Payers, Politics and Pandemonium: An Insight into the Future UK Pricing and Market Access Environment

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Objective

• The research sought to assess how recent policy changes and political developments will affect the pricing and market access environment in the UK for pharmaceuticals.

Background

- The UK political environment is causing both macro and micro-economic turbulence to a life science sector which still retains a reputation as one of the most attractive markets in the Western world.
- Britain's exit from the European Union ("Brexit"),¹ the funding crisis in the NHS² and the upcoming PPRS renegotiations in 2019³ all contribute to the political unrest and subsequent instability of the healthcare sector.
- Responses to these political and financial pressures can already been seen, for example, with the proposed introduction of a budget impact test within NICE technology appraisals, where companies that have a therapy with a budget impact of >£20 million in any of the first 3 years of its use have to engage in separate talks with NHS England on how to manage costs.⁴

Methods

- A roundtable was held on 3rd October 2017 with 13 experts in the field of pricing and reimbursement in the UK, coming from a range of backgrounds such as academia, consultancy, government, former payers (NHS Commissioning, NICE) and patient groups.
- Complementary literature searches were run to identify recent articles relating to the evolution of pricing and reimbursement of pharmaceuticals in the UK.
- The research used a primary documentary approach to obtain information, which was then analysed using a qualitative interpretative method.

Results

The Current State of the NHS

• Despite concerns over the funding levels within the NHS and the demotivation of staff (Figure 1), it was also felt by participants that despite its problems, the NHS had much to be proud of and, in particular areas, the standard of care provided was world class.

the NHS, what would it be?

Figure 1 If you had one word to describe the current status of



Figure 2 Implications of Brexit

Participants agreed that Brexit exacerbates a UK political environment which is filled with uncertainty; this causes problems for global life science companies and their investors who do not appreciate uncertainty when making strategic decisions

The removal of the EMA from London is more of a loss

to the UK than the EU – as the current work undertaken

by the MHRA will be picked up via existing institutions

cost of importing medicines

• Reduction in GDP means less money available for healthcare

NHS (at least in the short-term)

Implications of Brexit

Ultimately, there was a feeling that Ministers in the UK would seek to align the new regulatory process as closely as possible to the EMA and seek damage limitation – however, the transition to the new regulatory system would be lengthy

Brexit is most likely to mean less money available for the

Worsening of exchange rates means an increase in the

"The thing that is clear from Brexit is uncertainty; and just as payers do not like uncertainty, global pharmaceutical companies do not like uncertainty either."

Roundtable participant

Figure 3 The PPRS talks should adopt a proactive approach conducive to a healthy life science sector

"We are at a point in history where medical science can make a significant breakthrough in health. The key challenge is how we get public and

The ultimate aim of the PPRS negotiations is to rebalance the uncertainty facing the UK market and restore faith in the life science sector

To be avoided

Roundtable participant

in other markets

Narrow focus on cost-containment

inconsistency of decision-making.

- Token noises towards life science sectorNHS problems are considered in isolation of
- Iife science sectorBudget impact before cost-effectiveness and
- Budget impact before cost-effectiveness as undermining of NICE

PPRS 2019

To be encouraged

- Broader focus on health and life science sector
- Positive talks acknowledging financial challenges
 Acknowledging that elements within the life
- science sector are inextricably linked

• Further regionalisation with the introduction of initiatives such as the STPs (Sustainability and Transformation Partnerships⁵) continues to exacerbate postcode lottery prescribing, and whilst local access offers more flexibility than at a national level, frustrations remain regarding the

private interests to work together in the overall interest, rather than kicking each other."

- It was felt by some roundtable attendees that the depoliticisation of the NHS has not worked out as intended and the result is another top-down organisation in NHS England which lacks democratic accountability.
- There is considerable uncertainty about how Brexit will impact the NHS and the UK's life science industry, but several key challenges were discussed (Figure 2).

NICE and the Reimbursement Environment

- There was a concern that NICE was over-reliant on the cost per quality adjusted life year (QALY),⁶ but that the transparent and statutory nature of its guidance were highly valued.
- There was an overarching feeling from participants that budget impact was becoming increasingly important in the NHS and that pricing pressure is causing NHS England to interfere with NICE.
- Due to the ever-increasing requirement to deal with NHS England (e.g. budget impact threshold, managed access agreements, commercial arrangements), it was expressed that companies were beginning to question the rationale for the NICE process, particularly in the rare disease space.
- NHS England will have a much more prominent role within the upcoming PPRS talks, with a sole focus on affordability. Participants called for a more pro-active approach to the talks, which should take a holistic view of the life sciences industry as well as the NHS (Figure 3).

"If you look at how the HTA processes have evolved in 3–4 years, I would say we have gone beyond cost-effectiveness – it is about can we afford it, should we afford it and as a manufacturer, what else are you offering on top of cost-effectiveness."

Roundtable participant

"I think NHS England will definitely approach the next PPRS with one ambition – cost control. They will seek to maximise the number of patients who can benefit within a constrained budget. I don't think NHS England frankly cares about the health of the life science sector."

Roundtable participant

Conclusions

- Market access and policy are inextricably linked in the UK and the importance of policy in the decision-making over pharmaceuticals cannot be underestimated.
- The future UK pricing and market access environment has many positive signs to retain a leading role in the research, development and commercialisation of pharmaceuticals. However, concerns remain about the role of NHS England, the methods used by NICE and the wider impact of Brexit on the life science sector.
- The UK is dealing with considerable uncertainty both on a macro and micro-economic level and therefore the importance of stability in the 2019 PPRS renegotiations has significantly increased if the UK wants to retain a leading role in the lifescience sector.

References

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