EVIDENCE 2016

Essential payer insights

WORLD PHARMA PRICING & MARKET ACCESS CONGRESS 2016

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As patient expectations heighten, today's medicine needs to demonstrate value and effectiveness in the real world environment.

Collaboration is core to sustainable successful patient access. It is crucial to ensure patients have the right treatment as quickly as possible.

Therein lie some important questions. How do we all work together effectively whether you are a patient, payer, part of industry or from HTA organisations? What are the latest funding and pricing challenges? How can you turn these funding and pricing hurdles into opportunities? Join us as we tackle the practicalities of effective collaboration and what this requires.

We put our key questions to several key thought leaders from the payer community. Their views make compelling reading for anyone who is interested in getting the right drug, to the right patient at the right cost.

These eminent figures will be expanding on their views at **Evidence Europe 2016** and **World Pharma Pricing and Market Access** on 23-25 February in London.

I look forward to seeing you there.

Nick Crabb
Programme Director
Scientific Affairs, **NICE**

1. What is your background and current role?

I worked for 20 years in analytical science, process technology and general management in the chemical, pharmaceutical and contract laboratory industries prior to joining NICE as the associate director for the Diagnostics Assessment Programme in 2010 where I was responsible for the establishing and managing the programme. In 2014 I was appointed Programme Director for Scientific Affairs where I have responsibility for NICE Scientific Advice, the Science Policy and Research programme and the recently launched Office for Market Access.

2. How can payers, industry and HTA come together to ensure patients have the right treatment as quickly as possible?

The pathways from product R&D to widespread adoption of medicines are complex and changing rapidly, driven through innovation in R&D and regulatory science and the need to get products addressing unmet need to patients. It is important that organisations responsible for health technology assessment, pricing and reimbursement and service commissioning ensure that their processes evolve and align to remain fit for purpose in this changing landscape. Evolving regulation means that products addressing unmet need are likely to come to NICE and other HTA organisations sooner in their development cycle with less evidence. A key priority is working with partner and stakeholder organisations to find a way to provide patients with access to promising new medicines while the evidence is still emerging, in a financially sustainable way. Collaboration with regulators, other HTA organisations, payer organisations and the life sciences industry is essential in finding solutions. NICE is actively engaged in the EMA adaptive pathways pilots and collaborating on these issues with European partners through the EUnetHTA partnership. The NICE Scientific Advice service together with NICE's recently launched Office for Market Access also provide key opportunities for dialogue between NICE and product developers on these issues.

3. What do you see as the solutions to pricing challenges?

The development of a mutual understanding of the challenges and costs of pharmaceutical R&D and what health care systems can afford is key to building understanding and realistic pricing expectations. Transparency in the decision frameworks used by HTA and payer organisations is also very important. In some cases, where products first come to market through expedited regulatory approval mechanisms and the evidence for HTA is limited, managed access arrangements with innovative pricing and payment models and post-launch evidence generation may also be important.

David Watson

Director Pricing and Reimbursement, **ABPI**

1. How is the funding landscape changing globally and where are the opportunities?

Pharma pipelines have turned a corner, and are increasing the delivery of new medicines in areas of great clinical need, at the same time healthcare systems are under pressure possibly never seen before, how these two factors are addressed will determine whether industry is part of the problem or part of the solution going forward.

2. How can payers, industry and HTA come together to ensure patients have the right treatment as quickly as possible?

A degree of realism is required from all sides, not all medicines will be affordable, at the same time, medicines are one of the main ways to improve outcomes and allow clinical pathway re-design. Cost effective medicines need to be allowed an accelerated pathway, which also requires active focus on de-commissioning, something that healthcare systems find challenging.

We need to be smarter in data gathering and outcome measurement, and this relies partly on healthcare system design.

3. What do you see as the solutions to pricing challenges?

The field is simply getting too complex for single solutions, but at the same time multiple approaches can't be managed by healthcare systems. In the middle we need to find better cost containment approaches, which might focus on older medicines, and at the same time allow investment, and reward, for newer medicines that make the biggest difference to outcomes. On top of this we need to recognise the challenges faced by different customers, and their roles in commissioning.

My role is Director Pricing & Reimbursement at the ABPI. I lead on the implementation of the 2014 PPRS, the scheme which supports the cost of branded medicines in the UK.

Greg Swarbrick

Head of Healthcare Outcomes, **BUPA**

1. What is your background and current role?

My career has been an attempt to strike a balance between variety and depth and I hope to continue in this way! I studied classics (Latin and ancient Greek literature, history and philosophy) at school and university before embarking on a graduate training scheme at British Airways, followed by seven years developing co-operation with airlines such as Iberia, Cathay Pacific and Aer Lingus in areas such as sales, cargo, safety and IT.

After that I chose to change sector and started at Dr Foster Intelligence working with our healthcare analytics team to develop useful data for hospitals, commissioners and charities, as well carrying out research to understand the career paths, values and motivations of top leaders in the NHS as a resource for future leadership.

I then joined Bupa in 2012 to set up a programme of gathering evidence about the effectiveness of treatments for patients experiencing a range of conditions, and in my current role I lead on the collection and use of numerous outcomes data for Bupa in the UK – for our care homes, insurance business, home healthcare, clinics and hospital. We all recognise the importance of collecting this information for our business and for our customers, but the real value is in using it to improve the delivery of care.

2. What are the current challenges and how are you going to address these at Evidence 2016?

Bupa has 30 million customers spread across 190 countries, so that presents a wide range of challenges as we seek to meet our corporate purpose of helping them to enjoy longer, healthier, happier lives. The central challenge is the tension between increasing healthcare costs – and we are striving to make healthcare as affordable and accessible for our customers – and an ever-changing picture of need, with an ageing population and age-related diseases, greater urbanisation and the stress and costs of unhealthy lifestyles, and people having complex and chronic conditions.

Twentieth-century models of care are not coping well with this demand and customers are expecting greater personalisation, more care in their homes or available at a time of their choosing. They want to know about their treatment options, that are delivered by integrated health systems which speak to each other, but where there is proper security of information and control or at least consent over data sharing. Customers and funders are rightly wary of paying for unnecessary, expensive treatments or those for which there is little clinical evidence, and we also want to support their growing demand for prevention rather than reactive treatment, and we are doing interesting work in this area via schemes such as workplace wellness. But for all this we need to have evidence that supports decisions, which means making it available to the right people at the right time, in a way they can understand and use in decision-making.

This may sound simple, but systematising data is one of the major challenges of our generation. We need to get healthcare data collected and structured in such a way that enables these cross-functional, multi-purpose uses, and what's more link it to other datasets

to better understand causes and effects. And that's the challenge I want to address at Evidence 2016.

3. How can payers, industry and HTA come together to optimise patient outcomes?

What we call 'Outcomes' encompasses a range of different sets of data – clinical and safety data, efficiency metrics as well as patient feedback on experience and the impact of treatment. Whilst they will each have some specific needs, the payers, industry and HTA all require many of the same key metrics... but at the moment we're fragmented: if we collect data, it's collected in different systems using different processes. And if patients are asked to complete similar questionnaires from different service providers, this can only inconvenience them and survey fatigue sets in.
So a process that identifies the various interests of payers, industry and HTA – as well as the interests of the patients, who should be at the heart of this all – would be of great benefit. We need to help patients clearly understand what's in it for them and why their data should be linked or shared between different service providers. I know from experience the real challenge of getting a sufficiently broad range of patients to tell us how they're doing before and after treatment, when they're not obliged to do so – so we need to make it easy for all of them to participate and find sensible ways to share that data as well as the clinical details that can be automatically processed.

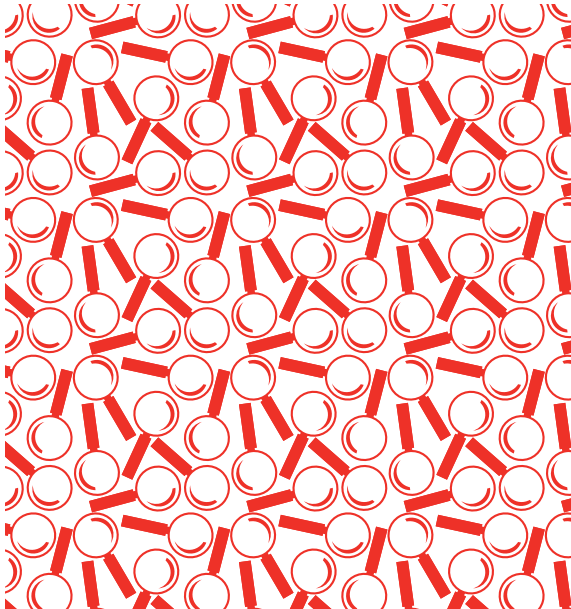
One approach that is now underway for private healthcare is PHIN, the Private Healthcare Intelligence Network, which is gathering a range of patient outcome data to fulfil the mandate of the Competition & Market Authority which wants to enable more quality data to become available to inform consumer choice. Whether or not PHIN is the right vehicle for pharma and associated industry, it should at least act as a useful reference point to advance how quality data can be shared between relevant parties and the practical patient benefits for improving outcomes.

4. What would be your advice on using data better? How can we develop evidence strategies effectively?

The first question you should ask about any data is what is its intended use – what point are you trying to make, and how well does your data serve you to fulfil that purpose? Is your evidence clear and comprehensive, or are you missing something really important that will later undermine what you're trying to say? Who are you trying to inform or persuade, and what do they need to hear?

The best way to refine data is to expose it to a range of relevant users – so for example clinicians and patients, providers and payers. If your evidence is accurate and useful, then that's great to know, but more often you'll be getting important insight about gaps in what's being presented or angles you should cover to strengthen its validity. That's a constantly evolving process, and the challenge then becomes how to deliver a clear but concise message as you take into account various considerations and possibly competing viewpoints, all at the right level of detail.

And if you are experiencing any difficulty obtaining data in the first place, you may need to address motivational or psychological concerns – why might people not want to give you data? In the case of outcomes, for example, might clinicians be worried about how you might use it, and therefore hesitate sharing it with you in the first place? So this goes back to the beginning – be clear about why you need the data, and how you're not going use as well as use it. Around that there's also a second cycle – to show how you've already used data and evidence, the changes you've made and what impact that had, because nothing is more powerful than evidence of past effectiveness.



Edmund Pezalla

Vice President and National Medical Director, Pharmaceutical Policy and Strategy, **AETNA**

Dr. Pezalla is a recognized leader in the development of advanced coverage and payment systems for pharmaceuticals. Dr. Pezalla focuses on public policy and company strategy to maintain access to live saving and live changing treatments for patients.

Dr. Pezalla has consulted on projects related to technology development and coverage decisions for the President's Council of Advisors on Science and Technology, the American Academy of Pediatrics, the Institute for Clinical and Economic Review and the Brookings Institution. He is a member of the Board of Directors of the Pharmacy Quality Alliance and the Connecticut Biosciences Innovation Fund.

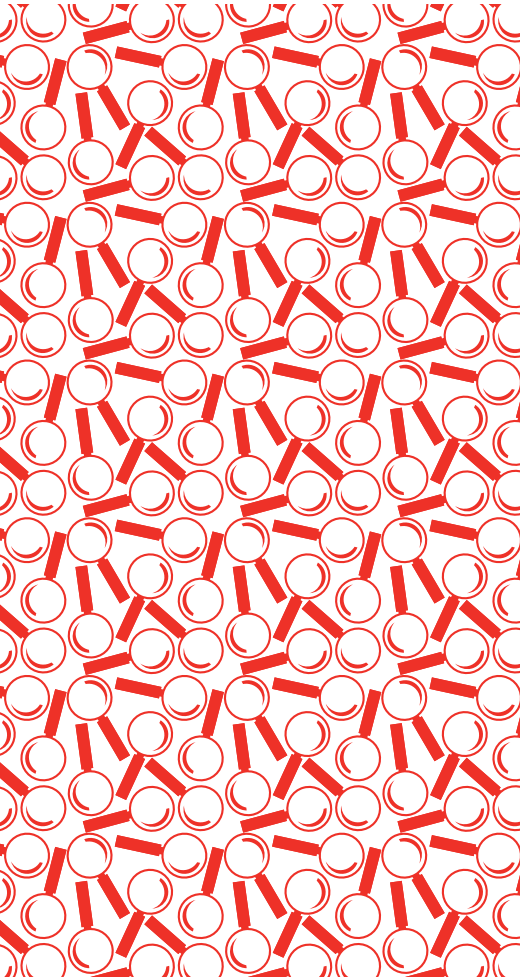
Dr. Pezalla received his bachelor's degree in Biophysics and his degree in Medicine from Georgetown University, and Masters in Public Health from the University of California at Berkeley. He was a health services research fellow and PhD student at the University of Michigan in Ann Arbor where he completed all but the dissertation in the program in Health Services Organization and Policy.

1. What are the current challenges and how are you going to address these at World Pharma Pricing and Access?

The US healthcare system is dealing with three key problems:

- Affordable access to care
- Uneven quality and use of evidence-based medicine
- Lack of overall population health systems and approaches

Bio-pharmaceuticals and bio-pharma companies face both a challenge and an opportunity. Pharmaceuticals are one component of increases in healthcare spending. New therapies, and especially curative therapies, may give us the tools to manage costs by realizing the cost-savings that have been promised by the pharmaceutical industry, and provide improved quality and outcomes. Firms can contribute to quality and the use of evidence by promoting the use of standardized outcomes measures for patients being treated by the target conditions.



2. How can payers, industry and HTA come together to ensure patients have the right treatment as quickly as possible?

The trend towards earlier discussions with payors in the US and with HTA in Europe and other countries should continue. Incorporation of economic and humanistic outcomes into the overall development strategy, including pivotal trials, is a requirement for streamlining processes, increasing efficiency and most importantly demonstrating improvements in outcomes that matter to patients.

Collaboration should continue after approval and market launch with work to demonstrate that value is being realized through measurement of patient outcomes and partnership with providers to ensure appropriate use.

3. What do you see as the solutions to pricing challenges?

We must realize that costs will continue to go up and also that a fair return should be realized by those developing new therapies. However, the cost of pharmaceuticals should reflect the value that they add to the lives of patients and to society at large. In the US payors are increasingly interested in value assessment tools such as the ICER Model, ASCO Frameworks and the cost-effectiveness tools used by European HTA agencies. Although these tools have not been adopted in the US they are being discussed and becoming more influential.

Pharma firms should consider how new products will be judged and make some reasonable adjustments to development programs and expenditures in order to provide drugs at prices within a reasonable range.

In some cases it will not be possible to manage the cost of development, especially for gene therapies and ultra-orphan diseases. In this case we must begin to think out of the box in terms of creating novel payment systems, creation of investment opportunities for payors to offset future costs, and other innovative financing schemes.

Martin van der Graaff

Secretary Scientific Advisory Board, **ZINL**

I have a lifelong infatuation with innovative medicinal products that fit in a sustainable health care system. I started my PhD at Organon and Solvay Pharma, trying to contribute to the R&D effort. Later on, I worked for the pharma industry association in the Netherlands, Nefarma, fostering stakeholder dialogue. And now, as Secretary of the Scientific Advisory Board of an HTA/payer organisation called Zorginstituut, I liaise with stakeholders, helping forge sustainable agreements on reimbursement.

We live in highly exciting times with a great output of new therapeutics. Some of them work great, some of them less so. Most of them carry a hefty price tag. Many of them lack convincing outcomes in daily practice. This means that we have to creatively investigate novel access approaches. Accelerated access approaches are fine as long as they are counterbalanced by a modest pricing strategy and effective exit options.

But first and foremost we need to define outcomes that are quantifiable, make a clinically relevant difference to patients, help HTA decision making and ensure data can be collected in a reasonable timeframe.

If we cannot define what we are looking for, or have no real perspective of emerging insights, we must not engage in conditional reimbursement, coverage with evidence development, registry building or any other form of MAPPs. And if data are collected, public access should be guaranteed. All too often, we find that industry or academia sit on the data. That is unacceptable, given that these data are collected on treatments that are basically paid for by public money.

If both safety and effect can be monitored by all relevant stakeholders and an acceptable growing model for pricing is introduced, we will indeed be able to protect patient safety, ensure better and earlier therapeutic gains and contribute to sustainability of the health delivery systems.

The last word...

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