DDT Vol. 7, No. 9 May 2002

Rethinking the formula

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The *8th Annual Pharmaceuticals Conference, Rethinking the formula* (13–14 February 2002, London, UK), provided an opportunity to look at the changing face of the pharmaceutical industry in the 21st century. The conference was organized by *Economist Conferences* and was attended by ~150 delegates.

Drivers of change in the pharmaceutical industry

The first session, chaired by Trevor Jones (Director General, Association of the British Pharmaceutical Industry, London, UK), provided an overview of the industry with a review of current market trends, and introduced some of the themes that were to be discussed over the course of the conference. Franz Humer (Chairman and CEO, F. Hoffman-La Roche, Basel, Switzerland) gave the keynote address, which focused on the 'drivers of change' that would be either winners or losers for pharma in the coming decade and beyond. Over the past decade research costs for the development of new drugs have increased >7% with clinical costs increasing by 12%. Despite all the technological advances of the past decade, the commercial risks involved in bringing a new drug to the market have not decreased and, in 2001, ~50% of Phase III projects did not result in the launch of a new product. This indicates huge losses because, at this stage, 80–90% of the investment has already been made. The policy of pricing still remains an issue: price controls mean that Europe can sell drugs at 40% of the US price, whereas in Japan prices are on the increase for innovative products. The lag time for drug approval was also under scrutiny: EU drugs typically take 2–3 years before patients are allowed access. However, Humer does believe there is hope, as given by crucial new platforms, such as medical genetics, indicating that it has never been a more exciting time to perform drug discovery research than at present.

The Human Genome Project

Since the elucidation of the first draft of the Human Genome Project, the potential number of drug targets has increased 20-fold. The challenge is to go from hit-to-lead to proof-of-concept with increasing speed and accuracy. The promise of genomics in determining the underlying biology of disease could lead to targeted drug prescriptions and the treatment–diagnosis paradigm of the future; that of personalized medicine. Herceptin™ was the first genomic drug for breast cancer; by including only women who overexpress the relevant protein (Her2), the success rates for the drug increased significantly. This implied that, in the future, Phase III trials will have to be larger to accommodate all genetic variations and produce defined phenotypes.

Survival of the fittest

The future of drug discovery and development in a changing environment was discussed by Rolf Stahel (CEO, Shire Pharmaceuticals Group, Chineham, UK), who identified the key strategies in separating the winners from the losers. He emphasized the importance of size in the marketing sector, not in R&D, for the success of a new drug product. Recently, as a result of enhanced threats of bioterrorism and the increased awareness of the HIV/AIDS epidemic in Africa, public opinion has become increasingly positive with regards to the pharma industry in general.

Stahel stressed that patients should be used as allies to open up healthcare budgets around the world. There is increasing pressure on every nation's budgets because of the global ageing population, but this was seen as positive because it will lead to a higher total expenditure. The 'omics' revolution is seen as offering opportunities for further growth. He described the key to a successful strategy as being focus, leadership, innovation, marketing and risk management, knowledge of the therapeutic area and transparent financial reporting.

The law

Gavin Robert (Linklaters, London, UK) spoke from an anti-trust perspective, focussing on four main areas of risk and challenge: (1) generic competitiveness on patent expiry, (2) parallel trade, (3) pricing and (4) merger control. This gave a good background to the laws governing the pharmaceutical trade, such as the 180-day exclusivity period for a first patent filer, the EU single market policy, pricing 'abuse', and increasing consolidations and 'mega mergers'.

New business models – the end of an era?

The future of product pipelines looks uncertain and drug companies are being forced to change the way they operate over the next five years. Jan Leschly (CEO, Care Capital, Princeton, NJ, USA) gave his keynote address on 'big pharma's dilemma being biotech's opportunity'. With the increasing pressures of pricing, marketing promotions, FDA issues and the rise in generic products, pharma is not the profitable industry that it has been for the past 20 years. The dilemma is faltering revenue growth, profit margin squeeze and the lack of productivity in R&D. From the top 15 companies, 14 new products were approved last year: the cost

  PII: S1359-6446(02)02276-6

of R&D in 2001 was US$30 billion, which is US$2 billion per drug.

The solution to this is to decrease R&D cycle times and costs, and acquire new platforms for technology (i.e. SNP-profiling, proteomics, HTS and bioinformatics), which could lead to the concept of personalized medicines. There are currently ~2500 platform and toolkit biotech companies competing with 40 large and 650 mid-size pharma companies, leading to the question: Will biotech fill the product gap for big pharma?

Outlook

The outlook for business models was presented by David Bellaire (VP, Booz Allen Hamilton, New York, NY, USA) and Peter Barrett (Senior Principal, Atlas Venture, Boston, MA, USA). Bellaire compared both sides of the Atlantic, with the expense of trials and commercialization being the same, whereas in Europe public funding and budget constraints are more of a problem than in the USA, which raised the question: 'Is Europe poised for the challenges to pharma wealth distribution?'

Barrett spoke about the present environment with the emergence of new capabilities, such as information power, parallel experimentation and therapeutic approaches. Biotech is more dynamic in technology integration and has more extensive capital resources than before. Continued pressure exists on pharma returns, increasing the value of in-licensing late stage products. Alliances are a key component of business models: biotech has platforms to offer to pharma's products and innovation compared with market power. The overall outlook for biotech business models is to drive innovation and put less emphasis on the direct sale of technology and services with alliances being of great importance.

Capturing value through marketing and sales

The importance of sales and marketing is central to companies that are looking for ways to recover their R&D costs. Mark Trudeau (VP, Commercial Operations, Bristol-Myers Squibb, UK) presented on the link between science and marketing, the importance of market research and the goal of improving lives through medication. There is usually too much money spent on the marketing of a drug too early in the development process and drugs rarely recoup the development costs. Market research is essential and must aid in the design of clinical trials to enable product differentiation. The importance of the compliance of product users was also emphasized, as was marketing and education.

Pierre Morgan, VP of Marketing at Aventis Pasteur (Lyon, France) described the vaccine industry as a wild market, which has more regulations but fewer competitors, and increasing R&D costs but fewer acquisitions and mergers because of anti-trust. He also emphasized the increasing importance of e-marketing, and looked at the impact on ROI of direct-to-consumer (DTC) and journal advertising.

The future of the blockbuster

The risk of investing money in a blockbuster drug is increasing because R&D is becoming more complex, elusive and time-consuming. A selection of industry experts joined together for a panel discussion on how to handle the risks involved in producing a blockbuster. The panel were David Bellaire, David Ebsworth (ex-head of Business Group Pharma at Bayer, Leverkeusen, Germany), Pierre Morgan and Stephen Parker (Finance Director at Oxford GlycoSciences, Abingdon, UK).

Ebsworth described the importance of having a blockbuster drug: of the 66 blockbuster drugs, only five companies have two or more. The criteria for a blockbuster drug are billion dollar sales in the first year after launch. Morgan spoke about whether the first HIV vaccine would acquire blockbuster status, with the bulk potential consumers being in the poorest parts of the world, which increases the pressure to make the product available at cost.

The right European legal framework

The second day of the conference was chaired by Shereen El Feki, Healthcare Correspondent at *The Economist*, and started with a keynote address from the Commissioner for Enterprise and Information Society at the European Commission, Erkki Liikanen, who discussed pharma in Europe. The challenges for the industry in the immediate future include improving the competitiveness of European-based pharma, developing the EU science base and meeting EU citizens' expectations to have access to the latest generation of high quality medicines as quickly and safely as possible. The ongoing review of European pharma legislation and optimizing a balance between centralized and decentralized procedures were discussed. Liikanen reinforced the success of the European Medicines Evaluation Agency, which was established in 1995, and the setting up of a centralized procedure for the authorization of pharmaceuticals. Also, the introduction of a new system aimed to ensure the availability of better, patient oriented and valid information was described.

Customer revolution

The customer of today is increasingly informed and empowered, creating a challenge for an already complex industry. Per Wold-Olsen, President of Human Health, Europe, Middle East and Africa (Merck, Darmstadt, Germany), spoke about the changing playing field and updated on the DTC market in Europe, as well as summarizing the Internet and other e-initiatives, which have opened up a wealth of information for the patient. This has been exemplified by the increase in information regarding HIV/AIDS and the demand by citizens for breakthrough medicines. He went on to

stress that we are in the midst of a therapeutic revolution in medicines; for example, a watchdog committee recently pointed out that of the 15 million people who should be prescribed statins, only one million receive this medication, the major reason being the lack of permission to relay drug information to patients.

The birth of the megabrand

David Ebsworth and Brian Kelly (MD, Sudler and Hennessey, London, UK) spoke about the future of corporate and product branding and what the pharma industry can learn from traditionally brand-led industries. Megabrands are not created but are built by an organization over a long period of time. Ebsworth described how few companies have more than two blockbuster drugs, which are characterized by significant sales (US$1 billion) in the product launch year and peak sales of several billion dollars. Drivers are a medical need and innovation, a population-sized market place, an appropriate pricing potential and extensive promotional rights. The key is to use marketing and sales investments and to capture the market share quickly. Key factors are a global branding challenge, giving a clear message, and a consistent lifecycle managed over time.

Kelly focussed on the drivers of megabrands being the customers and the media by which these brands are advertised, and looked at lessons that could be learnt from the big branding consumer companies. He stressed the importance of consumer media; television, radio, magazines and the increasing use of the Internet, and emphasized the importance of health in pharma decision making.

Pharma in the next decade

William Haseltine, Chairman and CEO of Human Genome Sciences (Rockville, MD, USA), in his closing keynote address, described the clear recognition of the need for new drugs as old drugs go off patent. The future of pharma in the next decade is through mergers; of the major mergers in the past few years they are all doing well. However, this is not sustainable without significant structural reform or the engagement of industry with society. The effects of genomics and pharma developments are overplayed, he believes, with the origins of new drugs coming from either classic NCEs or antibodies. The use of antibodies, in conjunction with novel technologies, could shave up to seven years off the usual product pipeline times as the rates for biologics in clinical trials is more rapid than for NCEs.

The consistent theme throughout this conference was the importance of patient compliance and access to information. The added challenges of an ageing population means that new drugs need to be brought to the market more quickly than ever before, and the added activism of patients indicates the need for increased safety and efficacy of clinical trials. The meeting brought together members from across the pharmaceutical industry, marketing and the law, to engage us in the current topics and dilemmas facing the industry at present.