Pharmaceutical Industry- Innovation is the only way forward.

Posted on August 14, 2013 by Barbara Arzymanow

The headline news from the <u>Health and Social Care Information Centre</u> (HSCIC) states that more than 1 billion prescription items were dispensed by community pharmacies in England for the first time in 2012. However, we must not be complacent about the serious challenges ahead for pharmaceutical companies. With 59% of prescription items going to people aged over 60, the ageing population is almost bound to lead to rising prescription numbers. Over the past ten years prescription numbers have consistently risen by 4%-6% per annum. However, the cost of medicines has moved very differently. Sales (net ingredient cost) peaked at £8.8 billion in 2010 and have subsequently declined to £8.5 billion in 2012. These sales figures are the total through English community pharmacies on the basis of what the Government pays to pharmaceutical companies and are not in any way adjusted for prescription charges levied on the patient or professional prescribing fees. In fact, all but 9% of prescriptions are free to the patient and no charge is made to persons over the age of 60.

The pharmaceutical industry as we know it is unusual because it cannot survive without<u>innovation</u>. Without new drugs all patents would eventually expire and profits in the industry would ultimately fall to perhaps a sixth of present levels. Instead of being a major driver of improving health and increased life expectancy the pharmaceutical industry would become no more than a supplier of standard medicinal chemicals formulated for human use. Drug businesses would be reduced to providing me-too products or commodities in rather the same way as other companies supply bandage or hospital catering.

Each of the largest multi-national pharmaceutical companies generally earns most of its profit from no more than ten drugs, which are generally patented products that they have discovered or in-licensed. The pharmaceutical industry is about finding new products of major benefit in areas of unmet medical need. In order for the industry to grow and prosper it is imperative that this endeavour continues and that the financial returns should be sufficient to justify the risks taken.

Most industries have very different dynamics from pharmaceuticals. The overall profitability of many other industries would not change as dramatically if innovation stopped. For example, if car manufacturers ceased improving their models, cars would still be needed and their prices might not change very much. Similar considerations apply to most manufacturing and service industries. Innovation in most of the economy is about competition between companies, which may achieve a cost saving through improved processes or be able to develop a superior product. In such circumstances individual companies may gain or lose very substantially but the relevant industry as a whole may still prove to be highly resilient

In pharmaceuticals <u>successful innovation</u> often expands the market rather than raising competition. A drug will certainly add to competition if it meets an unmet medical need by proving superior to existing top-selling products, for example by avoiding side effects or by being more effective. However, the most innovative drugs often address complaints where little else had been available or where inferior alternatives were already out of patent. In such cases the commercial impact of the new drug in raising competition may be minimal.

The lifeblood of the pharmaceutical industry is bringing to the market important new, patented medicines of major potential benefit to identifiable patients and to society. Helping drug companies to achieve this is and should be an important policy objective subject only to the costs involved. A secondary aim of UK policymakers should be to

encourage the pharmaceutical industry to manufacture and carry out R&D in the UK as opposed to elsewhere in the world.

In all drug companies far more products are researched than eventually prove suitable for use as medicines. A high failure rate is inevitable because many drawbacks such as unacceptable side effects, the rapid emergence of resistance or the speedy breakdown of the agent in the human body can be unpredictable. Total, direct R&D spending on each drug that eventually succeeds varies enormously but a ballpark would be in the region of £100m The time from discovering a drug to reaching the market is typically around ten years. In practice, pharmaceutical companies collectively spend much more money in total on drugs that fail than on successes. Total R&D spending divided by numbers of major drugs launched is often as high as £1 billion, which is a guide to the effective R&D spend required to yield one important product.

A full discussion of policy in all areas affecting pharmaceuticals is clearly beyond the scope of this brief blog. The following is a very short summary of my conclusions:-

- The most important need is for <u>drug prices</u> around the world to be high enough to encourage R&D. Spending £1bn on R&D spread over 15 years without any certainty of developing a successful drug is not a matter to be undertaken lightly. Every country has a responsibility to make an appropriate contribution to sustaining adequate <u>drug prices</u>. A country's <u>pricing system</u> is also the biggest single indicator to pharmaceutical companies of how much the government of that country really supports the industry and is therefore a major factor in decisions about where to locate R&D and manufacturing.
- The UK represents only 3% of the world pharmaceutical market. Companies must therefore do what R&D seems best in an international context. The UK authorities will only drive R&D out of the UK if they try to influence management decisions over what to research. The industry knows that it must focus on genuine, unmet medical needs.
- All companies have barren periods in R&D. These phases are when most financial encouragement is needed, not when a major block-buster drug is ready for launch. Trying to reward drug companies purely on the basis of the <u>value of their successful drugs</u> is too simplistic.
- Incentives for developing drugs for rare diseases need to be strengthened internationally so that drug companies do not focus entirely on common conditions.
- Ways of encouraging drug companies other than through pricing (e.g. the <u>Patent Box</u>and <u>R&D Tax Credits</u>) are <u>very helpful</u>.
- Effort must be put into improving the standards in academia and teaching hospitals as well as encouraging cooperation with R&D in industry.

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About Barbara Arzymanow

Barbara Arzymanow is a Research Fellow at 2020health and is a founding director of an independent healthcare consultancy firm. She has been an investment analyst specialising in Pharmaceuticals for 25 years, prior to which she carried out academic medical research in university laboratories. Her experience, obtained entirely from outside the pharmaceutical industry, gives her a unique, political perspective independent of commercial lobbies. She has extensive experience in financing the biotechnology industry, which is vital for the long-term standing of medical research in the UK. She has always been inspired by the scientific excellence within the UK and would like to see collaborations between industry, the NHS and academia strengthened. For more information about Barbara's research and writings including submissions to Government Departments please visit http://www.researchideas.co.uk . Barbara also tweets as @barbararesearch .

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