The Academy of Medical Sciences | FORUM

The Academy of Medical Sciences 2008 FORUM Annual Lecture

The UK pharmaceutical industry: what does the future hold?

Andrew Witty, CEO, GlaxoSmithKline

The Academy of Medical Sciences

The Academy of Medical Sciences promotes advances in medical science and campaigns to ensure these are converted into healthcare benefits for society. Our Fellows are the UK's leading medical scientists from hospitals and general practice, academia, industry and the public service.

The Academy seeks to play a pivotal role in determining the future of medical science in the UK, and the benefits that society will enjoy in years to come. We champion the UK's strengths in medical science, promote careers and capacity building, encourage the implementation of new ideas and solutions – often through novel partnerships – and help to remove barriers to progress.

The Academy's FORUM with industry

The Academy's FORUM is an active network of scientists from industry and academia, with representation spanning the pharmaceutical, biotechnology and other health product sectors, as well trade organisations, Research Councils and other major charitable research funders. Through promoting interaction among these groups, the FORUM aims to take forward national discussions on scientific opportunities, technology trends and the associated strategic choices for healthcare and other life-science sectors.

The FORUM builds upon what is already distinctive about the Academy: its impartiality and independence, its focus on research excellence across the spectrum of clinical and basic sciences and its commitment to interdisciplinary working. The FORUM Annual lecture provides an opportunity for FORUM members, Academy Fellows and other stakeholders to hear from international leaders in biomedical science. The 2008 lecture was given by Andrew Witty, CEO of GlaxoSmithKline and was chaired by Academy President, Professor Sir John Bell FRS PMedSci.

This report provides a summary of the lecture and subsequent discussion.

For further information please contact Dr Robert Frost, Senior Officer, FORUM (robert.frost@acmedsci.ac.uk).

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Report of the 2008 FORUM Annual Lecture

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Lecture report: Chairman's introduction

Professor Sir John Bell FRS PMedSci began the evening by introducing Andrew Witty and thanking him for giving the 2008 FORUM Annual Lecture. He also gratefully acknowledged the ongoing support given by GSK to the Academy and its FORUM with industry.

In his introduction, Sir John emphasised that GSK represents a major part of a pharmaceutical sector that brings both health benefits to patients and makes an important contribution to the UK economy. The sector is going through challenging times and faces some difficult issues with regard to its R&D pipeline and its evolving business model. However, while there are many uncertainties to resolve, what is clear is the importance of strong leadership to drive change: this strong leadership is personified by Andrew Witty.

Lecture report: The UK pharmaceutical industry: what does the future hold? Andrew Witty, CEO, GlaxoSmithKline

Introduction

This lecture takes place during a period of uncertainty within the pharmaceutical industry with change in the sector being driven by a number of converging factors. There is now widespread recognition that, despite increasing expenditure on research and development (R&D), the number of new molecules approved for use continues to fall. Challenges around the development of new medicines are compounded by the impending expiration of patents on many older medicines, leading to loss of profits and increased generic competition. In the foreseeable future, $200 billion of patent-protected global sales will disappear in the sector, with, on average, only 30-50% of these earnings replaceable by the current pipeline. These difficulties are further magnified by the conservatism of regulatory authorities, increasing risk aversion in the community-at-large, and an increasing power of the payer in the marketplace. In sum, this situation has led to a shortfall in the number of new products available to patients and falling confidence from investors.

What does the future hold? As we move forward there will be a continuing need for companies to navigate through a difficult transition period and to work in partnership with UK and other policymakers to address some of the challenges facing the industry. There is, however, room for optimism. Demand for medicines is rising as the population grows, as new medical needs emerge and as advances in basic research create new opportunities for innovative medicines. To make sure new scientific developments are translated into benefits for patients, the industry must focus on areas of unmet medical need, forge collaborations to drive innovation and work alongside payers to adopt a realistic interpretation of price and value.

Unmet medical need

Medicines have contributed to many people enjoying longer and healthier lives. Some therapeutic areas, such as asthma and hypertension, can be regarded as relatively well served by current medicines. However, there remain many other therapeutic targets, where there is significant unmet medical need, for example cancer, Alzheimer's disease and other diseases associated with ageing.

Advances in biological research over the past decades have generated countless insights into the pathophysiology of disease. Excitement in scientific discovery is discernable across a broad front: for example in understanding the role of stem cells in cancer, osteocytes in musculoskeletal disorders, fat distribution in metabolic disease and in the very rapid pace of advance in use of proteomics and other 'omics technologies. Optimism for the future can be seen by extrapolating from analysis of what has previously occurred in the area of cancer. Historically, during the 1970-1980s, oncology R&D had appeared unproductive. However, key scientific foundations were being laid during this period and half of the sector's pipeline is now composed of compounds to treat cancer.

A resurgence in the quality and quantity of drug development can be expected as a highly productive phase in basic science begins to be translated into novel therapeutic approaches. Moreover, this will occur in disease areas that are societal priorities. Delivering medicines that make a difference to patients will be one way of building trust with the public. In this regard, pharmaceutical companies need to meet new expectations of transparency, and deserve to be judged on present, not past, behaviour.

There are significant unmet opportunities for the pharmaceutical industry. These opportunities exist in areas that present difficult therapeutic targets, but success will be more likely if companies capitalise on opportunities for collaboration and external partnerships.

Transforming drug discovery

To foster innovation it is necessary to draw on the best basic science and provide a supportive environment in which talented scientists can exercise their creativity.

Good science evolves around great people. To enable the development of innovative new medicines we must create supportive environments that foster and inspire talented researchers. Such environments are not compatible with excessive bureaucracy or rigid disciplinary boundaries, and drug discovery cannot be industrialised in terms of factory processes. Drug discovery should be regarded as a wholly personal process. If great teams can be built around great scientists then these relationships can be repeatedly successful.

Companies need to create a vibrant 'ecosystem' of innovation, breaking up large scale operations where necessary and driving collaboration between basic and clinical research. A key theme being pursued by GSK and others involves increasing externalisation of R&D. Companies are looking to foster innovation by working in partnership with SME's, other large companies and the academic community. Barriers between the sectors have begun to break down. A good example of the sort of collaboration the UK should be aiming to increase is the GSK Clinical Imaging Centre (CIC). Located at the Hammersmith Hospital, the CIC stimulates active collaborations within GSK, Imperial College and other key imaging centres, academic centres and medical schools. Industry, academic and NHS researchers are co-located and work together on research that will help to increase understanding of disease processes, determine if a drug reaches and interacts with its intended target and measure downstream responses. Such advances have the potential to accelerate effective drug discovery and development.

If the UK is to benefit from the increasing externalisation of pharma R&D, it will be important to redress a situation where the UK biotech sector is declining in strength relative to continental European competitors. In Switzerland

many successful smaller companies have been started as spin-outs from large pharmaceutical companies; the UK should try to emulate this strategy. Key barriers are the lack of maturity of the UK bioscience venture capital sector and the tendency for both venture capital firms and big pharma to look for greater proof of value before entering into agreements. While some pharmaceutical companies may indeed be looking for greater certainty in their deals, by contrast GSK is interested in deals based on early stage science and is investigating what the company can do to stimulate the UK biotech sector.

How can the opportunities for partnership be extended? Are there further prospects for companies themselves to collaborate in pre-competitive research? In the future there will be more such collaboration. Most notably, the EU Innovative Medicines Initiative (IMI) is a tremendous opportunity for pre-competitive activity within the sector. IMI is a ten year partnership between the European Commission and the European Federation of Pharmaceutical Industries and Associations (EFPIA) designed to fund projects to address current bottlenecks in the R&D process, including drug safety and efficacy, knowledge management, and education and training. Involving consortia built from across the sectors, it has the potential to make a real difference to joint working across industry and academia in Europe.

In the future, there will be more opportunities for the best academic institutions to play an increasingly important role in drug development through collaboration. Seizing this opportunity will take resources and may require tough choices regarding the allocation of funding. The challenge for Government is recognising that the UK needs globally competitive, elite Higher Education Institutions on which biomedical funding must be concentrated. If that can be achieved, there will be increasing transplantation of industry discovery groups into the academic setting. Academic excellence is anchored in the best possible science and it is crucial the UK biomedical sector harnesses this strength.

Delivering and protecting value

With a new generation of innovative products for priority diseases in prospect, there is an additional challenge for industry. In an increasingly conservative and resource-constrained environment, industry must pay more attention to providing the data required to demonstrate the cost-effectiveness of novel medicines. Ensuring that patients get access to new treatments will also require new ways of thinking about the value of medicines. Increasingly payers must not judge the value of a medicine solely in terms of what it delivers to the health system alone, but must be more prepared to value benefits that are important to patients. In the future, both industry and payers will need to change their approach and be more flexible, if we are to ensure that patients get access to the new medicines currently in the pharma pipeline.

Should different forms of incentives be developed? Patents have in the past, and should in the future, play a critical role, creating an arc of protection for inventions that can be easily copied. Another important way of valuing and stimulating innovation is to ensure good data exclusivity. The various options to deliver and harmonise data exclusivity merit further attention.

Implications for the UK

It is entirely appropriate that GSK makes its perspective on the challenges and opportunities faced by the pharmaceutical industry clear to a UK audience: even though the UK accounts for only 3% of global sales, 40% of the global R&D investment of GSK is located in the UK.

The UK remains a leader in the biomedical field. However, this lead is dwindling. In the past the UK was able to generate 50% of the top selling drugs worldwide; many foreign governments have noted the UK's success and are now pursuing an agenda to compete. India, for example, is developing a scale of scientific resources not available in the UK and provides the location for the GSK collaboration on medicinal chemistry with Ranbaxy.

Recent experience from the GSK Centre of Excellence for External Drug Discovery shows that, of 12 collaborative deals made on discovery with the biotech sector, 10 were with US companies, two with European companies and none with companies based in the UK. A further shortcoming in the UK sector is illustrated by the absence of a single industrial-scale biological facility for large molecules; this is despite a general expectation that within 10-15 years around half of all drugs in development will be biologicals.

The UK Government understands the risk from increasing globalisation and has made the right decision to support the UK science base through encouraging collaboration, tackling institutional barriers, and connecting basic with clinical research. Much more will be needed to grow and sustain a vibrant, world-class biomedical sector, promoting mobility between academia and industry and stimulating biotech sector activity.

Summary

These are challenging times for the pharmaceutical industry, however, there is hope for the future. Across a broad front there are exciting advances in basic science and demand for effective medicines is rising as the population ages and new medical needs emerge. To capitalise on these opportunities and boost innovation, industry must find new ways of working. Organisational change may be needed and alliances forged to encourage greater collaboration across different sectors. Companies must act to upgrade skills and must work with academia and healthcare providers, not only to collaborate on the translation of basic science to drug discovery but also to develop new consensus on value and on risk tolerance. If successful, companies will deliver increasing value to patients and to health systems, and increasing economic benefit to themselves and to the UK. The great UK heritage in biological science and medicine must not be allowed to dissipate.

Biography: Andrew Witty

Andrew Witty was named CEO designate for GSK in October 2007 and assumed the position of Chief Executive Officer on 22 May 2008. He is a member of the Board and Corporate Executive Team and previously held the role of President, Pharmaceuticals Europe, for 5 years.

Andrew joined Glaxo in 1985 and held a variety of roles in the UK business. He has worked in the company's International New Products groups and has been involved in multiple new product development programmes. In 1993, Andrew was appointed Managing Director of Glaxo South Africa and later Area Director for GlaxoWellcome, South and East Africa.

Prior to his appointment to the Corporate Executive Team as President of GSK Europe in 2003, Andrew worked in North Carolina as Vice President and General Manager, Marketing for GlaxoWellcome Inc., and then in Singapore where he led the Group's operations in Asia. Andrew has served in numerous advisory roles to Governments around the world including South Africa, Singapore, Guangzhou China and the UK.

Andrew is currently a Non-Executive Director of the UK's Office for Strategic Co-ordination of Health Research (OSCHR), sits on the Imperial College Commercialisation Advisory Board, is a member of the Health Innovation Council and is a member of INSEAD UK Council.

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Dr Tim Rolph, Pfizer UK

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Professor Alex Markham FMedSci, Chief Executive, Cancer Research UK

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