



Lifesciences Conference

Doing Pharma in the European Union

Exporting and Partnering
Key Legal Issues and Practical Pitfalls

21 November 2013
Dedeman Hotel, Istanbul, Turkey



With the support of



Why attend?

You...

- act as a Turkish-based Lifesciences company in the European market?
- wish to expand your business into the European market?
- are thinking of cooperating with Lifesciences companies based in the EU?
- wish to meet experts on Lifesciences issues in the EU and network with them?

Then this conference provides an excellent opportunity for you to receive first-hand information and for networking. Participation is free of charge.

Meet experts from

| | |
|--------------------------------|---|
| Pharma companies: | Abdi Ibrahim, Boehringer Ingelheim, Janssen Cilag/Johnson & Johnson, Aenova Group |
| Private legal practice: | CMS Legal Services |
| Business consultancy: | Deloitte |
| Insurance company: | Chubb |
| Regulator: | Federal Institute for Drugs and Medical Devices, Germany |

Topics covered

- The pharmaceutical market in the EU: trends and developments
- Market access: cooperation and distribution models
- The regulatory framework and pricing legislation
- Competition law in the pharma sector
- Practical challenges: best practice and case studies

The one-day conference actively supported by the international law firm CMS and the Pharmaceutical Manufacturers Association of Turkey (IEIS) is primarily aimed at Turkish-based companies active in the Lifesciences sector and related areas who seek to cooperate with companies based in the EU, export their products into the EU or simply expand their business opportunities.

Its purpose is to give the participants an overview of the key legal issues and practical pitfalls to be considered when acting in the European Market as well as providing a neutral platform for the exchange of opinions and ideas.

Supporters



The Pharmaceutical Manufacturers Association of Turkey (IEIS) represents 60 member companies. One of IEIS' missions is to increase the international competitiveness of the Turkish pharmaceutical industry and to represent the interests of the exporting pharmaceutical companies. For more information, please visit www.ieis.org.tr.



CMS is a leading international law firm with 2,800 lawyers across 54 offices advising clients on all aspects of national and international commercial law. The CMS Lifesciences Sector Group is made up of over 150 lawyers across Europe, many of whom have specialised in the Lifesciences industry for several years. The group can offer pan-European and local, national advice and assistance to the Lifesciences industries. For more information, please visit www.cmslegal.com.

Speakers

Gabriele Eibenstein

Federal Institute for Drugs and Medical Devices (BfArM),
Germany

Dr Gregor-Konstantin Elbel

Partner
Life Sciences & Health Care, Deloitte Consulting GmbH

Edmon Oude Elferink

Advocaat
CMS Brussels

Dr Hakkı Gursoz

Vice President of Turkish Medicines and Medical Devices
Agency of Ministry of Health

Okan Oncel

General Manager, International Markets
Abdi Ibrahim Pharmaceuticals

Dr Thomas Roth

Boehringer Ingelheim Pharma GmbH & Co. KG
Head of Legal Germany Team Ingelheim

Dr Werner Schneider

Vice President Business Development
Aenova Group

Peter Solberg

Member of the Management Board
Janssen-Cilag GmbH

Chris Tait

Life Science Underwriting Manager for Europe
Chubb Insurance Company of Europe SE

Turgut Tokgöz

Secretary General
IEIS

Dr Roland Wiring

Senior Associate
CMS Hamburg

Dr Jörn Witt

Partner
CMS Hamburg

Moderator

Dr Jens Wagner

Partner
CMS Hamburg

Venue

Dedeman Hotel Istanbul

Yildiz Posta Caddesi, 52
Esentepe 34340
Istanbul, Turkey
<http://www.dedeman.com/hotel-istanbul/dedeman-istanbul.aspx>

Programme

| Time | Topic | Speaker |
|-----------------------|---|--|
| 9–9.30 a.m. | Registration | |
| 9.30–9.45 a.m. | Introduction | Dr Roland Wiring Turgut Tokgöz Dr Hakkı Gursoz |
| 9.45–10.30 a.m. | The Pharmaceutical Market in the European Union <ul style="list-style-type: none">— Recent trends and developments— Focus on key markets— Business opportunities for Turkish companies | Dr Gregor-Konstantin Elbel |
| 10.30–11.15 a.m. | Doing Pharma in the EU: The Regulatory Framework <ul style="list-style-type: none">— Important rules and regulations— The interplay between EU rules and national rules— Importing into the EU: regulatory issues | Gabriele Eibenstein |
| 11.15–11.45 a.m. | Coffee break | |
| 11.45 a.m.–12.30 p.m. | Market Access (I): The M&A Route or the Cooperation Route? <ul style="list-style-type: none">— Joint ventures, mergers and acquisitions in the pharmaceutical industry— Distribution models— Case study | Dr Roland Wiring |
| 12.30–1.15 p.m. | Market Access (II): European Pricing and Reimbursement Legislation <ul style="list-style-type: none">— Key principles at EU and national levels— Recent developments and future trends in key markets— Early benefit assessment | Dr Thomas Roth |
| 1.15–2.15 p.m. | Lunch | |
| 2.15–3 p.m. | Practical Challenges (I): Avoiding and Managing Liability Issues <ul style="list-style-type: none">— Risk management and insurance coverage— Product liability and clinical trial risks— Managing liability risks in practice | Chris Tait |
| 3–4 p.m. | Practical Challenges (II): Best Practices and Case Studies <ul style="list-style-type: none">— Dealing with practical and legal challenges in practice— Case studies— Panel discussion | Okan Oncel Dr Werner Schneider Dr Jörn Witt |
| 4–4.30 p.m. | Coffee break | |
| 4.30–5.15 p.m. | Unfair Competition and Healthcare Compliance: Marketing Pharmaceuticals <ul style="list-style-type: none">— Transparency codices— Cooperation with healthcare professionals— Recent trends and practical implications in key markets | Peter Solberg |
| 5.15–6 p.m. | Competition Law in the Pharma Sector <ul style="list-style-type: none">— Interplay between EU rules and national rules— Key issues for the pharmaceutical industry— Recent case law/sector enquiry of the EU Commission | Edmon Oude Elferink |
| 6–6.15 p.m. | Wrap-Up | Dr Roland Wiring |

Registration

Lifesciences Conference | Doing Pharma in the European Union | 21 November 2013

Participation is free of charge

Yes, I will participate at the conference

Surname, first name: _____

Position: _____

Company: _____

Street: _____

Postcode, city: _____

Email: _____

Telephone: _____

Fax: _____

Date, signature _____

Please return by 12 November 2013 to:

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or CMS Legal Services
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