

Federal agency for medicines and health products

Future famhp initiatives to support drug development and innovation from SME's and academics: Questionnaire presentation

Karolina Szlufcik – 02/05/2016

Introduction

2016 INITIATIVES

COMMUNICATION PLAN: focus on targeted communication and sensibilisation

Events: Workshop, Knowledge for Growth, BLOWIN Day 2016
Website update (scientific-technical advice, portfolio meetings)

FORMALIZED FAMHP MEMBERSHIP EU INNOVATION NETWORK

QUESTIONNAIRE + FOLLOW-UP WORKSHOP

ACTION PLAN



Introduction

Why this questionnaire?

Impression:

- “gap” between existing incentives at national and European level and the awareness about these incentives
- “gap” between the existing incentives at national level and the support needs from the field

Workshop = starting point of a number of future initiatives

Which actions should be taken in the near future to stimulate and facilitate R&D/innovation, in the first step for the target groups of the workshop and in the second step for other stakeholders in R&D??



Practical arrangements

1. Draft questionnaire presentation: workshop **02/05**

2. Suggestions welcome till **13/05**

Issues/additional questions/target public – can be sent per e-mail:

STAworkshop@fagg-afmps.be

3. Final version per e-mail: mid May - **deadline 30/06/2016**

4. Collection and interpretation of data: **July – August 2016**

5. Internal discussions + Action Plan: **30/09/2016**

6. **Mid October**: announcement of the follow-up workshop

7. **Mid December**: Follow-up workshop + publication of the results

- Identified key interesting issues
- Presentation of the Action Plan and way forward



Content Questionnaire

Purpose:

- 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 friendly policy and support at Agency's level
- to identify the main current and future activities at the level of SMEs and academic research centers in Belgium

3 parts:

1. Responder's profile
2. Section about the current and potential future services (to be) foreseen at Agency's level
3. Section about the national and European scientific advice services



Content Questionnaire

3 parts:

1. Responder's profile

2. General Section

Questions about:

- Difficulties/hurdles presently faced

scientific, regulatory, technical, financing...

- Difficulties/hurdles emerging within 3-5 years

- Awareness about existing famhp core services/departments

national STA, joint STA/HTA advice, CTA, CU/MNP, portfolio meetings, MAA, variations, GxP inspections, Domains of Excellence...

- Relevance of potential future general SME/innovation support activities

project kick-off meetings, workshops/training events, SME newsletter, SME website, Innovation Office, SME Membership/Recognition, SME/academics fee reductions for scientific advice,...



Content Questionnaire

3 parts:

3. National and European Scientific Advice

Questions about:

- Awareness about national scientific-technical advice at famhp
- Awareness about European scientific advice from SAWP and existing EMA incentives for SMEs
- Relevance of potential future national scientific-technical advice support activities

fast-track scientific-technical advice for EPD clinical trials/in case of public major health threats, pre-submission guidance for national scientific-technical advice, iterative scientific-technical advice with a reduced fee,...

Free-text space provided for your additional comments/suggestions in order to support and accelerate drug product development and innovation in SMEs and academic research centres/hospitals



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 68

fax + 32 2 528 40 01

e-mail sta@fagg-afmps.be or staworkshop@fagg-afmps.be

www.afmps.be



A large, stylized graphic of a human eye is centered in the background. The eye is composed of several overlapping, semi-transparent shapes in shades of light blue and grey. The iris is a light blue circle with a white pupil. The eyelids are represented by grey, curved shapes at the top and bottom. A dark blue horizontal bar is superimposed over the center of the eye.

Your medicines and health products,
our concern