technical advice (national – EMA)

How relevant would be the following potential national scientific-technical advice support activities to your organization?

	Very relevant/Relevant
STA fee reduction/exemptions	82 %
Technical-regulatory advice	82 %
Fast-track STA for EPD	79 %
Presubmission guidance STA	74 %
STA fee reduction for innovative products	70 %
Iterative STA	67 %
Fast-track STA in case of public health threat	58 %
	85 % AC/H – 44 % SME

Results - Section about scientific-technical advice (national – EMA)

Do you have any other comments/suggestions concerning national STA?

Make the procedure less "rigid"/formal with an open access to obtain an early (regulatory)advice – stimulate early dialogue

Open the procedure for medical devices and diagnostics

Broaden the scope of the written advice with shorter deadlines and allow multiple questions within the same area/expertise domain

Concluding remarks

Concluding remarks

- Step-wise approach: first SMEs/academics – later on bigger companies

  → Any suggestion to improve the response rate is welcome

- National Innovation Office = very relevant

- Discrepances between different groups: specific needs – specific support

Contact

Scientific - Technical Advice & KM Unit

Federal agency for medicines and health products - famhp

Place Victor Horta 40/40
1060 BRUXELLES

tel. + 32 2 528 40 00
fax + 32 2 528 40 01
e-mail sta@fagg-afmps.be

www.afmps.be

Your medicines and health products, our concern

famhp

.be