



GENERIC MEDICINES A GLOBAL MARKET A GLOBAL INDUSTRY

Hotel Quinta Da Marinha
Cascais - Portugal
30 June - 2 July 2003



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STRATEGIC GENERIC DRUG DEVELOPMENT FOR THE UNITED STATES MARKET

Introduction of generic drugs in the United States is increasingly difficult because branded companies take advantage of legal loopholes in patent and drug laws in efforts to keep generics at bay. It is now more important than ever that generics not merely react to the strategies of the branded companies, but that they take a more aggressive stance, and actively use the legal system to their advantage.

This full-day seminar – now in its third year – is intended to provide generic companies with information and insights into strategies for new product introduction into the U.S. market. The interplay between patent and regulatory issues will be closely examined. Orange Book issues will be discussed as they apply to patent litigation, litigation avoidance, and long term planning, with an eye to not only gaining market entry, but also responding to, and antici-

pating, strategies of branded companies. Also covered are recent developments and trends – judicial, legislative and regulatory – and possible future changes. Topics to be Covered Include:

- The Orange Book and patent certification
- The Hatch-Waxman Amendments
- The future of Bolar and Hatch-Waxman
- Patent term extensions
- Marketing and information exclusivities
- Planning for strategies of branded pharmaceuticals
- Developing pro-active strategies for generics

The seminar is a lively, interactive meeting that presents information critical for generics. In order to maintain the informal atmosphere, **attendance is limited to 50 people**, so sign up early! ([see conference registration form](#)).

ABOUT THE PRE-CONFERENCE SEMINAR FACULTY

• **Yehudah Livneh, Ph.D.**, is the Director of the Patent Department of Teva Pharmaceutical Industries, Ltd., and was formerly Director of the patents at Biotechnology General (Israel) Ltd. Dr. Livneh is a registered Patent Attorney in Israel, and is registered to practice before the United States Patent and Trademark Office. He has a Ph.D. in Biochemistry from Brandeis University in the U.S. and a Bachelor of Science from The Hebrew University of Jerusalem, Israel. Dr. Livneh is the Chairman of the Intellectual Property Committee of the IGPA and a member of the AIPPI. He played an active role in the passage of Hatch-Waxman type amendments to the Israeli Patent Law.

• **Neil F. Greenblum, Esq.**, founding partner at Greenblum & Bernstein, P.L.C., received a Bachelor of Science in Chemical Engineering from City College of New York, and a Juris Doctor degree from American University. He has been admitted to the Bar of the District of Columbia, the Bar of the Commonwealth of Virginia, is a member of the Bar of the Court of Appeals

for the Federal Circuit, and is registered to practice before the United States Patent and Trademark Office. Mr. Greenblum advises generic pharmaceutical companies in all aspects of intellectual property, and is experienced with the special strategic, legal, and litigation aspects of patent law particular to generic pharmaceuticals. He also regularly lectures on U.S. litigation strategy and practice at the University of Strasbourg, France (CEIPI).

• **Paul A. Braier, Ph.D., Esq.**, associate at Greenblum & Bernstein, specializes in patent law, with emphasis in drug law and regulation as they relate to marketing and patent law, and frequently lectures on the subject for organizations and conferences. Dr. Braier received a Bachelor of Science in Chemistry with High Honors from the College of William and Mary, a Ph.D. in Chemistry from the University of Chicago, and a Juris Doctor degree from the Georgetown University Law Center. Dr. Braier has been admitted to the Virginia State Bar and is registered to practice before the United States Patent and Trademark Office.

A MUST - ATTEND EVENT!

The IGPA conference has now become the single most important annual event for the global generic medicines industry. The sixth conference provides a unique opportunity for networking and for gaining the latest information on the commercial, regulatory and legal fields affecting our industry. Numerous ideas, findings and key people in the industry ... all under one roof!

HERE IS HOW YOU WILL BENEFIT...

- You will gain an independent and accurate insight into critical markets, customers and competitors.
- You will receive the latest market and regulatory intelligence, enabling you to take full advantage of the opportunities emerging in the generic medicines industry.
- You can maintain and develop a network of industry contacts.
- And... you will return to your company informed and updated with new ideas to assure your competitiveness in the growing generic market.



WHO SHOULD ATTEND

- CEO'S and senior management from the generic pharmaceutical industry
- Regulatory experts, patent lawyers, market specialists, and senior sales managers from generic companies worldwide
- Senior staff in Research & Development
- Corporate analysts, strategists and academics
- API manufacturers and suppliers
- Clinical Research Organizations

THE PROGRAMME

JUNE 30, 2003: MONDAY

12.00 – 14.00 **Registration**

14.00 – 17.00 **IGPA Workshops** (open only to registered delegates)

These Workshops provide an opportunity for interactive discussion on key topics affecting the international generic industry

Intellectual Property

Chairman – Yehudah Livneh

(Director of Patent Dept, TEVA)

Expert – Leo Palma

(Senior Counsel, Advisory Centre on WTO Law)

- Doha Declaration on TRIPs & Public Health
- Bolar Exception
- Data Exclusivity
- PLT and SPLT

Science

Chairman – Michael Spino

(Senior Vice President Scientific Affairs, Apotex)

EU Speaker – Suzette Kox

(Senior Scientific & Regulatory Affairs Advisor, EGA)

- Bioequivalence
- Bio-generics
- CTD (ICH)
- Polymorphs

19.00 – 20.00 **Welcome drink/light buffet reception**

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JULY 1, 2003: TUESDAY

09.00 – 09.05 **Opening of the Conference:**

Dr Jorge Ruas da Silva (CEO, Tecnimede-Farmoz)

09.05 – 09.20 **Welcome Address: Health Minister of Portugal**

09.20 – 09.45 **Reports of IGPA Workshops**

Chairman – Kathleen Jaeger (President, CEO, GPhA)

Intellectual Property – Yehudah Livneh

Science – Mike Spino

09.45 – 10.30

The Global Branded Market

Chairman – Greg Perry (Director General, EGA)

Expert – Graham Lewis (Vice President Europe, Pharmastrategy, IMS Health)

10.30 – 11.00

Coffee Break

11.00 – 12.00

The Global Generics Market

Chairman – Dilip G. Shah (General Secretary, IPA)

Expert – Graham Lewis



Lisbon town

- 12.00 – 13.00 **Country Reviews and Market Trends – 1**
 Chairman – Greg Perry
 USA – Kathleen Jaeger
 EU – Greg Perry
 Canada – Jim Keon (President CGPA)
 India – Dilip G. Shah
- 13.00 – 14.30 **Buffet lunch sponsored by** 
- 14.30 – 15.30 **Country Review and Market Trends – 2**
 Chairman – Jim Keon
 Latin America – Fabiana Jorge (International Consultant, GPhA)
 Africa / South Africa – Stavros Nicolaou (CEO Aspen Pharmacare International Division South Africa)
 Middle East / Egypt – Dr. Mahfouz Kassem (Consultant for R & D TQM, Medical Union Pharmaceuticals)

- 15.30 – 16.00 **Strategic Issues and M & A Trends in the generics pharmaceutical sector**
 Tommy Erdei (Vice President, Healthcare, ABN AMRO Corporate Finance)
- 16.00 – 16.15 **Coffee Break**
- 16.15 – 17.15 **Future of Generic Industry: What CEOs Think**
 Craig Baxter (President, Apotex International)
 D. S. Brar (CEO, Ranbaxy)
 Israel Makov (CEO, Teva)
- 18.15 Sight-seeing bus departure from Hotel Quinta da Marinha to ferry port Lisbon
- 19.15 **Boarding ferryboat for Portuguese barbecue Evening cruise sponsored by**  HOVIONE
- 22.00 Bus trip back to the Hotel Quinta da Marinha

JULY 2, 2003: WEDNESDAY

- 09.00 – 11.15 **Public Health, IPR & Access to Generic Medicines**
 Chairman – Yehudah Livneh
 WTO – Leo Palma (Senior Counsel, Advisory Centre on WTO Law)
 Prof. Carlos Correa (Buenos Aires University)
 Global Fund – Guido Bakker (Manager for Procurement)
 WHO – Dr. Jonathan D. Quick (Director EMD)
- 11.15 – 11.45 **Coffee Break**
- 11.45 – 13.00 **APIs: Business and Regulatory Developments Impact on the Generic Industry**
 Chairman – Dr Jorge Ruas da Silva
 Paolo Romagnoli – (IGPA, API Expert)
 Guy Villax (CEO Hovione)
- 13.00 – 13.30 **Q & A**
- 13.30 **End of Conference**

— VENUE AND EVENTS

The conference is taking place at the Golf & Conference Resort Hotel Quinta da Marinha, 2750-715 Cascais ([30 minutes drive from Lisbon Airport](#)). Please view the resort on their website <http://www.quintadamarinha.com>. There are 4 swimming pools at the resort and other attractions close at hand including the beaches of Guincho, the Estoril Coast, and the castles and palaces of Sintra and Lisbon.

There will be extensive networking opportunities throughout the conference and during the following events:

- A welcome cocktail reception on 30th June
- A relaxed sunset barbecue dinner cruise on the Tagus river enjoying beautiful views of Lisbon with the added flavour of a Brazilian band on 1st July
- In addition, golf and tennis tournaments will be available for conference delegates at the resort (Tel: +351-21-486 0180)

EXHIBITION

Exhibition space is also available for registered Delegates at a cost of € 1,499.00 per stand. Please contact Annette Bourgelle (annette@gpaconferences.com).

CONFERENCE DRESS CODE

Casual but smart for all events, warm sportswear for river cruise barbecue.



BOOK HOTEL NOW!

Hotel rooms at the Hotel Quinta da Marinha, five stars golf & conference resort will be guaranteed for IGPA delegates until 4 April 2003 at the special price of 145 € single and 158 € double (including breakfast).

So book now quoting "IGPA Conference" (Tel: +351-21-486 0145
Fax: +351-21-486 9482)

For other hotels in the area , please contact:

- Estalagem Da Senhora Da Guia Hotel - Tel: +351-21-486 9239
Fax: +351-21-486 9227 - www.senhoradaguaia.com
- Village Hotel Cascais - Tel: +351-21-482 6000
Fax: +351-21-483 7319

FLIGHTS - TAP AIR PORTUGAL OFFICIAL CARRIER

Please phone your nearest TAP Office & quote code IT3TPC06003 with the confirmation of your registration. For further information please consult the website www.TAP-AirPortugal.pt



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Postal Code: City: Country:
Tel N°: Fax N°:
E-mail: Website:
Names Invitee(s):

• **PRE-CONFERENCE SEMINAR (29 JUNE 03)** •

Please note the Seminar price is inclusive of coffee breaks & lunch

- I would like to register for the Sunday 29 June Pre-Conference Seminar "Strategic Generic Drug Development for the United States Market" and I will pay an extra fee of (€ 380.00 + 19% VAT) = € **452,20**.

• **IGPA CONFERENCE (30 JUNE – 2 JULY 03)** •

Please note all prices are inclusive of coffee breaks, lunches & conference dinner. Golf and Tennis Tournaments are not included.

- My Company / Association is a Member of the IGPA (CGPA EGA GPhA IPA) and will pay the IGPA Member Fee of (€ 1,499.00 + 19% VAT) = € **1,783.81**
 My Company / Association is not a Member of the IGPA and will pay the normal Non-Member Price of (€ 1,799.00 + 19% VAT) = € **2,140.81**.
 I am registered for the conference and I wish to apply for stand space at the price (€ 1,499.00 + 19% VAT) = € **1,783.81**.
 I am registered for the conference and I would like to invite 1 2 3 people to join me for all the Lunches & Dinners at a cost of (€ 350.00 + 19% VAT) = € **416.50** per person.

Please note that the registration will not be effective until payment is made

Method of payment (please note that the bank charges are your responsibility)

- By Bank transfer to the account name: GPA Conferences, Account n° 001-3925426-09, Fortis Banque, 18 Place de Jamblinne de Meux, B-1030 Brussels, BIC/Swift code: Gebabebb, IBAN: BE520013-9254-2609, Bank tel: +32-2 739 4480.
 By Credit Card: Visa Eurocard/Master Card (American Express is not accepted) N°

Cardholder's: Expire date:

Total Amount: Signature:

Cancellation policy: cancellations must be made before 15 May 2003. After this point we are NOT able to refund your fee. Should you be UNABLE to attend, a substitute delegate is welcome at no extra charge.

Signature: Date and Place:

Please note that the organisers are not responsible for the accommodation booking

If you need any information please contact:

Annette Bourgelle (annette@gpaconferences.com) or Cristina Romagnoli (cristina@gpaconferences.com) Tel.: +32-2 533 9814 – Fax: +32-2 533 9819



THE ORGANISERS



INTERNATIONAL GENERIC PHARMACEUTICAL ALLIANCE



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The Conference programme and the registration form can also be found on the Internet on www.egagenetics.com/igpa/igpa.htm

Production, distribution of Conference brochure, delegate bag, Conference proceedings sponsored by

