

# Executive Summary

The UK pharmaceutical industry has traditionally been of major strategic importance to the UK economy, and continues to make a significant contribution. However, pharmaceutical companies are currently confronting a number of challenges as different factors and changing conditions create a rapidly evolving modern healthcare landscape.

This policy paper provides a detailed and analytical examination of the current issues and challenges confronting the UK pharmaceutical industry. Where appropriate and applicable, we seek to provide solutions and ‘food for thought’ on how pharmaceutical companies, and other interested parties, can best respond to these challenges during a time of increasing economic and strategic uncertainty.

The relative decline of the ‘blockbuster drug’ and the increase in the production of generic medicines, combined with the rising application of biotechnology to produce personalised medicines, are challenging traditional business models. Further challenges are likely to manifest themselves as governments increase their demand for preventative medicines over reactive treatments. Counterfeit medicines are also creating a major problem for pharmaceutical profits and patient health alike, as globalisation and technological advances enable easy cross-border trafficking. Diversity in the product pipeline and more investment in generics will be increasingly important components of future pharmaceutical development.

Emerging economies, such as those comprising the E7 (China, India, Brazil, Russia, Indonesia, Mexico and Turkey), are challenging established pharmaceutical markets. This is particularly pertinent to the UK in terms of strategic residence for company tax bases, manufacturing, research and development (R&D) operations, clinical trials and labour costs.

Developed economies such as Ireland, Switzerland and Singapore are also creating competitive business environments as exemplified by low corporation taxes, fiscal credits, decreased regulation, and strong investment in scientific education and skills.

The UK is falling behind its competitors on many of these issues, and therefore requires dynamic and incentivised action to address these growing concerns.

A lack of government investment is another factor adversely affecting the UK pharmaceutical industry. Spending on drugs and medicines is lower in the UK than in many other established economies. Furthermore, reimbursement schemes such as the *Pharmaceutical Price Regulation Scheme* (PPRS) are facing heightened scrutiny as the government looks to maximise value for money through the increased application of formal evaluation and cost-effectiveness criteria. As a direct consequence,

health economics and bodies such as the *National Institute of Health and Clinical Excellence* (NICE) are becoming increasingly important elements in the UK healthcare system.

Risk-sharing schemes are likely to grow in prominence and prevalence as governments seek to diversify and reduce the risk associated with healthcare investment in the future. This means industry will have to improve patient compliance in order to optimise profitable returns from such schemes and better demonstrate the intrinsic value of those products coming to market.

Long standing issues such as animal rights activism remain a concern despite a reported decrease in recent levels of activity in the UK. However, an increase in activity has been noted in Europe, accentuating the need for continued vigilance and cross-country cooperation.

### **1.1. Solutions and Recommendations**

The paper offers the following key recommendations to address and tackle the challenges as described above.

#### **a) *The Changing Business Model***

In response to the disintegration of the 'blockbuster' model, pharmaceutical companies should consider:

- Investing in generic products in order to stem eroding profits from patent expiries and to gain access, and a foothold, in emerging markets;
- Seeking increased and enhanced diversity in the product pipeline to encourage flexibility and to spread product risk and uncertainty; and,
- Improving understanding of the move towards personalised medicines as based on patient genomes and the increasing strategic and clinical importance of biotechnology.

#### **b) *The Growth of Counterfeit Medicines***

Given the increase in the problem posed by counterfeiters, the following action is required:

- As a whole, the pharmaceutical industry needs to cohesively implement further measures, such as initiatives like the Anti-Counterfeiting Trade Agreement (ACTA), to improve global and systemic coordination;
- Utilise available and advancing technology, for example product "finger printing", to reduce the scope for counterfeiting activity;

- Through the UK government, ensure legislation is appropriately tightened and suitable deterrents and penalties are put into place to deal with counterfeiting; and,
- For national governments – with the help of international organisations – to work cooperatively and collaboratively to better coordinate international action against counterfeiting.

**c) *The Shifting Healthcare Landscape***

As the future healthcare landscape increasingly shifts from curative/reactive to preventative medicine, pharmaceutical companies need to consider the following:

- Focusing R&D and associated activity around preventative products to respond to a likely shift in healthcare demand; and,
- Being cognisant of the fact that future reimbursement opportunities are likely to be geared around demonstrating the preventative capabilities of medicinal products.

**d) *Emerging Markets***

As the forces of globalisation continue to push and pull, and emerging markets in countries such as India, China and Brazil grow in importance and significance, the UK pharmaceutical industry increasingly requires the following action:

- An improved understanding, particularly from the UK government, of the seriousness of global competition and a coherent policy strategy to accentuate Britain's competitive advantage relative to other countries;
- For the UK government to engage in cross comparison and evaluation with other countries and markets to assess dynamic competitiveness and associated opportunities; and,
- For the UK government to formulate a cohesive and creative industrial policy to reverse the current trend of decline and international displacement in pharmaceutical manufacturing and R&D.

**e) *UK Competitiveness and Regulation***

In light of the increasing pressures and challenges confronting the UK pharmaceutical industry, the following action points – particularly for the UK government – confer amplified importance:

- A reduction in the rate of UK corporation tax to retain a healthy presence in British R&D, clinical trials and manufacturing plants;
- Implement tax credits for new product introduction and technological development;
- Consider strategic energy rates for manufacturing plants to overcome prohibitively high gas and utility costs as compounded by the ongoing global “credit crunch” and economic crisis; and,
- Simplify taxation rules and reduce the burden of complex legislation and regulation through the utilisation of cutting-edge approaches.

**f) Education and Tomorrow’s World**

In response to recurring and persistent concerns regarding a lack of adequately skilled scientific and technical labour in Britain, the following policy issues demand increased attention:

- For the UK government to increase investment in science at all academic levels and establish a strategy group with responsibility for monitoring progress;
- Earmark educational and university grants to protect and preserve science departments;
- Join up government policy across different departments to deal more effectively with this imperative; and,
- Promote positive campaigns to incentivise science and scientific careers.

**g) Pricing and Reimbursement**

As the UK government continues to seek value for money from healthcare spending, and more efficient and effective resource allocation, pharmaceutical companies will need to understand more fully and be aware of the following:

- The need to better and more clearly demonstrate product value, and hence the need to carefully tailor economic and clinical arguments to justify optimal reimbursement;
- The importance of improving clinical trial design and early product selection to support economic arguments when going to market;
- The increased use and application of risk-sharing schemes and thus the need for cogent and evidence-based economic strategising; and,
- The increased emphasis being placed on patient and product compliance, and the associated need to demonstrate product capabilities in this regard.

#### ***h) Growth in Health Economics***

As decision-makers become more cost-conscious, and the shared principles of value for money and cost-effectiveness increasingly inform decisions pertaining to pricing and reimbursement, pharmaceutical companies need to understand the following:

- The intrinsic need to have economic as well as clinical evidence to justify optimal or “best case” reimbursement and hence the increased application and importance of health economics;
- The need to clearly and strategically understand the growing importance of health technology appraisal and formal economic evaluation as undertaken by institutions such as NICE;
- The opportunities for upfront application of health economics, particularly in the form of economic modelling and statistical analysis, to support decisions pertaining to R&D allocation and the efficient utilisation of scarce pharmaceutical resource; and,
- The increasing requirement to invest in and expand Global Health Outcome teams to support the use and application of health economics for pricing and reimbursement activity.

#### ***i) Animal Rights Activism***

Given that the issue of animal rights activism continues to represent a problem to the UK pharmaceutical industry, the following action is recommended:

- The UK government continues to recognise the threat posed by extremist activity and utilises amending legislation as required;
- International governments, particularly at the European level, increase cooperative and collaborative efforts to deal with this persistent problem; and,
- The UK government clearly asserts and emphasises the critical importance of British based pharmaceutical and scientific research into life-saving treatments.