DIA Brexit Summit | Ensuring Continuity for Patients and Business

8 December 2017

Millennium Hotel London Mayfair, London, UK

PROGRAMME COMMITTEE

Steve Bates
Chief Executive Officer
BioIndustry Association, United Kingdom

Elizabeth Kuiper
Executive Director, Public Affairs
European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium

Alan Morrison
Vice President, International Regulatory Affairs
MSD, United Kingdom

Aimad Torqui
Director, Global Regulatory Policy
MSD, The Netherlands

Venue

Millennium Hotel London Mayfair
44 Grosvenor Square, Mayfair
London W1K 2HP
United Kingdom

Meeting room: Mayfair Suite

OVERVIEW

Brexit will have a considerable impact on the regulation and supply of medicines to patients. With the time frame for Brexit fast elapsing, governments, regulators, companies, healthcare systems and patients are all seeking to prepare for the "known unknowns" and to brace for the "unknown unknowns". However, information is scarce and not always accessible or confirmed.

This conference will bring stakeholders together to share insights and planning for operational and strategic measures being taken to prevent or minimize impacts to the development, manufacturing, regulation and supply of medicines for Europe. With the clock ticking, stakeholders will consider explicitly in this conference the dimension of time in shaping what opportunities for action companies – and indeed all stakeholders - must consider.

OBJECTIVES

- To update participants on current developments, operational and strategical challenges impacting drug development, licensing and supply to patients
- To exchange practical experiences with regulatory authorities, industry and other stakeholders in preparing for Brexit
- To provide a shared understanding of the timing for changes that will drive many of the final impacts of Brexit

WHO SHOULD ATTEND

- Regulatory and drug development professionals from Health Authorities, Academia and Industry
- Patient groups and medical research charities
- Any stakeholder interested in the impact of Brexit

Ensuring Continuity for Patients and Business

FRIDAY, 8 DECEMBER

09:00 REGISTRATION AND WELCOME COFFEE

10:00 OPENING REMARKS

Steve Bates, Chief Executive Officer, BioIndustry Association, United Kingdom

10:10 KEYNOTE SPEECH

Alan Morrison, Vice President, International Regulatory Affairs, MSD, United Kingdom; EFPIA Brexit Task Force Chair and ABPI-BIA Brexit Regulatory Co-Chair

- Industry views and preparations for Brexit
- Key issues for companies facing the transition to come
- Our key messages for UK and EU
- What companies need to do next

10:40 BREXIT CONSIDERATION OF HMA AND PAUL-EHRLICH-INSTITUT

Klaus Cichutek, President, Paul-Ehrlich-Institut, Germany

10:55 SESSION 1

MANUFACTURING AND SUPPLY – ENSURING PATIENTS' ACCESS

Session Chair: **Yvonne Stewart,** Head of Brexit Implementation, Office of the CEO and CFO, GSK, United Kingdom

This session will review issues related to the manufacturing and supply chain, for Day 1 and looking forward. This will summarise what we know, what we still don't know and what we have to do to be prepared. The session will consider these perspectives from the different areas of manufacturing and supply.

Industry Case Example: Putting Brexit Supply Impact in a Global Perspective

Elizabeth Kuiper, Executive Director, Public Affairs, European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium

UK Third Country Scenario Implications on Supply

Gerald Heddell, Director, Inspection Enforcement & Standards Division, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

A National Member State's Perspective

Paul Sexton, GMP Manager, Health Products Regulatory Authority (HPRA), Ireland

11:40 SESSION 2

CLINICAL TRIALS – FROM DIRECTIVE TO REGULATION

Session Chair: **Nick Sykes**, Senior Director, Worldwide Safety & Regulatory, Pfizer, United Kingdom

This session will review issues related to clinical research, for Day 1 and looking forward. This will summarise what we know, what we still don't know and what we have to do to be prepared. UK issues vs. EU 27: IMP supply and the complex transition via Brexit and then into the new system.

Panel Discussion with Q&A

Panellists:
Niall Dickson, Chief Executive, NHS Confederation, United Kingdom
Emma Du Four, Head of International Regulatory Policy & Intelligence, AbbVie, United Kingdom
Emlyn Samuel, Senior Policy Manager, Cancer Research UK, United Kingdom

12:25 LUNCH

13:25 SESSION 3

REGULATORY PLANNING – PREPARING FOR DAY 1

Session Chair: **Zamshed Harun**, Director, Head of European Regulatory and R&D Policy, Amgen, Switzerland
This session will review issues related to licensing, for Day 1 and looking forward. This will summarise what we know, what we still don't know and what we have to do to be prepared.

Industry: Day One Contingency Plans and Practical Considerations

Chris Walker, Vice President, European Head of Regulatory Affairs, Amgen, United Kingdom

The View from EU Regulators:

- **EMA Relocation and Business Continuity Planning: Insights in the Operations and Relocation Preparedness Task Force**
  Noël Wathion, Deputy Executive Director, European Medicines Agency (EMA), European Union
- **Decentralised Arrangements & How Other National Regulators Are Responding to the Brexit Challenge**
  Peter Bachmann, Deputy-Head, European Union and International Affairs, Federal Institute for Drugs and Medical Devices (BfArM), Germany
- **Responding to the Brexit Challenge – Ireland**
  Rita Purcell, Deputy Chief Executive, Health Products Regulatory Authority (HPRA), Ireland

The View from UK Regulators:

- **MHRA Relocation and Preparation for Post-Brexit Regulatory Framework**
  Keith McDonald, Deputy Director, Licensing Division, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

14:30 PANEL DISCUSSION WITH Q&A

Panel session on operational aspects.
Moderator: **Zamshed Harun**, Director, Head of European Regulatory and R&D Policy, Amgen, Switzerland
Panellists:
Noël Wathion, Deputy Executive Director, European Medicines Agency (EMA), European Union
Peter Bachmann, Deputy-Head, European Union and International Affairs, Federal Institute for Drugs and Medical Devices (BfArM), Germany
Klaus Cichutek, President, Paul-Ehrlich-Institut, Germany
Keith McDonald, Deputy Director, Licensing Division, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom
Rita Purcell, Deputy Chief Executive, Health Products Regulatory Authority (HPRA), Ireland
Geraldine Moore, Senior Registration Manager, Central Regulatory Affairs (EMEA), Mylan, United Kingdom; Member, Medicines for Europe, Belgium
Chris Walker, Vice President, European Head of Regulatory Affairs, Amgen, United Kingdom

15:15 COFFEE BREAK

15:45 SESSION 4

PHARMACOVIGILANCE - CONTINUED COLLABORATION BETWEEN THE UK AND EU

Session Chair: **Vicki Edwards**, Vice President, Pharmacovigilance Excellence and QPPV, AbbVie, United Kingdom

This session will review issues related to pharmacovigilance, for Day 1 and looking forward. This will summarise what we know, what we still don't know and what we have to do to be prepared.

PRAC and UK Vigilance Post-Brexit

Mick Foy, Group Manager, Vigilance Intelligence and Research Group, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

Industry Case Example: Day One Practical Considerations

Vicki Edwards, Vice President, Pharmacovigilance Excellence and QPPV, AbbVie, United Kingdom

16:15 SESSION 5

BREXIT TIME CHECK: WHAT'S NEXT FOR MEDICINES?

Session Chair: **Peter O'Donnell**, Journalist, Belgium

The aim of this session is to get to the broader level vision of what's coming next in the Brexit schedule of change. This session will bring together a broad range of stakeholders to contribute their expectations, concerns and needs for the next stages of Brexit and the future partnership arrangements.

Panellists:

Robert Johnstone, Patient Advocate; Board Member, European Forum for Good Clinical Practice (EFGCP), United Kingdom

Virginia Acha, Executive Director, Global Regulatory Policy, MSD R&D Innovation Centre, United Kingdom

Elizabeth Kuiper, Executive Director, Public Affairs, European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium

Oliver Sude, Legal Counsel, EU Affairs, European Confederation of Pharmaceutical Entrepreneurs (EUCOPE), Belgium

17:05 CLOSING REMARKS

Alan Morrison, Vice President, International Regulatory Affairs, MSD, United Kingdom; EFPIA Brexit Task Force Chair and ABPI-BIA Brexit Regulatory Co-Chair

17:15 END OF CONFERENCE

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This conference has been accredited with 5.75 credits.

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The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

DIA is an independent, non-profit organisation has its Global Center in Washington, DC, USA with the European office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China.

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REGISTRATION FORM | ID# 17113

DIA Brexit Summit | Ensuring Continuity for Patients and Business
8 December 2018 | London, UK

CATEGORY	Member *	Non-Member*
Industry	€ 900.00 ❑	€ 1'055.00 ❑
Charitable/Non-profit/Academia (Full-Time)	€ 450.00 ❑	€ 605.00 ❑

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Registration fee includes: refreshments, lunches, reception and meeting materials.

*All fees are subject to the applicable VAT. Payment due 30 days after registration and must be paid in full by commencement of the event.

TOTAL AMOUNT DUE: € _____

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- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00

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The DIA will be pleased to assist you with your registration from Monday to Friday between 08:30 and 17:00 CET.

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