



INTERNATIONAL GENERIC
PHARMACEUTICAL ALLIANCE

GENERIC MEDICINES A GLOBAL MARKET A GLOBAL INDUSTRY

HOTEL WESTIN, DRAGONARA RESORT

Malta | 19 June 2005

HOTEL HILTON CONFERENCE CENTRE

Malta | 20 – 21 – 22 June 2005



organised by



in conjunction with



Making Medicines Affordable



Members of the International Generic Pharmaceutical Alliance



GREENBLUM & BERNSTEIN, P.L.C.
PATENT, COPYRIGHT & TRADEMARK CHARTERS
WWW.GBPATENT.COM

IP STRATEGIES FOR GENERIC DRUGS IN THE US MARKET

| JUNE 19 2005 – 09.00 - 17.00 – HOTEL WESTIN DRAGONARA RESORT MALTA |

Just last year, laws and regulations relating to approval of generic drugs saw their most significant changes in almost 20 years. Added to this are the branded companies' continual efforts to take advantage of legal and regulatory loopholes in efforts to keep generics at bay, and increasing inter-generic competition for exclusivities. In order to remain competitive (or become competitive) generic companies must have a broad understanding of the current legal framework in order to effectively predict and respond to the strategies of branded and generic companies.

This full-day seminar – now in its fifth 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 anticipating, 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
- Impact of changes to patent and FDA law
- Patent term extensions
- Marketing and information exclusivities
- Planning for strategies of rival brands and generics
- Developing pro-active generic strategies

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**. Last year's seminar sold out, so sign up early!



TECHNICAL & LICENSING REQUIREMENTS FOR ESTABLISHING A PRESENCE IN THE NORTH AMERICAN GENERIC MARKET

| JUNE 19 2005 – 09.00 - 17.00 – HOTEL WESTIN DRAGONARA RESORT MALTA |

The North American market for generic drugs is currently the single largest in the world, providing significant market opportunity for International generic drug companies. This workshop will discuss specific requirements and strategies needed to establish a position in this market. The workshop will include presentations from industry experts and panel discussions with the speakers and the attendees. Topics included will be:

- An Overview of the North American Generic Market
- The ANDA Process and Managing the OGD and TPD
- How to Prepare for Technology Transfer - API and CMC Issues

- Partnering with a CRO in the USA and Canada
- Selling and Distributing Generics in North America
- Technology Transfer Opportunities with North American Pharmaceutical Companies
- Options for Partnering – International Companies
- Licensing Branded Generics into the North American Market A Case History
- General Do's and Don'ts in Establishing a North American Generic Business

THE LEGAL FRAMEWORK & REGISTRATION PROCEDURES FOR GENERIC MEDICINES IN THE EUROPEAN UNION

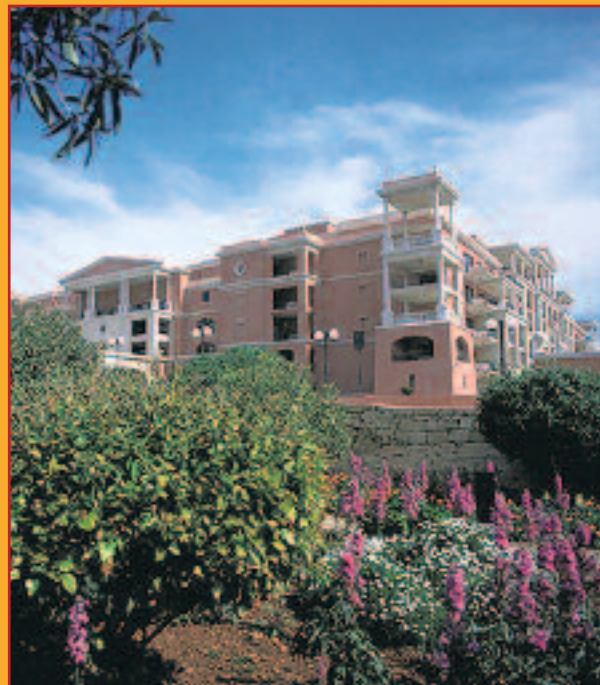
| JUNE 19 2005 – 09.00 - 16.00 – HOTEL WESTIN DRAGONARA RESORT MALTA |

The Westin Dragonara Resort | Malta

This workshop provides an up-to-date review of the legal and regulatory environment for making a generic application in the EU. The workshop provides an excellent opportunity for those wishing to know the new procedures and new legal framework which will be operable in the EU from 1st November 2005. The workshop covers 4 main topics:

- The new legal framework for generic applications (e.g. data exclusivity, Bolar and definitions of generic medicines)
- Legal obligations of the generic market authorization holder
- Making generic applications under the MRP (Mutual Recognition Procedure) and new DCP (Decentralised Procedure)
- Making Generic and Biosimilar applications under the EMEA's Centralised Procedure

The workshop is led by **Suzette Kox**, Senior Director Scientific and Regulatory Affairs EGA. Presentations will be given by leading experts in the field. The workshop is suitable for both those new to the EU regulatory environment, as well as for those wishing to ensure that current knowledge is fully up to date.





Valetta - Fort St Elmo



Valetta - Fishing boat



Central Malta - Mdina



Gozo - Mnajdra Temples

Photos by courtesy of Malta Tourism Authority

MONDAY 20 JUNE - CONFERENCE PLENARY DAY I - HILTON CONFERENCE CENTRE

| 08:00 - 09:00 | **Conference Registration at the HILTON CONFERENCE CENTRE**

| 09:00 - 10:30 | **Opening Session** | Chaired by Jim Keon, President CGPA / Chair IGPA

- Welcome Speech | Robert Wessman, CEO Actavis
- Opening Address | Prime Minister of Malta | Dr Lawrence Gonzi, LL. D.
- Address by the Minister of Health, the Elderly & Community Care | Dr Louis Deguara, M.D.
- Key Note Speech | Commissioner Günter Verheugen, European Commission (TBC)
- Key Note Speech | Lester M. Crawford | Acting Commissioner, Food & Drug Administration

| 10:30 - 11:00 | **Networking Coffee Break**

| 11:00 - 13:00 | **Global Developments** | Chaired by Dilip Shah, Secretary General IPA

- Europe's pricing and reimbursement systems – Help or hindrance for increasing generic competition in the EU | Emile Loof, CEO Pharmachemie BV/ Chairman EGA
- How has the US industry adapted to changes in the Hatch-Waxman Act | Kathleen Jaeger, President GPhA
- How the patent and regulatory systems are being misused to delay generic entry | Jean-Guy Goulet, CEO Ratiopharm Canada Chairman CGPA
- Will India become the global centre for pharmaceutical research and development? | Brian Tempest, CEO Ranbaxy, India
- Will Japan become a new major generics market? | Juichi Riku, Sawai Pharmaceuticals

| 13:00 - 14:00 | **Buffet Lunch**

| 14:00 - 16:30 | **IP Session – IP Laws, TRIPS and Trade Agreements** | Chaired by Yehudah Livneh Chair IGPA IP Committee

- Current status of TRIPS exceptions - transition periods - Bolar and Article 31 | Adrian Otten, WTO
 - The implication of IP for medicines procurement from the perspective of a development institution | Yolanda Tayler, World Bank
 - Australia - US Free Trade Agreement – Implications of bi-lateral trade agreements for the generic industry | Sanya Reid Smith, Third World Network
 - Expert Panel: Current IP developments in USA, EU, Canada and India | Kathleen Jaeger, Greg Perry, Jim Keon and Dilip Shah
- Questions and Answers Session

| 16:30 | **End of Day Coffee**

| 20:00 | **Evening Cruise and Dinner**



TUESDAY 21 JUNE - CONFERENCE PLENARY DAY II – HILTON CONFERENCE CENTRE

- | 08:30 - 11:00 | **Science Session – Are We Moving Towards Harmonisation?** | Chaired by Nick Cappuccino
- Recent developments on ICH | Nick Cappuccino, IGPA
 - Pharmacopoeia | Roger Williams, CEO USPC and Agnes Artiges Director EDQM
 - Bio-generics perspectives | John Purves, EMEA and Helen Winkle Director OPS-FDA
 - A global perspective on access to HIV Medicines for developing countries | Hans Hogerzeil, WHO, acting Director of EDM
 - Comments by industry experts | Suzette Kox, Senior Director of Scientific and Regulatory Affairs EGA and Gordon Johnston, Vice-President Science GPhA
- Questions and Answers Session
- | 11:00 - 11:30 | **Networking Coffee Break**
- | 11:30 - 13:00 | **Keys for Competing Successfully in Generics** | Chaired by Kathleen Jaeger
- Maximising quality API source | Guy Villax, CEO Hovione
 - Assuring a quality bio-equivalence study | Malcolm Summers, Kendle CRO
 - Avoiding the patent traps | William A. Rakoczy, Rakoczy Molino Mazzochi Siwik
- | 13:00 - 14:30 | **Networking Buffet Lunch** _____ Sponsored by  **medichem** and
- | 14:30 - 16:30 | **Future Projections for the Global Generic Market** | Chaired by Greg Perry
- The Analyst's Perspective**
- Graham Lewis, Vice-President IMS
 - David Maris, Managing Director, Equity Research, Speciality Pharmaceuticals, Bank of America Securities, USA
- CEO Perspective** | Chaired by Richard B. Silver, Lehman Brothers
- Dr Reddy's Laboratories - Satish Reddy CEO
 - PLIVA | Zelko Covic CEO
 - IVAX | Frank Condella CEO (Europe)
- | 16:30 | **Closing Speech** by Dr Austin Gatt, LL. D. Minister for Industry and Information Technology, Malta
- Announcement of IGPA 2006** by Greg Perry, EGA Director General
- | 20:00 | **Conference Gala Dinner at Palazzo Parisio, Naxxar** _____ Sponsored by  **MaltaEnterprise**
- Speech by Mr Joseph Zammit Tabona, Malta Enterprise Chairman

COMBINO  PHARM

WEDNESDAY 22 JUNE - BUSINESS NETWORKING DAY AND CULTURAL VISIT

- | 09:00 - 13:00 | **Cultural Trip** _____ Sponsored by 
- | 13:00 - 14:30 | **End of Conference Cocktail** _____

A MUST ATTEND EVENT

IGPA – THE BIGGEST GENERIC GATHERING WORLDWIDE

The Annual IGPA conference has become the biggest conference gathering of the global generic pharmaceutical industry. The event, organised by GPA Conferences together with the world's leading generic industry associations, provides the very latest insight into the commercial, legal and regulatory developments concerning the sector.

THE MALTA PROGRAMME

This year's event – held in the magnificent Malta Hilton Conference Centre – is without precedent. The two-day plenary session – to be opened by the Prime Minister of Malta – offers presentations from eight CEOs, two association chairmen, four association presidents,


the World Bank, IMS, WTO, WHO, EMEA, FDA, USPC, EDQM, Lehman Brothers and Bank of America Securities. In addition, there will be contributions from technical experts, CROs, specialised law firms and industry associations. For those wishing to strengthen their specialist knowledge, three pre-conference workshops are also available in regulatory and legal issues covering the US and European markets.

UNPARALLELED BUSINESS NETWORKING


IGPA Malta 2005 also provides unparalleled business networking opportunities with a welcome reception, two buffet lunches, two dinner events, four networking coffee sessions, a half day cultural trip in this historical Island and an end of conference cocktail. IGPA Malta 2005 is an event DEFINITELY not to be missed!

SOCIAL PROGRAMME for spouse programmes details and bookings please consult www.alliancemalta.com/igpa



SUNDAY 19 JUNE 2005


- 20.00 – 22.00 • Welcome Cocktail Reception on the Beach
Venue: Westin Dragonara Resort. Dress code: casual, but smart _____ Sponsored by 

MONDAY 20 JUNE 2005


- 10.00 – 15.00 • Spouse Programme, Valletta sight seeing & museums
20.00 – 24.00 • Evening Cruise and Dinner on Maltese Yachts Herra I, II & Fernandes II
around historical flood-lit Valetta harbour. Dress code: casual, but smart _____ Sponsored by 

TUESDAY 21 JUNE 2005

- 09.30 – 17.30 • Spouse Programme, Gozo Island & the Megalithic Temples
13.00 – 14.00 • Networking Buffet Lunch _____ Sponsored by  medichem 

- 20.00 • Conference Gala Dinner at Palazzo Parisio. Dress code: formal, elegant _____ Sponsored by 

WEDNESDAY 22 JUNE 2005

- 09.00 – 13.00 • Cultural Trip, "The Three Cities", Vittoriosa, Cospicua and Senglea _____
13.00 – 14.30 • End of Conference Cocktail _____ Sponsored by 



INTERNATIONAL GENERIC
PHARMACEUTICAL ALLIANCE

Sponsored by 



Sponsored by



COMBINO PHARM



Sponsored by



Sponsored by

VENUES

PRE-CONFERENCE SEMINARS *only for conference delegates*

The PRE-CONFERENCE SEMINARS are taking place at the WESTIN Dragonara Resort Malta, Dragonara Road, St Julian's STJ02 Malta (10-minute walk from the Hilton). Please view hotel and its facilities by accessing website www.westinmalta.com

MAIN CONFERENCE

The MAIN CONFERENCE is taking place at the brand new HILTON Conference Centre Malta, Portomaso, PTM01, MALTA (30-minute drive from Malta International Airport). Please view hotel and its facilities by accessing website www.hiltonmalta.com.mt

REGISTRATION

BOOK NOW TO AVOID DISAPPOINTMENT - IGPA 2004 WAS SOLD OUT! Registration online at www.gpaconferences.com
Registrations close officially 10 June 2005 and are also subject to availability.

- Seminar fee - € 650.00 + 18% VAT (per person)
- Conference fee for IGPA Members - € 1,599.00 + 18% VAT (per person)
- Conference fee for NON Members - € 1,899.00 + 18% VAT (per person)

EXHIBITION

Possibility of table top from € 3,500.00 + 18% VAT including one entrance at the Conference.

More info on www.gpaconferences.com



BOOK YOUR ACCOMMODATION NOW *(June is high season in Malta!)*
Either at the Hilton or the Westin Dragonara Resort. All details on www.gpaconferences.com **Conference organisers are not responsible for travel & accommodation.**

TRAVEL – AIR MALTA OFFICIAL CARRIER

Please contact any Air Malta Office for discounted fares for the participants and their accompanying partners. These discounts will be valid on Air Malta flights only on presentation of a copy of the e-mail confirmation as proof of participation. The booking procedures and outstation office contact details can be found on the Air Malta link at the Conference website.

VISA REQUIREMENTS

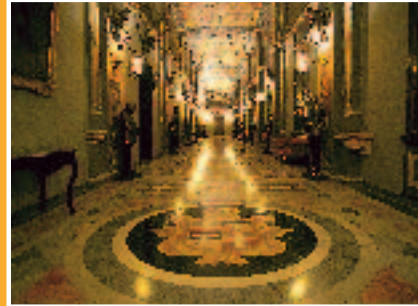
In case of special visa requirements, an application must be made directly with the Immigration Police in Malta. Application forms are available at the Conference website. Applicants are kindly requested to apply well in advance (3/4 weeks) and to keep us copied.

Conference organisers are not responsible for visa applications.

2005

MALTA

| THE 8TH ANNUAL IGPA CONFERENCE |

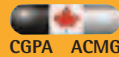


Grand Master's Palace - Malta

Organised by



in conjunction with



Making Medicines Affordable



Sponsored by



and



THOMSON DESIGN CENTER WWW.TDCS.BE

For further details & to register online visit www.gpaconferences.com