Biosimilars – Understanding the Regulatory Processes and the Commercial Realities

Presented by INTERPHARM Consultancy

Overview of workshop:

The aim of this workshop is to give participants a good overview of the whole topic of biosimilars while investigating in more depth those topics that merit it. Biosimilars have attracted a great deal of interest recently and are seen by some as the new generic frontier, since it is widely thought that lower levels of competition will lead to higher margins in an industry notorious for its generally low margins on commodity generics.

However, while lower regulatory barriers in less regulated markets have allowed a biosimilars market to take off, the higher regulatory barriers in Europe and issues of interchangeability have resulted in a limited number of product launches so far and slow progress for those that are already in the market. Across the Atlantic, the situation is changing with the long awaited legislation now in place to simplify biosimilars registration. How will the legislation actually work and is it what the generic industry was hoping for?

The workshop will look at all these issues and take a look into what the future may bring.

Upon completion of this workshop, attendees should have:

- A good overview of the Biosimilars picture across the world
- An overview of the barriers to entry
- Insight into the varying regulatory approaches prevailing in different regions
- An understanding of the commercial situation as it is now and how it is likely to develop in the future
- Enough background to determine whether entering the biosimilars market is an appropriate strategy for their company

Programme with approximate timings

9:00 **Welcome & Introductions**

- Peter Wittner's experience and qualifications
- Purpose and scope of the workshop

9:10 **Overview - Biosimilars? Biogenerics? Follow-on Biologicals?**

- What are we actually talking about?
- Summary of issues affecting Biosimilars
  - Regulatory
  - Legal / IP
  - Commercial
- Interchangeability - what is the issue?

9:45 **The regulatory process and its pitfalls**

- Europe - a straight forward case
  - EMEA guidelines
  - Overview of successful and failed applications
  - The USA – How will the new legislation work out?
  - Comparison of proposals and the final version
  - Probable shape of the new regulatory mechanism
- Japan
  - How it compares to EU / US
- Situation in other parts of the world
  - Less regulated markets

10:45 **Break**

11:00 **Biosimilars – the commercial reality**

- What is the big attraction?
  - Biologicals market and prospects
  - Potential Biosimilars market
- What has happened so far?
  - Europe and the USA
  - Asian markets and Latin America
- Patents, IP and other issues
  - What are the patent issues?
  - Interchangeability – a potential roadblock
  - Differing national legislation
- Where do Biosimilars go from here?

12:10 **Discussion Session**

12:30 **Close of Workshop**

About the workshop host:

Peter Wittner, B.Sc., is an independent consultant specialising in the commercial aspects of generics with more than 30 years' pharmaceutical experience. Before starting his own business, Peter headed the European sales and marketing departments of the UK generics companies Evans Medical and H.N. Norton, which later became part of IVAX.

He later joined the Indian generic leader Ranbaxy as Managing Director to help set up its UK business and then returned to consultancy work. Interpharm advises new market entrants on generic strategies, assists in business development for generic companies based outside the EU that are trying to enter the market, works with companies that are seeking to enlarge their product portfolios and acts as an agent for a CRO providing biostudies to the generic industry. While mainly oriented to the commercial side with services such as market intelligence and pricing overviews for example, Interpharm also advise on IP and patent issues as well as the legal background to the pharmaceutical industry in Europe.

On the other side of the equation, Interpharm has also worked with originator companies that are looking at ways of defending their major brands from generic incursion.

In addition, Peter is a regular speaker at generic conferences and conducts training seminars on behalf of Management Forum. He has written a number of reports on generics industry topics including "*Growth Strategies in Generics*", "*Generics Defense Strategies*" and "*US and European Prescription Generic Markets*" as well as a series of reports for Decision Resources including one on Indian Generics and several more during 2010 and 2011. Peter has also been a regular contributor to the GenericsWeb newsletter "*INNsight*".

About Interpharm Consultancy:

Interpharm Consultancy specialises in offering support to the generic industry, particularly companies that are new to the field or based outside Europe. Peter Wittner set up the company in 1998 after leaving Ranbaxy with the intention of sharing his experience of the generic industry at both the national and international level.

Interpharm has cooperated with a number of generic companies to help them work out their strategy for expansion, but also with branded companies concerned about the potential impact of generics on certain of their brands that are nearing the end of the patent protection period.

Apart from giving assistance with market development and growth strategies, Interpharm works with companies looking to buy in new generic products to expand their portfolio and uses its connections with the major European generic groups to introduce overseas manufacturers to potential new business partners and markets.

Interpharm also provides on-site training on strategic, legal and regulatory issues affecting the generics industry though seminars such as this.

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