

# World Generic Medicines

## Congress Europe 2009

24 – 27 February 2009, The Royal Horseguards, London, United Kingdom

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1 December 2008

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### Hear from



**Gerard van Odijk**

President and Chief Executive  
Officer,  
**Teva Europe**



**Dr. Fritz Oesterle**

Chairman and Chief Executive  
Officer, **Celesio AG**



**Wlodzimierz Gryglewicz**

Chief Executive Officer,  
**Polpharma**



**The Honorable  
Henry A. Waxman,**  
Member of Congress,  
**United States**



**Heather Bresch,**

Executive Vice President,  
Chief Operating Officer,  
**Mylan Labs**

More highlights Page 3 >>  
Full programme Pages 4 - 5 >>



Excellence.

## The business of affordable medicines

**Hear from and meet top generic pharmaceutical leaders:** Teva, Sandoz, Mylan, Hospira, Actavis, Alliance Boots, Novartis, Celesio, Insmad, Zentiva, Dr Reddy and Beijing Double Crane [page 4 and 5>>](#)

**Meet the experts in their field** Help to shape the future of the generics industry [page 4 and 5>>](#)

**Highly interactive pre and post conference workshops:** regulation, the future of generics and business models [page 6>>](#)



### Gala dinner speaker

Rebecca Stephens is the first British woman to climb Everest. Hear Rebecca's inspiring presentation at the *World Generic Medicines Gala Dinner* at the end of Day One.

All details [page 5 >>](#)

Speaker line up – more details [page 3](#)  
Full conference programme [pages 4 - 5](#)  
Conference workshops [page 6](#)  
All booking offers & options [back page](#)

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See back page for details

[www.healthnetworkcommunications.com/2009/genericsuk](http://www.healthnetworkcommunications.com/2009/genericsuk)

Produced by:

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COMMUNICATIONS

4 day Gold pass  
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 See page 8

**"A very distinguished audience"**

**Dr Thomas Brauner**, Head of Regulatory Affairs, **Ratiopharm**

**"Well chosen and interesting subjects with speakers to match"**

**Tony Allen**, Business Development Director, **Arrow Generics**

**"Good variety of subjects and high level speakers"**

**Daniele Gardose**, President, **Infa Group**

# Revolutionise your generics strategy

World Generic Medicines Congress is Europe's largest strategic generics meeting of choice for the industry leaders. The 3rd annual event is now bigger and better than ever before;

- Major representation from key generic pharmaceutical leaders
- Industry experts reviewing global markets
- Unprecedented amount of networking opportunities across the 4 days

Global generic medicines is now a \$100 billion market, growing at over twice the rate of the branded market. The predicted growth is 14 - 15% for 2009 as healthcare providers across the world utilise generic medicines to curtail costs.

Between 2010 and 2012 there is \$100 billion worth of patents that will expire. Biosimilars are opening up a market currently worth \$40 billion and growing at 20% per year but there are significant hurdles to overcome. World Generic Medicines Congress Europe will address these key issues and the courses of action the generics industry will need to take.

This major congress will examine the key strategic and political drivers for generic activity and interpret what this will mean for the future of the industry.

Extensive research with senior members of the global generics market clearly identified the core issues that need airtime and discussion in February – here are some of the questions that our exceptional speaker faculty will be addressing:

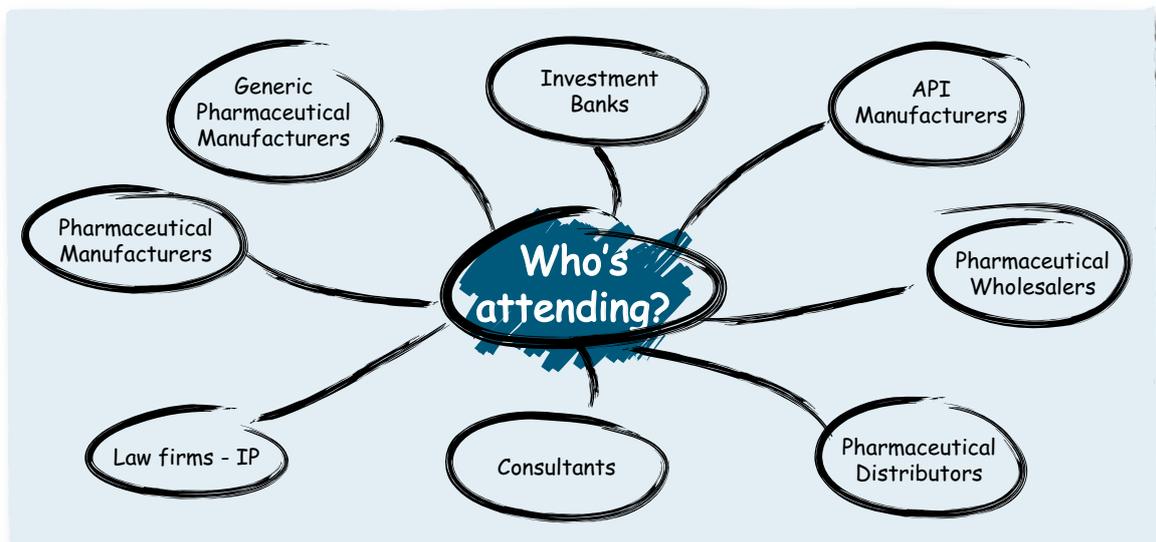
- **Globalisation:** building market share globally, aligning strategy across multiple cultures and



Interact with industry experts in the panel sessions

geographies. Opportunities for entering new markets.

- **Financial forecast:** M&A markets, financial performance, impact on innovator markets
- **Big pharma's plans for generics:** extending life cycles through brand defence strategies
- **Biosimilars:** market entry strategies, regulatory pathway submission, bringing a biosimilar to market and legislative update
- **Delayed entry pacts:** what is the current status and how will these impact other generic pharmaceuticals?
- **Purchasing power and distribution systems in Europe:** how are decisions on generic purchases evolving? How does vertical integration effect purchasing power?
- **European Commissions inquiry:** what impact will this have on the generics industry?
- **Operational challenges in Europe, Africa, Asia and the Americas** how are the markets growing and how to access them? What is the same and what is different with patent litigation?
- **Strategy, legal issues and patent reform:** competition enquiries and the future of authorised generics and settlements



# 8 REASONS

**Here are 8 reasons not to miss the meeting that your peers will be attending**

## Seniority

– 56% of the audience at our past *World Generic Medicines Congress Europe* events were at Chief Executive Officer, Managing Director and Chairman level and a further 26% at Vice President and Head of Department level

## Quality of content

There are no sales pitches and the content has been thoroughly researched with your peers

## A confirmed 6 Chief Executive Officers and 4 Executive Vice Presidents speaking so far

A truly international speaker line-up reflecting the mixture of local, regional and global issues tabled for discussion

## A choice of workshops

Tailor the congress to meet your content and networking needs

## Global reach

Audience profile boasting 31 countries and 5 continents represented at the 2nd annual event

## A proven track record

The success of the *World Generic Medicines Congress* speaks for itself – read the testimonials elsewhere in this brochure!

## 13 generics companies speaking under one roof

And counting – keep an eye on the website as this number looks set to grow....

## Unique overview of the distribution environment

For generics by Europe's top wholesaler

## A-list of generics industry experts

The 3rd annual *World Generic Medicines Congress Europe* brings together a record number of generics manufacturers and other industry experts.



Wholesale and distribution environment in Europe

**Dr Fritz Oesterle**, Chairman and Chief Executive Officer, **Celesio**



**Milan Todorovic**  
Executive Vice President,  
**Actavis Central Eastern Europe**



China – new trends and opportunities for the generic pharmaceutical industry

**Dr Wei Huacheng**, Chairman, **Beijing Pharmaceutical Groups Co. / Beijing Double Crane Pharmaceutical Co.**



Generic industry health check

**Francis Cloud**, Director, Co-Head Healthcare Investment Banking, **Nomura International plc**



Future intellectual property challenges for generic companies

**Julia Pike**, Intellectual Property Director & Counsel, **Hospira Global Pharma R&D Laboratories**



What are big pharma's plans for generics?

**Dr Anthony Ellery**, Formerly Head Lifecycle Management, **Novartis Pharma**



Case study: bringing a biosimilar to market in the US

**Geoffrey Allan**, Chief Executive Officer, **Insmed**

"Interesting and well known conference"

**Dr Maria Saurwein-Teissl**,  
Head of Regulatory Affairs Group,  
Biopharmaceuticals  
**Sandoz**

"Topics, speaker selection and talks are good"

**J S Murthy**,  
President Formulations,  
**Ven Genetec Ltd**

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**13 top generics companies speaking under 1 roof and**

## Day One Wednesday 25 February 2009

8.00 Registration & coffee

8.50 Opening remarks from the chair

9.00 Generic industry health check

- Financial performance
- Profitability
- M&A market
- Impact of innovator companies
- Nomura perspective

**Francis Cloud**, Director, Co-Head Healthcare Investment Banking, **Nomura International plc**,

9:30 **Keynote address: generics and healthcare provisions – opportunities in an International market**



- Changing environment and its effect on the traditional business model
- Lessons to succeed for generics companies

**Gerard van Odijk**, President and Chief Executive Officer, **Teva Europe**

10:00 **Keynote address: operational realities of running a generic company in the CEE**



- Review of the generic pharmaceutical business in CEE and strategies being implemented
- How are companies managing key challenges?
- Review of market dynamics

**Wlodzimierz Gryglewicz**, Chief Executive Officer, **Polpharma**

10:30 Morning tea

11:00 **SPEED NETWORKING** Fun, high-speed networking

11:30 **Keynote address: wholesales and distribution environment for generic medicines in Europe**



- Drivers of the changing environment
- The role of new distribution models like DTP in Europe
- When and how to outsource logistics as Gx industry
- Success factors for the cooperation with logistics providers

**Dr. Fritz Oesterle**, Chairman and Chief Executive Officer, **Celesio**

12:00 **Purchasing power – what is driving the purchasing decisions of pharmaceutical wholesalers, distributors and pharmacies?**

- What decisions big wholesalers make when selecting the generic label in their market – what is their criteria?
- 180 day exclusivity - how much influence does that really have on purchasing decisions?
- How much do patients care about the brand?
- How do they see the generic medicines market evolving?
- How are wholesalers and pharmacy chains competing with generic manufacturers?

**Tony Foreman**, Chief Executive Officer, Almus and Director of Commercial Affairs, **Alliance Boots**

12:30 **European Commission's findings on the pharma sector inquiry: impact on generic medicines**

- Patent strategies
- Litigation
- Settlements
- Other interventions

**Dominik Schnichels**, Head of Pharmaceutical Task force, **European Commission**

13:00 Lunch

14:00 **Keynote address: congressional update and Q&A on Hatch-Waxman reforms**



**The Honorable Henry A. Waxman**

### IP strategy, legal issues and patent reform

14:30 **Future intellectual property challenges for generic companies Enantiomer patents; what they reveal about variation in the standard for validity**

- Patent extension provisions worldwide; inconsistencies and opportunities
- Ongoing impact of TRIPS and bilateral free trade agreements on the global IP landscape
- US Para IV filing strategies; how to protect your 180 day exclusivity
- Proposals for patent issues under pending US biologicals Bills

**Julia Pike**, Intellectual Property Director & Counsel, **Hospira Global Pharma R&D**

15:00 **Patent litigation in Central & Eastern Europe**

- What is the same and what is different?
- What we have learned?
- How to succeed
- Future development

**Dr. Roman Lapka**, Director IP, **Zentiva a.s**

15:30 Afternoon tea

### Southern Europe market focus

16:00 **Review of generic markets in Spain**

- Market conditions for generics in Spain in 2009 and assumptions for 2013
- The players: who is winning and why?
- Is the Spanish Government pushing generics with political willing?
- The wholesale structure in Spain: a key factor for generics

**Angel Calvo**, Managing Director, **Actavis Spain**

16:30 **Review of generic markets in Italy**

- Market conditions for generics in Italy in 2009 and assumptions for 2013
- The players: who is winning and why?
- Is the Italian Government pushing generics with political willing?
- The wholesale structure in Italy: a key factor for generics

**Ezio Frisa**, consultant, formerly Chief Executive Officer, **Pliva Italy**

17:00 **Review of generic markets in Portugal**

- Market conditions for generics in Portugal in 2009 and assumptions for 2013
- The players: who is winning and why?
- Is the Portuguese Government pushing generics with political willing?
- The wholesale structure in Portugal: a key factor for generics

**Speaker to be confirmed**

17:30 **PANEL SESSION** Future of generic medicines in the provisions of healthcare

18:15 Closing remarks from the chair

18:30 Drinks reception

20:00 **GALA DINNER** The Gala Dinner will be held on the evening of the 25 February 2009. This is an opportunity to relax and network over a few drinks and enjoy great food with your fellow attendees. Also hear a truly inspirational speech from **Rebecca Stephens, the first British woman to climb Mount Everest**. See page 5 for details>

## Day Two Thursday 26 February 2009

**8:00 Registration and coffee****8:50 Opening remarks from the chair****9:00 Keynote: authorised generics and delayed entry pacts**

- Authorised generics and delayed entry pacts – current status
- Impact on the introduction of other generic pharmaceuticals
- Further considerations

**Heather Bresch**, Executive Vice President, Chief Operating Officer, **Mylan Labs**

**9:30 Keynote: globalisation and integration**

- Understanding the impact of culture in large scale acquisitions and mergers
- Improve integration process in future, with specific focus on people and culture issues
- Important dimensions: the clarity of business direction, trust, motivation, values, loyalty, results and vision as critical, both at local and global level for Actavis integration process

**Milan Todorovic**, Executive Vice President, **Actavis Central Eastern Europe**

**10:00 Morning tea**

**10:30**  **U turn is your turn. Because your knowledge and experience is important to us, this is where you select the topics and the speakers for a session.**

**11:00 Market opportunities for generics in South Africa and Sub Saharan Africa**

- Sociopolitical and macroeconomic overview
- Market dynamics
- Market entry strategies
- Growth opportunities
- Challenges of doing business in South Africa (and Sub Saharan Africa) and the role of affordable medicines

**Vikash Salig**, Chief Executive Officer, **Dr Reddy's Laboratories South Africa**

**11:30 China – new trends and opportunities for the generic pharmaceutical industry**

- Impact of changes in regulatory infrastructure on the healthcare market in China
- New challenges and opportunities on China pharmaceutical industry
- Best practice sharing of Beijing Pharmaceutical group under the business environment

**Dr Wei Huacheng**, Chairman, **Beijing Pharmaceutical Groups Co. / Beijing Double Crane Pharmaceutical Co.**

**12:00 Lunch****13:00 Big pharma's reaction to growth of generic drugs**

- Redefining the value proposition hurdle
- Identifying sustainable options to extend brand life cycle
- Looking for synergies with generics

**Tony Ellery**, Formerly Head of Lifecycle Management, **Novartis**

**13:30 Injectable Generics in Europe**

- Market evolution
- Competitive dynamics
- Pricing strategies
- Strategic considerations

**Michael Kotsanis**, President, Europe, Middle East and Africa, **Hospira**

- Biosimilar regulatory pathway: what is the difference? why does it matter?
- Ensuring quality by design: the story of the first two biosimilars (development, approval, marketing)
- From dream to reality: the real-life battle for recognition of therapeutic equivalence
- What next? the growing demand for affordable biopharmaceuticals and the need for harmonised global pathways

**Mateja Urlep**, Head Marketing and Medical team, **Sandoz Biopharmaceuticals**

**14:30 Clinical development strategy of biosimilars**

- Creating the clinical development plan
- Minimising financial exposure whilst getting the right answers
- How to cope with regulatory requirements

**Dr Yafit Stark**, Chief Clinical Officer, Innovative R&D, **Teva Pharmaceutical**

**15:00 Afternoon tea****15:30 US legislative update: diversifying into generic biologics**

- Update on the current legislation surrounding the development, registration and marketing of biosimilars in the US
- What are the differences with the process in Europe?
- Modelling the cost of litigation and structuring the financial benefits

**Stuart Williams**, Formerly Chief Legal Officer, **Mylan**

**16:00 Case study: bringing a biosimilar to market in the US**

- Dual path strategy for entry into follow on biologics arena
- Trial data for replication of biologic product
- Financial savings for healthcare
- U.S. Congress biologic approval pathway

**Geoffrey Allan**, Chief Executive Officer, **Insmad**

**16:30 ? PANEL SESSION Panel discussion: how has industry dealt with the new opportunity?**

Have your say and hear from a selection of the speakers in this interactive discussion as they view their thoughts on the following hot topics:

- Potential market entry strategies in the future
- How affordable are generic biologics?
- How big is the market expected to be and how many players can it support?

**17:15 Chair's closing summary**

Inspirational Gala Dinner speaker; **Rebecca Stephens, Mountaineer**

Rebecca is the first British woman to climb Everest and occupies a unique place in mountaineering history. To listen to Rebecca talk about Everest is to be up there on the mountain with her. It is a lesson about what every one of us can achieve. It's about working collectively with other people - about leadership and teamwork. Rebecca's story is a powerful metaphor for our lives and our careers. **Hear Rebecca's address at the networking Gala Dinner after day one.**

**BIOSIMILARS****14:00 Biosimilars - succeeding in the market of the future: the pioneer's perspective**

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Fun, high-speed breaks in the conference day for making new contacts and exchanging details.



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## contact

Arrange meetings online before you arrive. Access event resources, such as white papers and presentations, after you've left.



Meet and talk about the business issues on your brain.



An opportunity to relax and network over a few drinks and enjoy great food with your fellow attendees

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See page 8.

## Pre & Post Conference Workshops

Tuesday 24 February 2009

### Do generics have a future?

#### Objectives

This practical and interactive session will give a unique perspective on the possible ways forward for the generics industry over the next ten years. They do not guarantee accuracy but they can promise a thought-provoking session that will allow you to take some original thinking back to your companies.

#### 9:00 Registration and coffee Morning session

- Main influences on the generics industry today

#### 10:30 Morning tea

- Current financial environment's impact on generic companies
- Is MA the answer, either financially or strategically?

#### 12:00 Lunch Afternoon session

- Best survival strategies for the future
- A look to the future – industry in 2018

#### 14:30 Afternoon tea

- Big pharma; friend or foe?

### You workshop leaders

Frances Cloud has been following the industry for more than 15 years, mainly as an equity analyst but more recently as an investment banker. In both these roles, she has been actively involved in analysing industry trends and mapping out the financial implications of the choices that companies make. Frances is well known for her publications, including Nomura's European Generics Quarterly.

Malcolm Ross has worked in the generics industry for 30 years, in companies including Teva, Par and Taro. He has worked in Central and Eastern Europe and now consults for a number of companies in Europe and Asia. Malcolm's background is technical, mainly on the generic R&D side and as a senior manager he has been intimately involved in discussions of strategy and product life cycle management in different environments.

Friday 27 February 2009

### Regulatory strategy for generic pharmaceuticals

#### Objectives

Bringing a generic drug to market can be fraught with regulatory challenges and compliance issues. This one day seminar will address and clarify the latest regulatory changes and challenges. It will focus on the major strategic issues facing your generic drug submissions helping you to improve speed to market.

#### 9:00 Registration and coffee

#### 9:30 Review of mutual recognition and decentralised procedure for generic medicines

- The DCP and agency expectations
  - What is the effect of the DCP on MRP submissions?
  - Experienced gained and common pitfalls
- Peter Bachmann**, European and International Affairs, **BfArM**

#### 10:00 Current guidelines and expectations for eCTD submission

- European implementation status
- eCTD - guidance as the future submission
- Recommendation of how to submit electronically

**Dr Klaus Menges**, Head of Scientific Quality Assurance, **BfArM**

#### 10:30 Morning tea

#### 11:00 Regulatory review of European biosimilar regulatory submissions

- Clinical data required to register a biosimilar product
- Tips to overcome hurdles in biosimilar registration

**Dr Keith Chidwick**, Pharmaceutical Assessor, **MHRA**

#### 11:30 Regulatory review of inhaled products, design and models

- Review of regulatory changes
- Dr Andres Fuglsang**, Senior Advisor, **Norwegian Medicines Agency**

#### 12:00 Lunch

#### 13:00 Lifecycle management techniques applied to generics

- 505 (B)2 – supergenerics and ANDA
- Europe and US strategy for global development
- Clinical requirements for supergenerics
- Practical experience

**Andrew Willis**, Vice President, Regulatory Affairs & Consulting Service, **Catalent Pharma Solutions**

#### 14:00 Afternoon tea

#### 14:30 Panel discussion: regulatory environment for generics

#### 15:30 Close of workshop

# Becoming a sponsor or exhibitor

At the 3rd annual *World Generic Medicines Congress Europe* we will be building on the tremendous success in February 2008. This event is where the senior decision makers working within all areas of generics globally can meet with Regulatory Bodies and clients to build mutually beneficial partnerships.

If you are a CRO, Generic Manufacturer, Law Firm or Business Intelligence company and you want to promote yourselves within the global generics industry, then this event is the perfect platform on which to do so.

By sponsoring / exhibiting at this event you will be able to network with the senior decision makers working within generic medicines. You will be able to take advantage of the ideal promotional platform which includes direct and email marketing, face-to-face business development, press

relations, telemarketing, print and online advertisements and much more all of which will increase your business profile.

If you have an offering within the generic medicines market and increasing your brand awareness is part of your business plan, then the 3rd annual *World Generic Medicines Congress Europe* is an event you cannot afford to miss!

**To sponsor or exhibit contact**  
**James Hopkins on +44 (0) 20**  
**7608 7038 or email [jhopkins@healthnetworkcommunications.com](mailto:jhopkins@healthnetworkcommunications.com)**



Meet and do business with generics industry decision makers.

### Our Attendees:

At the 2008 event we attracted the key companies working within the generic medicines industry, 70% were Generic Pharmaceutical Manufacturers. From these we attracted the top decision makers, 56% were in Business Development, Licensing and Procurement roles and held Senior Director Level positions along with a further 26%

who were from Chief Executive, Managing Director and Chairman level. This shows we have a proven track record of attracting key generic professionals from all over the world. People attended from Europe, Asia, North and South America, Africa, the Far East which proves this truly is a global event.

### Media partners

### The venue



Overlooking the River Thames, The Royal Horseguards is perfectly positioned in the historic heart of London, just yards from Charing Cross mainline railway station. Its unique location makes it one of the most sought-after hotels in London.

[www.theroyalhorseguards.co.uk](http://www.theroyalhorseguards.co.uk)

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“Very good topics for presentations, several viewpoints on the issues that matter”

**Irina Tornikoski,**  
 Business Development Director,  
**Orion Corporation**

“All speakers of excellent calibre and all topics of interest, will be attending this event next year”

**Jayre Roberts,**  
 Regulatory Manager,  
**Fannin UK**

“Various aspects of the business covered, up to date information, along with a global vision”

**Garo Minassian,**  
 Head of Business Development,  
**Sandoz France**

Something to say?  
**Talk to us about speaker opportunities**  
 Call James Hopkins  
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# World Generic Medicines Congress Europe 2009

Excellence.

24 – 27 February 2009, The Royal Horseguards, London, United Kingdom



**It's quicker and easier to book and pay online**  
 go to [www.healthnetworkcommunications.com/2009/genericsuk](http://www.healthnetworkcommunications.com/2009/genericsuk)  
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Package	Before 01 Dec 08	Before 12 Jan 09	Before 09 Feb 09	After 09 Feb 09	How many	Calculate your ticket
<b>Gold pass – all 4 days</b> 24 - 27 February 2009	£2337.30 + VAT £409.03 = £2746.33	£2497 + VAT £436.98 = £2933.98	£2547 + VAT £445.73 = £2992.73	£2597 + VAT £454.48 = £3051.48	<input type="checkbox"/>	
<b>2 main days plus pre conference workshop</b> 24 – 26 February 2009	£1798.20 + VAT £314.69 = £2112.89	£1898 + VAT £332.15 = £2230.15	£1948 + VAT £340.90 = £2288.90	£1998 + VAT £349.65 = £2347.65	<input type="checkbox"/>	
<b>2 main days plus post conference workshop</b> 25 – 27 February 2009	£1798.20 + VAT £314.69 = £2112.89	£1898 + VAT £332.15 = £2230.15	£1948 + VAT £340.90 = £2288.90	£1998 + VAT £349.65 = £2347.65	<input type="checkbox"/>	
<b>2 day conference</b> 25 - 26 February 2009	£1259.10 + VAT £220.34 = £1479.44	£1299 + VAT £227.33 = £1526.33	£1349 + VAT £236.08 = £1585.08	£1399 + VAT £244.83 = £1643.83	<input type="checkbox"/>	
<b>Networking dinner</b> 25 February 2009 [conference attendees only]	£100 + VAT £17.50 = £117.50	£100 + VAT £17.50 = £117.50	£100 + VAT £17.50 = £117.50	£100 + VAT £17.50 = £117.50	<input type="checkbox"/>	
			<b>Total</b>			

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**Your voucher code**  (you'll need to quote this for telephone and online bookings)

All tickets include refreshments, lunch and full conference documentation. The fee does not include hotel accommodation.

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For groups of more than 2 please attach a separate sheet with details of all attendees. Alternatively call +44 (0)20 7608 7056.

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- Alternatively, you may choose a letter of credit for the full value of the registration price (valid for 1 year), which may be put towards another Health Network Communications event.
- The company regrets that no cancellations will be accepted within 30 days of the conference start date. Prepayments will not be refunded and invoiced sums will be payable in full, except in cases where it has been possible to mitigate loss.
- Course documentation will, however be made available to the delegate. Health Network Communications reserves the right to alter the programme without notice.

**If you reserve your ticket but pay by invoice or bank transfer payment must be received in 7 days**