

# Risk-Sharing & Value-Based Pricing & Reimbursement Models

*Achieving preferential patient-access through innovative agreements with payers*

Conference Dates: 15th-16th April, 2010, Pre-Conference Workshop: 14th April, 2010

Venue: Austria Trend Bratislava Hotel, Bratislava, Slovakia

## Event Overview

There is clearly an increasing need for more innovative pricing and reimbursement agreements to help to balance the often conflicting objectives of pharmaceutical and medical technology manufacturers, payers, health technology assessors (HTA), physicians and patients. The industry faces a sustained increase in the cost of healthcare and ever-increasing range of expensive drugs and technologies available as potential therapies. Clearly, difficult choices need to be made by payers and HTAs about which products receive funding from increasingly restricted healthcare budgets, especially with often insufficient clinical and real-life evidence available. In terms of innovative agreements, risk-sharing and value-based schemes are being proposed more often by more manufacturers, in more countries. Such agreements are increasingly being seen as a method in which pharma and medical device companies can obtain HTA approval to finance the drug from limited budgets, but also a strategy to gain a competitive advantage and preferential market access. Both life sciences companies and policy-makers are looking to achieve a clearer picture of how risk-sharing and value-based agreements can and do work effectively in the real-world. Many examples of complex agreements exist in practice, whilst many governments and pharma companies have far less experience with such schemes. All stakeholders need answers to important questions such as: What is the definition of risk-sharing and value-based pricing schemes? Are such schemes necessary? What are the alternatives? What successful models exist? How can clear endpoints and goals be defined? How can we measure performance effectively? How different schemes are being viewed by different stakeholders? Can risk-sharing and value-based agreements bring a competitive advantage to pharma companies?

## Why Attend?

- ◆ Understand the opportunities, obstacles and challenges in designing and implementing innovative agreements.
- ◆ Find out when risk-sharing & value-based agreements are required and how they can be designed to satisfy all stakeholders to gain market access.
- ◆ Understand whether or not the turbulent macroeconomic environment will increase payer motivation for flexible agreements.
- ◆ Obtain the best and most focused picture of risk-sharing and value-based pricing models today.
- ◆ Learn how drug effectiveness is being demonstrated in different regions.
- ◆ Understand the best ways to communicate value and achieve maximum patient and market access.
- ◆ Hear the perspectives of all stakeholder groups: Payers, regulators, insurers, health economists and the pharmaceutical industry.
- ◆ Discover how payers are evaluating conditional reimbursement agreements.

## Who will benefit

### Pharmaceutical companies:

Vice-Presidents, Directors, Managers involved in: Pricing & Reimbursement, Market Access, Health Economics & Outcomes, Government & Stakeholder Relations, Regulatory Affairs, Medical Affairs, Marketing & Commercial, Therapy Area Heads, Country Managers, Business Unit Heads.

### Solution providers & consultants:

CEOs, Business Development, Senior Consultants, Regional Heads.

Independent Academics, Health Economists, Senior Doctors, & Patient Representatives.

## Your Prestigious Speaker Panel:

### PAYERS & POLICY MAKERS

#### Paolo D. Siviero

Head of the Center for Strategic Studies

**Agenzia Italiana del Farmaco (AIFA), Italy**

#### Dr. Cornelius Erbe

SVP, Head of Product Management  
**D A K (leading German statutory health insurance)**

#### Anne Hines

Lead Pharmacist  
**Merseyside and Cheshire Cancer Network, NHS, UK**

#### Prof. Adrian Towse

Director of the Office of Health Economics  
**OHE, UK**

#### Dávid Dankó, MSc

Deputy Head for Strategy, Analysis and Integration. Department of Reimbursement  
**National Health Insurance Fund Administration, Hungary**

### PHARMA INDUSTRY

#### Simon Holt

VP Global Access Economics & Value Proposition, Market Access, Global Product Strategy

**Solvay Pharmaceuticals & Licensing AG, Switzerland**

#### Elisabeth Paternostre

Vice President, Market Access & Pricing  
**Sanofi-Aventis, France**

#### Christoph Glaetzer

Senior Director Worldwide Health Economics & Pricing B.I.O  
**J&J Pharmaceutical Services, L.L.C., USA**

#### Dr. Klaus Suwelack

Executive Director, Health Value Management  
**Janssen-Cilag GmbH, Germany**

#### Dr. Stefan Sauer

Head Health Care Management & National Health Policy Manager  
**Novartis Pharma GmbH, Germany**

#### Jorge Wernli

VP Global Pricing & Government Affairs,  
**Vifor Pharma, Switzerland**

### DIAGNOSTICS INDUSTRY

#### Jim Vaughn

Vice President, European Markets  
**Genomic Health, Switzerland**

### LEADING ACADEMICS

#### Prof. Jaime Espin

Professor  
**Andalusian School of Public Health, Spain**

#### Dr. Christopher Milne

Associate Director  
**Tufts Center for the Study of Drug Development, USA**

#### Mondher Toumi MD, PhD

Professor of Market Access  
**University of Lyon, France**

### EXPERIENCED SOLUTION PROVIDERS

#### Andrew Hobbs

Managing Director  
**Pope Woodhead and Associates, UK**

#### Jim Furniss

Director of Market Access Solutions  
**Bridgehead International, UK**

#### W. Neil Palmer

President & Principal Consultant  
**PDCI Market Access Inc.**

## Event Partners

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**PDCI** MARKET ACCESS

Bridgehead International





## 13.40 Registration & Coffee

### Workshop: Innovative Pricing Agreements (IPAs)/Risk Sharing Schemes: How to select, develop and implement a successful scheme

The workshop is designed for Pricing and Reimbursement, Market Access, Health Economics and Marketing professionals who want practical advice on when and how to successfully employ innovative pricing agreements as part of a market access strategy. It will help you to:

- ✦ Decide when to use an IPA.
- ✦ Understand how to evaluate scheme options.
- ✦ Appreciate the processes involved in designing an IPA.
- ✦ Deal with health authorities and other stakeholders.

## 14.00 - The rationale and context for IPAs

14.45

- ✦ The rationale for risk sharing – financial and outcomes uncertainty.
- ✦ Types of IPAs.
- ✦ Recent examples of IPAs.

## 14.45 - Why and when to consider an IPA

15.35

- ✦ Economic and healthcare system considerations.
- ✦ Understanding the perspectives of all the stakeholders e.g. company, payers, physicians, pharmacists and patients.

## 15.30 Networking & Coffee Session

### 15.45 - Designing and implementing an IPA

17.30

#### Evaluating the options.

- ✦ Overview of process and selection criteria.
- ✦ Impact and risk analysis.

#### Developing the concept.

- ✦ Modeling variations of the preferred concept.
- ✦ Designing an efficient scheme: data requirements, information flow, IT and support tools.
- ✦ Testing the concept with users.
- ✦ Negotiation with health authorities.

#### Finalising and implementing the scheme.

- ✦ Systems/IT development.
- ✦ Communication and training.
- ✦ Scheme evaluation.

## 17.30 - Conclusions and thoughts on future developments

18.00

### Your workshop leaders:

François Lucas and Chris Easley will run the workshop; both are experienced consultants who have managed a broad range of market access projects including the evaluation, design and successful implementation of innovative pricing agreements. They will be joined at the workshop by Prof. Adrian Towse of the Office of Health Economics.

Pope Woodhead and Associates are a specialist benefit risk consulting group providing a broad range of market access services to the life sciences sector.

popewoodhead

## Why Bratislava?

Sitting aside the Danube, and the capital of the Slovak Republic, Bratislava is emerging as an ideal venue for conferences. Its attractive, cosmopolitan and historical old town centre is an ideal location for relaxed business occasions.

Located close to Vienna (60km) and Budapest (250km) and easily accessible from the Czech Republic & Poland, Bratislava is proving to be a very convenient location for business in the centre of Europe.

### How to fly to Bratislava?

**Option 1:** Bratislava International Airport (airlines include Ryanair, Lufthansa, CSA, LOT)

**Option 2:** Vienna International Airport (and then just a 45-minute taxi ride!)



## Media Partners



## What our previous delegates said . . .

### Sanofi-Aventis, Vice President, Market Access & Pricing

"This meeting has been very good compared to other meetings. It is one of the first focused directly on risk-sharing and everyone now understands exactly what this is all about."

### Astellas Pharma, Senior Director, Pricing & Market Access Europe

"NextLevel seems to work harder than other conference organisers, to deliver a good conference & customer service, please do not follow the others down the 'cost cutting route'"

### Medtronic, Director, International Pricing Strategy

"The average level of the speakers was very high. It is a pleasure to see a conference with so many people. It has been very well organized"

### Talecris Biotherapeutics, Head of Marketing, Europe

"The conference has been great. We took home a lot of useful information and the service has been very good".



08.30 Registration & Coffee

09.00 Chairperson's opening remarks

## INNOVATIVE REIMBURSEMENT TRENDS IN KEY MARKETS

### 09.10 Selecting and implementing innovative pricing strategies

- ✦ Why, what, when?
- ✦ Theory Vs. reality.
- ✦ The need for real innovative pricing: Personalized Medicine/Biomarkers and their impact on pricing.

**Christoph Glaetzer**, Senior Director Worldwide Health Economics & Pricing B.I.O J&J Pharmaceutical Services, L.L.C., USA

### 09.50 Challenging the emerging feverous support of risk-share approaches

- ✦ Bullets TBC

**Simon Holt**, VP Global Access Economics & Value Proposition, Market Access, Global Product Strategy, **Solvay Pharmaceuticals & Licensing AG, Switzerland**

## 10.30 Networking & Coffee Session

### 10.50 Defining performance based risk-sharing agreements

- ✦ An economic framework for categorising them.
- ✦ Cost and practicability.
- ✦ Renegotiation alternatives.
- ✦ Critical Success factors.

**Prof. Adrian Towse**, Director of the Office of Health Economics, OHE, UK

### 11.30 Differences and commonalities in pricing and reimbursement systems in Europe

- ✦ Common aspects in P&R.
- ✦ Future payer & non-pharma trends in P&R.
- ✦ The role of HTA in new P&R systems.
- ✦ Risk-sharing models in key markets.

**Prof. Jaime Espin**, Professor, **Andalusian School of Public Health, Spain**

## PAYERS' PERSPECTIVES & INITIATIVES

### 12.10 Implementing risk-sharing agreements in Hungary from the National Health Insurance Fund's perspective

- ✦ Medical risk-sharing versus financial risk-sharing.
- ✦ Who captures what data? And is it the right data?
- ✦ Do pharma companies accept the sick fund's financial data to be used in risk-sharing schemes?
- ✦ Can third-party data be used in risk-sharing agreements?
- ✦ Ways to overcome data accuracy and other methodology-related barriers?
- ✦ How can compliance-based schemes complement outcome-based schemes?
- ✦ Further initiatives for innovative reimbursement schemes.

**Dávid Dankó, MSc**, Deputy Head for Strategy, Analysis and Integration Department of Reimbursement, **National Health Insurance Fund Administration, Hungary**

## 12.50 Luncheon Break

## 13.50 Networking & Coffee Session

### 14.10 Risk-sharing agreements for high-value oncology treatments

- ✦ Conditional reimbursement and risk-sharing models in the Italian context.
- ✦ Risk-sharing agreements and post marketing evaluation.
- ✦ Risk-sharing and time to access.

**Paolo D. Siviero**  
Head of the Center for Strategic Studies  
**Agenzia Italiana del Farmaco (AIFA), Italy**

### 14.50 Front line experiences of risk-sharing schemes within the NHS

- ✦ How have risk-share schemes influenced the approval of new cancer drugs within the NHS?
- ✦ How the diversity of existing schemes within the NHS may be a risk for non uptake.
- ✦ What cost is the management of cost effectiveness? An audit of uptake and administration of risk-share schemes within NHS trusts.
- ✦ Risk-share schemes are here to stay – how can we make them better?

**Anne Hines**, Lead Pharmacist  
**Merseyside and Cheshire Cancer Network, NHS, UK**

## 15.30 Networking & Coffee Session

### 15.50 Public health insurance considerations

- ✦ Preparing, developing and negotiating innovative reimbursement schemes.
- ✦ Implementation challenges.
- ✦ Lessons learned from past-experience.

**Dr. Cornelius Erbe**, SVP, Head of Product Management  
**D A K (leading German statutory health insurance)**

### 16.30 NICE and not-so-NICE: Adaptive approaches to risk-sharing

- ✦ Who is following the NICE model for risk-sharing schemes and why?
- ✦ Who's not following the NICE model and why - country, health care system and therapeutic area determinants?
- ✦ What are the factors that weigh for and against the use of risk-sharing factors in the major and emerging markets?
- ✦ How are companies adapting their approaches to account for these factors?

**Dr. Christopher Milne**, Associate Director  
**Tufts Center for the Study of Drug Development, USA**

### 17.10 Panel discussion: Payers' needs & considerations while deciding on an innovative model?

- ✦ Risk-sharing, value-based pricing or other innovative schemes?
- ✦ What can convince payers to stay with traditional reimbursement procedures?
- ✦ Future payer initiatives.

**Simon Holt**, VP Global Access Economics & Value Proposition, Market Access, Global Product Strategy, **Solvay Pharmaceuticals & Licensing AG, Switzerland**

**Prof. Adrian Towse**, Director of the Office of Health Economics, OHE, UK

**Paolo D. Siviero**, Head of the Center for Strategic Studies  
**Agenzia Italiana del Farmaco (AIFA), Italy**

**Dr. Cornelius Erbe**, SVP, Head of Product Management  
**D A K (leading German statutory health insurance)**

17.40 Chairperson's closing remarks

17.50 End of Day One

- 19.00: EXCLUSIVE NETWORKING DINNER FOR ALL EVENT ATTENDEES -

# Risk-Sharing & Value-Based Pricing & Reimbursement Models

*Achieving preferential patient-access through innovative agreements with payers*

08.15 Registration & Coffee      08.35 Chairperson's opening remarks

### INDUSTRY CASE STUDIES & EXPERIENCES

#### 08.45 UK case study - Designing and implementing a successful and efficient patient access scheme

- ✦ Rationale for the scheme.
- ✦ Process for selecting the right option.
- ✦ Step-by-step process from design to validation to implementation.
- ✦ Negotiations with health authorities.
- ✦ Impact of the scheme.

**Andrew Hobbs**, Managing Director  
Pope Woodhead and Associates, UK

#### 09.10 Risk-Share Contract in the field of osteoporosis between sick funds and Novartis Pharma in Germany

- ✦ From situation analysis to the idea for a risk-share contract.
- ✦ Negotiation & implementation experiences.
- ✦ 2 years after implementation: what works well and where there is room for improvement?

**Dr. Stefan Sauer**, Head Health Care Management & National Health Policy Manager  
Novartis Pharma GmbH, Germany

#### 09.50 Development of value based pricing and risk-sharing in the UK

- ✦ The OFT Report, value-based pricing and the government's response.
- ✦ The 2009 PPRS agreement.
- ✦ The framework for price adjustment.
- ✦ The framework for risk-sharing.
- ✦ The potential and limitations for companies with innovative products.

**Jim Furniss**, Director of Market Access Solutions, Bridgehead International, UK

#### 10.30 Networking & Coffee Session

#### 10.50 New contracting models with payers including disease management: Schizophrenia case

- ✦ Rationale for engagement in care management.
- ✦ Involvement of doctors in contracting models.
- ✦ Outlook: Taking over budget risks.

**Dr. Klaus Suwelack**, Executive Director, Health Value Management  
Janssen-Cilag GmbH, Germany

#### 11.30 How are different schemes viewed by payers and by companies?

- ✦ Bullets TBC

**Elisabeth Paternostre**, Vice President, Market Access & Pricing, Sanofi-Aventis, France

#### 12.10 Canada: Risk-Sharing & Value-Based Pricing & Reimbursement

- ✦ Overview of Canadian pricing and reimbursement systems.
- ✦ Provincial reimbursement schemes requiring listing agreements.
- ✦ Financial vs outcomes based risk sharing agreements.
- ✦ Elements of successful agreements: Canadian case studies.
- ✦ Outlook for listing agreements; implications for price transparency, price regulation and assessing value for money.

**W. Neil Palmer**, President & Principal Consultant, PDCI Market Access Inc.

#### 12.50 Luncheon Break

#### 13.50 Networking & Coffee Session

#### 14:10 Gaining Market Access with an innovative genomic classifier

- ✦ Why the need to risk-share for a molecular diagnostic?
- ✦ The negotiation process: identifying common requirements and areas for compromise.
- ✦ Agreement structure & the challenges in monitoring & measuring success.
- ✦ Future potential.

**Jim Vaughn**, Vice President, European Markets, Genomic Health, Switzerland

#### 14:50 Pitfalls of risk sharing agreement

- ✦ What is not a risk-sharing agreement?
- ✦ Why companies enter into risk-sharing agreements?
- ✦ Do risk sharing agreements contribute to value creation?

**Mondher Toumi MD PhD**, Professor of Market Access  
University of Lyon, France

#### 15:20 Panel Discussion: Measuring contracts' success

- ✦ Defining clear and realistic end points.
- ✦ Following agreement's implementation.
- ✦ How should the industry approach future agreements?

**Dr. Stefan Sauer**, Head Health Care Management & National Health Policy Manager  
Novartis Pharma GmbH, Germany

**Christoph Glaetzer**, Senior Director Worldwide Health Economics & Pricing B.I.O  
J&J Pharmaceutical Services, L.L.C., USA

**Anne Hines**, Lead Pharmacist  
Merseyside and Cheshire Cancer Network, NHS, UK

**Dr. Christopher Milne**, Associate Director  
Tufts Center for the Study of Drug Development, USA

**Jorge Wernli**, VP Global Pricing & Government Affairs  
Vifor Pharma, Switzerland

15.50 Chairperson's Closing Remarks      16.00 End of Day Two

## NextLevel Pharma: Upcoming Events



**Innovative Market Access Strategies for Medical Devices & Technologies**

*Understanding & satisfying payer & stakeholder needs to demonstrate cost-effectiveness & product value*

Conference Dates: 18th-19th March, 2010 - Venue: Budapest, Hungary



- THIRD ANNUAL -

**Pharmaceutical Pricing & Reimbursement In Central & Eastern Europe**

*Optimising & implementing innovative market access techniques in an exciting & complex market*

Venue: Budapest, Hungary - Conference Dates: June 7th-8th, 2010

# Risk-Sharing & Value-Based Pricing & Reimbursement Models

# event registration

## HOW TO REGISTER:

**OPTION 1:** Please complete this form and fax back to: **FAX: +421 232 662 622**

**OPTION 2:** Scan and email to [luke.rogers@nextlevelpharma.com](mailto:luke.rogers@nextlevelpharma.com)

**OPTION 3:** Click here to register online!

### Please write in BLOCK CAPITALS

**Organisation:** \_\_\_\_\_

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**City:** \_\_\_\_\_ **Country** \_\_\_\_\_

**Phone:** \_\_\_\_\_

**VAT Number:** \_\_\_\_\_

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#### DELEGATE 1

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**Job Title:** \_\_\_\_\_

**Email:** \_\_\_\_\_

#### DELEGATE 2

**Name:** \_\_\_\_\_

**Job Title:** \_\_\_\_\_

**Email:** \_\_\_\_\_

#### DELEGATE 3

**Name:** \_\_\_\_\_

**Job Title:** \_\_\_\_\_

**Email:** \_\_\_\_\_

### DELEGATE PACKAGES: (Please Select your Delegate Package) - 2 DAY CONFERENCE:

<b>2 day Conference + half day workshop:</b>	€2689.00 + 19% VAT	<input type="checkbox"/>
2 delegates -10% Discount :	€2420.10 + 19% VAT Each	<input type="checkbox"/>
3 delegates -15% Discount :	€2285.65 + 19% VAT Each	<input type="checkbox"/>
<b>2 day Conference (only):</b>	€2190.00 + 19% VAT	<input type="checkbox"/>
2 delegates -10% Discount :	€1971.00 + 19% VAT Each	<input type="checkbox"/>
3 delegates -15% Discount :	€1861.50 + 19% VAT Each	<input type="checkbox"/>
Academic Rate	€950.00 + 19% VAT	<input type="checkbox"/>
*Available only for the first 20 attendees and before the specified date **Please enquire about discounts for larger groups & academics		
Event video recordings & documentation (only)	€799.00 (no VAT)	<input type="checkbox"/>
Event documentation (only)	€399.00 (no VAT)	<input type="checkbox"/>

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**Name** \_\_\_\_\_

**Date** \_\_\_\_\_

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**THE HOTEL BOOKING FORM WILL BE SENT TO YOU AFTER THE EVENT REGISTRATION.**

### NEXT LEVEL PHARMA Conference Agreement Terms & Conditions of Booking:

- Registration fees include programme materials, food and refreshments.
- Once a completed registration form has been received, full payment is required within 5 working days from receipt of invoice. A receipt will be issued following payment.
- The client recognises that NextLevel Pharma organises high quality events, with strictly limited numbers of attendees and incurs expenses as a result. NextLevel Pharma relies on all it's clients to honour the agreement and make the required payment in order to guarantee the conference's success.
- Cancellation & Substitutions: Upon receipt of payment, substitutions of delegates can be made at any time before the meeting at no further cost. Once a completed registration form has been received any cancellations will result in a 50% cancellation fee. Cancellations received only 1 month before the conference date cannot be refunded whatsoever. In the result of a cancellation, NextLevel Pharma is willing to provide a credit at full value to the client at any time within 24 hours of the event taking place, upon receiving full payment and written notice of non-attendance. Non-attendance or non-payment does not make this contract void. Payment is always required once the registration form has been received. Payment must be received before the start of the event.
- \* For group discounts to apply all delegates must register on the same day.

- Whilst all reasonable care and effort has been made, NextLevel Pharma reserves the right to alter the programme content without notice. If, for any reason NextLevel Pharma decides to cancel, postpone or merge this conference with another conference, NextLevel Pharma is not responsible for covering hotel, airfare, or other expenses incurred by clients. The conference fee can be credited to a future conference.
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