



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 batch from the reception desk after which you need to follow the workshop's signalisation to the first floor 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

FINAL PROGRAMME

12.00 – 13.00	Registration and walking lunch
13.00 – 13.15	Welcome & introduction 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 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 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 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 Vinciane Wouters, Director Regulatory Affairs, Promethera Biosciences
15.15 – 15.30	Questions and Answers 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 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 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 Karolina Szlufcik, scientific file manager, scientific-technical advice & KM unit, famhp
17.15 – 17.45	Questions and Answers Moderator: Christophe Lahorte, head of scientific-technical advice & KM unit, famhp
17.45 – 18.00	Closing remarks and the way forward Greet Musch, general director DG Pre-Marketing Authorisation, famhp

Access plan

Federal agency for medicines and health products - famhp

Eurostation II (Building in front of the Midi Station)

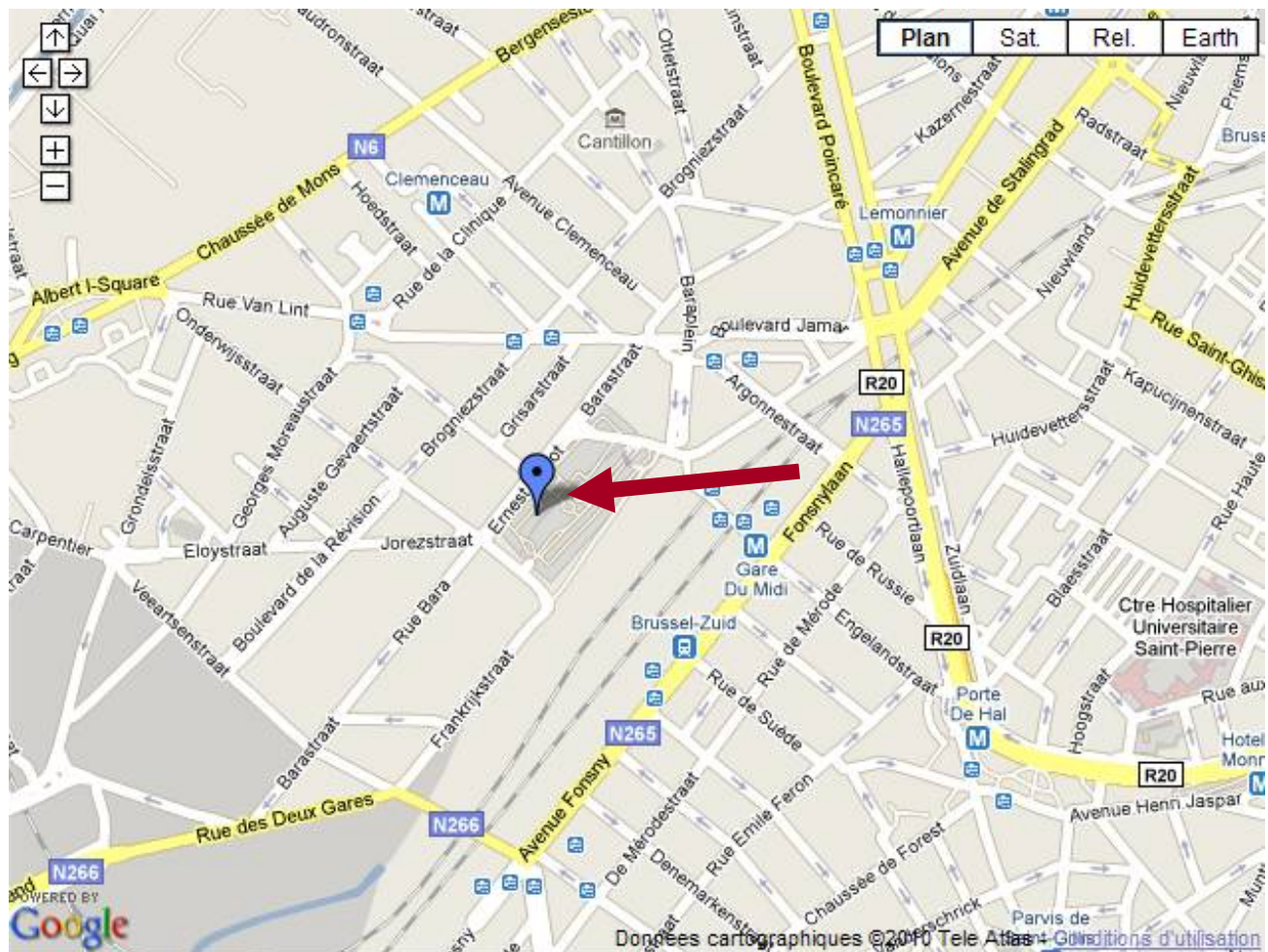
Place Victor Horta 40/40 – floors 6 and 8

B-1060 Brussels

www.afmps.be – www.fagg.be



Plan



<http://maps.google.be/maps/ms?hl=fr&ie=UTF8&msa=0&msid=115601369905894671871.000458551c1e51b3f14bc&source=embed&ll=50.837208,4.334364&spn=0.009025,0.016544&z=16>

Do you come by public transport?



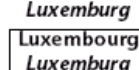
Points de vente tickets STIB
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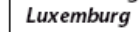
Entrée/sortie station Métro



Nom arrêt STIB bus/tram



Terminus STIB bus/tram



Arrêt STIB bus/tram



Arrêt STIB sous-sol tram



Arrêt TEC / DE LIJN



Voiture partagée CAMBIO



Numéro ligne bus / tram



Accès aux personnes
à mobilité réduite



Parking



Parking vélo



Poste



Zone piétonne



Bus STIB: 27, 49, 50, 78

Bus DE LIJN: 116, 117, 118, 134, 136, 137, 140, 144, 145

Bus TEC: W, 123 and 365

Metro: 2, 6

Train: stop at « Bruxelles-Midi »

Trams: 31, 32, 81, 82, 83 and 3, 4, 33, 51

www.stib.be

www.delijn.be

www.infotec.be

www.stib.be

www.b-rail.be

www.stib.be

Do you come by car?

Possibility to park at **level – 6** at the Q-Park near “Midi Station” (Entrance at rue de France 40 or at place Victor Horta 1060 Brussels).

To go there, take a ticket at the entrance of the car park and go down to level – 4.

Insert then your ticket at the barrier and go on down until level – 6.

The validation of your ticket is only accepted if you parked your car at level – 6.

Then take the lift, go up to level 0 and go out on place Victor Horta.

Don't forget your ticket in your car since you need to get it validated at the reception of the Eurostation II building when leaving the building before returning to the parking.

Do you come from “Brussels Airport”?

Taxi: direction « Bruxelles midi » - « Gare du midi »

Train: direction « Bruxelles Midi » stop at « Bruxelles-Midi »