EUROPEAN DIAGNOSTIC REIMBURSEMENT & MARKET ACCESS

Overcoming Evolving Healthcare Environments through Evidence Development to Support Positive Funding and Reimbursement Decisions, Utilization of Health Technology Assessments throughout Europe within the Diagnostic Industry

LEADING HEALTH TECHNOLOGY ASSESSMENT PERSPECTIVES

GERMANY: IQWIG
Julia Kreis
Research Department
Non-Drug Interventions
IQWIG

UK: NICE
Martina Garau
Senior Economist
OFFICE OF HEALTH ECONOMICS

FRANCE: CNEDIMTS
Alain Bernard
Vice President
CNEDIMTS

INDUSTRY KEYNOTE PRESENTATIONS

Mattias Borst
VP & General Manager, Central Europe
BECTON DICKINSON

Carolyn Bodnar
Manager Health Economics – Medical Diagnostics, Global Evidence Generation
GE HEALTHCARE

Lisse-Lotte Hermanson
Director Health Economics for Global Marketing at ImmunoDiagnostics
THERMO FISHER

Torsten Horns
VP Sales Europe
EPIGENOMICS

Seong Chen
Project Leader, Strategic Initiatives, Global Business Development
ROCHE DIAGNOSTICS

Anne Postulka
Director of Medical and Economic Value, Europe
CEPHEID

LEADING EXPERT CASE STUDIES

Jan vanEmelen
Director Innovation & Strategy
MLOZ INSURANCE FUNDS OF BELGIUM

Peter Bogaert
Partner
COVINGTON & BURLING

Gijs Hubben
Director of Health Economics
BASECASE

Josselin Thuilliez
Researcher
SORBONNE ECONOMY CENTER, PARIS

Chris Teale
Principal Consultant, Market Access, Healthcare
GIK BRIDGEHEAD

Christian Fulda
Partner
JONES DAY

Irina Odnolektova
Project Manager Innovation
MLOZ INSURANCE FUNDS OF BELGIUM

WHAT YOU WILL LEARN FROM ATTENDING THIS PROGRAM

- Strategies to achieve market access in a time and cost-effective manner in more than one EU country at a time
- How to approach European key-market Health Technology Assessors and present strong value for your diagnostic interventions
- Better understanding of areas of scrutiny from European HTAs and strategies to meet expectations
- Maximize downsized teams and lower budgets within the reimbursement function
- Peers experiences in generating and exhibiting strong economic and medical evidence
- Thorough understanding of new regulations and healthcare reforms impacting reimbursement
- Opportunities and benefits of pan-EU workgroups (EUnetHTA, Euro DRG Project)
DAY ONE / THURSDAY, SEPT. 13 / EU DIAGNOSTIC REIMBURSEMENT & MARKET ACCESS

10:00 DEVELOPING A STANDARDIZED APPROACH TO REIMBURSEMENT FOR MULTIPLE EUROPEAN MARKETS

Though each European nation has a specific regulatory, application and evaluation process to allow access of a diagnostic to the market, the pathways to obtain reimbursement do show similarities that can be utilized. By identifying parallels in each country-specific process, reimbursement and market access executives can build a standardized process that will fit multiple European markets, allowing undeniable cost and time saving. Considering a centralized approach and examining strategies to develop it in the most efficient manner will help in accessing more markets in less time.

• Studying European reimbursement pathways and identifying parallels
• Developing the most cost-effective approach to multiple markets
• Tailoring the process to meet country-specific evidence requirements

Lisse-Lotte Hermansson, Director Health Economics for Global Marketing at ImmunoDiagnostics

10:45 STRATEGIES FOR SUCCESSFUL GENERATING OF EVIDENCE THROUGH CLINICAL TRIALS

An ongoing challenge faced by reimbursement and market access teams is to ensure a sufficient amount of product efficiency evidence is generated throughout clinical testing. Indeed providing the right amount and level of data required by health authorities is critical to ensure positive decisions. Bridging the gap between teams involved in clinical testing and reimburse- ment executives offers undeniable opportunities to develop strategies with both fields’ requirements met, and a faster access to the targeted market.

• Evaluating health authority evidence requirements ahead of the trial
• Bringing together clinical and reimbursement intelligence
• Opportunities in conducting trials in the targeted market

Carolyn Bodnar, Manager Health Economics Diagnostics, Global Evidence Generation

GE HEALTHCARE

11:30 EUNETHA: POSITIVE IMPACT OF DIAGNOSTIC REIMBURSEMENT THROUGH HTA NETWORK

After 2 years of building a sustainable HTA network throughout Europe, in 2010 EUNETHA developed the Joint Action to stimulate knowledge sharing and communication between Health Technology Assessors in the Union. Notably in the field of evidence requirements and studying, the liaison between European HTAs aims at a better and facilitated approach of health technology reimbursement and market access on a pan-European level.

• Overview of EUnetHTA accomplishments
• Understanding the underlying benefits in the network
• Impact on diagnostic reimbursement
• Forecasting the evolution of EUnetHTA in the years to come

Irina Odnoletkova, Project Manager Innovation

MLOZ

Chairwoman

HEALTH TECHNOLOGY ASSESSMENT WORKGROUP

12:15 LUNCHEON FOR ALL SPEAKERS, SPONSORS & ATTENDEES

1:15 HTA EXAMINATION PROCESSES: UNDERSTANDING AREAS OF SCRUTINY TO ENSURE MARKET ACCESS

In the current evolving healthcare landscape, Health Technology Assessors are restructuring and updating processes for medical technology evaluation. With an even stronger emphasis on effectiveness and beneficial patient outcomes than before, reimbursement and market access executives need to perfectly understand how their diagnostics will be examined and tested, to ensure a successful issue and ultimately, market access. Focusing on the three largest European markets, participants in this session will better understand HTA processes in the UK, Germany and France.

UNITED KINGDOM – NICE:

• NICE’s Technology Appraisals for test- treatment combinations
• Understanding NICE’s Diagnostics Assessment Programme
• Does the current assessment process consider all the relevant aspects of value generated by diagnostics?

Martina Garau, Senior Economist

OFFICE OF HEALTH ECONOMICS

GERMANY – IQWIG:

• Outlining differences between in & out-of-hospital procedures
• Effectiveness as a base for HTA decisions
• New legislation “Versorgungsstrukturgesetz” impact

Julia Kreis, Research Department Non-Drug Interventions

IQWIG

FRANCE – HAS/CNEDIMTS:

• Understanding the French Single Assessment
• Concerns surrounding CE marking
• Clarifying the T2A reform

Alain Bernard, Vice President

CNEDIMTS

2:15 PANEL DISCUSSION: SUCCESSFULLY MEETING HTA EXPECTATIONS

Market access of a diagnostic product in Europe implies meeting the exact product evidence and value dossier requirements from HTAs. A full understanding of what HTAs expect and will examine is critical in order to achieve positive decisions and ensure that the product value dossier is sufficiently well developed. Opening discussion with representatives of the 3 European key-market HTA representatives and affiliates will allow clarifying of these expectations and obtaining replies to lingering questions.

• Country by country perspectives on evidence requirements
• Strategies to meet expectations
• Building the value dossier accordingly

MODERATOR:
Paul Mernagh, BASECASE

PANELISTS:
Martina Garau, OFFICE OF HEALTH ECONOMICS
Julia Kreis, IQWIG
Alain Bernard, CNEDIMTS

2:45 CASE-STUDY: COMMUNICATING ECONOMIC VALUE TO HEALTHCARE PROVIDERS – DELIVERING TAILORED VALUE MESSAGES IN A VISUAL, INTERACTIVE FORMAT

In a changing healthcare industry, successful market adoption of new tests depends increasingly on presenting a compelling business case to healthcare providers. However commercial teams are not comfortable using complex economic spreadsheets in front of customers. In this case-study, the co-presenters will outline how Thermo Fischer leveraged BaseCase technology to present the economic value proposition for a novel IVD test.

• How to visualize complex economic data
• How to deliver a tailored value story for different customers and regions

Lisse-Lotte Hermansson, Director Health Economics for Global Marketing at ImmunoDiagnostics

GJS Hubben, Chief Executive Officer

BASECASE

3:15 COFFEE & NETWORKING BREAK

3:45 EURO DRG PROJECT: CROSS-COUNTRY COMPARISON FOR BETTER PRODUCT INTEGRATION

Over time, most European markets have transitioned to a Diagnosis Related Group (DRG) process as a mechanism for hospital financing. The hospital payment system is an important factor influencing the adoption and use of technological innovation in health care. Through a European cross-country study and comparison, health economists are working to evaluate how DRGs capture variation in resource use, what influence the hospital has on the overall utilization of the resources and the incentives for a hospital to adopt innovative medical products.

• Overview of the EuroDRG Project goals
• Short-term payment instruments vs long-term updating mechanisms
• Hospital resource management assessment
• Incentives for European hospitals to adopt new diagnostic tests

Josselin Thulliez, Researcher

SORBONNE ECONOMY CENTER, UNIVERSITY PARIS 1

Thomas Renaud, Former Statistical Engineer

IRDES (FRENCH INSTITUTE FOR RESEARCH & DOCUMENTATION IN HEALTH ECONOMICS)

4:30 INNOVATIVE DIAGNOSTIC INTEGRATION & REIMBURSEMENT SUCCESS STORIES IN EUROPEAN KEY-MARKETS

With the rapid development of personalized medicines, diagnostics can now target from very small to large patient populations. But developing tests for specific populations also implies integrating the product into existing reimbursement systems throughout Europe. As requirements differ from one country to another, especially for new and innovative tests, achieving a successful integration is often a hurdle for reimbursement and market access executives. Through several best practices, participants in these sessions will learn about strategies to successfully integrate an innovative product into European key-markets.

GERMANY:

• Understanding the current G-DRG mechanism
• Overview of the NUB Process
• Industry’s forecast of ‘Versorgungsstrukturgesetz’ impact

Matthias Borst, VP & General Manager/Central Europe

BECTON DICKINSON

President

GERMAN DIAGNOSTIC INDUSTRY ASSOCIATION (VDGH)

ITALY:

• Identifying “Best Practices” for integrating new & innovative diagnostics
• Working with decision makers, budget holders and regional bodies
• Developing strategies for faster access to funding and results

Anne Postulka, Director of Medical and Economic Value, Europe

CEPHEID

5:30 CLOSING REMARKS & DAY ONE CONCLUSION
DAY TWO / FRIDAY, SEP. 14 / EU DIAGNOSTIC REIMBURSEMENT & MARKET ACCESS

8:30 REGISTRATION & COFFEE

9:00 CASE STUDY: SUCCESSES IN EXHIBITING EVIDENCE FOR STATE OF THE ART DIAGNOSTICS
Developing a value dossier for an innovative test is a challenge faced by all reimbursement teams, as it needs to fully exhibit evidence of a new product that might not be comparable to an existing one. Not only must the dossier reflect the clinical purpose and advantages in the utilization of the innovative diagnostic, but also shed light on positive economic factors & projections. Through this case study, participants in the session will learn from a peer's experience on successful strategies to present state of the art diagnostic evidence to health authorities.
- Understanding the level and amount of evidence required
- Giving a positive spin to innovation
- Stressing economic added value
Zivjena Vucetic, Director Global Scientific Affairs
FUJIREBIO DIAGNOSTICS

9:45 OPPORTUNITIES IN EARLY PLANNING OF DIAGNOSTIC REIMBURSEMENT
Throughout diagnostic development, testing and application, all steps of the product elaboration research and development can influence reimbursement and market access strategies. While most organizations start developing their approach to target markets once the diagnostic has obtained CE marking, proactive examination of requirements and reimbursement/market access pathways assists in having the test fit in the system. Early thinking and elaboration of the reimbursement/market access plan in key countries will enhance successful outcomes and market access.
- Considering reimbursement systems during product research and development
- Developing & tailoring reimbursement/market access strategy prior to CE mark approval
- Benefits and challenges in working closely on strategy with sales affiliates in the targeted markets
Seong Chen, Project Leader, Strategic Initiatives, Global Business Development
ROCHE DIAGNOSTICS

10:30 COFFEE & NETWORKING BREAK

11:00 THE EVOLUTION OF REIMBURSEMENT IN ONCOLOGY
DIAGNOSTIC TESTING
With the release of HER2 testing, the diagnosis and prognosis of cancer patients was forever changed. As a result, the funding of diagnostic tests has also evolved, and will most certainly continue to evolve as the platform for biomarker based drugs continues to grow from HER2 via KRAS, EGFR to ALK, ALK and beyond. Understanding the various perspectives that have enabled this evolution, including payers, pathologists, physicians, patients, and the developers will provide unique insights for executives on the future of diagnostic testing reimbursement.
Chris Teale, Principal Consultant, Market Access, Healthcare GIK BRIDGEHEAD

11:45 FORTHCOMING TRANSPARENCY DIRECTIVE ON PRICING & REIMBURSEMENT OF COMPANION DIAGNOSTICS IN EUROPE
In the current evolving healthcare environment, the diagnostic industry is facing new directives to understand and comply with in a timely manner. The Transparency Directive first applied to the pharmaceutical industry and now also concerns manufacturers seeking reimbursement for companion diagnostics. Through this presentation, participants will have a thorough overview of this directive that will impact pricing and reimbursement strategies.
- Forecasting the impact of new IVDR Regulation on P&R
- Interconnection of molecular diagnostic assessment with medicine approval
- IVDs, the new Transparency Directive and Public Procurement Directive
Peter Bogaert, Partner
COVINGTON & BURLING

12:30 LUNCHEON FOR ALL SPEAKERS, SPONSORS & ATTENDEES

1:30 FOLLOWING EVOLVING HEALTHCARE REFORMS IN KEY EUROPEAN MARKETS FOR ROBUST REIMBURSEMENT STRATEGIES
In order to develop the most efficient reimbursement strategy possible, it is critical to stay abreast of all evolutions in the healthcare framework of this partner state country. In the past year, legisation and recommendations have been implemented in large key-European markets such as the UK, Germany and France aiming at a better control of market access and improving health outcomes. By examining changes in the healthcare environment of all three countries, reimbursement strategies will be reinforced to fit updated requirements.

GERMANY:
- Impact of the 2010 healthcare reform
- Implementing the “Versorgungsstrukturgesetz”
- Considerations on AMNOG and companion diagnostic pricing

UK:
- Overview of the UK healthcare reform
- Reviewing the new NHS and policy of UK reimbursement pathway
- The “Nicholson Challenge” and its impact on value dossiers and pricing

FRANCE:
- Examining the ongoing healthcare reform
- AFSSAPS becoming ANSM and impact on market access
- Forthcoming Xavier Bertrand Law on medical advertising
Christian Fulda, Partner
JONES DAY

2:15 FACILITATING MARKET ACCESS THROUGH PERSONALIZED MEDICINE TRENDS
At this time, an increasing and certainly promising trend in the healthcare industry is to bring together a diagnostic test and a pharmaceutical product to ensure that the patient is most applicable to the utilization of a therapy. This partnership between the pharmaceutical and the diagnostic industries opens doors to a facilitated pathway to obtaining reimbursement for diagnostics in Europe, while also posing considerable challenges for manufacturers as they create partnerships with the pharmaceutical industry.
- Developing a diagnostic for it to target an existing therapy
- Setting partnerships between pharma & diagnostic corporations
- Matching timelines for market access
Executive to be determined
EDMA

3:00 COFFEE & NETWORKING BREAK

3:15 WORKING WITH EUROPEAN THIRD PARTY PAYERS TO ENHANCE OVERALL REVENUE & REIMBURSEMENT
Although to some extent less prevalent within the European market, third party payers continue to play a vital role in the reimbursement picture throughout Europe. Working with third party payers is critical to ensuring overall success, and is substantially different than working with government health systems to secure market access. Having a thorough understanding of the information third party payers are looking for, how to best engage them, as well as obtaining positive reimbursement decisions from these organizations is a key aspect that every reimbursement executive needs to fully understand.
- Overview of the private payer market in Europe
- Key statistics on third party payer reimbursement
- Evidentary requirements from third party insurers
Jan van Emelen, Director Innovation & Strategy
MLOZ (INDEPENDENT HEALTH INSURANCE FUNDS, BELGIUM)
Head of Disease Management Workgroup
INTERNATIONAL ASSOCIATION OF MUTUALS

4:00 BEST PRACTICES IN ACCESSING THE PRIVATE PAYER MARKET, FOCUS ON GERMANY
Amongst all pathways towards obtaining reimbursement of a diagnostic in European countries, accessing the private payer market may appear as an easy access to the targeted market, especially as a first step and test launch. The private payer market has its own challenges. Through this practical presentation, participants in the session will better understand access, rules, dos and don’ts for a successful private payer market access in Germany, one of the largest European private in vitro diagnostics markets.
- Opportunities in targeting private payers
- Understanding IGeL Market rules in Germany
- Paths and pitfalls towards private payer market access
Torsten Horns, VP Sales Europe
EPIGENOMICS

4:45 CLOSING REMARKS & CONFERENCE CONCLUSION
KEY SPEAKER SPOTLIGHT:

Matthias Borst  
VP & General Manager/Central Europe  
BECTON DICKINSON  
President  
GERMAN DIAGNOSTIC INDUSTRY ASSOCIATION (VDGH)

In January 2002, Matthias joined BD in Heidelberg as Marketing Director Consumer Healthcare Germany. End of 2003, he became Business Director Diabetes Care. In October 2004, he was appointed Country General Manager for BD in Germany, Switzerland and Austria. Since October 2010, Matthias is leading the Central Europe area as Vice President & General Manager, Central Europe, being responsible for 16 countries from an overall business perspective.

In addition to his job with BD, Matthias is Chairman of the Board of the German trade association of the Diagnostics Industry (VDGH) and an executive member of the American Chamber of Commerce in Germany and joined the Board of Directors in 2011.

Prior to BD, Matthias worked ten years with Abbott Laboratories, lastly as a National Sales Manager for Abbott Diabetes Care. From 1986 to 1991 he studied medicine at the University of Ulm.

WHO SHOULD ATTEND:

Executives that will find this program of greatest relevance are those currently working to secure funding and reimbursement for diagnostic products throughout the European market. Job titles of those executives that will find this program to be most applicable to their job functions include:

- Reimbursement & Market Access
- Health Policy
- Pricing
- Government Affairs
- Health Technology Assessment
- Health Economics & Outcomes Research

SPONSORSHIP OPPORTUNITIES:

At this time, there are a variety of sponsorship and exhibition opportunities available for companies wishing to increase their visibility and participation in the program, ranging from keynote speaking opportunities through to exhibitor and documentation sponsors.

Organizations most suitable for this type of exposure provide services and solutions including:

- Reimbursement Consultants
- Regional Reimbursement Experts
- Health Economics Researchers
- Health Technology Assessors
- Clinical research Organization
- Diagnostic Companies
- Pharmaceutical Corporations

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PREVIOUS ATTENDEES INCLUDE:

Marketing Manager, 77 Elektronika  
CEO, Abaxis GmbH  
Director of Reimbursement, Abbott/Mkt, Access & Govt Affairs, Abbott Diabetes Care  
Director, Herculean Leadership, Abbott GmbH  
Dir., Pricing & Access, AstraZeneca Diagnostics  
Director of Reimbursement, Beckman Coulter  
Mgr, Health Policy & Reimb, Becton Dickinson  
Sr, QA & RA Specialist, Becton Dickinson  
Country General Manager, Becton Dickinson  
Area Manager, BioHit, SA  
Global Marketing Head, Bio-Rad  
Director, Medical & Economic Value, Cepheid  
CEO, Chempaq A/S  
VP Strategic Marketing, Dako  
Director, Strategic Marketing, Dako Denmark  
CEO, DiaGenic ASA  
CEO, Dialog Devices  
Country Manager, DiaSorin Deutschland GmbH  
Sr. Director Market Development, DxS Qiagen  
Manager Scientific Marketing, Epigenomics  
VP, Sales, Epigenomics AG  
Director, Global Health Development, F. Hoffman La Roche  
Director, Biomedical Research, Fresenius  
Director, International Sales, Fujifrebio Diagnostics  
Head, Quality Assurance, Regulatory Affairs, GE  
Dir., HTA & Managed Care, Genomic Health  
CFO, Genomic Vision  
Director, Product Development, Genomic Vision  
Of Counsel, Greenberg Traurig, LLP  
Director, Business Development, Hitachi Diagnostics  
Business Development Manager, Hologic  
General Manager, Hycor Biomedical  
Product Manager, Immunocor  
Principal Product Developer, Innogenetics NV  
Mgr, Application Development, Life Technologies  
Exec, VP, International Operations & Pricing, Myriad Head, Market Access Diagnostics, Novartis  
Director, Global Marketing - New Products, Novartis  
Director, Business Development, OncoMethylome  
Director, Reimbursement, Ortho Clinical Diagnostics  
Segment Leader, PerkinElmer  
Director, Health Economics, Phadia AB  
Product Manager, Central Marketing, Phadia GmbH  
Head of Marketing, Renishaw Diagnostics  
Head, Medical Shared Services, Roche Diagnostics  
Head, Healthcare Marketing, Roche Diagnostics  
Head, Payer Marketing, Roche Diagnostics GmbH  
CMO, Roche Professional Diagnostics  
VP, Marketing & Sales, Salada Biomedical  
COO & President, Salada Biomedical  
Director, Clinical & Commercial Operations, SciBase  
Director, Strategic Pricing, Siemens Healthcare  
Mkt Analyst & Business Developer, SSI Diagnostica  
VP, Global Marketing, Systagenix Wound Mgmt.  
Country Manager, The Binding Site  
UK Sales Manager, Thermo Fisher  
Export Manager, Wako Chemicals GmbH  
... AND MANY MORE!