What does an attractive UK environment look like? An industry perspective,
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What drives investment decisions in industry?

It is important to recognise that this is a very complex area. Investment decisions are made from early discovery, through development, manufacturing and to place resources behind commercialisation. Different factors drive these different decisions. However, at the broadest level, across all areas, our decision to invest is based on two key factors: the capacity to invest, and the attractiveness of a given location for investment. There is a direct link between the industry’s capacity to invest and the global commercial environment in which it operates. This is because the industry’s investment capacity is directly related to its profitability which is of course related to factors such as pricing and uptake of medicines.

For some sorts of investment, such as clinical research, there is a strong influence from the local commercial environment. Trials are run globally, with the design heavily influenced by the standard of care in the United States; if the US standard is not available in the UK, this drives up the cost per patient of doing trials here, as the comparator arm needs to be purchased. Thus no/slow uptake of new medicines has an impact on clinical trial volumes.

The UK government has the ability to influence its attractiveness as an investment location, relative to other countries, through policies such as those relating to taxation, the science base and skills. It also has the ability to support the industry’s capacity to respond to this attractive environment through policies that support industry profitability and the development of a strong environment for the use of the industry’s medicines.

The 2007 NERA report has been quoted as a reason why the UK Government should disregard the commercial environment for the use of medicines as a driver of investment. What the report said is that the key drivers of investment are around tax and science policy but that if all these elements are equal, then the local commercial environment (defined as the combination of pricing, access and use of medicines) can play a swing factor in deciding between countries. In particular “firms often have a number of alternative locations for investment assets that are broadly equal in other dimensions and in these situations market conditions can be an influence on the ultimate choice”.

In the current climate, it is also important to consider disinvestment decisions; here, the commercial environment can play a key role. Some recent disinvestment decisions have taken out a specific capability in a company e.g. streamlining therapy area R&D into one location and another global location was chosen. However, others are part of general cost containment policies by companies and will be influenced by the local General Manager’s ability to protect and sell investment in his or her company to global decision-makers. In this case the commercial environment can be crucial.

What does this mean for the UK?

The Government’s ability to influence the global industry’s capacity to invest is significant. This is because the UK commercial environment for the use of medicines has greater influence over the success of the industry than its share of global sales (~3%) would suggest, as the UK NHS is well regarded. UK prices are directly referenced in 25% of world markets and then indirectly in a further 15% (OFT report 2007, Global Insights February 2011, PhRMA (March 2011) Issue in Brief: International Reference Pricing & IMS World Review 2011). This referencing can take place both at launch and throughout a product’s lifecycle. In addition, NICE decisions have influence around the world; this has a particular
impact on British-headquartered companies where NICE is often the first global HTA body to assess a new medicine that the company will then plan to launch globally.

The UK has a lot to gain (or lose) from the increasing (or decreasing) capacity of the industry to invest, as the second largest global beneficiary of investment by the pharma sector, behind the USA. Recent job losses at Sandwich, Charnwood, Horsham and Harlow resulted from the need for these companies to reduce global capacity due to the global environment.

Traditionally, the Government has been focused on retaining and growing roles in R&D and manufacturing but there are significant numbers of high quality, well-paid roles, valued by healthcare professionals and their representative bodies, within the local operating companies (LOCs) of both Multi-National Companies (MNCs) and British-Headquartered companies. The deterioration of the UK commercial environment has been responsible for LOC’s making substantial numbers of employees redundant over the last 5 years. Just five of the ABPI’s member companies, four of which are top 10 global companies, who were employing a total of c7000 people in their UK Operating Companies in 2005, have seen a loss of over 2400 jobs over the last 5 years, i.e. a 37% reduction.

Given (a) the link between industry’s capacity to invest and the commercial environment, (b) the UK Government’s ability to influence this, and (c) the significant existing investment in the UK, it makes sense for the UK to pursue policies that simultaneously maintain or increase the investment capacity of the industry and increase the attractiveness of the UK as a location to invest i.e. supporting a thriving industry that can deliver high quality patient outcomes whilst ensuring the UK can compete successfully for future investment.

**What is the industry view of the current UK environment?**

We appreciate the strong industry-Government dialogue with the UK and that the Government has, over recent years, introduced a number of policy measures that increase the UK’s attractiveness, such as increasing science spending and introducing tax incentives such as the Patent Box. The efforts of the NIHR have been significant and in some areas, the UK is starting to increase clinical trials, although delivery to target remains far from ideal; speedy implementation of the Budget commitments, particularly around speeding up trial approvals, will be critical to maintaining momentum. The UK is now more competitive than it was regarding these targeted measures.

However, the industry is operating in a challenging global environment; in 2010, there was an approximate 5% price deflation in the EU for medicines and governments, with fiscal austerity targets to meet, have been focusing on controlling health spending and within that, medicines spending. The UK NHS is no exception with tough QIPP targets.

Industry supports the Department of Health having a dual role of delivering value for money from NHS spending and sponsorship of the life sciences sector. But, it appears to industry that the UK Government is looking to divorce its sponsorship role from the commercial environment in which the industry operates. Whilst the pharma sector is prioritised for the Growth Agenda, medicines spending is a key target in QIPP and the PPRS commitment to “promote a strong and profitable pharmaceutical industry that is both capable and willing to invest in sustained R&D to encourage the future availability of new and improved medicines for the benefit of patients and the industry in this and other countries” appears to be absent from the Government’s thinking on VBP.

Ten years ago, the UK was a market of first launch for new medicines as prices were top quartile in Europe and access for patients was fast. Today, the UK is increasingly under threat of becoming a mid- or late-tier launch market because prices are bottom quartile in the EU, access is often delayed and even when NICE makes a positive recommendation, significant effort is needed to overcome local market access barriers.
What would a good UK environment look like?

The industry would like to see the UK become a nurturing UK environment for innovation where life sciences companies, large and small, work together, in partnership with academia, to discover, develop, manufacture and launch new technologies, delivering patient benefit, improved health outcomes and economic growth. In particular, it would have:

- An outstanding skills base and world-class scientists with a culture in academia and the NHS that proactively seeks engagement with industry and understands the contribution that collaboration with industry can bring to advance clinical research, improve patient outcomes and drive growth in the economy.
- A strong cohort of entrepreneurial academics, translating excellent science into clinical benefit, supporting a vibrant SME sector, able to secure sustained funding.
- A vibrant advanced manufacturing sector in life sciences, able to forge well-funded public-private partnerships to develop new technology that can then be deployed in the UK swiftly with minimal regulatory delay.
- Fair regulatory processes, proportionate to risk that allows the UK to take a lead position in attracting research, clinical trial and manufacturing investment.
- An attractive fiscal environment, including the Patent Box and R&D tax credits.
- Pricing and reimbursement for medicines which ensures that the NHS’s need to deliver value to the taxpayer also considers the significant economic impact of the life sciences sector and the UK’s potential to impact the global profitability of the sector.
- Within this, a specific issue to deal with is where generics (with very low UK prices relative to other countries) are compared directly to a patented medicine either by NICE or by the NHS; we have one of the most efficient generic markets which, accompanied by the upcoming patent cliff, should provide ample headroom to invest in innovation.
- An NHS environment which embraces new medicines more rapidly than other countries, providing benefits to patients, to research and to the growth of UK-based companies.

And what does a good commercial environment look like?

As the question asked originally by MISG for this paper is what a good commercial environment for medicines looks like, we have been more explicit; a strong commercial environment, which would set a positive example to other countries would be:

- A broader definition of value being applied to the assessment of medicines, that allows more new medicines to be used early in their lifecycle.
- Significantly greater flexibility in the assessment of value of a medicine, e.g. where there is uncertainty in the evidence base, where currently industry takes all the risk, or where the comparator is a generic and is thus not priced to reflect its value or where there is significant unmet patient need or severe disease.
- Free pricing at launch with reimbursement terms agreed at the point of licensing.
- Fair and reasonable prices, in line with those in comparable EU countries, that reward both ‘breakthrough’ and ‘incremental’ innovation, with the flexibility to negotiate confidential discounts. UK medicines spending per capita is low relative to other countries of similar GDP; couple with the upcoming ‘patent cliff’ a good case can be made that there should be flexibility for this to increase, to deliver improved outcomes and savings elsewhere in the system.
- Once a value-based price is established, no further local or national barriers to access beyond a clinical decision should be created (e.g. no therapeutic tenders, NICE-appraised medicines/ medicines in National guidelines automatically on local formularies without reappraisal or qualification).
- This removal of local barriers should be coupled with positive incentives to balance conservatism in the NHS re use of new technology to ensure rapid uptake and diffusion of innovative medicines, such that UK patient outcomes are amongst the best in Europe.
- A collaborative culture between industry and the NHS focused on improving patient outcomes and delivering care effectively.
A negotiated, long-term agreement should be developed, between industry and government, covering all of the above.

**References**

Global Insights (February 2011)


PhRMA (2011) Issue in Brief: International Reference Pricing