# WORKSHOP

## "National & EU scientific regulatory support mechanisms and initiatives for innovation in drug development"

## (02/05/2016 - PM)

**Introduction:**

The federal agency of medicines and healthcare products (famhp), DG Pre-Marketing Authorization organizes an interactive workshop to illustrate the role and importance of national and European scientific-regulatory advice as support mechanisms in drug development performed by academic research centres/spin-offs, university hospitals, and in small- and medium-sized-enterprises (SMEs). This workshop will also provide an overview of the innovation support mechanisms and SME-specific incentives that are in place at the level of the European Medicines Agency (EMA). Two case study sessions are foreseen to highlight and discuss the different hurdles and challenges that investigators from academia/university hospitals and SME's are facing during the transition from basic academic research into clinical research. Finally, the workshop also aims to identify and discuss with the audience which other guidance and early dialogue mechanisms would be most needed in the future to facilitate and speed up innovation in drug development at the Belgian level.

**Main target audience:** Academic research centres/spin-offs, university hospitals, small- and medium-sized-enterprises (SMEs), Technology Transfer Offices (TTO's).

**Venue**

This workshop will be held at **EUROSTATION II building** (**Place Victor Hortaplein 40, 1060 Brussels – in front of the railway station Brussel-Zuid/Bruxelles-Midi) in meeting room "Espace Bara"**. At the ground floor of the building, you will need to register and get a visitor batch from the general reception desk after which you need to follow the workshop's signalisation to the first floor (on the right side of the reception desk) where we will welcome you in the meeting room "Espace Bara". The workshop presentations will be given in English.

The participants arriving by car can use the underground parking of the Eurostation building (Q-Park - entrance at rue de France 40 or at place Victor Horta 1060 Brussels) where the famhp has a number of parking places available at level -6 (please insert your parking ticket at level -4 in order to open the barrier). Upon return, the parking ticket can be validated at the general reception desk (i.e. on the ground floor of the building) in order to leave the parking without any charges.

The workshop is an initiative of the famhp's Scientific-Technical Advice & KM unit from the DG Pre-Marketing Authorization.

Federal agency for medicines and health products (famhp)

Eurostation II
Place Victor Horta 40/40
B-1060 Brussels

**How to register?**

Please send an e-mail to staworkshop@fagg-afmps.be mentioning your name, institute/company name, address, phone number and e-mail address. You will receive a confirmation of registration and a detailed route description afterwards. Participation to the workshop is free of charge.

## FINAL PROGRAMME

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| **12.00 – 13.00** | **Registration and walking lunch** |
| **13.00 – 13.15** | **Welcome & introduction**<br>Greet Musch, general director DG Pre-Marketing Authorisation, famhp |
| **13.15 – 13.45** | **The famhp and DG Pre-authorization – key activities in evaluation and approval of innovative drug products at national and EU level**<br>Greet Musch, general director DG Pre-Marketing Authorisation, famhp |
| **13.45 – 14.15** | **National Scientific & Technical/Regulatory advice from the famhp: current procedures and experience**<br>Christophe Lahorte, head of scientific-technical advice & KM unit, famhp |
| **14.15 – 14.45** | **The role and importance of European Scientific-Regulatory advice mechanisms – incentives for SME's & academics**<br>Dieter Deforce, Director of the Laboratory of Pharmaceutical Biotechnology, Faculty Pharmaceutical Sciences, UGent and SAWP member |
| **14.45 – 15.15** | **Case study 1: How can scientific advice be helpful in drug development? – experience from a SME**<br>Vinciane Wouters, Director Regulatory Affairs, Promethera Biosciences |
| **15.15 – 15.30** | **Questions and Answers**<br>Moderator: Christophe Lahorte, head of scientific-technical advice & KM unit, famhp |
| **15.30 – 15.45** | **Coffee break** |
| **15.45 – 16.15** | **Case study 2: The hurdles of translating basic academic research into applied clinical research**<br>Ilse Sienaert, Innovation Manager, KU Leuven Research & Development |
| **16.15 – 16.45** | **EU scientific regulatory support mechanisms and initiatives for innovation in drug development: the EMA perspective**<br>Zahra Hanaizi, Scientific officer, PRIME coordinator, Product Development Scientific Support Department, European Medicines Agency |
| **16.45 – 17.15** | **Future famhp initiatives to support drug development and innovation from SME's and academics: Questionnaire presentation**<br>Karolina Szlufcik, scientific file manager, scientific-technical advice & KM unit, famhp |
| **17.15 – 17.45** | **Questions and Answers**<br>Moderator: Christophe Lahorte, head of scientific-technical advice & KM unit, famhp |
| **17.45 – 18.00** | **Closing remarks and the way forward**<br>Greet Musch, general director DG Pre-Marketing Authorisation, famhp |

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