

Why the pharmaceutical industry should get into bed with academia

By Dave Sharma, a Qualified Person from Cambridge

The US is often seen as the land of opportunity, where people can go and live the American dream. A commentary by Michael Anisfeld, president of Globepharm, in *Industrial Pharmacy* (2007;13:3), however, paints more of an American nightmare. One in seven Americans — 47 million people — does not have access to health insurance. This tragedy, in a country often portrayed as advanced, has occurred for a reason. There is no price control of drugs in the US so a somewhat Darwinian approach is adopted: survival of the fittest could be rewritten as survival of the richest.

Difficulties in accessing medicines are more usually associated with the developing world: AIDS, malaria and tuberculosis kill six million people a year. A key question posed by Mr Anisfeld is: does the pharmaceutical industry bear responsibility to the less well-off in the world to develop drugs for diseases that are not prevalent in our own societies, and that will not be sold at high profit? An additional issue is whether or not anything can be done to change the way medicines are developed.

The cost of developing medicines is huge, but the returns on investment have, historically, been far higher than in other industries. It can cost up to \$1bn to develop a medicine for market. However, this figure includes money spent on molecules that fail to make the grade — of 10,000 new molecular entities screened, only one might make it to the market. In addition, it can take between eight and 10 years to develop a medicine for market. This leaves a company six to eight years to recoup the costs of research and development, make a profit to keep shareholders happy and invest for tomorrow's pipeline.

Every day lost in development can cost a company as much as \$1.5m, as a patent's life is further reduced.

Industry performance

There has been a recent decline in the performance of the pharmaceutical industry. For example, the number of molecules gaining authorisation has decreased although the number of molecules in the R&D pipeline has increased. This raises the question of whether or not the pharmaceutical industry is any good at discovering new compounds for debilitating diseases.

There have been some developments in the treatment of cancers, but no real effort to tackle diseases in the developing world. Industry still seeks the big blockbuster — the drug for all, which will make over \$1bn per

year. Gaps in the new product pipeline need to be filled and the only quick-fix solution is to "in-licence" a compound, normally from a smaller start-up institution. This leaves the industry to do what it does best — develop the compound through the costly process of clinical trials.

The general public has a low perception of the pharmaceutical industry: some even group it with the tobacco industry, which is shocking considering that pharmacy is, essentially, about saving lives and increasing the quality of life. Corporate social responsibility programmes can do some good, but are seen by many as a public relations exercise.

Developing medicines for diseases in the developing world costs money and is unlikely to be profitable but it will raise the profile of the industry and save lives.

An ethical pharmaceutical model

To expect the pharmaceutical industry to resolve some of the most difficult developing world medical needs may be naive, but it is not all doom and gloom. Those who read Briony Hudson's article on William Allen (*PJ*, 24 March, pp344–5) will understand that great social changes are initiated by individuals and not large corporations. The same is occurring, at an early stage, in drug discovery.

Arguably, much could be achieved if industry worked more closely with university researchers. Already, more academics are focusing on developing world diseases. Sunil Shaunak, professor of infectious diseases, division of investigative science, at Imperial College London, states in *Hospital Doctor* (4 May 2006:29): "People in academic medicine have a choice. They can use their ideas and creativity to make large sums of money for small numbers of people, or they can look outwards to the global community and make affordable treatments for common diseases."

Infection with hepatitis C causes premature death for millions worldwide. The cost of treatment is high and so those who cannot pay, or whose government cannot afford such medicines, are excluded. In conjunction with Stephen Brocchini, professor of chemical pharmaceuticals at the School of Pharmacy, University of London, Professor Shaunak has managed to devise a novel way of producing pegylated interferon which does not infringe existing patents.

These two academics have redesigned the molecule by glycosating on the inside of the interferon protein (adding a large sugar molecule inside). This has highlighted the important role of academia in drug development.

Some in the pharmaceutical industry might even be concerned because these two academics are aiming to produce a pegylated interferon treatment for hepatitis C at a fraction of the current cost.

The Medical Research Council (MRC) has produced 27 Nobel prize winners. Their discoveries have had a major impact on understanding diseases and developing new medicines. One example is the development of monoclonal antibodies: Cesar Milstein and Georges Köhler from the MRC laboratory devised a way to produce mouse antibodies of a particular type and Sir Gregory Winter, another MRC researcher, found a way to humanise mouse monoclonal antibodies, making them more suitable for human use. These discoveries have improved the quality of life for patients and have resulted in a healthy revenue stream for the MRC. According to the MRC, Abbott Laboratories recently paid it over £100m in lieu of future royalties for an MRC molecule.

Many discoveries are made by accident. The discovery of penicillin is an excellent example. Academia and small start-up organisations tend to make the greatest leaps forward in medicine. This should be a big enough carrot for drug companies to be seriously interested in academic institutions. This is not to suggest that the pharmaceutical industry does not possess great scientists. Far from it, but, in some respects, it suffers from inept administration and poor research governance.

Small start-ups and academia offer scientists an environment in which they are encouraged to experiment without too many rules and restrictions. It is the scientist who thoroughly investigates anomalies who can really take our understanding of disease forward. In order for industry to continue to grow, it will need to work with these much smaller, less bureaucratic and more creative organisations. The pharmaceutical industry is unlikely to resolve its own underlying research governance issues quickly, which means it will depend on individuals in smaller discovery centres.

Individuals such as Professor Shaunak have added a new dimension. Not only are academics and small start-ups producing promising new drugs for all diseases, this ethical pharmaceutical model will create new drugs leading to better medicines to treat the poor.

The pharmaceutical industry must adopt a collaborative approach if it wants to deliver shareholder value, raise its profile and treat deadly diseases such as hepatitis C.