

**QUESTIONNAIRE**

**“*Implementation of the national Innovation Office at famhp*”**

1. **INTRODUCTION & OBJECTIVES:**

In order to promote and facilitate as much as possible the research and development of new innovative drug products, the famhp prepares the establishment of an Innovation Office. This office will serve as an easy and central access point to the regulatory and scientific expertise of the famhp with the final aim to accelerate the availability of innovative medicinal products to patients, especially in therapeutic areas where an unmet medical need exists. The three key activities of the Innovation Office will be: (1) national scientific-technical/regulatory advice service, (2) innovation support and (3) specific services to support small and medium-sized enterprises (SMEs) and academia.

In order to finetune the Agency’s Innovation Office plans and to align the objectives of the Innovation Office to the current and future needs of the SMEs in the pharmaceutical sector and academia this questionnaire has been developed. A selected number of questions are included to gather detailed feedback from SMEs and academic researchers in order to:

* capture the responder’s awareness about the current key activities from the famhp already in place and which are relevant to academics and SMEs
* identify current and future challenges faced by SMEs and academia
* determine specific (future) needs for establishing an SME friendly policy and support at Agency’s level
* identify the main activities at the level of SMEs and academic research centers

The questionnaire can be completed on a voluntary basis and the provided input will be treated anonymously. The results of the questionnaire will be shared afterwards with the participants and will be further discussed during a follow-up workshop at the famhp later on this year in order to finalize the Agency’s action plan for setting up a national Innovation Office.

1. **METHODOLOGY**

The questions are clustered in two parts. **Part I** is a General Section about the current and potential future services (to be) foreseen at Agency’s level to promote innovation and the development of new medicinal products; **Part II** concerns the national and European scientific advice services.

**How to complete the questionnaire?**

Each question can to be answered electronically :

- By clicking in the appropriate box,

and/or

- By filling in the empty boxes with free text answers

For those questions/statements that would NOT apply to your specific situation, please leave the answer boxes open.

**How to send back the questionnaire?**

Please send the completed questionnaire back to [STAworkshop@fagg-afmps.be](mailto:STAworkshop@fagg-afmps.be) before **31/08/2016**. Please mention your name, affiliation, address, phone number and e-mail address.

1. **QUESTIONNAIRE**
2. **Responder’s profile**

**What is your organization’s profile?**

|  |  |
| --- | --- |
|  | Academia, Clinical Trial Centre associated with the university |
|  | Phase-1 unit |
|  | Academic spin-off |
|  | Hospital (public or private) |
|  | Small and medium-sized enterprise |
|  | Regulatory consultancy |
|  | Technology Transfer Office |
|  | Innovation centre |
|  | Ethics Committee |
|  | Other - please specify: |

**What is your regional location?**

|  |  |
| --- | --- |
|  | Brussels |
|  | Flanders |
|  | Wallonia |
|  | Outside Belgium |

**What is your field of activity?**

|  |  |
| --- | --- |
|  | Human |
|  | Veterinary |
|  | Human and Veterinary |
|  | Other – please specify: |

**What is your company’s sector?**

(Bio)Pharmaceutical

Early Research & Discovery /manufacturing stage

Clinical development stage

Commercialisation/Marketing stage (EU/Non-EU)

Medical Device and Technology

Development stage

Commercialisation/Marketing stage (EU/Non-EU)

1. **Part I. General Section**
2. **What are the top 3 specific difficulties/hurdles (eg. scientific, regulatory, technical (GMP), organizational, funding and finance, juridical,…) and challenges you are presently faced in R&D or/and translation of basic academic research to clinical research and please comment shortly on measures the famhp and the sector could introduce to address these challenges in the future?**

1ST CHALLENGE:

2ND CHALLENGE:

3RD CHALLENGE:

1. **What are the hurdles and challenges that are considered as emerging ones within the next 3-5 years and please comment shortly on measures (scientific, regulatory, other…) the famhp and the sector could introduce to address these challenges in the future?**

1. **To what extent are you aware of the currently existing famhp’s core services listed below?**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | To a great extent | To some extent | To a minor extent | Not aware at all |
| National scientific-technical advice |  |  |  |  |
| Joint scientific-HTA advice (famhp-RIZIV/INAMI) |  |  |  |  |
| European scientific advice (from Scientific Advice Working Party at EMA) |  |  |  |  |
| Clinical trial applications |  |  |  |  |
| Compassionate use – medical need programmes |  |  |  |  |
| Portfolio meetings |  |  |  |  |
| Marketing authorization applications |  |  |  |  |
| Variation procedures |  |  |  |  |
| GxP inspections (eg. GMP, GCP) |  |  |  |  |
| famhp’s Domains of excellence  (i.e. early phase development, vaccines, oncology) |  |  |  |  |
| famhp’s representation at EMA committees and working parties |  |  |  |  |

EMA : European Medicines Agency; HTA: Health Technology Assessment; GMP: Good Manufacturing Practice; GCP: Good Clinical Practice

1. **To what extent are you aware which famhp department/unit is responsible for the coordination of the core activities mentioned under question 3?**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| To a great extent | To some extent | To a minor extent | Not aware at all |  |
|  |  |  |  |  |

1. **Do you, as an SME or academic researcher, need specific support services from the famhp? If yes, go to question 6. If not, please skip question 6.**

|  |  |  |
| --- | --- | --- |
| Yes | Not really at present, but useful in the future | No – please skip question 6 |
|  |  |  |

1. **How relevant the following potential support activities would be to your organization?**

**Innovation Office:** Acentral contact point for information about and access to the technical/regulatory and scientific expertise of the famhp and guidance towards the famhp services and other national/EU regulatory bodies with the aim to increase the accessibility to the Agency’s services.

|  |  |  |  |
| --- | --- | --- | --- |
| Very relevant | Relevant | Not relevant | Not applicable yet |
|  |  |  |  |

**SME Innovation Office Membership**: In return for a willingness to pay for a membership (eg. renewable on a yearly basis) a number of possible advantages could be offered, such as free of charge regulatory advice in early-phase development setting, fee reductions for certain types of scientific-technical advice, scientific-technical advice presubmission guidance, fee reduction for participation to workshops/training sessions, free of charge project kick-off meetings,...

|  |  |  |  |
| --- | --- | --- | --- |
| Very relevant | Relevant | Not relevant | Not applicable yet |
|  |  |  |  |

**Project kick-off meetings:** Informal meetings providing thepossibility to present a (clinical) research project in an early stage where the Agency can give general high-level strategic, scientific and/or regulatory guidance with the aim to facilitate the early dialogue and to determine proactively the critical scientific and regulatory hurdles when initiating a project and which may impact the feasibility and funding of the project.

|  |  |  |  |
| --- | --- | --- | --- |
| Very relevant | Relevant | Not relevant | Not applicable yet |
|  |  |  |  |

**Workshops and training events eg.** Workshops on how to prepare scientific-technical (regulatory) advice requests related to drug development; advanced therapies, biosimilars, clinical trial regulations, etc.

|  |  |  |  |
| --- | --- | --- | --- |
| Very relevant | Relevant | Not relevant | Not applicable yet |
|  |  |  |  |

**SME Newsletter:** A trimestrial newsletter providing the latest national and European news from the regulatory field relevant to SMEs/academia.

|  |  |  |  |
| --- | --- | --- | --- |
| Very relevant | Relevant | Not relevant | Not applicable yet |
|  |  |  |  |

**Dedicated website to SMEs and academia:** A specific famhp website providing targeted information on SME-related initiatives and incentives at national and EU level, pharmaceutical innovation, guidance documents, specific links,…

|  |  |  |  |
| --- | --- | --- | --- |
| Very relevant | Relevant | Not relevant | Not applicable yet |
|  |  |  |  |

**Networking collaboration platforms:** to help SMEs and academia to develop partnerships with eg. other SMEs, national/EU stakeholder platforms, investors, translational medicine centers, large pharma companies, …

|  |  |  |  |
| --- | --- | --- | --- |
| Very relevant | Relevant | Not relevant | Not applicable yet |
|  |  |  |  |

**A specific national designation for innovative drug products** under (pre)clinical development intended to treat serious or life-threatening conditions where a unmet medical need exists. Such type of designation could give access to a number specific incentives such as : assignment of a dedicated famhp review team for iterative scientific/regulatory guidance, possibility to organize meetings with the sponsor and the review team throughout the development of the drug product and the product life-cycle (eg. after initial marketing authorisation), fee reductions for national scientific-technical advice/joint national scientific-HTA advice accelerated guidance towards European procedures, …

|  |  |  |  |
| --- | --- | --- | --- |
| Very relevant | Relevant | Not relevant | Not applicable yet |
|  |  |  |  |

**Other:** Please mention any other specific needs / types of support and guidance you may be needing and provide suggestions on how such specific support and guidance mechanisms for SMEs and academia could be put into place at the Agency’s level? (eg. SME-friendly policies).

1. **PART II. QUESTIONS REGARDING SCIENTIFIC-TECHNICAL/REGULATORY ADVICE**
2. **Have you already requested a national scientific-technical advice at the famhp?**

Yes

**If yes:**

Which type of advice did you request and how many times?

Type 1 (written) n =

Type 2 (face-to-face meeting; related to one expertise domain) n =

Type 3 (face-to-face meeting; multidisciplinary advice) n =

To which extent was the received national scientific-technical advice helpful for your drug development plan/project?

|  |  |  |  |
| --- | --- | --- | --- |
| To a great extent | To some extent | To a minor extent | Not at all |
|  |  |  |  |

No

**If no:**

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

Yes

In which expertise domains:  regulatory

quality

non-clinical

clinical

other, please specify:

No

Please specify the main hurdles at current for not seeking the scientific advice at national level?

To which extent are you familiar with the current famhp’s procedure to request national scientific-technical advice?

|  |  |  |  |
| --- | --- | --- | --- |
| To a great extent | To some extent | To a minor extent | Not at all |
|  |  |  |  |

1. **Have you already requested a European scientific advice (i.e. from the Scientific Advice Working Party (SAWP) at EMA)?**

Yes

If yes: how many times? n =

No

If not, please specify the main hurdles at current for not seeking the scientific advice at European level?

1. **Are you aware of the existing EMA incentives for recognized SMEs relevant to the SAWP procedures?**

|  |  |  |  |
| --- | --- | --- | --- |
| Yes, to a great extent | Yes, to some extent | Yes, to a minor extent | Not aware at all |
|  |  |  |  |

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

National scientific-technical advice fee reductions/exemptions/deferrals for SMEs/academia

|  |  |  |  |
| --- | --- | --- | --- |
| Very relevant | Relevant | Not relevant | Not applicable yet |
|  |  |  |  |

National scientific-technical advice fee reduction for innovative products in therapeutic areas with a high unmet medical need

|  |  |  |  |
| --- | --- | --- | --- |
| Very relevant | Relevant | Not relevant | Not applicable yet |
|  |  |  |  |

Fast-track scientific-technical advice (with shorter timelines) for example regarding feasibility of an early-phase development clinical trial in Belgium

|  |  |  |  |
| --- | --- | --- | --- |
| Very relevant | Relevant | Not relevant | Not applicable yet |
|  |  |  |  |

Fast-track scientific-technical advice (with shorter timelines) in case of major public health threats (eg. viral outbreaks, pandemic flue,...)

|  |  |  |  |
| --- | --- | --- | --- |
| Very relevant | Relevant | Not relevant | Not applicable yet |
|  |  |  |  |

Iterative scientific-technical advice: advice throughout the development process with a reduced fee for a follow-up advice regarding the same medicinal product

|  |  |  |  |
| --- | --- | --- | --- |
| Very relevant | Relevant | Not relevant | Not applicable yet |
|  |  |  |  |

Technical – regulatory advice regarding: GMP, GCP, GLP, GDP aspects of drug development

|  |  |  |  |
| --- | --- | --- | --- |
| Very relevant | Relevant | Not relevant | Not applicable yet |
|  |  |  |  |

Presubmission guidance for national scientific-technical advice: guidance on needed documentation, help with defining and formulating the appropriate critical questions to be addressed by the famhp’s experts….

|  |  |  |  |
| --- | --- | --- | --- |
| Very relevant | Relevant | Not relevant | Not applicable yet |
|  |  |  |  |

Other – please specify:

1. **Do you have any other comments/suggestions concerning national scientific-technical advice in order to better support and accelerate drug product development and innovation at the level of SMEs and academic research centres/hospitals?**

**Thank you very much for completing this questionnaire!**