

# Economic Development and Transport Committee

## EDT(2) 12-05 (p6)

**Date:** 6 October 2005  
**Time:** 2:00 pm to 5:00 pm  
**Venue:** National Assembly for Wales, Cardiff Bay  
**Title:** ABPI

### NATIONAL ASSEMBLY FOR WALES: ECONOMIC DEVELOPMENT AND TRANSPORT COMMITTEE – SCIENCE POLICY REVIEW SEPTEMBER 2005

#### Key points

- Globalisation of the pharmaceutical industry means that competition for attracting R&D investment has never been greater.
- Increasing regulatory hurdles and demands for ‘perfect’ risk-free medicines means that R&D productivity is declining and costs escalating – this is set against a backdrop of downward pressure on prices, as typified by the 7% price reduction imposed by the UK Government as part of the PPRS negotiations.
- Companies consider four key factors when making decisions on new R&D investment: access to skills and knowledge; regulatory environment (encompassing all regulation, not just clinical); support for innovation; and fiscal environment including the cost of research.
- Historically the UK has excelled in skills and knowledge, especially relating to discovery research, pharmacology, *in vivo* sciences and early clinical or experimental medicine.
- Today the UK’s competitive advantage is being lost as other countries are able to provide the skills companies require at lower cost and Government policies are making it more difficult for pharmaceutical companies to collaborate with UK universities at a reasonable cost (especially with the introduction of full economic cost).
- Currently the UK remains a positive place for collaboration, however this can no longer be taken for granted and the National Assembly for Wales has an opportunity to create a competitive environment for the future by:
  - expanding delivery of skills that are of value to the pharmaceutical and biopharmaceutical industries;
  - facilitating interaction between universities and industry on collaborative research, rather than focusing on cost recovery and retention of IP; and
  - focusing on particular capabilities that are available, such as the co-location of diagnostic and device companies and clinical environments – the marriage of these will be critical if the future potential of biomarkers in improved patient outcomes is to be realised.

#### Background and Context

The Association of the British Pharmaceutical Industry (ABPI) represents more than 80 pharmaceutical companies in Britain engaged in the research, development, manufacture and supply of prescription medicines. The ABPI brings together companies who produce such medicines, whether

branded or generic, many smaller organisations involved in pharmaceutical and bio-pharmaceutical R&D and those with an interest in the pharmaceutical industry operating in the UK.

ABPI member companies manufacture and supply more than 80 per cent of the medicines prescribed through the NHS and are major exporters to countries all over the world, providing a positive trade surplus of £3.6 billion for Britain in 2003. In addition pharmaceutical companies invested £3.2 billion per annum in 2003

The ABPI Cymru Wales office in Cardiff was established during 2003, in response to devolution and recognising the changing political context in Wales. ABPI Cymru Wales works closely with member companies who have an active and declared interest in Wales. Established in 2001, this coalition of members is called the ABPI Cymru Wales Industry Group (WIG) and is currently chaired by Jennie Hammond from Lilly & Co.

ABPI Cymru Wales fully supports “A Winning Wales”, the Welsh Assembly Government’s National Economic Development Strategy that highlights the pharmaceutical and bio-technology sector, as one of its ten key economic sectors.

Education is an essential element in creating the foundation for the skills pipeline that supports investment by the pharmaceutical and biopharmaceutical industry. Consequently, the ABPI supports and encourages student interest in science at both primary, secondary and tertiary levels<sup>1</sup>, as well as disseminating information on the wide range of careers that are available in the industry<sup>2</sup>.

ABPI Cymru Wales takes an active role on encouraging interest in science and technology by:

- organising and sponsoring an annual lecture in Cardiff as part of the Public Understanding of Science in Health (PUSH) series of lectures arranged by Wales College of Medicine, Biology, Life and Health Sciences at Cardiff University;
- being a major sponsor for the ‘Medicines in May’ programme of events organized by the National Botanic Garden of Wales during 2005, specifically supporting the public lecture “Willow and meadowsweet to heart disease and cancer” by Prof Peter Elwood; and
- being a key sponsor for the Speaking of Science Event held at Cardiff University.

The ABPI is therefore delighted to be asked to contribute evidence to the National Assembly for Wales - Economic Development and Transport Committee during its science policy review.

### ***The environment for pharmaceutical R&D and manufacturing investment***

The pharmaceutical industry is currently facing difficult challenges in its global business environment which is requiring companies to fundamentally re-think their strategies, approaches to the market and investment decisions. This is caused by two factors:

- First, regulatory agencies are reducing the risk threshold for new medicines – no medicine is perfect and it is questionable whether even aspirin would pass current requirements. This means that ever larger and more costly requirements are being placed on clinical studies dramatically escalating the costs of research.
- Second, the pharmaceutical industry is coming under increasing pressure to contain costs and constrain prices - the recent 7% price cut imposed on the industry during the recent PPRS negotiations is despite the real term cost of new medicines declining over the last few years (see figure 1).

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<sup>1</sup> [www.abpischools.org.uk](http://www.abpischools.org.uk)

<sup>2</sup> [www.abpi-careers.org.uk](http://www.abpi-careers.org.uk)

Companies are therefore focused on two issues: speeding drug development through the application of new and emerging technologies such as high throughput technologies for screening and synthetic chemistry, informatics and computational chemistry; and ensuring value from research investments. Any research investment must therefore either provide a unique capability or research interaction or investments are directed towards low cost economies.

Governments can have a major influence on investment decisions made by the industry and thereby on the contribution made by the industry to the local economy. It is against this background that new national partnerships between industry, academia and Government should be formed to develop a better mutual understanding and develop solutions that benefit all partners.

As Table 1 illustrates, the number of collaborations between the UK-based pharmaceutical industry and institutes of Higher Education in Wales is relatively low. The reason for this is unknown, but it may be associated with either lack of proximity to sites of companies' investments and partly related to this ease of access to and visibility of research expertise in Wales.

**TABLE 1: Number of collaborations with all UK and Welsh universities indicated following a survey of the ABPI's Academic Liaison Advisory Group in academic year 2003/4 (excludes clinical research)**

No. of Collaborations:	No. of Studentships	No. of Grants	Total
All UK Universities	692	423	1115
Welsh Universities	13	5	18

### **Factors creating a competitive environment for R&D investment**

Over the last 10 to 15 years the UK has maintained its share of global pharmaceutical R&D investment at around 9% - well above the 3% share of the global market. In addition the UK has been able to buck the European trend and become the most significant country for pharmaceutical investment (see Figures 2 and 3). However the UK has lost significant ground to the USA (Figure 4). Today, over 50% of all pharmaceutical R&D investment is in the USA.

Furthermore for the first time outside of a year when a major merger or acquisition occurred, 2003 saw a decline in pharmaceutical R&D investment in the UK. Although small (Figure 2) –from £3.3 billion in 2002 to £3.2 billion in 2003 – this follows year-on-year declines on R&D capital investment from 2000 to 2003.

So what are the key elements in creating a competitive environment that attracts R&D investment?

#### ***1. Access to skills and knowledge – from discovery to clinical research***

- A key determinant in any R&D investment decision for the pharmaceutical industry is the availability of appropriately skilled staff and access to new knowledge. Historically the UK has retained its R&D investment at around 9% through the availability of exceptional skills and ease of engaging universities in collaborative (not contract) research.
- A strong skills pipeline relevant to the industry: in particular chemistry, pharmacology and *in vivo* sciences are skills that are in demand and qualified individuals are difficult to find and recruit<sup>3</sup>.
- Easy access to high quality centres of world-class research in universities – increasing collaborative research costs and making it more difficult to exploit IP reduces attractiveness for

<sup>3</sup> Interim findings of the ABPI STEM Skills and Education Task Force, due to report in November 2005.

R&D investment. Collaborative research requires shared intellectual input from both parties and brings benefits to academics as well as industry – this is especially true for access to unique facilities and new compounds. When companies in the ABPI own IP from such collaborations, good practice dictates that they include milestone payments, rewards and royalties if the IP is exploited – if it is not, reversionary clauses allow the university partner to seek alternative routes of exploitation.

## ***2. Attractive commercial environment for innovative medicines and vaccines***

- The local environment must be attractive. This requires stable, steadily growing markets that offer substantial size and encourage competition. Governments must adopt a strategic approach to the industry and avoid ‘knee-jerk’ actions that create unpredictability.
- Early adoption of new innovative medicines and vaccines is critical – the UK is not an early adopter of new medicines, meaning that patients may lose out.
- Pricing and reimbursement models such as the PPRS recognise and reward innovation and consider the value provided by a medicine or vaccine, rather than just the cost. This model also recognises the social, economic and technological contribution provided by the industry. It is important that every Government department acknowledges this model and does not develop policies which undermine the principles employed in the model.

## ***3. Supportive regulatory environment***

- An effective and efficient regulatory framework – not just in terms of clinical regulation, but all regulations that impact upon the industry.
- Whilst patient safety is paramount, regulation of clinical research should be competitive and allow quick start up of clinical trials and facilitate rapid patient recruitment. In particular ABPI Cymru Wales has welcomed the opportunity to support and contribute to the development of a strong clinical trials infrastructure in Wales as organized by WORD.
- A focus on better regulation in all areas such as employment, health, safety and environmental regulation will also encourage investment.

## ***4. Regular industry/government partnership and dialogue***

- A sophisticated and explicit form of partnership and regular dialogue between industry and Government is important. In addition, an integrated approach to Government policy and actions, which brings together healthcare regulation and industrial policy, is likely to be most effective. A good example of this was the Pharmaceutical Industry Competitiveness Task Force (PICTF) in the UK in 2001.

## ***5. Providing an attractive fiscal and economic climate***

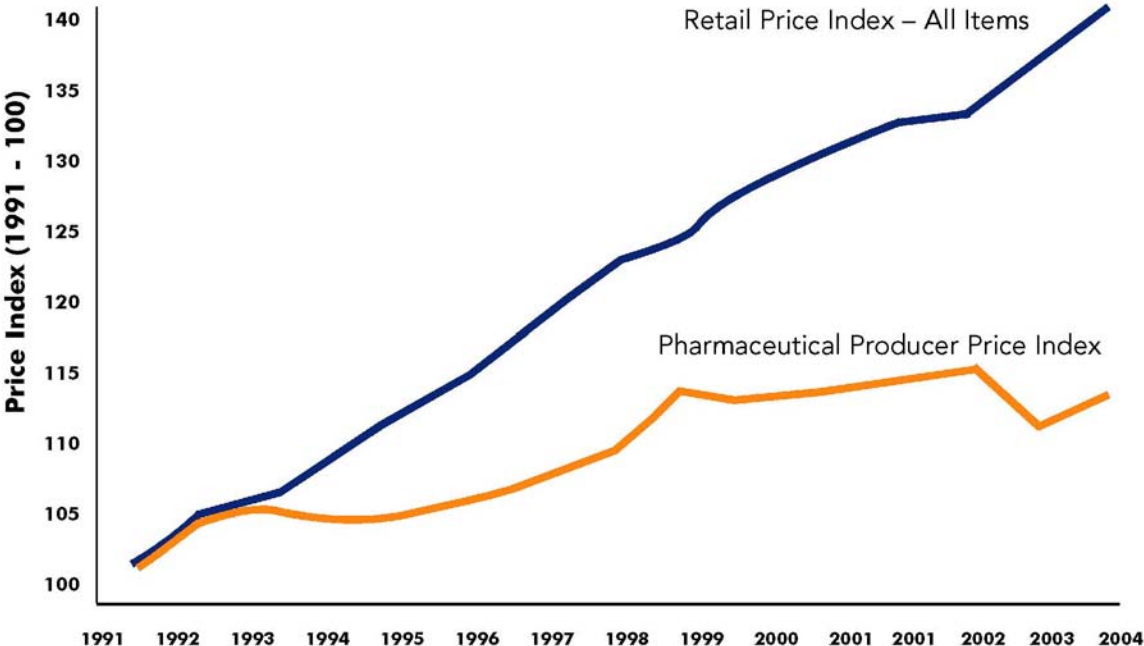
- The emerging countries such as China, India and Eastern Europe, all have a significant skills base for high quality research. These economies are low cost either in terms of wages or they provide significant financial incentives (e.g. Singapore) such as low corporation tax or provide custom-built facilities. Wales must explore how it can compete – this could include alternative incentives or assistance in building new facilities. A favourable planning environment and a good transport infrastructure can facilitate investment.

## **Closing comments**

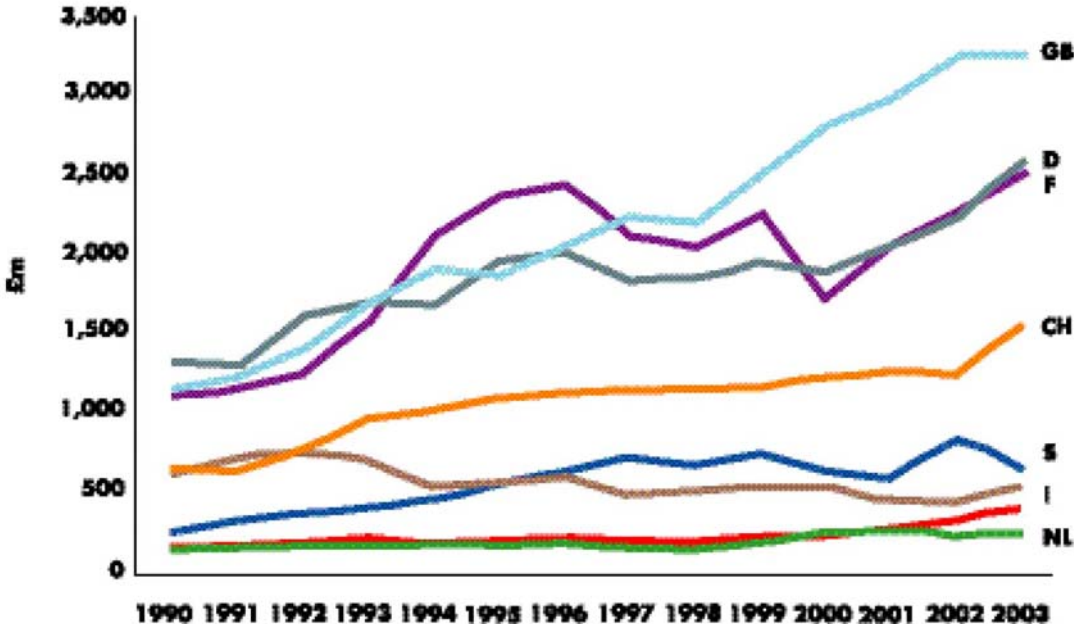
Wales has a unique opportunity to create competitive advantage and attract new pharmaceutical investment. To do this it needs to focus on providing the skills and access to knowledge, without

pricing itself out of the global market. The proximity of a strong biomedical devices and diagnostics sector with a strong clinical environment, provides a unique opportunity for Wales to position itself as a leader as new medicines and technologies transform the clinical environment in the future.

**FIGURE 1: Cost of medicines (pharmaceutical producer price index) versus retail price index since 1991**



**FIGURE 2: Pharmaceutical R&D investment across Europe**



**FIGURE 3: Pharmaceutical R&D investment in the UK**

Year	Expenditure £ million	Pharma R&D as a % of turnover	Pharma R&D as a % of al UK industry R&D
1985	546	14	11
1990	1,140	17	14
1995	1,813	19	20
2000	2,846	23	25
2001	3,040	21	25
2002	3,304	21	25
2003	3,241	22	24

**FIGURE 4: Global pharmaceutical R&D investment – US versus rest of the world**

