The Future of Market Access

A FirstWord ExpertViews Dossier Report
The Future of Market Access

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Research objectives

This FirstWord expert views report provides a broad-based look at the market access challenges that the pharmaceutical industry faces and the key issues that are shaping the market in the future. These include the regulatory impact of developing value-based medicines supported by cost-benefit and real-world data, and the potential impact that generics and biosimilars will have on access to innovative medicines. It discusses how amendments to pricing and reimbursement policies could impact the future uptake of medicines and the risk-sharing strategies that pharma has started to adopt to address these challenges. It identifies who the future gatekeepers to MA are and the different strategies companies need to adopt to meet regional and local demands. It discusses the need for pharma to plan in advance and engage with clinical and non-clinical stakeholders early on in drug development and pivotal role that key account management (KAM) will play in improving the accountability and transparency of healthcare provision. It reviews the critical role that HTA bodies have on coverage decisions and how this might change in the future in the face of healthcare and political reforms.

Key questions asked during the course of the research include:

1. How will the healthcare reforms affect market access in the medium and long terms?
2. Who are the key decision-makers for P&R and how might policies change in the future to meet healthcare demands?
3. What impact will the uptake of generics and biosimilars have on the future MA of innovative medicines and the long-term sustainability of healthcare systems?
4. HTA bodies are getting stronger and demanding value for money; what impact will this have on MA in the future?
5. Cost-effectiveness and real-world evidence (RWE) have supplemented the established requirements of safety, efficacy and manufacturing quality: will this remain the case for the foreseeable future?
6. Will ‘financial’ and ‘outcome’ risk-sharing schemes continue, and if so, to what degree will they be applied in the future?
7. How are manufacturers organising themselves internally to respond to the new challenges they face in gaining MA?

8. Will personalised medicines and disease pathway management play a bigger role in improving MA for medicines in the future?

9. How might the implementation of new targeted regulations and reimbursement strategies impact access to personalised medicines, orphan drugs and regenerative medicines in the future.
Research methodology

The information for this report was gathered from multiple sources. In-depth research was conducted across multiple secondary resources, including in-house data, scientific journals, analyst reports, company presentations and conferences. Expert insight was obtained from telephone interviews (30–45 minutes) conducted during April–June 2016 with market access specialists from pharmaceutical companies and consultancies (n=8) from the US and Europe.

- Colin Wight, Chief Executive and Founder, GalbraithWight Ltd
- Janice Haigh, Principal, Quintiles Advisory Services, Europe
- Paul Catchpole, Value and Access Director, Association of the British Pharmaceutical Industry
- Sean McGrath, Chairman and Founding Partner, Succinct Medical Communications Group and Director of Oncology, the OPEN Health Group
- Steve Turley, Managing Director, UCB
- Market Access Expert, European Pharma Company
- Market Access Expert, European Specialist Pharma Company
- Market Access Expert, US Pharma Company
Duplication of information leads to inefficiencies

National and regional stakeholders require different levels of information, leading to duplication and inefficiencies in the healthcare systems; this is often a major challenge for pharma companies as reiterated by our experts:

“There are still huge inefficiencies in the healthcare system. There are a huge number of national, regional and local decision-makers, each of which kind of duplicate each other’s work, so there’s huge duplication of effort, all of whom then decide whether they’re going to pay for something or not, which delays getting the innovations to patients, whilst they all do the same thing and come to varying conclusions.”

Colin Wight, Chief Executive, GalbraithWight Ltd

“The plurality of gatekeepers will remain. But it is very important in the healthcare systems where resources are finite that we don’t see duplication in the system.”

Steve Turley, Managing Director, UCB

Increasing layers of bureaucracy slow down market access

Some experts even argue that the layers of bureaucracy are increasing rather than decreasing. For instance, in 2012 an EU-funded research project was initiated called AdHopHTA,¹³ to develop and strengthen the use of hospital-based HTAs tools. The aim was to establish an AdHopHTA database containing information about hospital-based HTAs and utilise it to inform decisions in the hospital setting. If adopted this would present companies with additional challenges in terms of time and resources to fulfil the hospital HTAs; for example, in the UK there are more than 200 individual organisations within the NHS, including commissioning groups and hospital trusts, that all make and/or monitor funding decisions – and each of these would have required a separate HTA under the AdHopHTA scheme, which was closed in 2015.

“Things are getting worse not better: we have to redo HTA appraisals at every individual hospital level now as well… they’re adding layers to it, not taking away layers.”

Colin Wight, Chief Executive, GalbraithWight Ltd

Can RWE be used to guide treatment decisions?

Questions remain over who will ultimately pay for the collation of RWE – pharma or the patient? The European authorities recognise the importance of gathering long-term data in the real-world setting and have already made significant efforts to optimise RWE access and use, in order to align the interests of the various stakeholders typically involved in healthcare (PMLive, 2015). For example, England’s NICE has established a new system, via the revamped Cancer Drugs Fund, to fund RWE collection.

Moving forward it will be increasingly important for stakeholders to work together to demonstrate the value of new medicines, and ensure RWE is used appropriately to facilitate market access to innovative medicines for patients, and not delay the process.

A few of the experts we spoke to raised their concerns regarding the utility of RWE:

“In order for payers to make informed decisions, real-world evidence in relevant patient populations is essential, but this will increase the costs of entry.”

Market Access Expert, US Pharma Company

“The journey towards real-world evidence is almost certainly going to continue to gather pace and the medicines that we produce will have to make a difference to patients and bring value; however, the ability to be able to accurately capture data and aggregate that data is still very immature.”

Steve Turley, Managing Director, UCB

“There is no point collecting real-world evidence if nobody does anything with it or if it turns out to be of insufficient quality to support decision-making.”

Paul Catchpole, Value and Access Director, ABPI
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