



Making Medicines Affordable

THE EUROPEAN GENERIC MEDICINES ASSOCIATION

Ensuring a Competitive Environment for Generic Medicines in Europe

| 11th EGA Annual Conference |

Berlin Hilton Hotel
Mohrenstrasse 30, D-10117 Berlin, Germany

21 & 22 November 2005

SUNDAY 20TH November 2005

Pre-conference Activities

19:00 Registration - Welcome cocktail reception & flying buffet in the Panoramafoyer, Hilton Hotel

MONDAY 21st November 2005 - Bankettsaal A-C

Day I

08:00 Registration & welcome coffee in the Panoramafoyer

Session One - Chair | *Emile G.W.H. Loof, President EGA, President Pharmachemie TEVA Europe*

09:00 Opening Speech

Emile G.W.H.Loof, President EGA, President Pharmachemie TEVA Europe

09:10 **Keynote Speech: Current Healthcare reforms in Germany and the role of Generic Medicines**
Franz Knieps, Director General for Health Care and Long Term Care, Ministry of Health & Social Security, Germany

09:30 Current developments in pharmaceutical policy in Germany and implications for generic competition

Rolf Stuppardt, CEO IKK Bundesverband, Chairman AIM Medicines Committee

Current developments in pharmaceutical policy in Germany and implications for generic competition - focus on added therapeutic value

Reinhard Rychlik, Institute for Empirical Health Economics

Current developments in pharmaceutical policy in Germany and implications for the generic industry

Hermann Hofmann, Managing Director Pro Generika

10:45 Coffee break

Session Two - Chair | *Greg Perry, Director General EGA*

11:15 Overview of the EU generic market and trade dynamics

Per Troein, Vice President Strategic Alliances, IMS Health Europe

11:45 Can the EU generic industry sustain high competitive drive in the current environment?

Emile G. W. H. Loof, President EGA, President Pharmachemie TEVA Europe

12:15 Creating a sustainable environment for pharmaceutical competitiveness in the European Union. The role of the generic industry, viewpoint of the EU Commission.

Nils Behrndt, Deputy Head of Unit F2, DG Enterprise, European Commission

13:00 Conference buffet lunch in the Restaurant Beletage, Hilton Hotel



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TRACK A: Pricing and Reimbursement - Bankettsaal A-C

Session Three A - Pricing & Reimbursement Systems for Generic Competition

Chair | *Frank Bongers, Chair EGA Healthcare Economics Committee, Chairman BOGIN*

- 14:15** Pricing and reimbursement systems in the EU and implications for generic competition
Panos Kanavos, London School of Economics, UK
- 14:40** Securing sustainable Health Care in Europe - examples of national initiatives
Kees de Joncheere, Regional Adviser for Pharmaceuticals, WHO Europe
- 15:05** Medicines: EU-collaboration on Assessment for Reimbursement
Ad R. Schuurman MBA, Head of Pharmacy Department Dutch Health Care Insurance Board (CVZ) & Vice President of Medical Evaluation Committee (MEDEV) Brussels
- 15:30** Comparative analysis of generic policies in the EU
Greg Perry, Director General EGA & Ana Wisse Teixeira, Health Economic Affairs Manager EGA
- 16:00** Coffee break

Session Four A - Chair | *Panos Kanavos, London School of Economics* - Co-Chair | *Greg Perry*

- 16:30** Round Table: Is there optimum pricing & reimbursement system for generic competition?
Panel of experts from national governments, industry, EU Commission, WHO and IMS Health
- 18:00** End of the session

TRACK B: Regulatory Environment - Salon Corinth

Session Three B - New Regulatory Environment for Generic Medicines. Is the EU prepared?

Chair | *Nils Behrndt, Deputy Head of Unit F2, DG Enterprise, European Commission*

- 14:15** Centralised procedure for generic applications and bio-similar
John Purves, Head of Sector Quality of Medicines, EMEA
- 14:45** Decentralised procedure for generic applications
Peter Bachmann, Federal Institute for Drugs & Medical Devices, German Member of CMD(h)
- 15:15** Viewpoint of the industry
Michael Banks, Regulatory Affairs Director, IVAX Europe
- 16:00** Coffee break

Session Four B - Quality Assurance

Chair | *Susan De Stasio, Chairman EGA Regulatory & Scientific Affairs Committee, Head of Regulatory Affairs Arrow Generics*

- 16:30** New GMP requirements for Active Pharmaceutical Ingredients. Implications for the EU Pharmaceutical Industry.
Chris Oldenhof, Vice-Chairman of Active Pharmaceutical Ingredients Committee (APIC), Board Member EFCG / CEFIC
- 17:00** CROs and Bio-studies. How to ensure quality provision of Bio-studies?
Malcolm Summers, Director European Regulatory Consulting & Submissions, Kendle
- 18:00** End of the session

- 19:30** Conference dinner at the “Opernpalais”

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ratiopharm is one of the leading international generic producers and in its home country Germany the top selling and most commonly prescribed pharmaceutical brand. The company produces high quality medicines and sells them at low prices. By doing so, it contributes to cost containment in the healthcare sector.

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TUESDAY 22nd November 2005 - Bankettsaal A-C

DAY II

08:00 Networking coffee in the Panoramafoyer, Hilton Hotel

Session Five - “Evergreening” and Patent Linkage - New Threat to Generics in Europe

Chair | *György Thaler, Chair IP & Legal Affairs Committee EGA, Development Director Gedeon Richter*

09:00 Evergreening Strategies in the EU
Howard Rosenberg, Director IP & API Strategy, Merck Generics

09:30 Evergreening Strategies Worldwide
Yehudah Livneh, Chairman IGPA IP Committee

10:00 Patent Linkage - New Threat to Generic Competition
Suzette Kox, Senior Director Scientific Affairs, EGA

10:45 Coffee break

Session Six - CEO Perspectives of the European Generic Medicines Market

Chair | *Emile G. W. H. Loof, President EGA, President Pharmachemie TEVA Europe*

11:15 Round Table: Looking at the Future Potential of the Generic Market: Generics, Super Generics, OTC Generics, Paediatric Formulations and Bio-similars

Erik Bogisch, CEO Gedeon Richter
Željko Covič, President of the Management Board & CEO Pliva
Hank Klakurka, CEO Merck Generics Group

13:00 End of conference flying buffet lunch in the Panoramafoyer, Hilton Hotel

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