



# GENERIC MEDICINES IP/ LEGAL & REGULATORY ISSUES

Topics to be covered include:

- Understand the European Generic marketplace
- Patents and how they affect generics
- Data Exclusivity
- DCP and European Regulatory System
- Key aspects of European legislation



With  
**Peter Wittner** Interpharm



Register on-line at [www.management-forum.co.uk](http://www.management-forum.co.uk)  
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Taj Land Ends, Mumbai  
Taj Palace, Delhi  
Taj Krishna, Hyderabad

16 November 2009  
18 November 2009  
20 November 2009



**World Generic Markets**



The aim of this seminar is to shed some light on the legal background to the European generic industry for those who work outside Europe, and to provide an understanding of how it affects all parts of the business. Misunderstanding the various factors that influence the time and speed of registration can lead to regulatory delays with a knock-on effect on launch dates for new products. This can, in turn, lead to undesirable commercial delays, which might have an impact on a company's competitive position.

## BENEFITS TO YOU

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- A better understanding of the new Directive 2004/27/EC.
- An overview of IP issues and their importance to the generics industry.
- An opportunity to discuss EU IP issues with fellow professionals.
- Awareness of the potential impact of the legislation on the commercial side of the generics business.
- A brief look at how the US environment differs from Europe

## WHO SHOULD ATTEND?

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- Marketing and sales personnel looking at European opportunities
- Regulatory personnel involved with overseas registration
- Production personnel manufacturing products for the European markets
- Directors of Indian generic companies who want to understand how the European industry works
- Anyone involved with European business

## COMMENTS FROM PREVIOUS PARTICIPANTS

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"Very good level of information." O. Depaire, Delegate

"Very comprehensive overview of this area" C. Erwin, Delegate

## COURSE LEADER

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**Peter Wittner** has been in the pharmaceutical industry for nearly 30 years of which the second half has been mainly in the area of generics. He worked for the former Evans Medical and then Norton Pharmaceuticals (now part of IVAX) where he was responsible for European Sales & Marketing. After leaving Norton, Peter set up his own consultancy in 1993 and operated independently until 1996 when he joined the Indian company Ranbaxy to set up the infrastructure of their new UK subsidiary. After spending two years with them he returned to his consultancy work and has spent the last 12 years providing consultancy and training services, specialising in the field of generics.



## ONLINE TRAINING MODULE ALSO AVAILABLE

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Generics are attracting an enormous amount of interest around the world and the generic industry is growing strongly. Why?

If you want to understand who the big players in the industry are, how they got there and where the big generics markets are, Management Forum has created an on-line training course. The course is broken down into 6 modules covering all the important topics of markets, competitive environment, players, law, patents and regulations that affect generics.

Contact [judith.black@management-forum.co.uk](mailto:judith.black@management-forum.co.uk) for further information.

## MEDIA PARTNERS

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### World Generic Markets

Updated daily on the web or twice-monthly in print, World Generic Markets distils the important generic market news worldwide. Published by Espicom Business Intelligence. For further information please visit [www.espicom.com/wgm](http://www.espicom.com/wgm)

### www.PharmCast.com

[www.PharmCast.com](http://www.PharmCast.com) is the world leading website designed specifically for pharmaceutical, clinical and biotechnology professionals. [www.PharmCast.com](http://www.PharmCast.com) brings up-to-date information and is maintained by pharmaceutical and biotechnology professionals. Visit [www.PharmCast.com](http://www.PharmCast.com) and discover for yourself why it is so popular among professionals.

### BPCouncil

The BPCouncil's (<http://www.bpcouncil.com>) mission is to enable a vibrant meeting place for brand owners, professional services providers, technology vendors, enforcement agencies and regulatory bodies. To join the BPCouncil go to <http://www.bpcouncil.com/Registration.aspx>

### Generics bulletin

This is the global generic industry's essential source of news and views. A weekly electronic newsflash and a twice-monthly paper publication provide both immediacy and depth from a generics industry perspective. For further information please visit [www.generics-bulletin.com](http://www.generics-bulletin.com) or contact Val Davis at [val.davis@generics-bulletin.com](mailto:val.davis@generics-bulletin.com) or call +44 (0)1564 777550.

### PharmaAsia

This publication provides timely and useful insights into cutting edge techniques and practices for improving the pace of pharmaceutical research and development in the region. PharmaAsia features articles on research and technology, news and market trends, product listings, updates on regional events and company profiles. For more information, contact Alvin Lim at +65 6780 4521 or [alvin.lim@rbi-asia.com](mailto:alvin.lim@rbi-asia.com)

## PROGRAMME

09.30 ▶ **Introduction and Welcome**

09.45 ▶ **Understand the Generic marketplace**

- How big are the markets in Europe and Worldwide?
- Increasing industry consolidation – Europe and the US
- Contrasts between US and Europe
- UK generic market trends
- Generic market growth areas
- Forthcoming patent expiries and future opportunities
- How Europeans see the challenge from Asia
- How generics companies are moving up market
- How branded companies defend themselves

11.00 ▶ **Coffee**

11.20 ▶ **Patents and how they affect generics**

- Patent types
- Patent process
- Patent extensions – Europe
- Patent extensions - USA
- Example – Atorvastatin – extensions and disputes

12.30 ▶ **Lunch**

13.45 ▶ **Data Exclusivity and its impact on generics**

- What is it and why does it matter?
- How long does it last?
- Is there any way around it?
- How does it differ from patent exclusivity?

**The DCP and European Regulatory Systems**

- How should they work?
- Do they work properly?
- What are the obstacles?
- What solutions are available

15.30 ▶ **Tea**

15.45 ▶ **Key aspects of European legislation and their implications**

- Directive 2004/27/EC – a brief history
- Changes introduced
- SmPC harmonisation
- Harmonisation of Data Exclusivity – what is 8+2+1?
- Bolar Clause – what impact will it have?
- European Reference product
- Generic definition and its hidden significance
- The Sunset Clause

16.45 ▶ **Final Discussion**

17.00 ▶ **Close of Meeting and Networking reception**



# GENERIC MEDICINE IP / LEGAL & REGULATORY ISSUES

## APPLICATION TO REGISTER

16, 18 & 20 November 2009, Conf. No. A11-4009

Please PRINT your details:

Title..... First name .....

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## YOU MAY REGISTER BY:-

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please contact Registration Department.

If you do not want to receive future mailings from Management Forum please contact nick@management-forum.co.uk  
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## REGISTRATION INFORMATION

Registration & Refreshments 09.00  
Conference Start 09.30 – Finish 17.00

### Venue

Please tick the venue you would like to attend

**Monday 16th November 2009 Taj Lands End, Mumbai**  
Band Stand, Bandra (West), Mumbai 400 050 - India  
TAJ Toll-Free Reservation line in India: 1800 111 TAJ (825)  
Tel No. : (91-22) 6668 1234  
Fax : ((91-22) 6699 4488  
Email: landsend.mumbai@tajhotels.com

**Wednesday 18th November 2009 Taj Palace, Delhi**  
Sardar Patel Marg, Diplomatic Enclave,  
New Delhi 110 021 - India  
TAJ Toll-Free Reservation line in India: 1800 111 TAJ (825)  
Tel: (91-11) 2611 0202  
Fax: (91-11) 2611 0808  
Email: palace.delhi@tajhotels.com

**Friday 20th November 2009 Taj Krishna, Hyderabad**  
Road No. 1, Banjara Hills, Hyderabad - 500 034 - India.  
TAJ Toll-Free Reservation line in India: 1800 111 TAJ (825)  
Tel: 91 - 40 - 6666 2323  
Fax : (91-40) 66661313  
Email: krishna.hyderabad@tajhotels.com

### Conference Fee

**Multinational companies: £585 + tax**  
**Domestic companies: 19,500 Rps + tax**

Conference No. A11-4009

Group discount available on request.

### Cancellation Policy:

Over 14 days prior to the Seminar: Cancellation fee of £75.  
7/14 days prior to the Seminar: 50% of the fee. Fewer than 7  
days or if no notification received: Registrant liable to pay  
FULL seminar fee.

**NB: Cancellations must be received in writing by  
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In the event of circumstances beyond its control,  
Management Forum reserves the right to alter the  
programme, the speakers, the date or the venue.

Exhibition spaces and promotional opportunities will be available at this meeting.  
For further information please contact Judith Black  
(email: judith.black@management-forum.co.uk)

MANAGEMENT FORUM LTD., 98-100 Maybury Road, Woking, Surrey GU21 5JL, UK  
Tel: +44 (0)1483 730071 Fax: +44 (0)1483 730008 Website: www.management-forum.co.uk