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The World's Industrial Transformation Series

Shifting Patterns in the Pharmaceutical Industry

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Summary points

- Until now large developed-country pharmaceuticals companies (Big Pharma) have dominated the industry worldwide, owing to their superior research capabilities, sales and marketing networks, and understanding of regulatory systems.
- Over the next decade the industry will grow faster than the world economy, particularly in developing countries. The global balance of sales will shift in favour of these countries, especially those in Asia.
- The global balance of diseases will also change as chronic problems associated with ageing and a 'Western' lifestyle, such as diabetes and dementia, spread around the world.
- Big Pharma's business model is increasingly threatened by downward pressures on prices by healthcare providers, and the rising costs of finding new drugs and bringing them to market.
- The industry could be revolutionized by new drugs derived from genetic breakthroughs that allow targeted therapies and may reduce the competitive advantage of Big Pharma, and by pressures on public funding of drugs, which may promote private funding.

Introduction

The global research-based pharmaceutical industry – comprising those firms focused primarily on the research, development, manufacture and marketing of prescription medicines – saw a big expansion in the later decades of the twentieth century. The principal drivers for this are well known: a pharmacological revolution in the discovery and development of new medicines; public demand for better healthcare from informed and activist post-war 'baby boomers'; and health systems that – in developed countries – were able to finance the growth in demand from their citizens.

This favourable combination of supply and demand factors served the industry well. However, by the late twentieth and early twenty-first century there were signs that both such factors were now putting this model under strain.

The paper examines the sources of these strains and identifies the developments in science, the economics of healthcare and regional economic power that are likely to determine the future of the global industry. In view of the uncertainties surrounding the timing and impact of these forces, a scenario approach is used to highlight the potential outcomes. The term 'Big Pharma' is used here as shorthand for the group of large companies based in the developed countries, while 'Emerging Pharma' refers to companies based in the emerging markets, primarily in Asia and Latin America.

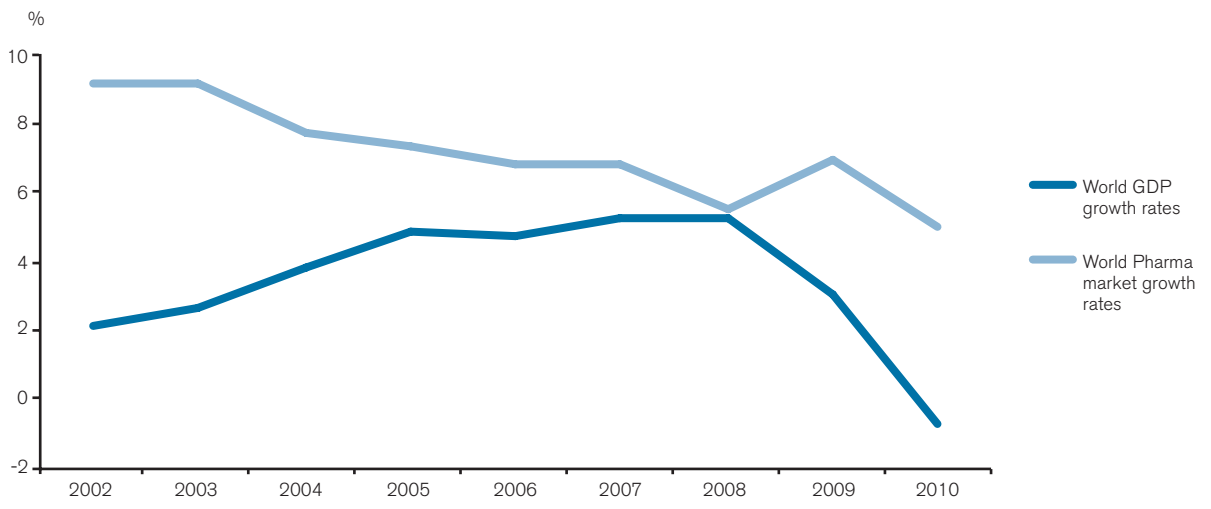
The signs of strain

Price pressures

The 'blockbuster' drugs that ensured the financial success of many pharmaceutical firms were equally 'cost-buster' drugs for many healthcare systems and payers. Cost containment measures had long been in place for controlling the price and/or reimbursement of drugs financed by third-party payers. The agencies responsible for purchasing drugs questioned their increasing costs, and the debate switched from price to 'value'. Pharmaceutical companies sought to justify their prices, not only via the general principle that what might be perceived as high prices fund research into currently untreatable diseases, but also by stating that they provide good 'value' in dealing with treatable ones, since new medicines often replace more expensive treatments such as surgery, and/or reduce the length of hospital stays. A new discipline grew up, adopting terms ranging from 'pharmacoeconomics' to 'health technology assessment', to analyse the economic impact of pharmaceuticals on health systems and patient health outcomes. Payers still tended to focus on cost rather than value, although pharmacoeconomic arguments in some instances may have attenuated the most severe cost containment pressures.

Where drugs (such as antibiotics and vaccines) unequivocally prevented loss of life, the case for their use and the

Figure 1: Pharmaceuticals growth vs GDP growth



Sources: World Bank; Author's estimates based on industry data.

associated expenditure were less likely to be challenged. Where new drugs could be seen to reduce other visible healthcare costs, such as hospitalization and expensive surgical procedures, a case for their use could be demonstrated. However, where the costs of the disease lay outside the strict healthcare budget – such as those borne by families or social care services (including official agencies) – then it was much harder to justify the use of expensive drugs to payers.

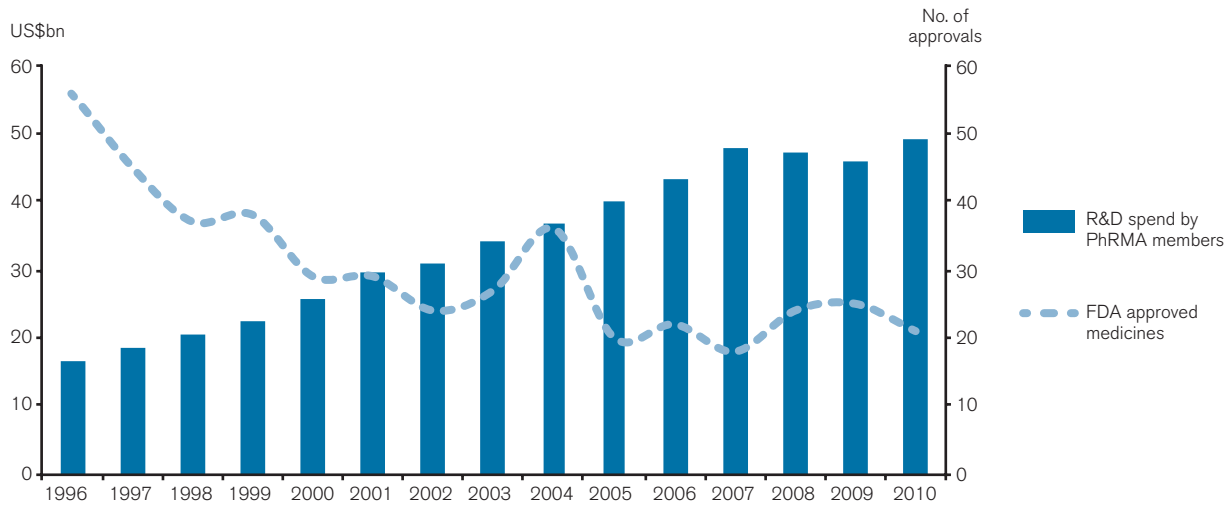
As newer therapies often not only increased lifespan but enhanced quality of life, health economists developed the concept of the QALY ('Quality Adjusted Life Year') to integrate the two aspects of health outcomes from drug treatment. In response, payers began to draw up their own criteria for economic evaluation of medicines, which could include setting maximum costs per QALY to justify the rationing of drugs in the reimbursed sector. Public relations battles developed over to whether the lack of availability in public health systems of an expensive new drug in a high-profile disease area was due to uncaring, insensitive governments or to greedy, profiteering pharmaceutical companies.

The demand pressures on drugs were accompanied by pressures from generic competition. Before the late 1980s, the research-based pharmaceutical industry developed a number of strategies to minimize the impact of generic products. However, a new spur to generic competition came from the Waxman-Hatch Act in the United States in 1984, which extended patent life for new medicines but gave the opportunity for more rapid market entry by generic products once patents had expired. Generic prescribing and dispensing now rapidly erode the post-patent sales of originator brands. In many European countries, the spur came from reference price systems that included the prices of generic products when setting reimbursement prices for product categories.

Research productivity

The companies that grew through the development and sale of 'blockbuster' drugs created a big self-imposed imperative to continue launching new revenue-producing drugs, not only to continue to maintain growth as products matured, but also to avoid the precipice of revenue fall on patent expiry. However, this was becoming increasingly difficult not only because of the challenges of making new research breakthroughs but also as a result of heightened regulatory criteria, especially in the area of drug safety. This is reflected in the statistics on the numbers of drugs approved by the US Food and Drug Administration (see Figure 2).

Figure 2: The decline of R&D productivity



Sources: FDA and PhRMA data.

Industry implications

The combination of demand- and supply-side pressures meant that the industry was faced with a squeeze on margins. In economic terms, the average cost for many companies of producing a drug, from basic research through development to registration for sale, was becoming higher than the average revenue from it. Industry consolidation would be the usual result of such economic trends. However, most companies were able to use the cash flow from earlier products to stave off these pressures for several years, driven by the hope that research programmes would be their salvation. Quite a few companies that did not achieve the requisite research success eventually succumbed to the economic inevitabilities and were absorbed by larger ones. However, the pace of this consolidation was relatively slow until the end of the 1990s, when a spate of significant mergers and acquisitions (M&A) activity by the leading firms led to an increase in the share of the global market held by the top 10 pharmaceutical firms.

These developments have led many to conclude that the traditional model of the pharmaceutical industry that has evolved over recent decades is no longer valid, and that a new industry process and structure will need to emerge. From the evidence, the changes in the structure of demand and supply in the pharmaceutical market are bringing about significant changes. The question is whether the industry will adapt and evolve, or whether there will be a major transformation to a substantially different mode of operation and existence. To address this issue requires examination of the forces affecting the industry.

Future drivers of the pharmaceutical industry

Demand

The intrinsic demand for health and pharmaceutical expenditures continues to rise for a number of reasons. First, increased longevity has meant that, while many acute illnesses that caused morbidity and mortality in earlier decades have been tackled very effectively, there has been an increase in more chronic conditions associated with ageing. While improved healthcare has been among a number of factors contributing to increased life expectancy, demand for healthcare has also risen from the increasing numbers of elderly people in the population. Secondly, the definition of 'being in good health' has evolved, leading to rising expectations of what should be available from healthcare systems. Better-informed patients – particularly as a result of growing internet use – have put pressure on health providers to make the latest treatments available. The border between 'therapeutic' drugs and 'lifestyle' products has become blurred. Drugs for sexual potency and cognitive enhancement and to combat obesity have raised questions about how many areas of treatment should be publicly funded. Thirdly, new areas for intervention have been identified, such as attention deficit hyperactivity disorder (ADHD), social anxiety and even restless leg syndrome – conditions that were not acknowledged in the past.

World and regional market growth

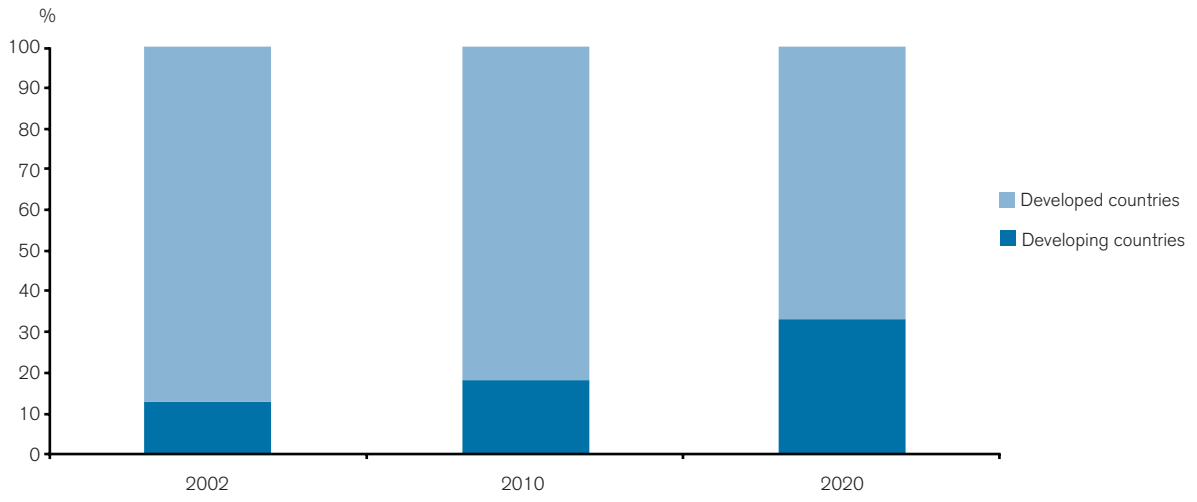
In this study, the most likely outlook is assumed to be steady if unspectacular world economic growth up to 2020. At a macro level, pharmaceutical market growth has consistently exceeded GNP growth by a significant factor. Over the past nine years, the global pharmaceutical market has grown at an annual rate of 7%. Growth rates in the mature markets of North America and Europe have been lower, and in Japan considerably lower at 4%. The markets that have grown strongly in recent years have been in the Asia-Pacific region and Latin America, where economic development has resulted in stronger middle-class demand for healthcare, especially in the former. China has now become the third largest pharmaceutical market, after the United States and Japan.

Table 1: Global pharmaceutical market rankings

	2001		2011
1.	United States	1.	United States
2.	Japan	2.	Japan
3.	France	3.	China
4.	Germany	4.	Germany
5.	Italy	5.	France
6.	UK	6.	Italy
7.	Canada	7.	Brazil
8.	Spain	8.	Canada
9.	China	9.	Spain
10.	Brazil	10.	UK
11.	Mexico	11.	Russia
12.	Australia	12.	India
13.	South Korea	13.	South Korea
14.	India	14.	Australia

Source: Industry data.

Figure 3: Evolving global shares of developed vs developing regions



Source: Author's estimates based on industry data.

Over the next ten years, annual world market growth is expected to be around 6%, with the strongest growth in the Asia-Pacific region, especially China and India, where strong double-digit growth is anticipated. As a result of the sharp differentiation in growth rates between the developed and developing regions, the developing world's share of the global market is expected to increase significantly.

Regional disease patterns

Traditionally, chronic diseases were mainly a feature of more developed economies, while less developed economies were more affected by acute conditions. This was reflected in the patterns of drug use. However, as the emerging economies have developed and their populations have aged, they have begun to take on the disease characteristics of the more advanced nations. They are showing a declining proportion of acute diseases but a growing proportion of chronic diseases or conditions such as diabetes and hypertension.

In many parts of the developing world, infectious disease is still rife and climate change is likely to alter disease patterns among countries. Resistance to anti-infectives remains a key challenge and the risk of pandemics is still an underlying threat in the world.

Sources of funds

(i) Demand and funding

From the evidence, the intrinsic demand for healthcare is likely to be as strong as ever, and the demand from patients and physicians for pharmaceuticals to address current and unmet therapeutic needs will consequently grow. The issue is the extent to which funds will be made available to finance this 'demand'. In the developed markets, healthcare – and pharmaceutical – funding has become ever more institutionalized, and those institutional purchasers/healthcare organizations are also becoming increasingly tougher negotiators with healthcare providers, including pharmaceutical companies. The current trends described above show no signs of abating – quite the opposite, in fact.

Healthcare in the United States was traditionally delivered by a varied multi-provider system, with a combination of a fee-for-service insurance market, usually financed by employers as a workplace benefit, a private healthcare market, and other institutional providers such as the Veterans' Administration. The elderly benefited from federal Medicare and the poor received state-financed Medicaid. The rising costs of healthcare by the 1980s prompted the growth of Health Maintenance Organizations (HMOs) that sought to negotiate price contracts for the provision of health services, instead of the open-ended fee-for-service insurance system.

By the end of the 1990s the overwhelming bulk of pharmaceutical sales were made through a contracted system, which gave market power to institutional purchasers. It has given scope for pharmaceutical companies to negotiate some innovative deals with healthcare organizations, involving guarantees of cost savings for specific medicines, payment by results in terms of therapeutic outcomes and certain forms of risk-sharing agreements with payers. The US outlook will be significantly influenced by the so-called 'Obamacare' health legislation designed to extend coverage to previously excluded groups such as the unemployed, the transient and those not in employer schemes. For pharmaceutical companies, this holds the prospect of increased volumes but sales are likely to entail tougher negotiations – and hence downward pressures – on pricing, which will inevitably spill over into other market sectors.

Another factor that will influence the US pharmaceutical environment is the underlying discontent among the population that the perceived high prices are 'subsidizing' the rest of the world. This is a political conundrum that is difficult to address and is mirrored in wider international issues of price disparities and access to medicines (see below).

In Europe, healthcare authorities are focusing their efforts on cost containment with ever more zeal. At one time, pharmaceutical expenditure appeared to be divorced from economic/fiscal cycles. However, it has been far from immune from the recent severe government expenditure cuts. Pharmaceuticals are now more likely to be subject to fiscal cycles than in the past. Value arguments are also certain to be at the forefront of purchasing/reimbursement decisions and health outcomes from therapy will continue to be a source of major debate between companies and public health authorities.

(ii) Supply

The proposition that the traditional pharmaceutical industry model will not work any more is predicated not only on demand-side resistance, but also on an apparently failing record in research and development (R&D).

The 'biotech' sector – which encompasses a range of innovative technologies – has been lauded as a significant source of new candidate drugs, and Big Pharma has sought to negotiate in-licensing deals, partner with or acquire the more creative and dynamic smaller-scale biotech companies. However, the early enthusiasm of venture capitalists to fund these start-up enterprises has waned with the spiralling 'burn rate' (i.e. the continuing funding costs), against a background of economic uncertainty.

For the industry as a whole, there are a number of reasons why the output of new chemical entities approved for therapeutic use is not commensurate with the continuing rise in R&D expenditure. First, the majority of currently unmet therapeutic needs now involve far more challenging biological targets, requiring much deeper understanding of the disease process to identify a route for intervention, and this is proving to be more costly and protracted. Secondly, the costs of undertaking clinical trials in these more challenging therapeutic areas have also proved higher and often frustrating, as establishing convincing clinical endpoints in chronic diseases sometimes proves elusive. Thirdly, drug regulatory authorities have been chastened by a number of drug safety incidents and have become much more cautious in their approach, and this has added to the development costs of pharmaceutical companies as well as slowing down the rates of new drug approvals. These trends have combined with the demand-side pressures to produce an unfavourable climate for the traditional firms in the industry.

New horizons

Against this, the potential of the pharmaceutical industry is being transformed by a steadily emerging raft of new technologies originating in the completion of the human genome-mapping project. This is opening up a new vista of opportunities for scientific innovation.

Traditionally, the pharmaceutical industry was often cited as treating symptoms of disease, rather than tackling the underlying causes. There was much justification behind this claim, although the treatments represented the state of the art in disease understanding, and have provided great advances in the treatment of patient suffering, even if sometimes only symptomatically.

From the knowledge gained from the human genome project new scientific approaches were developed. These have sought to better understand the genetic basis of disease and design therapeutic interventions to tackle their root causes, which could be fundamentally more effective than treatments of the past. New specialisms emerged, such as pharmacogenetics and

pharmacogenomics, which led to enhanced understanding of the pathophysiology of disease and identification of which patients will respond to which therapies.

The application of the science has proved slower to develop than was predicted by the early enthusiasts. Diseases caused by a single gene (monogenic) – such as cystic fibrosis – were more readily identified. However, the majority of diseases are multigenic and even the presence of a pathogenic gene does not automatically lead to the development of the disease, since this will depend on its interaction with various environmental factors.

What has emerged clearly is a better understanding of the nature of many disease states. There are many more disease variants subsumed under what was previously described as a single disease. Diabetes is not simply Type 1 or Type 2, but many more types have been identified through various patient sub-types, each with its individual genetic profile. This has helped to explain the nature of drug response. To put it simply, drugs with an effectiveness rate of 50% could well be 100% effective in some patient sub-types but have nil effectiveness in others. Identifying which patient sub-types respond to which drugs could transform the nature of diagnosis and therapy.

These developments have led to the concept of 'personalized medicine', implying that individual therapy can be administered according to genetic profile and drug design. This is probably unrealistic for all sorts of reasons, although it is feasible for patients to be grouped into a number of sub-types for which effective therapies can be identified and administered. However, for this to become a reality will require the ability to develop and validate biomarkers to predict which patients will respond to a given therapy. There will need to be a close interaction between diagnosis and therapy, as they will be inextricably linked. This will pose a range of regulatory and reimbursement issues that are not insuperable but not yet currently resolved.

Another issue often raised by this potential new area is whether the economics of drug discovery and marketing can be sustained, given the need to develop a range of targeted therapies, rather than a single therapy for a whole population. The counter-argument is that the costs of development would be significantly lower than with a standard new entity, since the proof of concept could be much more easily validated and the need for extensive and expensive clinical trial programmes would be eliminated. There are not yet sufficient empirical examples that could verify whether the new economic model can work. However, it is not difficult to understand the long-term logic of this therapeutic revolution in drug development and delivery.

Global issues for the pharmaceutical industry

In one dimension, the pharmaceutical industry has always been very international in its perspective and location. In terms of availability of funding for commercial drugs, the developed world has traditionally comprised between 80% and 90% of the global market by value. As noted above, the pharmaceutical industry reflected the effective demand, which was to supply the needs of the more affluent parts of the world, most of which had third-party institutions that financed healthcare. These needs comprised treatments for acute conditions and – increasingly as a result of ageing populations – chronic conditions. In the poorer parts of world, the greatest need was for anti-infective and respiratory therapy.

However, the rising affluence in emerging markets – especially in the Asia-Pacific region – has substantially changed the dynamics of the global market, as shown earlier. The global companies have taken steps to take advantage of the opportunities in the emerging markets, and there has been a marked increase recently in alliances, joint ventures and acquisitions. Even so, in many cases their global profiles are still mainly focused on their traditional developed-country markets. IMS Health has identified a number of emerging markets (representing around 17% of the world market) where the pharmaceutical market is growing strongly ('Pharmerging markets').[1] However, for the major corporations overall, these markets account for only half this proportion of their total sales, highlighting their under-representation in the fastest-growing markets. This can be attributed to a combination of historical focus, the strength of local companies in markets such as India and China, and the large proportion of generic sales in these markets owing to the lack of affordability of innovative products.

1 IMS Health, 'Pharmerging shake-up: New Imperatives in a Redefined World', 2010.

The slowdown in growth in the developed markets has shifted the emphasis towards the emerging areas, as a source not only of revenue growth (albeit at lower price and profitability levels) but also of new research. The quality of science and technology in countries such as India and China has given new impetus to the diversification of R&D investments. Moreover, the potential new R&D model need not require the huge scale of investment that has characterized the industry to date. New skills in such fields as bioinformatics lower the entry barriers for new firms in emerging markets.

The industry globally is still dominated by US and European firms.[2] Other countries have not made it into the upper echelons. The major global firms have been able to entrench their position by acquiring products and companies, and through their dominance of the sales and marketing networks. This latter aspect may become less important as more targeted therapies lessen the effectiveness of mass-marketing sales force muscle. The Japanese pharmaceutical industry has many successful firms but none has made the breakthrough into the top flight. The question is what it will take for an emerging country firm to achieve global success. If future industry success factors are now being changed by the scientific cost function, then a wider range of capabilities will be required, with more alliances, collaborations and global networks. In this potential climate, new entrants might well enter the market.

In the light of the many uncertainties facing the global pharmaceutical industry, attempting to forecast a single path ahead might be unrealistic. In these circumstances the use of broad scenarios offers an important approach that can illustrate the range of possible ways ahead, highlighting the various factors that will influence the direction and pace of developments for the industry in the medium to long term.

Scenarios for the pharmaceutical industry

In looking at potential scenarios for the pharmaceutical industry, the following might seem to be reasonably certain assumptions:

- the world population will continue to grow and age;
- strong economic growth will continue in emerging markets; and
- health patterns will evolve in emerging markets.

In terms of uncertainties, there are reasons to question whether the Chinese economic model will continue to prosper inexorably, although this is the most likely scenario. The other industry uncertainties centre on the key drivers in the interaction between science and economics, namely:

- the speed and extent of the therapeutic application of new science; and
- the pressure on funding, which could take the industry into new relationships with payers and the public.

Looking first at the scientific dimension, it is clear that the potential for science to transform therapeutic disease interventions is of a revolutionary nature. However, the pace at which this revolution will proceed is uncertain for a number of reasons. First, there are numerous technical hurdles to overcome before the concept of highly effective targeted therapeutic treatments based on genetic profiling becomes reality in a clinical setting. Secondly, even if the scientific challenges can be successfully overcome, this might take much longer to achieve than some expected. The promise of ten years ago, in terms of the genetic revolution, has yet to be delivered, which is not uncommon in major theoretical breakthroughs. Not only does the detailed work to produce a final result take longer than expected, but the expectations are themselves influenced by the enthusiasm of the pioneers, who are prone to exaggerate the speed with which breakthroughs can be turned into products. However, there is a third factor that complicates the speed of the genomic revolution, and that is the social and ethical aspect of genetics. There are enormous implications for individuals stemming from knowledge of their genomic profile and disease susceptibility – knowledge that would be necessary to diagnose and treat non-infectious diseases. Such knowledge could have profound psychological implications for individuals and families as well as potential economic repercussions

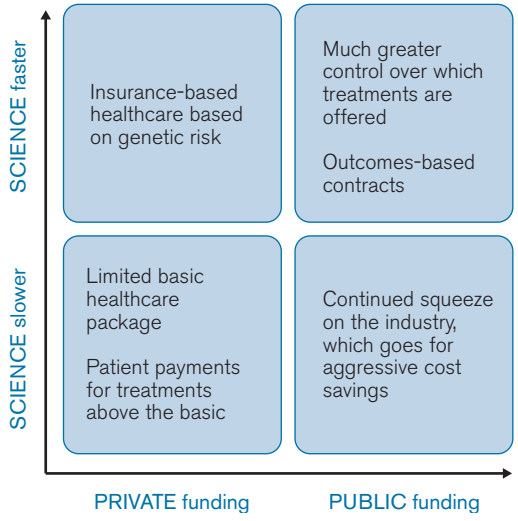
2 'Trade and Innovation: Pharmaceuticals', OECD Trade Policy Working Paper No. 113 March 2011, Table 5, p. 13.

in such areas as insurance and employment. There are also wider issues involving population-wide genetics and the need for 'bio-banks' to analyse and determine the sub-types predisposed to specific diseases. This raises concerns about confidentiality that have been very much to the fore in public debates on data storage and usage, whether by governments or private institutions. A public backlash would slow the development and implementation of scientific advance.

The other dimension of uncertainty is of an economic nature. In Western markets, it is governments or government-sponsored third-party payers that have largely financed the availability of medicines to the public. In emerging markets, it has predominantly been a private market, although in some countries there have been moves to establish forms of public funding schemes, as is consistent with a specific stage in a country's economic development. If the resistance of Western third-party payers to the growth of expenditures continues, then they will either seek to contain and ration their exposure, or they will both facilitate and encourage the growth of private funding so as to reduce third-party funding to a minimum. These potential developments will also be influenced by the extent to which the new pharmaceutical technologies produce new, more effective treatments for currently untreatable or poorly treated diseases.

Figure 4 shows a possible combination of 'scenarios' based on the interaction of these scientific and economic uncertainties.

Figure 4: Potential scenario outcomes



Science slower and public funding

If scientific progress in achieving therapeutic innovation is slow, and funding mechanisms – defined here as 'public' for simplicity – remain largely the same, then the current trends are likely to continue: Big Pharma's traditional business model would continue to falter owing to continued pressure on financial margins, as research costs rise and purchasers held down prices. Purchasers would still resort to the use of use fairly blunt cost containment methods through price cuts on existing therapies, which would lower the comparator base for judging the value of innovation. Hence the industry would experience relatively sluggish growth, in comparison with historical trends, but new products would still be developed, based more on extensions of the existing technology. Some individual firms whose research productivity was well above par would survive better than the rest. Many firms would face pressure to merge, as an increasing percentage of their sales became subject to generic competition in the absence of major scientific innovation. The industry overall would nevertheless try to keep going through aggressive cost savings, probably including a more cautious approach to research expenditure, with an increasing number of firms prepared to trim research budgets. Big Pharma would feel that it was not being sufficiently rewarded for innovation and would tend to restrict activities to lower-risk research projects. It might also undertake more diversification into generics and over-the-counter drugs to generate sales to compensate for pressure on its research-based portfolio.

'Emerging Pharma' companies will benefit from the moves by Big Pharma to seek opportunities to outsource many functions, such as clinical development and manufacturing, to lower-cost locations, especially in Asia. Emerging Pharma will continue to have a cost advantage in generics and would be set fair to take a larger global share of this market, both in alliance with Big Pharma and in some cases with independent operations. However, there is also a risk of more head-on competition between Big and Emerging Pharma, as each targets the generic market to try to bolster revenue growth.

Science slower and private funding

In this environment, scientific progress in achieving therapeutic innovation is slow, but the funding agencies seek to shift the costs towards the private sector, in order to reduce the increasing burden on third-party payers. A possible mechanism for this would be to define a more limited basic healthcare package, including medicines, which would be available to all; but individuals would be able to pay for a higher standard of treatment through their private resources. This would create an overt 'two-tier' system of healthcare, which would have political repercussions in some countries. In others, private funds already buy faster access to care but in neither case does 'rationing' tend to be a politically acceptable word.

In these circumstances, Big Pharma would see more scope for the development of innovative products, since there would be an alternative source of demand provided by the development of a thriving private insurance market. Big Pharma would seek to negotiate various care packages for insurers to offer. A sharper distinction would be likely between those firms that were still in the forefront of innovation and those that had chosen to retrench. Firms with a broader portfolio of products would be able to offer more attractive deals to insurers. The industry would hope that such negotiations would be more commercially driven – and hence more enlightened from the standpoint of Big Pharma – than would be the case with public bodies driven by cost containment through more bureaucratic processes.

As in the previous scenario, Emerging Pharma would have similar opportunities as lower-cost locations for Big Pharma. With a more subdued innovation environment, many emerging companies would see low-cost generics as a big opportunity. In this scenario, there could well be less competitive rivalry between Big Pharma and Emerging Pharma in the area of generics, since there would be a larger number of funding organizations. This could provide more scope for direct deals with insurers, as well as through Big Pharma alliances.

Science faster and public funding

In this outlook, the promise of the genetic revolution finally comes to fruition in major therapeutic advance. Targeted treatments would offer highly effective therapies for a greater number of disease areas than hitherto. For third-party payers this would bring a greater certainty that the treatment funding was well directed and more effective. However, there would be a greater demand on funding because of the new therapeutic opportunities, so authorities would be forced to exercise much greater control over what treatments were funded, allowing the older, less effective treatments to be discontinued. This would put even greater pressure on big companies that were not part of the new therapeutic impetus. The more traditional companies would be likely to leave the industry or be taken over.

Big Pharma would negotiate contracts with payers based on *ex-post* treatment outcomes, rather than on the flawed system of *ex-ante* outcomes from limited clinical trial data. Research would have a new impetus – more selective and less serendipitous – but Big Pharma would also be more conscious of the need to ensure an end market for the product through close liaison with payers. It is also possible that the nature of product design and development would change from one where companies offer products of their own conception to more of a defence-type procurement system, in which payers set out what products they want and are prepared to pay for. There will still be a mindset among public funders to regard the therapeutic breakthroughs as a cost threat rather than a benefit opportunity. Hence Big Pharma would see the potential to link up with patient groups, who would wish to take full advantage of the new therapeutic opportunities and act as a joint lobbying force on public funders.

Emerging Pharma would see opportunities to tap into the new technologies, in which there would be cost advantages in such areas as information processing and application. For Emerging Pharma, there would probably be a sharper distinction between firms at the forefront of the new technologies and the rest. The successful Emerging Pharma companies would have developed a strong science and technology base. They would also be efficient sub-contractors – as well as partners – to Big Pharma in meeting the needs of the public funding agencies.

Science faster and private funding

In this final scenario, the realization of the genetic revolution takes place in a setting where the health authorities have withdrawn from a universal healthcare provision and

have instead encouraged private-sector provision through a thriving private insurance sector. As a result of the wealth of genetic data now available, insurance companies would have a comprehensive knowledge of the risk factors applying to different population sub-groups and be able not only to assign risk premiums but also to use normal insurance principles of risk-spreading across the customer base. Individuals would take responsibility for managing their risk profiles through lifestyle and behaviour, and the system would become more akin to that of motor insurance, where premiums are based on underlying risk factors but can be adjusted by cooperatively managed health programmes. Public authorities are also able to subsidize certain disadvantaged groups that would otherwise suffer discrimination from the pure insurance principle.

This scenario is likely to provide the best growth prospects for the industry, through the realization of the genetic breakthrough in targeted therapy. Big Pharma would be closely involved in the development and supply of medicinal therapies for specific population genotypes. It also faces big challenges from at least two main areas. First, the economics of drug development and pricing in a freer market have not been worked through. The proposition is that the lower costs of development through greater certainty of outcome would offset the smaller patient numbers for differentiated therapy.[3] This needs to be verified in practice. Secondly, the scientific developments might well blur the distinctions between different types of healthcare, such as prevention, genetic screening, genetic counselling, lifestyle management, diagnostics and therapeutic options. Big Pharma can either be a marginal provider or a big orchestrator of a whole well-being programme in partnership with other specialist functions. This dimension might be a big differentiator within the industry. A very different range of skills and key success factors would be required for the industry.

For Emerging Pharma, this scenario probably provides the most fluid and receptive environment for new entrants – both as alliance partners and as independent enterprises – since the more open technology will put a premium on innovators and dynamic fast followers – abilities that will play strongly to the strengths of many of the Asian companies, in particular, over the coming years. The agility of Emerging Pharma in embracing these more high-tech challenges could shift the centre of gravity of the pharmaceutical world towards Asia, and not just in sales terms.

This scenario raises the question of whether an Emerging Pharma company could challenge the dominance of the big US and European companies in the next ten years. The short answer is 'probably not', since the traditional barriers to entry – understanding the commercial development requirements, know-how of the regulatory systems, and a strong sales and marketing network – are still likely to prevail, although they are also likely to become less decisive the faster the pace of scientific advance. Streamlined development processes facilitated by genomics, together with more specialized products requiring less mass-marketing muscle – which might well be in retreat as a force through market resistance – could open up the field for smaller, niche companies offering new technologies and competences in the pharmaceuticals sector.

Conclusion

The major driving forces for these scenarios, which will determine the future landscape of the global pharmaceutical industry, are science and economics. Both will undergo a substantial transformation, although the precise timings are uncertain. The dynamic interaction between these forces will be pivotal in shaping the global industry of tomorrow. There is likely to be a sea change in the industry's operating model and its relationships with its key constituents – payers, healthcare professionals and patients.

The scenarios have focused on the healthcare systems of the developed countries, since these traditionally constituted the mass of pharmaceutical sales by value. In some instances, if the private sector becomes more of a feature in these markets, a more overt 'two-tier' system of access to medicines, in relation to the affordability of innovative drugs, could well develop.

The scenarios have, however, also raised the issue of different levels of access to medicines between the developed and developing world. How the pharmaceutical

3 One possible model is described in PricewaterhouseCoopers, 'Pharma 2020: Virtual R&D' (2008), pp. 15–17.

industry will interact with this highly political issue will be influenced by whichever scenario predominates in the coming decade and beyond. Health priorities in developing and emerging countries are likely to remain quite different for the next two decades, even though the differences will be less marked than 20 years ago. Companies try to alleviate some of the disparities through donations, concessionary pricing and out-licensing. However, if access to medicines on a broad scale in emerging markets is not possible via the normal commercial model, since the supply prices of Western-made drugs are unaffordable to most of their populations, then a different mechanism might be needed, such as a charity or NGO model.

Another issue raised by the scenarios is the shifting balance of economic power from West to East and its likely impact on the pharmaceutical industry. Economics and technology will interact with this change in the balance of geographic influence in a way that could see fundamental realignments in the structure and centre of gravity of the global industry. In some scenarios, emerging companies could increase their share of the world market.

While the drivers and uncertainties can be mapped, assumptions made and projections scoped out, the timing and dynamics of the precise future path for the global pharmaceutical industry remain open questions. The forces of innovation and globalization are likely to take the industry to new horizons over the coming decades.

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