THE NINTH INTERNATIONAL Pharmaceutical Compliance Congress and Best Practices Forum GHG SCIENCES

May 11 – 13, 2015

Crowne Plaza Brussels - Le Palace Brussels, Belgium





CO-SPONSOR:



OFFERED IN SEQUENCE WITH AN EFPIA STAKEHOLDER WORKSHOP

The European Federation of Pharmaceutical Industries and Associations (EFPIA) is offering an independent EFPIA STAKEHOLDER WORKSHOP on Monday, May 11, 2015.



FEATURING A CHIEF COMPLIANCE OFFICERS ROUNDTABLE:



Martin Fürle, Vice President, General Counsel and Chief Compliance Officer, Daiichi Sankyo Europe GmbH, Munich, Germany



Thomas K. Hauser, LLM, Chief Compliance Officer, Siemens Healthcare: Board Member, ETHICS, Nürnberg, Germany



Mwana Lugogo, Chief Compliance Officer, Takeda, Zurich, Switzerland



Jeff Rosenbaum, Vice President, Chief Compliance Officer, Vertex Pharmaceuticals, Boston, MA, USA

DIAMOND **GRANTOR:**



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CONTINUING EDUCATION CREDITS: Accounting Professionals:

Approved for up to 13 NASBE CPE credits.

Compliance Professionals:

Approved for up to 13.0 Compliance Certification Board CCB Credits.

Attorneys: The Congress is currently pending approval to offer California and Pennsylvania MCLE Credit.

GRANTORS:







King & Spalding











KEYNOTE SPEAKERS:



Robert Barrington, PhD, Executive Director, Transparency International-UK, London, UK



Richard Bergström, Director General, European Federation of Pharmaceutical Industries and Associations (EFPIA), Brussels, Belgium



Marc de Garidel, Chairman and Chief Executive Officer, Ipsen; Vice President, European Federation of the Pharmaceutical Industries and Associations (EFPIA), Paris, France



Brendan Shaw, PhD, Assistant Director General, International Federation of Pharmaceutical Manufacturers and Associations

(IFPMA), Geneva, Switzerland

CONGRESS CO-CHAIRS:

www.InternationalPharmaCongress.com



Online: In your own office or home live via the Internet with 24/7 access

for six months

Ann Beasley, Chief Compliance Officer, Biogen Idec International, GmbH; Former Global Compliance Officer, Novartis Pharma AG; Board Member and Co-chair, Strategic Committee, International Society of Healthcare, Ethics and

Compliance Professionals (ETHICS), Cambridge, MA, USA

See page 2



Michael Bartke, PhD, Director, Compliance Management, Daiichi Sankyo Europe GmbH; Co-chair, EFPIA Compliance Committee, Munich, Germany



Dominique Laymand, Esq., President, International Society of Healthcare Ethics and Compliance Professionals (ETHICS), Paris, France



Roeland Van Aelst, Regional Vice President - HCCO MD&D EMEA and Canada, Office of Health Care Compliance and Privacy, Johnson & Johnson; Board Member,

International Society of Healthcare, Ethics and Compliance Professionals (ETHICS); Chairman, MedTech Compliance Network, Brussels, Belgium

FEATURING PLENARY SESSIONS:

- Keynote Address: Innovation, Ethics and Compliance
- Keynote Address: The C-Suite Perspective
- European Commission Keynote Address
- Transparency International Keynote Address
- Global Chief Compliance Officer Roundtable
- Understanding the New Life Sciences Marketplace
- The New Marketplace: The Purchasers Perspective
- Roundtable on Compliance Issues Raised by the Changing Marketplace
- IFPMA International Codes Update
- Global Transparency Roundtable
- · Anticorruption 2.0: Thinking Strategically/ Managing Risks
- Crafting the Compliance Program of the Future
- · The Evolution of the Role and Responsibility of Compliance Professionals

AND MINI-SUMMITS:

- Basic Compliance Concepts and Skills I
- How to Engage with Medical Societies and Congress Organizers in Order to Ensure that Industry Standards are Understood and Taken into Consideration
- Competition/Antitrust Law Update
- Global Transparency, Disclosure and Aggregate Spend Update
- Annual Central and Eastern European (CEE) Compliance Update
- Basic Compliance Concepts and Skills II
- **Global Compliance Auditing and Monitoring Best Practices**
- VIII: What's Next in Global Compliance?
- IX: Clinical Trials Compliance
- Data Analytics Supporting Compliance Monitoring, Risk Prevention and Mitigation
- XI: Advanced Strategies in Compliance Training
- Annual Middle East/Africa European (MEA) Compliance Update
- XIII: Medical Device Compliance Issues Update
- XIV: Advanced Issues in Anti-corruption Compliance
- XV: Best Practices in Third Party Supplier Management

he First International Pharmaceutical Compliance Congress and Best Practices Forum was held in Brussels in June 2007 to bring together company compliance professionals, regulators, lawyers, and consultants working in this interesting and expanding field. The purpose was to hold a truly global conference, addressing the key issues of the day. The first international conference agenda was mainly developed by company compliance professionals around topics that they wanted to know more about, which is one of the great strengths of these conferences and continues to be one of their key features.

In addition to Brussels, other international conferences have been held in Paris (2008), Rome (2009), Berlin (2010), Istanbul (2011), Budapest (2012) and Madrid (2013). Over the years the international conference agendas have developed to focus particular streams on the European Union (EU), Central and Eastern Europe (CEE), and Middle East and Africa (MEA), in addition to plenary sessions on global topics. The 2015 conference continues this trend.

In 2015 we are pleased to return to Brussels. The Ninth International Pharmaceutical Compliance Congress and Best Practices Forum will address the leading pharmaceutical and medical device ethics and compliance issues in the European Union (EU) and include updates from Central and Eastern Europe (CEE), the Middle East and Africa (MEA) and India. The Congress will feature the following plenary sessions and mini summits:

FEATURING PLENARY SESSIONS:

- Keynote Address: Innovation, Ethics and Compliance
- Keynote Address: The C-Suite Perspective
- **European Commission Keynote Address**
- Transparency International Keynote Address
- Global Chief Compliance Officer Roundtable
- Understanding the New Life Sciences Marketplace
- The New Marketplace: The Purchasers Perspective
- Roundtable on Compliance Issues Raised by the Changing Marketplace
- IFPMA International Codes Update
- Global Transparency Roundtable
- Anticorruption 2.0: Thinking Strategically/Managing Risks
- Crafting the Compliance Program of the Future
- The Evolution of the Role and Responsibility of Compliance Professionals

AND MINI SUMMITS:

- I: Basic Compliance Concepts and Skills I
- II: How to Engage with Medical Societies and Congress Organizers in Order to Ensure that Industry Standards are Understood and Taken into Consideration
- III: Competition/Antitrust Law Update
- IV: Global Transparency, Disclosure and Aggregate Spend Update
- V: Annual Central and Eastern European (CEE) Compliance Update
- VI: Basic Compliance Concepts and Skills II
- VII: Global Compliance Auditing and Monitoring Best Practices
- VIII: What's Next in Global Compliance?
- IX: Clinical Trials Compliance
- X: Data Analytics Supporting Compliance Monitoring, **Risk Prevention and Mitigation**
- XI: Advanced Strategies in Compliance Training
- XII: Annual Middle East/Africa European (MEA) Compliance Update
- XIII: Medical Device Compliance Issues Update
- XIV: Advanced Issues in Anti-corruption Compliance
- XV: Best Practices in Third Party Supplier Management

In 2013 the new International Society of Healthcare Ethics and Compliance Professionals (ethics) has become the Congress sponsor and the Pharmaceutical Compliance Forum (PCF) has become the Congress co-sponsor.

WHO SHOULD ATTEND:

- · Pharmaceutical Manufacturers
- · Generic Pharmaceutical Manufacturers
- · Medical Device Manufacturers
- · Site Management Organizations
- · Clinical Research Organizations
- · Management Companies
- · Wholesale, Retail, Mail Order and Internet Pharmacies
- · Health Care Regulators and Policy Makers
- · Pharmaceutical and Health Care **Executives and Board Members**

- Regulatory and Compliance Professionals
- **Medical Directors**
- Physicians and Other **Health Care Professionals**
- Pharmacists
- · Food and Drug Law Attorneys
- · Health Care Attorneys and In-house Counsel
- Compliance Officers
- · Privacy Officers
- Ethics Officers and Corporate Social Responsibility Personnel

- Pharmaceutical Consultants
- Investment Bankers
- Venture Capitalists
- · Health Services Researchers and Academics
- Auditors
- · Promotion Signatories/ Approvers
- · Risk Management Personnel
- · Governmental Policy Makers and Regulators

SPONSOR:



INTERNATIONAL SOCIETY OF HEALTHCARE ETHICS AND COMPLIANCE PROFESSIONALS (ETHICS) is a new professional Society established in 2012 currently comprised of around 50 members, all active in major pharma and medical device companies. ETHICS intends to become the reference professional society for ethics and compliance practitioners in the healthcare sector with the ultimate goal to contributing to the professional development of individuals and the success of ethics and compliance organizations.

CO-SPONSOR:



PROFESSIONALS

THE PHARMACEUTICAL COMPLIANCE FORUM (PCF) is PHARMACEUTICAL a coalition of senior compliance professionals and legal counsel from more than 50 of the largest research-based pharmaceutical manufacturers. The PCF was founded

in early-1999 by compliance professionals from the pharmaceutical industry to promote effective corporate compliance programs. The members meet twice a year, for two days, focusing on open and informal sharing of compliance information, best practices, and current developments in the field, and sponsors a three-day compliance congress each Fall.

REGISTRATION DISCOUNTS AVAILABLE TO ASSOCIATION MEMBERS:

- International Society of Healthcare Ethics and Compliance Professionals (ethics)
- Pharmaceutical Compliance Forum (PCF)
- International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)
- European Federation of Pharmaceutical Industries and Associations (EFPIA)
- Pharmaceutical Research and Manufacturers Association, Gulf (PhRMAG)

PARTICIPATION OPTIONS

TRADITIONAL ONSITE ATTENDANCE

Simply register, travel to the conference city and attend in person.

PROS:

subject matter immersion; professional networking opportunities; faculty interaction.



LIVE AND ARCHIVED INTERNET ATTENDANCE

Watch the conference in live streaming video over the Internet and at your convenience at any time 24/7 for six months following the event.

The archived conference includes speaker videos and coordinated PowerPoint presentations.



Live digital feed and 24/7 Internet access for the next six months: accessible in the office, at home or anywhere worldwide with Internet access: avoid travel expense and hassle; no time away from the office.



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SAVE THE DATE

EFPIA STAKEHOLDERS WORKSHOP PROGRAMME



The European Federation of Pharmaceutical Industries and Associations (EFPIA) is offering an independent EFPIA STAKEHOLDER WORKSHOP on Monday, May 11, 2015 from 10:30 am to 3 pm.

Programme to be announced.

Chaired by:



Richard Bergström, Director General, European Federation of Pharmaceutical Industries and Associations (EFPIA); Former Director General, LIF Sweden, Brussels, Belgium

MONDAY, MAY 11, 2015

INTERNATIONAL PHARMA CONGRESS DAY I: OPENING PLENARY SESSION

3:30 pm Welcome



Dominique Laymand, Esq., President, International Society of Healthcare Ethics and Compliance Professionals (ETHICS), Paris, France (Co-chair)

3:35 pm

The Gabor Danielfy Memorial Keynote Overview: International Pharma Congress Vision and Overview



Ann Beasley, Chief Compliance Officer, Biogen Idec International, GmbH; Former Global Compliance Officer, Novartis Pharma AG; Board Member and Co-chair, Strategic Committee, International Society of Healthcare, Ethics and Compliance Professionals (ETHICS), Cambridge, MA, USA (Co-chair)



Michael Bartke, PhD, Director, Compliance Management, Daiichi Sankyo Europe GmbH; Co-chair, EFPIA Compliance Committee, Munich, Germany (Co-chair)



Dominique Laymand, Esq., President, International Society of Health-care Ethics and Compliance Professionals (ETHICS), Paris, France (Co-chair)



Roeland Van Aelst, Regional Vice President - HCCO MD&D EMEA and Canada, Office of Health Care Compliance and Privacy, Johnson & Johnson; Board Member, International Society of Healthcare, Ethics and Compliance Professionals (ETHICS); Chairman, MedTech Compliance Network, Brussels, Belgium (Co-chair)

4:00 pm

Keynote: Innovation, Ethics and Compliance



Richard Bergström, Director General, European Federation of Pharmaceutical Industries and Associations (EFPIA); Former Director General, LIF Sweden, Brussels, Belgium

4:30 pm

Transparency International Keynote Address:



Robert Barrington, PhD, Executive Director, Transparency International-UK, London, UK

5:00 pm

Global Chief Compliance Officer Roundtable



Martin Fürle, Vice President, General Counsel and Chief Compliance Officer, Daiichi Sankyo Europe GmbH, Munich, Germany



Thomas K. Hauser, MA, HSG, Global Chief Compliance Officer, Siemens Healthcare; Board Member, ETHICS, Erlangen, Germany



Mwana Lugogo, Chief Compliance Officer, Takeda, Zurich, Switzerland



Jeff Rosenbaum, Vice President, Chief Compliance Officer, Vertex Pharmaceuticals; Former Executive Director, Global Head of Ethics and Compliance, Novartis Oncology, Boston, MA, USA



Kris Curry, Principal, Fraud Investigation and Dispute Services, EY; Former Vice President, Health Care Compliance, Pharmaceuticals Group, Johnson & Johnson, Philadelphia, PA, USA (Moderator)

6:15 pm

ADJOURNMENT AND NETWORKING RECEPTION

TUESDAY, MAY 12, 2015

7:30 am

Registration Commences

DAY II: MORNING PLENARY SESSION

8:30 am

Welcome and Overview



Roeland Van Aelst, Regional Vice President - HCCO MD&D EMEA and Canada, Office of Health Care Compliance and Privacy, Johnson & Johnson; Board Member, ETHICS; Chairman, MedTech Compliance Network, Brussels, Belgium (Co-chair)

8:45 am

Understanding the New Life Sciences Marketplace



Frank Wartenberg, PhD, President, Central Europe, IMS Health, Frankfurt/Main, Germany

9:15 am

The New Marketplace: The Purchasers Perspective



Günter Danner, MA, PhD, Associate Director, European Representation, German Social Insurance, Brussels, Belgium



Klaus Hilleke, PhD, Chief Executive Officer and Head, Global Life Science Division, Simon-Kucher & Partners, Bonn, Germany



Frank Wartenberg, PhD, President, Central Europe, IMS Health, Frankfurt/Main, Germany



Andrew White, Head of Medicine Management - NHS, Greater Manchester Commissioning Support Unit, Manchester, UK



Olivier Wong, MD, Specialist in Family Medicine; Former Voting Member, French Transparency Committee, Paris, France



Michael Bartke, PhD, Director Compliance Management, Daiichi Sankyo Europe GmbH; Co-chair, EFPIA Compliance Committee, Munich, Germany (Moderator)

10:15 am



Marc de Garidel, Chairman and Chief Executive Officer, Ipsen; Vice President, European Federation of the Pharmaceutical Industries and Associations (EFPIA); Knight, National Order of the Legion of Honor (France), Paris, France

Keynote: Business Leader Perspective

10:45 am

Break

11:15 am

Roundtable on Compliance Issues Raised by the Changing Marketplace

- Market Access
- · Value-added Services
- Tendering
- Pricing
- Transparency
- Comparative Effectiveness Research
- Managing Third Party Relationships



Heather Simmonds, Director and Chair, Code of Practice Panel, Prescription Medicines Code of Practice Authority, London, UK



Nadine Sprangers, Senior Director Pricing, Reimbursement and Market Access, Daiichi Sankyo Europe GmbH; Former Senior Manager, Global Strategic Pricing, GlaxoSmithKline Biologicals, Munich, Germany



David O'Shaughnessy, Vice President, Compliance, Emerging Markets, Quintiles; Board Member, ETHICS; Former Vice President Compliance, International Pharmaceuticals, GSK; Former Vice President, Global Compliance Strategy, AstraZeneca, Reading, UK



Brian Riewerts, Principal, Global Governance Risk and Compliance Leader, Pharmaceutical and Life Sciences Advisory, PwC, Baltimore, MD, USA (Moderator)



NETWORKING LUNCHEON

HOTEL INFORMATION/RESERVATIONS

The Crowne Plaza Brussels - Le Palace is the official hotel for the 9th International Pharmaceutical Compliance Congress. A special group rate of €160.00 single per night has been arranged for Congress Attendees. The room rate includes breakfast and complimentary wi-fi in the guest room. To make hotel reservations please call +32-2-2036200. Please mention IPC 2015 to receive the group rate. Information for making a reservation online can be found on the conference website at www.InternationalPharmaCongress.com at the Travel/Hotel page.

Reservations at the group rate will be accepted until the cut-off date of **April 11, 2015.** After this, reservations will be accepted on a space-available basis at the prevailing rate.

The Crowne Plaza Brussels - Le Palace • Rue Gineste 3, Brussels 1210, Belgium

Hotel Front Desk: +32-2-2036200



DAY II: AFTERNOON MINI SUMMITS

MINI SUMMITS ROUND I

MINI SUMMIT I: BASIC COMPLIANCE CONCEPTS AND SKILLS I

1:30 pm Introductions, Panel Discussion and Q&A

Sue Egan, Director and Principal Consultant, Sue Egan Associates; Former Vice President Compliance, AstraZeneca, Great Missenden, Buckinghamshire, UK

Keith M. Korenchuk, JD, MPH, *Partner, Arnold & Porter LLP, Washington, DC, USA (Moderator)*

2:45 pm Transition Break

MINI SUMMIT II: HOW TO ENGAGE WITH MEDICAL SOCIETIES AND CONGRESS ORGANIZERS IN ORDER TO ENSURE THAT INDUSTRY STANDARDS ARE UNDERSTOOD AND TAKEN INTO CONSIDERATION

1:30 pm Introductions, Panel Discussion and Q&A

Christian-Claus Roth, Head Global Event Governance, Novartis Pharma; Co-President, International Pharmaceutical Congress Advisory Association (IPCAA), Basel, Switzerland (Moderator)

2:45 pm Transition Break

MINI SUMMIT III: COMPETITION/ANTITRUST LAW UPDATE

1:30 pm Introductions, Panel Discussion and Q&A

Catherine Higgs, MA Cantab, Senior Legal Counsel, AstraZeneca, Alderley, UK

Ulf H. Grundmann, JD, Partner, Life Science Practice Group, King & Spalding, Frankfurt, Germany (Co-moderator)

Fiona Carlin, LLB, Managing Partner, European and Competition Law Practice, Baker & McKenzie, Brussels, Belgium (Co-moderator)

2:45 pm Transition Break

MINI SUMMIT IV: ADVANCED ISSUES IN GLOBAL TRANSPAR-ENCY, DISCLOSURE AND AGGREGATE SPEND COMPLIANCE

1:30 pm Introductions, Panel Discussion and Q&A

Katrina Cahill, Global Transparency Lead, Biogen Idec, Weston, MA, USA

Nina Stoeckel, LLM, Head of Group Compliance Programs, Merck KGaA, Darmstadt, Germany

John Patrick Oroho, Esq., Executive Vice President and Chief Strategy Officer, Porzio Life Sciences, LLC; Principal, Porzio, Bromberg & Newman PC, Morristown, NJ, USA

Brian Sharkey, Esq., Counsel, Porzio, Bromberg & Newman; Director of Compliance and Legal Affairs, Porzio Governmental Affairs, LLC, Morristown, NJ, USA (Moderator)

2:45 pm Transition Break

MINI SUMMIT V: ANNUAL CEE COMPLIANCE UPDATE

1:30 pm Introductions, Discussion and Q&A

Paul J. Melling, Esq., Founding Partner, Baker & McKenzie - CIS, Limited, Moscow, Russia

Madina Plieva, PhD, Legal Director, Association of International Pharmaceutical Manufacturers (AIPM); Former Head of Legal Department, Kutafin Moscow State Law Academy, Moscow, Russia

Dumitru Uta, MD, MBA, CCEP, Ethics and Compliance Director, South-East Europe, Eli Lilly and Company, Bucharest, Romania

Mariusz Witalis, Partner, Fraud Investigation and Dispute Services, EY, Warsaw, Poland (Moderator)

2:45 pm Transition Break

MINI SUMMITS ROUND II

MINI SUMMIT VI: BASIC COMPLIANCE CONCEPTS AND SKILLS II

3:00 pm Introductions, Panel Discussion and Q&A

Zeynep Didem Değirmencioğlu, Head of Compliance, Intercontinental Region, Merck KGaA, Istanbul, Turkey

Keith M. Korenchuk, JD, MPH, Partner, Arnold & Porter LLP, Washington, DC, USA (Moderator)

4:15 pm Transition Break

MINI SUMMIT VII: GLOBAL COMPLIANCE AUDITING AND MONITORING BEST PRACTICES

3:00 pm Introductions, Panel Discussion and Q&A

Gary F. Giampetruzzi, Esq., Partner, Paul Hastings; Former Vice President and Assistant General Counsel, Head of Government Investigations, Pfizer Inc., New York, NY, USA

Dominique Laymand, Esq., President, International Society of Healthcare Ethics and Compliance Professionals (ETHICS), Paris, France

Pascale Paimbault, President, CEO and Founder, Consulting Alley; Treasurer and Strategic Committee Member, ETHICS; Former Chief Compliance Officer EMEA, Wright Medical Inc.; Former Senior Director, Compliance and Ethics, Business Program. EMEA, Bristol-Myers Squibb, Paris. France

Fabien Roy, DESS European Law, Senior Associate, Hogan Lovells, Brussels, Belgium

Kip Ebel, MBA, Principal, Fraud Investigation and Dispute Services, EY, New York, NY, USA (Moderator)

4:15 pm Transition Break

MINI SUMMIT VIII: WHAT'S NEXT IN GLOBAL COMPLIANCE

3:00 pm Introductions, Panel Discussion and Q&A

Peter Dieners, Esq., Partner and Head, Global Healthcare and Life Sciences Group, Clifford Chance; Co-chair, Legal Affairs Focus Group (LAFG), EUCOMED; Co-chair, Compliance Network (CN), EUCOMED, Düsseldorf, Germany

Angelique Lee-Rowley, Esq., Vice President, Associate General Counsel and Compliance Officer Spectrum Pharmaceuticals, Inc.; Former Director, Compliance, Siemens Healthcare, Irvine, CA, USA

Abdul Luheshi, MBA, Vice President, Health Care Compliance, Johnson & Johnson, Former Co-chair, Asia Pacific Pharma Congress, London, UK

Nathalie Raynaud, Corporate Compliance Director, Global Compliance and Business Integrity Department, Sanofi, Paris, France

Fatima Wolff, Esq. (Invited), Senior Compliance Counsel, Boston Scientific Corporation, Miami, FL, USA

Andy Bender, MS, MBA, President and Founder, Polaris, New York, NY, USA (Moderator)

4:15 pm Transition Break

MINI SUMMIT IX: CLINICAL TRIALS COMPLIANCE — THE NEW CLINICAL TRIALS REGULATIONS, THE EFPIA/ PhRMA JOINT PRINCIPLES AND THE NEW EMA POLICY

3:00 pm Introductions, Panel Discussion and Q&A

Eva Gardyan-Eisenlohr, Esquire (Germany)/DIAP (ENA, Paris), General Counsel and Compliance Officer, Bayer Pharma AG; Member, Strategic Committee, ETHICS, Berlin, Germany

Alice Lex, PhD, Health Care Compliance Officer, Janssen Research and Development in EMEA, Johnson & Johnson, Neuss, Germany

Daniel A. Kracov, Esq., Partner and Head, FDA and Healthcare Practice, Arnold & Porter, Washington, DC, USA (Co-moderator)

Elisabethann Wright, Esq., Partner, Hogan Lovells; Former Senior Legal Officer and Hearing Officer, EFTA Surveillance Authority, Brussels, Belgium (Co-moderator)

4:15 pm Trans

MINI SUMMIT X: DATA ANALYTICS SUPPORTING COMPLI-ANCE MONITORING, RISK PREVENTION AND MITIGATION

3:00 pm Introductions, Panel Discussion and Q&A

Carl Judge, *Director, Fraud Investigation and Dispute Services, EY, London, UK*

Dario Ghoddousi, Senior Vice President Global Transparency and MDM Solutions, Cegedim, Paris, France (Moderator)

4:15 pm Transition Break

MINI SUMMITS ROUND III

MINI SUMMIT XI: ADVANCED STRATEGIES IN COMPLIANCE TRAINING

4:30 pm Introductions, Panel Discussion and Q&A

Jacques Fontas, Executive Counsel, Compliance Leader, GE Healthcare Europe; Member, Strategic Committee, ETHICS, Paris, France

Piergiorgio Pepe, LLB, Masters in EU Law, EEMEA Director, Ethics and Compliance, AbbVie; Former Director, Compliance and Ethics, EMEA, Bristol-Myers Squibb, Paris Area, France

Marie Vandepaer, Senior Director, Compliance Awareness and Solution-Corporate Compliance, UCB SA, Brussels Area, Belgium

Cécile Gousset, Associate Vice President Compliance Risk Assessment, Education and Monitoring, Global Compliance, Sanofi; Member, Strategic Committee, ETHICS, Paris, France (Moderator)

5:45 pm ADJOURNMENT

MINI SUMMIT XII: ANNUAL MEA COMPLIANCE UPDATE

4:30 pm Introductions, Panel Discussion and Q&A

Flavia Bollinger, Head Integrity and Compliance MENA (Middle East, North Africa), Novartis Pharma Services AG, Dubai, UAE

Zeynep Didem Değirmencioğlu, Head of Compliance, Intercontinental Region, Merck KGaA, Istanbul, Turkey

Dr. Yacoub Haddad, Government Affairs Director MEAP Region, Abbvie; Chair, Pharmaceutical Research and Manufacturers Association, Gulf (PhRMAG), Dubai, UAE

Laura Nassar, Regional Pharma HCC Officer, Middle East, West Asia and Africa, Johnson & Johnson, Beirut, Lebanon

Khaled Mansour, Area Managing Director, Middle East, West Asia and Africa, Janssen; Chair, MEA Regional Ethics Group (LERB), Cairo, Egypt (Moderator)

5:45 pm ADJOURNMENT

MINI SUMMIT XIII: LESSONS FROM GLOBAL COMPLIANCE ISSUES AND INITIATIVES IN THE MEDICAL DEVICE SECTOR

4:30 pm Introductions, Panel Discussion and Q&A

Thomas K. Hauser, LLM, Global Chief Compliance Officer, Siemens Healthcare; Board Member, ETHICS, Nürnberg, Germany

Aline Lautenberg, General Counsel - Director, Legal and Compliance, Eucomed, EDMA and MedTech Europe, Brussels, Belgium

Christine Sainvil, Compliance Officer, EthicalMedTech, Brussels, Belgium

Roeland Van Aelst, Regional Vice President - HCCO MD&D EMEA and Canada, Office of Health Care Compliance and Privacy, Johnson & Johnson; Board Member, ETHICS; Chairman, MedTech Compliance Network, Brussels, Belgium

Jean McKiernan, Director, Advisory Pharmaceutical and Life Sciences, PwC LLP, Chicago, IL, USA (Moderator)

5:45 pm ADJOURNMENT



MINI SUMMIT XIV: ADVANCED ISSUES IN GLOBAL ANTI-BRIBERY COMPLIANCE

4:30 pm Introductions, Panel Discussion and Q&A

Suzanne Durdevic, LLM, Senior Director, General Counsel, EMEA, Boston Scientific International; Chair, Legal Affairs Focus Group, EUCOMED; Member, Strategic Committee, ETHICS, Paris, France

Erinn Hutchinson, Partner, Advisory Services, PwC, Philadelphia, PA

Michele Tagliaferri, Esg., Counsel, Sidley Austin LLP, Brussels, Belgium

Michael K. Loucks, Esq., Partner, Skadden Arps LLP; Former Acting United States Attorney, District of Massachusetts, Washington, DC, USA (Moderator)

5:45 pm ADJOURNMENT

MINI SUMMIT XV: BEST PRACTICES IN THIRD PARTY SUPPLIER MANAGEMENT

4:30 pm Introductions, Panel Discussion and Q&A

Brian K. Beeler, MBA, JD, Senior Vice President, Legal and Chief Compliance Officer, Horizon Pharma, Dublin, Ireland

Gary F. Giampetruzzi, Esq., Partner, Paul Hastings; Former Vice President and Assistant General Counsel, Head of Government Investigations, Pfizer Inc., New York, NY, USA

Maurits J.F. Lugard, MA, JD, LLM, Partner, Sidley Austin LLP; Former Member of the European Commission's Legal Service, Brussels, Belgium

Stephen Nguyen-Duc, Office of Ethics and Compliance, Regional International Operations, Western Europe and Canada, Abbvie; Former Director, Ethics and Compliance Officer; Member of the Executive Committee, Eli Lilly; Member, Strategic Committee Member, ETHICS, Paris, France

Melda Tanyeri, MS, MBA, *Director, Fraud Investigation and Dispute Services, EY, London, UK (Moderator)*

5:45 pm ADJOURNMENT

EXHIBIT AND SPONSORSHIP OPPORTUNITIES:

Take advantage of this unique opportunity to expand your reach! The Congress is attended by highly influential and experienced professionals. Sponsorship offers you strategic positioning as an industry leader. For more information call 206-673-4815 or email exhibits@hcconferences.com.

WEDNESDAY, MAY 13, 2015

7:30 am **Registration Commences**

DAY III: MORNING PLENARY SESSION

8:30 am

Welcome and Introductions



Ann Beasley, Chief Compliance Officer, Biogen Idec International, GmbH; Former Global Compliance Officer, Novartis Pharma AG; Board Member and Co-chair, Strategic Committee, ETHICS, Cambridge, MA, USA

IFPMA International Codes Update



Brendan Shaw, PhD, Assistant Director General, International Federation of Pharmaceutical Manufacturers and Associations (IFPMA); Former Chief Executive, Medicines Australia, Geneva, Switzerland

9:15 am

Global Transparency Roundtable



Holger Diener, PhD, Managing Director, Association of Voluntary Self-Regulation for the Pharmaceutical Industry, Berlin, Germany



George Fife, Executive Director, Compliance and Ethics, Bristol-Myers Squibb; Former Compliance and Internal Audit Leader, EMEA, GE Healthcare, Paris, France



Dr. Gudula Petersen, Chief Compliance Officer, Europe and Australia, Grunenthal, Aachen, Germany



Jose F. Zamarriego Izquierdo, *Director Unidad de Supervision* Deontologica, FARMAINDUSTRIA, Madrid, Spain



Michael Bartke, PhD, Director Compliance Management, Daiichi Sankyo Europe GmbH; Co-chair, EFPIA Compliance Committee, Munich, Germany (Moderator)

10:15 am

Break



Anticorruption 2.0: Thinking Strategically/ **Managing Risks**



Nicola Bonucci, DEA, DESS, LLM (Invited), Director, Directorate for Legal Affairs and Coordinator for Accession, Organisation for Economic Co-operation and Development (OECD); Former Legal Officer with the Food and Agriculture Organisation, United Nations, Paris, France



Peter Dieners, Esq., Partner and Head, Global Healthcare and Life Sciences Group, Clifford Chance; Co-chair, Legal Affairs Focus Group (LAFG), EUCOMED; Co-chair, Compliance Network (CN), EUCOMED, Düsseldorf, Germany



Nathaniel Edmonds, Esq., Partner, Paul Hastings; Former Assistant Chief, Foreign Corrupt Practices Act (FCPA), Fraud Section in the Criminal Division, United States Department of Justice, Washington, DC, USA



Paul J. Melling, Esq., Founding Partner, Baker & McKenzie - CIS, Limited, Moscow, Russia



Joseph B. Tompkins, Jr., Partner, Sidley Austin LLP; Former Deputy Chief of the Fraud Section, Criminal Division, United States Department of Justice, Washington, DC, USA



Ted Acosta, Esq., Principal and Americas Vice Chair, Risk Management, EY; Former Senior Counsel, Office of Inspector General, United States Department of Health and Human Services, New York, NY, USA and Paris, France (Moderator)

11:30 am

Crafting the Compliance Program of the Future and the Evolution of the Role and Responsibility of Compliance Professionals



Ann Beasley, Chief Compliance Officer, Biogen Idec International, GmbH; Former Global Compliance Officer, Novartis Pharma AG; Board Member and Co-chair, Strategic Committee, ETHICS, Cambridge, MA, USA



Michael Bartke, PhD, Director Compliance Management, Daiichi Sankyo Europe GmbH; Co-chair, EFPIA Compliance Committee, Munich, Germany



Isaure Kergall-Gayet, DEA-Law, Compliance and Business Integrity Director, France, Global Compliance and Business Integrity Department, Sanofi; Former Vice President, Chief Ethics and Compliance Officer, Ispen,



Dominique Laymand, Esq., President, International Society of Healthcare Ethics and Compliance Professionals (ETHICS), Paris, France



Arthur Muratyan, Esq., Secretary General, International Society of HealthCare Ethics and Compliance Professionals (ETHICS); Former Vice President, Head of Legal, Corporate and Global Compliance Officer, Sanofi, Paris, France



Roeland Van Aelst. Regional Vice President - HCCO MD&D EMEA and Canada, Office of Health Care Compliance and Privacy, Johnson & Johnson: Board Member, ETHICS; Chairman, MedTech Compliance Network, Brussels, Belgium



Marc Bartel, MBA, Master of Comparative Law, Master of Comparative Jurisprudence, Managing Partner, France, and Managing Partner EMEA, Legal and Compliance Practice, Heidrick & Struggles, London, UK and Paris, France (Moderator)

12:30 pm

ADJOURNMENT



MEMBERSHIP APPLICATION FORM

Please complete and return a scanned copy/the original form to one of the addresses listed at the bottom of this application form. You can also apply online at: **www.ethicspros.com**.

Cthics	1. Name:				
INTERNATIONAL SOCIETY OF HEALTHCARE ETHICS AND COMPLIANCE PROFESSIONALS	2. Telephone:		3. Email:		
	4. Company:	. Company: 5. Position:			
	6. Please specify whether you wish to join ETHICS as:	☐ A Benefactor Men	nber (fee for 2015 is 1500€)	☐ An Active Member (fee for 2015 is 200€)	
Please describe briefly	your function and reporting line:				
. What is your level of	Seniority in your current position?				
•					
. What is your level of	Seniority within the Compliance/Ethics functions?				
ETURN completed an	plication form to one of the following addresses:				
	tion's email: application@ethicspros.com	c. Via Post to:	ETHICS c/o Clifford Cha	ance	
b. To our Secretary General: Arthur.muratyan@gmail.com			9 Place Vendôme • 75002 Paris • France		

The Live Webcast and Archive Features Side by Side Presentation Video with Synched PowerPoint Presentation Slides



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SIXTEENTH PHARMACEUTICAL REGULATORY AND COMPLIANCE CONGRESS

October 21 – 23, 2015
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www.PharmaCongress.com

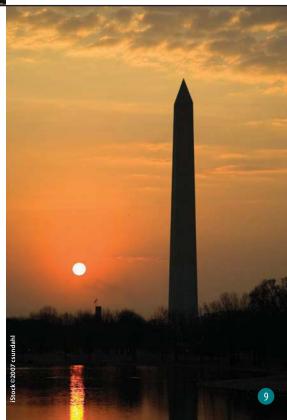
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THE FOLLOWING REGISTRATION TERMS AND CONDITIONS APPLY

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PRO FORMA INVOICES

Complete one of the online forms and generate a Pro Forma Invoice, or fill out the downloadable form to email, fax, or mail in your request for a Pro Forma Invoice. For questions about the registration process, contact the Registration Office at 1-800-503-8171 and 1-206-452-5528, or send an email to registration@hcconferences.com.

REGARDING WEBCAST REGISTRATIONS

- 1. Individuals or groups may register for Webcast access. Organizations may register for group access without presenting specific registrant names. In such instances the registering organization will be presented a series of user names and passwords to distribute to participants.
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- 3. Webcast registrants will enjoy six (6) months access from date of issuance of user name and password.
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- 5. User name and password use will be monitored to assure compliance.
- 6. Each Webcast registration is subject to a "bandwidth" or capacity use cap of 5 gb per user per month. When this capacity use cap is hit, the registration lapses. Said registration will be again made available at the start of the next month so long as the registration period has not lapsed and is subject to the same capacity cap.
- 7. For Webcast registrants there will be no refunds for cancellations. Please call the Conference Office at 1-800-503-8171 or 1-206-452-5528 for further information.

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- 1. For onsite group registrations, full registration and credit card information is required for each registrant. List all members of groups registering concurrently on fax or scanned cover sheet.
- 2. For onsite registrants there will be no refunds for "no-shows" or for cancellations. You may send a substitute or switch to the Webcast option. Please call the Conference Office at 1-800-503-8171 or 1-206-452-5528 for further information.

METHOD OF PAYMENT FOR TUITION

Make payment to Health Care Conference Administrators LLC by MasterCard, Visa or American Express. Credit card charges will be listed on your statement as payment to HealthCare (HC) Conf LLC.

REGISTRATION OPTIONS

Registration may be made online or via mail, fax or scan.

You may register through either of the following:

- $\bullet \ On line \ at \ www. International Pharma Congress. com.$
- Fax/Mail/Email using this printed registration form. Mail the completed form with payment to the Conference registrar at 22529 39th Ave. SE, Bothell, WA 98021, USA, or fax the completed form to 1-206-319-5303, or scan and email the completed form to registration@hcconferences.com.

The following credit cards are accepted: American Express, Visa or MasterCard. Credit card charges will be listed on your statement as payment to HealthCare (HC) Conf LLC.

For registrants awaiting company bank transfer, a credit card number must be given to hold registration. If payment is not received by seven days prior to the Congress, credit card payment will be processed.

TAX DEDUCTIBILITY

Expenses of training including tuition, travel, lodging and meals, incurred to maintain or improve skills in your profession may be tax deductible. Consult your tax advisor. Federal Tax ID: 91-1892021.

CANCELLATIONS/SUBSTITUTIONS

No refunds will be given for "no-shows" or for cancellations. You may send a substitute. Please call the Conference Office at 1-800-503-8171 and 1-206-452-5528, or send an email to registration@hcconferences.com.

INTERNATIONAL PHARMA CONGRESS CONTINUING EDUCATION CREDITS

COMPLIANCE CERTIFICATION BOARD (CCB) CREDIT

The event "Ninth International Pharmaceutical Compliance Congress" has been approved for 13.0 CCB Credits.

NASBA CPE CREDIT

Health Care Conference Administrators, LLC is registered with the National Association of State Boards of Accountancy (NASBA) as a sponsor of continuing professional education on the National Registry of CPE Sponsors. State boards of accountancy have final authority on the acceptance of individual courses for CPE credit. Complaints regarding registered sponsors may be submitted to the National Registry of CPE Sponsors through its website: www.learningmarket.org.

A recommended maximum of 13.0 credits based on a 50-minute hour will be granted for the entire learning activity. This program addresses topics that are of a current concern in the compliance environment. This is an update, group-live activity. For more information regarding administrative policies such as complaints or refunds, call 206-757-8053 or petergrant@dwt.com.

MCLE

The Congress is currently pending approval to offer California and Pennsylvania MCLE Credit.

CERTIFICATE OF ATTENDANCE

Onsite attendees can also request a Certificate of Attendance which they can file with appropriate entities for credit, and webcast attendees can request a Webcast Certificate of Attendance on which they can certify the number of hours they watched and can file with appropriate entities for credit.

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Registration (whether online or by this form) constitutes a contract and all of these terms and conditions are binding on the parties. In particular, these terms and conditions shall apply in the case of any credit card dispute.

GENERAL TERMS AND CONDITIONS

Program subject to cancellation or change. If the program is cancelled the only liability of the Congress will be to refund the registration fee paid. The Congress shall have no liability regarding travel or other costs. Registration form submitted via fax, mail, email or online constitutes binding agreement between the parties.

FOR FURTHER INFORMATION

Call 1-800-503-8171 (Continental US, Alaska and Hawaii only) or 1-206-452-5528, send e-mail to registration@hcconferences.com, or visit our website at www.lnternationalPharmaCongress.com.

HOW TO REGISTER: Fully complete the form on page 11 (one form per registrant, photocopies acceptable). Payment must accompany each registration (Euros, payable to Health Care Conference Administrators, LLC).

ONLINE: Secure online registration at www.InternationalPharmaCongress.com.

FAX: +1 206-319-5303 (include credit card information with registration) MAIL: Conference Office, 22529 39th Ave SE, Bothell, WA 98021, USA

FOR REGISTRATION QUESTIONS:

PHONE: 1800-503-8171 (Continental US, Alaska and Hawaii only) or

+1-206-452-5528, Monday-Friday, 7 AM - 5 PM PST

E-MAIL: registration@hcconferences.com

CONTACT INFORMATION - INTERNATIONAL CALL CENTER:

LONDON, UK — The International Pharma Congress has engaged the UK firm of Bamboo Events Ltd. as agent to handle telephone and email enquiries.

Hours: 9:00 – 17:00 (UK time) Phone: +44 (0)208 407 6167

Email: IPCcallcenter@hcconferences.com

VISA INFORMATION

For information regarding Visa requirements traveling to Belgium from your country, please visit the Belgian Consulate Website or **https://belgium.visahq.com/**. Travelers to Belgium from the United States, Canada and most European countries do not require a visa. Please check the website for specific information regarding your country of origin.

INTERNATIONAL PHARMA CONGRESS ADDRESS **COMPLETE THE FOLLOWING. PLEASE PRINT CLEARLY:** CITY/STATE or PROVINCE/POSTAL CODE NAME COUNTRY SIGNATURE OF REGISTRANT - REQUIRED TELEPHONE F-MAII JOB TITLE ORGANIZATION ☐ Special Needs (Dietary or Physical) ONSITE CONFERENCE ATTENDANCE WEBCAST CONFERENCE ATTENDANCE Onsite conference registration includes onsite attendance, professional networking, and live Webcast conference registration includes the live Internet feed from the Congress, plus interaction with the faculty. six months of continued archived Internet access, available 24/7. Please note during Mini Summits, only one session will be broadcast live. The other Mini Summits will be audio recorded and posted in the archive within one week after conference ends. Standard Rate: ☐ Through Friday, March 13, 2015* €1,795 As an alternative to post-conference archived Internet access, Webcast conference registrants ☐ Through Friday, April 10, 2015** €1.995 may choose to access conference content via Flash Drive, which includes video of all sessions ☐ After Friday, April 10, 2015 €2.195 and synched PowerPoint presentations. ETHICS/PCF/IFPMA/EFPIA/PhRMAG Member Rate***: **CONFERENCE** ☐ Through Friday, March 13, 2015* €1,395 ☐ Through Friday, April 10, 2015** €1,595 **Standard Rate:** ☐ After Friday, April 10, 2015 €1,795 ☐ Through Friday, March 13, 2015* € 895 ☐ Through Friday, April 10, 2015** € 995 **GROUP REGISTRATION:** ☐ After Friday, April 10, 2015 €1.095 Ten or more registrations submitted from the same organization at the same time receive the following discounted rate for conference registration. 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Group registration permits the organizational knowledge coordinator either to share conference access with colleagues or to assign and track employee conference participation. SELECT YOUR MINI-SUMMITS - Tuesday, May 12 (One from each group): Conference Access: **□** 5 or more €595 per person 20 or more €395 per person ROUND I - 1:30 pm ROUND II - 3:00 pm ROUND III - 4:30 pm **□** 10 or more €495 per person **□** 40 or more €295 per person ☐ I: Basic Compliance Concepts VI: Basic Compliance Concepts XI: Advanced Strategies See INTELLECTUAL PROPERTY POLICY, page 10. and Skills I and Skills II in Compliance Training ☐ XII: Annual MEA Compliance Update ☐ II: How to Engage with Medical VII: Global Compliance Auditing **CONFERENCE ELECTRONIC MEDIA:** ■ XIII: Lessons from Global Compliance Societies and Congress Organizers in and Monitoring Best Practices Webcast attendees — Following the Congress, the video and presentations are made avail-Order to Ensure that Industry Standards Issues and Initiatives in the Medical ☐ VIII: What's Next in able on a flash drive. 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Supplier Management Aggregate Spend Compliance ☐ X: Data Analytics Supporting ☐ V: Annual CEE Compliance Update Compliance Monitoring, Risk Prevention and Mitigation * This price reflects a discount for registration and payment received through Friday, March 13, 2015. **APPLICABLE VAT FOR ONSITE ATTENDANCE:** ** This price reflects a discount for registration and payment received through Friday, April 10, 2015. Upon registering to attend the Congress in-person onsite, you will be charged an additional 21% VAT tax. Upon receipt by the Congress of its Belgian VAT number, you will *** To qualify for the ETHICS/PCF/IFPMA/EFPIA/PhRMAG member rate an individual must be an individual be charged an additional VAT rate percentage of your total registration fees. member or an employee of a member company of the International Society of Healthcare Ethics and Compliance Professionals (ethics), the Pharmaceutical Compliance Forum (PCF), the International Federation of Phar-There is no applicable VAT tax for attending the Congress via the Internet webcast. maceutical Manufacturers & Associations (IFPMA), the European Federation of Pharmaceutical Industries and Associations (EFPIA) or Pharmaceutical Research and Manufacturers Association, Gulf (PhRMAG) REGISTRATION BINDING AGREEMENT **PAYMENT Discount Code:** Registration (whether online or by this form) constitutes a contract and all of these terms The use of a registration discount code cannot be the basis of requesting a and conditions are binding on the parties. In particular, these terms and conditions shall apply in the case of any credit/debit card dispute. For Webcast and onsite registrants there partial refund of fees already paid. will be no refunds for "no-shows" or cancellations TOTAL FOR ALL OPTIONS,

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You may also register online at www.InternationalPharmaCongress.com.

- ☐ Bank transfer (bank information provided upon receipt of form)
- ☐ Payment by credit card:☐ American Express ☐ Visa ☐ Mastercard

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