

Profiting & competing in the European Generics Industry

to take advantage of off-patent opportunities

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Wednesday 1st and Tuesday 2nd March 2000
Thistle Westminster Hotel, London

Attend this unique and intensive two-day event to . . .

- ⇒ **Identify** the blockbuster drugs and key markets to target
- ⇒ **Gain** contacts and insights into best practice across the industry
- ⇒ **Learn** how to save money and still stay ahead in the generics industry

With speakers from the major generics companies including

- DEBIOPHARM SA • BAYER GMBH • POLPHARMA SA •
- ALFA WASSERMANN SPA • CLONMEL HEALTHCARE LTD •
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Plus! Don't miss the Post-Conference workshop

Basic Principles of Designing a Successful Bioequivalence Study

Led By: **Dr Pieter Zanen** *Department of Pulmonary Diseases* UNIVERSITY OF UTRECHT
Friday 3rd March 2000 • Thistle Westminster Hotel, London

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Produced by:



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COMPETING IN THE EUROPEAN GENERIC INDUSTRY

DAY ONE - Wednesday 1st March 2000

EXAMINING CURRENT TRENDS AND BEST PRACTICE IN THE GENERICS INDUSTRY

09:00 Registration and coffee

09:30 Opening remarks from the Chair
Ian Senior
Special Advisor
NERA

09:40 **KEYNOTE ADDRESS - Embracing the challenge of the next ten years in generics - predicting a few possible scenarios**

- Quantifying the benefit to generics from the diminishing autonomy of the medical profession
- Analysing the effect of the informatics revolution on diagnosis and prescribing
- Assessing the implications of the empowerment of HMOs, insurance companies and governments for the generics industry
- Capitalising on the uncertainty produced by patient empowerment
- Appreciating the prospects for a third chemotherapeutics revolution and the implications for generics of its success or failure

Professor Bryan Reuben
Professor Emeritus of Chemical Technology
SOUTH BANK UNIVERSITY

10:20 **Examining the potential for biogenerics as a serious commercial prospect in Europe**

- Distinguishing between biological generics and biotech generics under the umbrella of 'biogenerics'
- Learning from past experience of 'pseudo generic' approvals
- Appraising the US versus the European approaches to effective and profitable biogenerics and integrating these two approaches into a global development plan
- Pinpointing biotech products coming off patent in the EU and USA
- Ensuring biogenerics are viable by meeting the challenge of making them cost effective

Dr Jean-Yves Le Cotonnec
Chief Executive Officer
TRISKEL INTEGRATED SERVICES

11:00 Morning coffee

11:30 **Improving generic products with new technologies and advanced delivery systems to gain a competitive edge in a crowded market**

- Examining the current status of drug delivery technology in the generics market
- Evaluating the contribution of new technologies and delivery systems as a means of improving on the original patented product
- Balancing the costs of research in formulation development with the prospects for increased profits
- Learning from examples of successful product improvements in the generic and ethical development of supergenerics

Kim Koh Bill
Business Development and Licensing Director
DEBIOPHARM SA

12:10 **Evaluating the benefits of combining a generic arm within a branded company**

- Appreciating the differing needs, cultures and core competencies of the generic and the ethical industries
- Determining requirements for an appropriate management structure to accommodate the two organisations
- Allowing the freedom for the generic arm to compete freely in the generic marketplace
- Achieving multinational coordination and synergy
- Understanding the impact on the value chain
- Assessing alternative commercial approaches

Norbert Bangert
Manager, Generics
BAYER GMBH

12:50 Lunch

EVALUATING EMERGING AND ESTABLISHED GENERICS MARKETS IN EUROPE

14:00 **Optimising market share to successfully compete in European markets**

- Evaluating the strongest European generics markets and predicting their future viability
- Acknowledging the potential of the Central and Eastern European markets
- Understanding the latest developments in France and Spain
- Assessing the impact of EU legislation on developed and developing markets in Europe
- Outlining the commercial reality of selling generic products in Europe with examples of successful business in practice

Clotilde Le Bideau
Senior Project Manager
IMS HEALTH GLOBAL SERVICES

14:40 **Understanding the market potential from European enlargement and the impact of competition from Central and Eastern European (CEE) generic manufacturers**

- Evaluating the size and maturity of the CEE markets and the prospects for successful market penetration for your generic products
- Examining the timetable towards EU integration and ongoing regulatory harmonisation
- Preparing for the threat of cheaper imports from CEE and avoiding consequent downward price spiral
- Assessing the possibility of sourcing active pharmaceutical ingredients from the CEE to cut costs of generic manufacture

Wojciech Kuzmierkiewicz
Director, Research and Development
POLPHARMA SA

15:20 Afternoon tea

15:50 **Understanding the French generics market as a model for European price harmonisation and increased generic substitution**

- Assessing the economic, political and health sector drivers for generic substitution as a cost-containment tool in France
- Analysing the consequences of measures to limit prescription drug spending through generic substitution and other interventions
- Evaluating the impact of generic substitution on pharmaceutical R&D and exploring the potential for innovative offerings in the retail generics market
- Discussing cross-border generic trade and the long-term prospects for the French generics market

Professor Leonard Lerer
Research Fellow
INSEAD HEALTHCARE MANAGEMENT INITIATIVE

16:30 **Anticipating the likely opening up of the Italian market to generic penetration**

- Assessing the impact of as yet unclear regulations on the possibility of a prosperous generics market in Italy
- Evaluating progress towards political recognition and the lifting of the hurdles and misconceptions about a regulated generic market
- Examining the prospects for growth and market penetration in Italy as compared to other southern European markets
- Analysing the key companies and their market potential in order to pinpoint business development opportunities

Dr Massimo Grilli
Director of Business Development
ALFA WASSERMANN SPA

17:10 End of day one

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TO TAKE ADVANTAGE OF OFF-PATENT OPPORTUNITIES

DAY TWO - Thursday 2nd March 2000

09:00 Registration and coffee

09:30 Opening remarks from the Chair

Colin Darroch

Managing Director

SCHEIN PHARMACEUTICAL UK LTD

UNDERSTANDING THE COMMERCIAL AND LEGISLATIVE ENVIRONMENT FOR THE GENERICS MARKET IN EUROPE

09:40 **CASE STUDY**

Successfully launching a new generic product

- Clearing the hurdles of patent defence lawyers and competitor activity
- Anticipating market conditions at launch date
- Planning registration strategy and launch co-ordination
- Choosing your markets and maximising the period of profitable sales

Rory O'Riordan

Chief Executive Officer

CLONMEL HEALTHCARE LTD

10:20 **Taking advantage of government initiatives to promote generic prescribing**

- Analysing the impact of financial awards and penalties as a means of boosting generic prescribing in various European markets
- Evaluating non-financial influences on prescribers and novel methods of encouragement
- Examining the influence of comparative electronic databases to boost generic prescribing:
 - eMIMS
 - Prodigy
 - Other systems
- Outlining the impact of government and industry incentives to pharmacists to encourage growth in generic substitution

Neil Turner

Editor, Pharmapricing & Reimbursement

PPR COMMUNICATIONS LTD

11:00 Morning coffee

11:30 **Understanding the benefits to the generics industry and to healthcare budgets of adopting a Roche/Bolar type provision in Europe**

- Analysing the impact of the US legislation
- Evaluating the likelihood of Europe following suit to stimulate the generics industry
- Assessing the interpretation of experimental use provisions in European countries
- Outlining the WTO litigation between the EU and Canada and its potential impact on the generics industry worldwide

Elizabeth Fuller

Director of Legal Affairs

TRISKEL INTEGRATED SERVICES

12:10 **Interactive brainstorming session on the future of generics**

Now the chance for you to ask all the questions that you've wanted to ask on the subject of generics and also to give some of the answers. Colin Darroch, Managing Director of Shine Pharmaceuticals UK Ltd, will be leading the discussion in what promises to be an open and lively debate.

Led By: Colin Darroch

Managing Director

SCHEIN PHARMACEUTICAL UK LTD

12:50 Lunch

CONSIDERING COST SAVING STRATEGIES AND ANTICIPATING LOGISTICAL PROBLEMS

14:00 **Appreciating the importance of strategic sourcing of active pharmaceutical ingredients (APIs) to reduce the vulnerability of companies to unstable markets**

- Understanding the cost implications of a single source per license against dual or multiple sourcing
- Assessing the effect of good manufacturing practice (GMP) auditing on suppliers outside the EU
- Quantifying the pros and cons of European Drug Masterfiles (EDMFs) versus Certificates of Conformity
- Analysing possible future strategies to decrease the cost of auditing different manufacturers

Jeff Rothwell

Manager of Regulatory Affairs

ROSEMONT PHARMACEUTICALS LTD

14:40 **Examining methods for avoiding downward price spirals in an increasingly free market and looking at cost-saving methods to safeguard profits**

- Analysing reimbursement policies in EU countries and appreciating the impact of moves towards harmonisation
- Understanding whether the new 'fourth hurdle' of economic evaluation for research-based medicines will benefit generics
- Anticipating the benefits of a Roche/Bolar type provision on pricing and profits for generics in Europe
- Competing effectively against cheap parallel imports from emerging markets

Brian Lovatt

Director

VISION HEALTHCARE

15:20 Afternoon tea

15:50 **Re-engineering generic distribution and wholesale in response to original patient packs and millennium shortages**

- Understanding the contribution of confusion around the patient packs to shortages in the supply of generic products at the end of 1999
- Quantifying the impact of millennium stockpiling and deriving lessons for future periods of increased demand
- Developing continuous and open dialogue between the Department of Health, manufacturers and wholesalers to avoid similar shortages in the future
- Counting the cost of failures in distribution and projecting the gains from getting it right through closer liaison

Tony Garlick

General Manager, Leeds Branch (Council Member of BAPW)

UNICHEM LTD

16:30 Closing remarks from the Chair

16:40 End of conference

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Basic Principles of Designing a Successful Bioequivalence Study

Friday 3rd March 2000 • Thistle Westminster Hotel, London

Led By: **Dr Pieter Zanen**

Department of Pulmonary Diseases UNIVERSITY OF UTRECHT

WHY YOU CANNOT AFFORD TO MISS THIS WORKSHOP

This workshop has been especially designed to provide an introduction to the complex area of bioequivalence. The workshop will address the key statistical and pharmacokinetic factors which need to be considered to ensure your study is acceptable.

You will leave the workshop with a grasp of the basic principles of bioequivalence which will ensure that you meet regulatory requirements.

TOPICS TO BE ADDRESSED

9:00 Registration and Coffee	13:30 Clarifying the basic theories of statistical analysis
9:30 Introduction to your workshop leader	14:30 Afternoon tea
9:45 Understanding the basic design of a cross-over bioequivalence study	14:50 Conducting the final calculations and dealing with problems that may arise
10:45 Morning coffee	15:50 Feedback and questions with your workshop leader
11:15 Defining the basic parameters for pharmacokinetic calculations	16:10 Close of workshop
12:15 Lunch	

ABOUT YOUR WORKSHOP LEADER

Pieter Zanen studied medicine at the Utrecht University in the Netherlands. After that he was trained as a general practitioner and briefly joined a heroin clinic. Subsequently he started to work for the Dutch generic company Pharbita, who specialised in anti-asthma products like theophylline sustained release and dry powder inhalers (salbutamol and beclomethasone). In those years he was responsible for all clinical equivalence trials of these products and the registration of them in various European member states. Alongside this he supervised the classical oral bioequivalence trials. As a result of this activity with inhaled drugs he obtained a research position at the University Hospital Utrecht to carry out research in optimising the formulation of inhaled drugs. In 1998 he defended his thesis successfully.

Being involved with equivalence trials he began to study the statistics of these trials, which resulted in a more general interest in this science. During those years he acted as a member of the registration working group of the European Generics Association (EGA) specialising in bioequivalence testing.

Since the beginning of 1998 he shifted from industry to academia and now works as lung physiologist in Utrecht. He is still involved in equivalence testing and together with a subdivision of the Dutch regulatory board he is setting up experiments to validate in vitro equivalence testing of inhaled drugs. He frequently advises on equivalence problems.

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Wednesday 1st and Thursday 2nd March 2000 • London

With twenty-two of the world's leading drugs worth £14 billion coming off-patent in the next three years, can you afford to be left behind in the cut-throat world of the generics market? From the moment a patent expires the race is on to bring out the first generic copy and thereby secure market share. At the same time, increasing overheads, legislative and political changes within Europe and the opening up of new markets mean that it is essential for you to get up to the minute information to guide your decision making and stay ahead of the field.

To help you do this, we have designed a meeting that will tackle directly the unique problems and pressures that you, as a professional in the generics industry, face from day to day. Gathering together an international panel of worldclass experts this event is ahead of the field in providing you with innovative practical advice, case studies and up to the minute news of the generics industry in Europe.

But don't just take our word for it - here are the comments of satisfied customers from previous IIR generics conferences:

"An all round approach and perspective to the generics industry - a good mix of speakers"
Jacqueline Acajos, *Divisional Healthcare Manager*, PROMAR INTERNATIONAL

"Stimulation and education very high. Excellent conference!"
David Hannaby, *Product Leader*, ELI LILLY AND CO LTD

"Gave me a good overview of my industry and how it's changing"
Alison Baden, *Commercial Generics Manager*, WARRICK PHARMACEUTICALS

PLUS don't miss out on the chance to attend our pre-conference workshop '**Basic Principles of Designing a Successful Bioequivalence Study**' and led by: Dr Pieter Zanen, Department of Pulmonary Diseases, UNIVERSITY OF UTRECHT. This workshop will give you an in depth introduction to the complex area of bioequivalence enabling you to ensure your studies are effective and conform to regulatory requirements .

This conference and workshop will give you focused advice, practical examples and individual insights into the challenges of successfully competing in the generic industry.

Book both workshop and conference and save £100!

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I look forward to meeting you at the conference.

Yours sincerely,



Dr Douglas Pretsell
Conference Producer, Pharmaceutical Division

Profiting & Competing in the European Generic Industry

Wednesday 1st & Thursday 2nd March 2000 • Thistle Westminster Hotel

CQ1492

Basic Principles of Designing a Successful Bioequivalence Study

Friday 3rd March 2000 • Thistle Westminster Hotel

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1st & 2nd March 2000
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WORKSHOP:
3rd March 2000
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Tel: 44 (0) 20 7834 1821
Fax: 44 (0) 20 7931 7542

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