GENERIC MEDICINES
Market/ IP / LEGAL & REGULATORY ISSUES

A one-day seminar to be conducted at your offices

Topics to be covered include:

- **Understanding 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 Consultancy, Israel

INTRODUCTION

It is often difficult for those involved in marketing generic medicines to understand the complicated legal and regulatory environment in which EU generic companies operate. Similarly, regulatory people themselves are often unsure how the legal and Intellectual Property framework can influence their own work.

Similarly, those working on the regulatory side often find it difficult to see how their activities can significantly affect the commercial aspects of their company's business.

The aim of this seminar is to shed some light on the commercial and legal background to the European generic industry 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

Attending this seminar will give you:-

- An overview of the generic and biosmilars market, the major players and how the market works
- A better understanding of the Directive 2004/27/EC and the changes that it has introduced to marketing generics in Europe
- An overview of IP issues and their importance to the generics industry
- An opportunity to gain an appreciation of how European legal and IP issues affect regulatory work.
- Awareness of the potential impact of the legislation on the commercial side of the generics business

- A clearer insight into and how the regulatory side does not exist in isolation from the commercial side but has a direct impact on it and the interplay between the two areas
- A brief look at how the US environment differs from Europe

WHO SHOULD ATTEND?

- Marketing and sales personnel looking at European opportunities who want a better grasp of the legal and IP issues
- Regulatory personnel who want to have a better understanding of commercial aspects
- Production personnel manufacturing products for the European markets
- Directors of non-European generic companies who want to understand how the European industry works
- Branded companies that want to obtain a better understanding of how the generic world works.
- Anyone involved with European business

COMMENTS FROM PREVIOUS PARTICIPANTS

"Interesting, informative and enjoyable."
"Very comprehensive overview of this area"

COURSE LEADER

Peter Wittner has been in the pharmaceutical industry for 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 18 years providing consultancy and training services, specialising in the field of generics

PROGRAMME COVERS THE FOLLOWING TOPICS

1- Understand the Generic marketplace

i) How big are the markets in Europe and Worldwide?
ii) Increasing industry consolidation – Europe and the US
iii) Contrasts between US and Europe
iv) UK generic market trends
v) Generic market growth areas
vi) Forthcoming patent expiries and future opportunities
vii) How Europeans see the challenge from Asia
viii) How generics companies are moving up market
ix) How branded companies defend themselves

2- Key aspects of European legislation and their implications

i) Directive 2004/27/EC – a brief history

ii) Changes introduced
iii) SmPC harmonisation
iv) Harmonisation of Data Exclusivity – what is 8+2+1?
v) Bolar Clause – what impact will it have?
vi) European Reference product
vii) Generic definition and its hidden significance
viii) The Sunset Clause

3- Patents and how they affect generics

i) Patent types
ii) Patent process
iii) Patent extensions – Europe
iv) Patent extensions - USA
v) Example – Atorvastatin – extensions and disputes

4- Data Exclusivity and its impact on generics

i) What is it and why does it matter?
ii) How long does it last?
iii) Is there any way around it?
iv) How does it differ from patent exclusivity?

5- The DCP and European Regulatory Systems

i) How should they work?
ii) Do they work properly?
iii) What are the obstacles?
iv) What solutions are available

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