

20-21 APRIL 2016

GRANDIOR HOTEL \*\*\*\*\*

PRAGUE, CZECH REPUBLIC



5th ANNUAL

# PHARMA LAWCONVENTION

## SILVER SPONSORS



**VAN BAELE & BELLIS**



## IN PARTNERSHIP WITH



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## DAY 1: WEDNESDAY 20. APRIL 2016

8:10 Welcome Coffee and Registration of Participants

8:30 **Keynote address**

**RICHARD BERGSTRÖM** - Director General, EFPIA - The European Federation of Pharmaceutical Industries and Associations

9:30 **PANEL SESSION 1**

### **THE NATIONAL BLUEPRINT APPROACH (EMVS)**

- Implementation of European Medicines Verification System (EMVS)
- European perspective, regional specifics
- Legal challenges of EMVS implementation
- Technical possibilities and solutions
- Central purchasing system
- Fight against counterfeit medicines

**JURATE SVARCAITE** - Secretary General,  
PGEU - Pharmaceutical Group of the European Union

**JAKUB DVORACEK** - Executive Director,  
AIFP - The Association of Innovative Pharmaceutical Industry

**PETR SAMEC** - Senior Associate, DLA Piper

**JOHAN VERHAEGHE** - Falsified Medicines Directive Project Manager,  
EGA - European Generic and Biosimilar Medicines Association

**EMVS Solution Provider** - TBC

### **Interactive Panel Discussion**

Networking Coffee Break in midsession

13:00 Networking Business Lunch

14:30 **PANEL SESSION 2**

### **PARALLEL TRADE**

- Parallel distribution industry perspective
- Manufacturer point of view & prediction of development
- Regulations of re-export
- Medicine shortages
- Legal framework analysis of parallel trade in EU

**HEINZ KOBELT** - Director European Affairs,  
EAEP - European Association of Euro-Pharmaceutical Companies

**HELENA SERTLOVA** - Senior Legal Counsel, Boehringer Ingelheim, Austria

**LUKASZ SLAWATYNIEC** - Legal Director, CEE Legal, Lilly, Poland

**A Senior Representative** from distribution company

### **Interactive Panel Discussion**

15:45 Networking Coffee Break in midsession

## DAY 1: WEDNESDAY 20. APRIL 2016

### 16:00 **PANEL SESSION 3**

#### **CHALLENGES OF COMPLIANCE**

- Investigations conducted by healthcare authorities. Overview of powers to investigate and legitimacy
- Comparative procedures in different CEE countries
- Best practice guidelines and risks mitigation
- Compliance trends
- New challenges ahead. Pharma business in the spotlight

**MARKETA BUDKOVSKA** - Head of Law, Patents & Compliance CZ/SK,  
Bayer, Czech Republic

**LUIZA BEDROS** - Attorney, Noerr

**AGNES TOMPA** - Attorney, Noerr

**Interactive Panel Discussion**

17:30 Cocktail Reception

## DAY 2: THURSDAY 21. APRIL 2016

8:45 Welcome Coffee and Networking

9:00 **PANEL SESSION 4**  
**TRANSPARENCY**

- EFPIA requirements, Data privacy & consent issues
- Implementation of EFPIA Disclosure Code
- Disclosure Code: first year of operation (2015) - upcoming public disclosure (2016)
- Impact of impending renewed European privacy rules (expected end of 2015)
- Legislative developments in different European countries
- Impact of impending renewed European privacy rules
- Are we ready for the DISCLOSURE? Tips and hints on last minutes checks.
- Are we ready for the reaction (HCPs, media, payers, general public)?
- Outlook for the future - what next?

**KAROLINA CZERNICKA-KUHL** - Head Legal & Compliance Europe East, Novo Nordisk, Poland

**PETER L'ECLUSE** - Partner, VAN BAEL & BELLIS

**A Senior Representative** from pharmaceutical company

panelist: **ANN-KATHRIN BECKER** - Compliance Manager, Boehringer Ingelheim

**Interactive Panel Discussion**

10.30 Networking Coffee Break

11.00 **PANEL SESSION 5**  
**PHARMA GOES DIGITAL**

- Doing pharma business in digital environment (legal perspective)
- Data monitoring & Data privacy in marketing
- Internet of things
- Big data

**NIGEL HUGHES** - Director Integrative Healthcare Informatics, Janssen Research and Development

**GABRIELA KLASA** - Legal Director, Ipsen, France

**MONIKA MASKOVA** - Attorney at law, PRK Partners

**A Senior IT Director** from pharmaceutical company

**Interactive Panel Discussion**

13.00 Networking Business Lunch

14.00 End of Conference