AGENDA – SUBJECT TO MODIFICATIONS

BRAS SYMPOSIUM 24 OCTOBER 2017

Future Healthcare – Roads under Construction

This year's BRAS symposium - to be held on 24 October 2017 - will focus on the "roads under construction" in healthcare. It is intended to professionals interested in regulatory affairs and market access. The following topics will be addressed: (i) The launch of patient support programmes (PSP), (ii) Early Access for Medicines with Unmet Medical Need*, (iii) Update on falsified medicines, (iv). The impact of Brexit on the pharmaceutical industry, and (v) The internet of medical things. All topics, which are essential to the future of healthcare, encompass both Belgian and European (EU) aspects and will be addressed both by speakers of the authorities and the industry. The language of the symposium will be English.*

09:00 Welcome & registration

09:30 Introduction by BRAS President (Marian Coquel)

09:35 - 10.35 Block I Patient Support Programme

This presentation will address the launch of patient support programs (PSP) from the FAMHP's perspective. By assisting patients with the correct use of products and helping them manage their disease, it is expected that PSP will add great value in treatment optimisation. It is, however, important to define what is meant by "PSP" and outline the regulatory challenges posed by these programs. Among them, the line between product advertising and patients' support and the regulation of risk minimisation activities, are worth considering.

09:35 - 10:20 Patient Support Program: where are we now ? - Hugues Malonne, DG Post FAMHP & Sarah De Clercq, FAMHP

10:20 - 10:35 Q&A

10:35 - 12:45 Block II Early Access for Medicines with Unmet Medical Need

Mrs Greet Musch from FAMHP will share the FAMHP's strategy on early access. She will elaborate on other national and European early access initiatives from a regulatory perspective and focus on the state of play for the ETA procedure at national level. Mrs Florence Lévêque from RIZIV/INAMI will provide a short overview of the process for ETR.

10:35 - 11:05 State of play at national and EU level - Greet Musch, FAMHP

11:05 - 11:20 ETR: the basics – the experience - Florence Lévêque, NIHDI

11:20 - 11:50 Coffee Break

11:50 - 12:45 Panel discussion and Q&A
Mrs Greet Musch and Mrs Florence Lévêque will be joined in the panel discussion by Professor René Westhovens, president of the CAIT/CATT. All parties will share their recent experience with ETA/ETR and the pro's and con's of the current process from the view point of their professional activity.

12:45 Lunch

14:00 - 15:25 Block III Hot Topics

During this session a status update will be provided on the falsified medicines directive. Pharmaceutical companies as well as the Belgian HA is preparing on the delegated Regulation and the new medicine verification system as it will apply as of February 2019. Mr Philippe De Buck from FAGG will during his presentation discuss the progress on implementation and experiences. Another hot topic is the impact of the Brexit on the pharmaceutical industry. Therefore we have invited two speakers, Mr Xavier De Cuyper will discuss the impact on the authorities and Mr Michael Gavey will present the impact on the pharmaceutical companies.

14:00 - 14:30: Falsified medicines - Philippe De Buck - FAMHP

14:30 - 15:15: Brexit
14 :30 - 14 :50 Impact on the Authorities - Xavier De Cuyper, FAMHP
14 :50 - 15 :15 Impact on the Pharmaceutical Companies - Michael Gavey, Partner Simmons & Simmons LLP (UK)

15:15 Q&A

15:25 Coffee break

15:55 - 17:15 Bloc IV Internet of Medical Things

In 2017, the patient is no longer patient. Digital health technologies are allowing anyone to manage their own health and prevent or deal with their syndromes or diseases from the comfort of their homes via connected infrastructures of medical devices and software applications that can communicate with various healthcare IT systems. More and more, the physical intervention of healthcare professionals is no longer required. However, digital health evolves faster than the law and may struggle to find its place in the current regulatory framework. This session will present the evolution of patient centricity in the era of mobile and computerised technologies, while focusing on the legal and regulatory aspects that digital health may face.

15:55 - 16:25 The patient is no longer patient - Christophe Jauquet, Business Director Health & Medical, InSites Consulting

16:25 - 16.55 Digital Disruption in Healthcare - Kevin Raymakers, Digital Marketing Lead, Pfizer

16:55 - 17:15 Legal and regulatory challenges in digital health - Annabelle Bruyndonckx, Counsel, Simmons & Simmons LLP

17:15 Q&A

17:20 Closing remarks

17:30 End of the symposium

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Registrations through our website. (www.bras-org.be)

For registration you click on the line of the course in “Future courses and events” on the Home Page and then sign up. If you are not yet registered on the website you will be asked to do so.

The system will send you a confirmation of registration with payment modalities by return mail. If you need more assistance please contact Brigitte at bras@bras-org.be or call her on 02.757 06 29.

Fees: BRAS member **625€** - Non-BRAS member **815€**

It is understood, to be admitted to the symposium, that the fees have been pre-paid. **In case of cancellation after 16 October 2017 or no-show, the fees are due and will be invoiced.**