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Future Pharma

Five Strategies to Accelerate the Transformation of the Pharmaceutical Industry by 2020

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Five Strategies to Accelerate the Transformation of the Pharmaceutical Industry by 2020

Contents

If you would like to discuss any of the ideas in this report or how they can be implemented, please contact any of our pharmaceutical team.

Executive Summary

This paper explores some of the major challenges facing the pharmaceutical industry today.

Four Major Challenges Facing the Pharmaceutical Industry:

1. Delivering shareholder/stakeholder value
2. Low growth business environment
3. R&D productivity
4. Rising risks and loss of trust

We believe that there is a real opportunity for the industry to redefine itself in the minds of shareholders, stakeholders, consumers and governments, following the disappointing business and share price performance of recent years.

Stagnation in mature Western Markets (WM) combined with rapid growth of Emerging Markets will change the shape and needs of the industry. Operating margins are peaking and the impact of Emerging Market growth on the current cost base will bring margins down. Businesses need to ensure investment in growth markets reflects the new industry and not a template from the past. Social media and information technology offer potentially significant new ways to contact prescribers and consumers more efficiently.

R&D productivity has been sub-optimal and poorly measured. We assess that returns on capitalised R&D spending have been steadily falling. A shift to an internal rate of return measure of development spending is needed, together with some information about why the companies believe that spending on development projects will give shareholders a return greater than the cost of capital for the company.

> With well chosen strategies combined with disciplined implementation, I believe the pharmaceutical industry has the platform from which to prosper over the next 10 years."
>
> Chris Stirling, European Sector Leader

Scientific, political, legal and personnel risks are all rising. We see a need for a review of governance standards from Board level downwards, together with a fresh look at internal appraisal systems to ensure the best qualified employees are in the key roles and get the best training for the changing marketplace.

Pharmaceutical companies must win back trust; they have created the perception that they put their commercial goals above the interests of governments, payors, prescribers and patients.

This situation can be changed as part of a series of transformational steps in both the operations and culture including better internal and external communication of risks and more consistent compliance with regulatory standards.

There are many new relationships to develop with government agencies in the growth markets, in addition to increasing complexity in relations with governments and payors in established markets. Improving these relationships can best be achieved by adopting better standards of governance at all levels of the industry.

In our vision for 2020 we see an industry that will be simpler for investors to understand not because it will be structurally simpler: developing new medicines will be an ever more complex process.

But because the geographically diverse nature of its business will increase with the growth of Emerging Market influence, the pharmaceutical industry could take on the appearance of a high value consumer products industry to its shareholders. Whether a diversified or specialist business model is better to meet the 2020 challenges is a much more company specific analysis that we have not attempted to cover here.

We have identified five strategies to accelerate the transformation of the industry to meet them.

Five Strategies to Accelerate Industry Transformation:

1. Reassess product strategy
2. Invest in the marketing and sales infrastructure of 2015 and beyond
3. Acquire more talent and experience from other industries
4. Use internal rate of return to prioritise and rationalise the R&D portfolio
5. Review and revise governance standards

The industry is responding positively to a number of other important issues, such as working with governments and providers to address the rising cost of healthcare.

The selective and focused approach that we have chosen means that this paper does not cover these other challenges in any detail.

Key Challenges

Facing the Pharmaceutical Industry

1. Delivering shareholder/stakeholder value
2. Low growth business environment
3. R&D productivity
4. Rising risks and loss of trust

Challenge 1

Delivering Shareholder/ Stakeholder Value

The pharaceutical industry has performed disappointingly over the last ten years, relative to other industries **(Figure 1)**. This is the result of a complex ebb and flow of positive and negative factors on both revenues and profits that has marginally favoured the negatives.

Factors influencing revenues include:

Positives:

- Strong growth in Emerging Markets **(Figure 2)**
- Aging populations
- Price increases in the US **(Figure 3)**
- Influenza pandemics
- Enduring willingness of payors to support demonstrably innovative therapies

Negatives:

- Increasing speed and intensity of product competition **(Figure 4)**
- Increasing rebates to government and third party providers in the US
- Budget deficit driven price reductions in Europe
- Exposure to loss of revenues following patent expiration **(Figure 2)**
- Ferocity of early generic competition
- Higher regulatory hurdles, leading to greater uncertainty and fewer product approvals
- Greater restrictions on reimbursement
- Declining R&D productivity

Figure 1

Relative Share Price Performance from 2005

Source: Bloomberg

Challenge 1

Delivering Shareholder/ Stakeholder Value

The balance of factors influencing profits has contributed to making the consistent delivery of shareholder/ stakeholder value more difficult and this continues to be the case.

Factors influencing profits and earnings

Positives:

- An industry-wide drive to reduce costs and improve efficiency
- Improved operating margins **(Figure 5)** and
- Strong cash flow growth fuelling increased cash returns to shareholders through increased dividend pay-out ratios and share repurchase programmes **(Figure 6)**

Negatives:

- Royalty payments increasing due to greater collaboration and risk sharing
- Increased legal settlements with plaintiffs and governments
- Increased clinical trial demands
- Increased regulatory filing requirements
- M&A activity that has added complexity, whilst rarely generating obviously better returns
- Growing safety requirements post-approval

Figure 2

Emerging Markets are the Key Drivers of Total Spending

Source: IMS Market Prognosis; KPMG

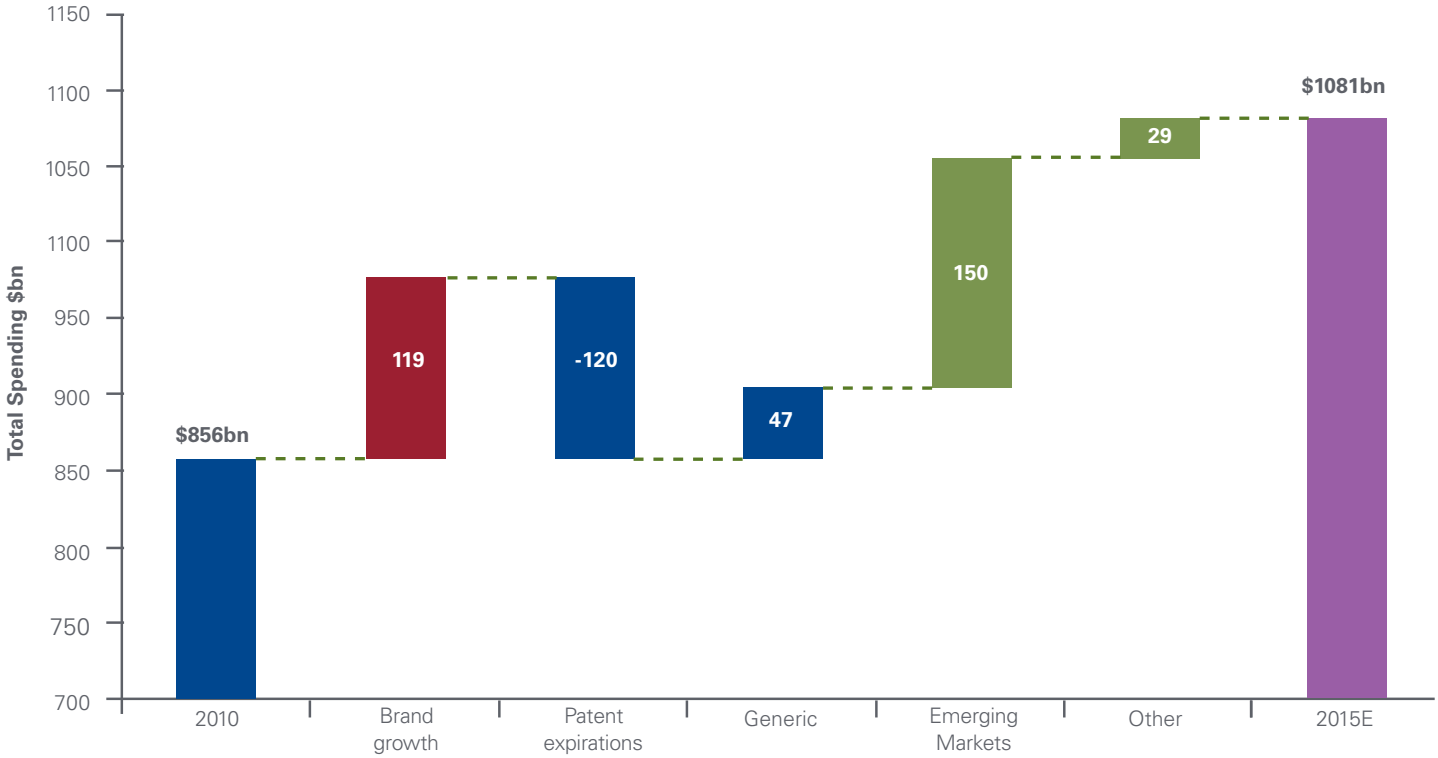


Figure 3

Average Annual Percent Change in US Retail Prices for Widely Used Brand Name Prescription Drugs

Source: AARP RxWatchdog Report, August 2010

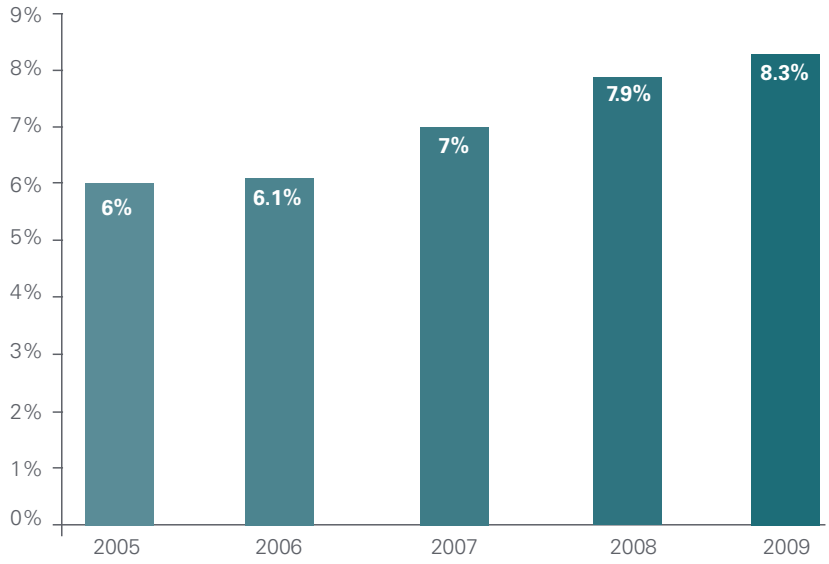
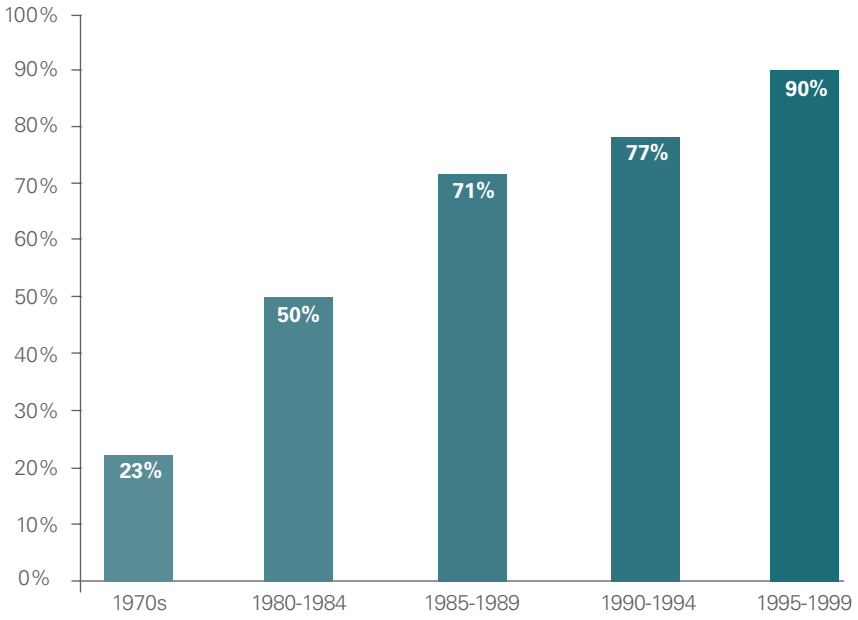


Figure 4

Speed and Intensity of Competition

Source: DiMasi and Faden; Tufts Center for the Study of Drug Development, Working paper 2009; PhRMA

Percent of First-in-class medicines with a competitor in phase II testing at the time of approval.



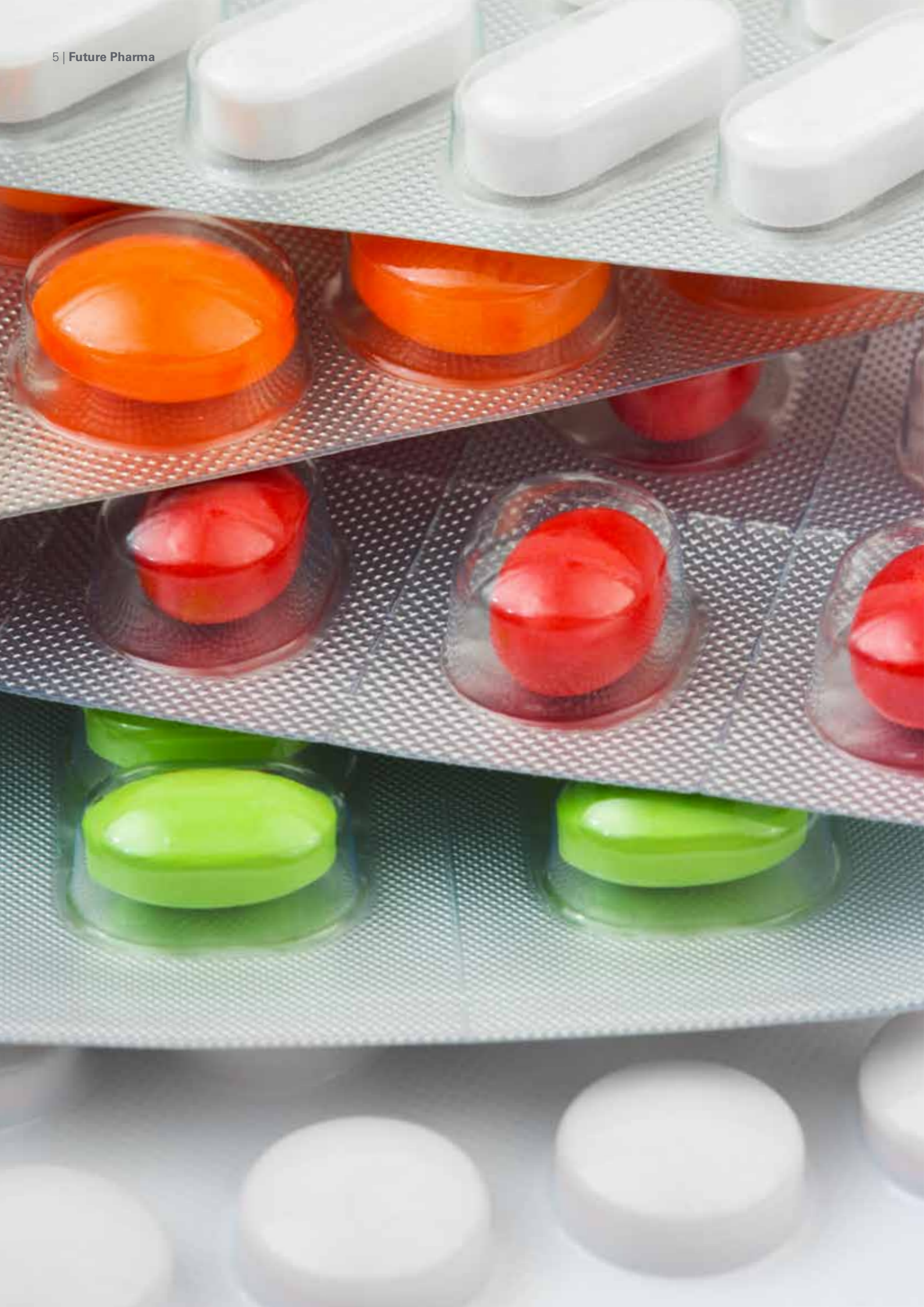


Figure 5

Industry Pharmaceutical Division Operating Margins

Source: KPMG estimates

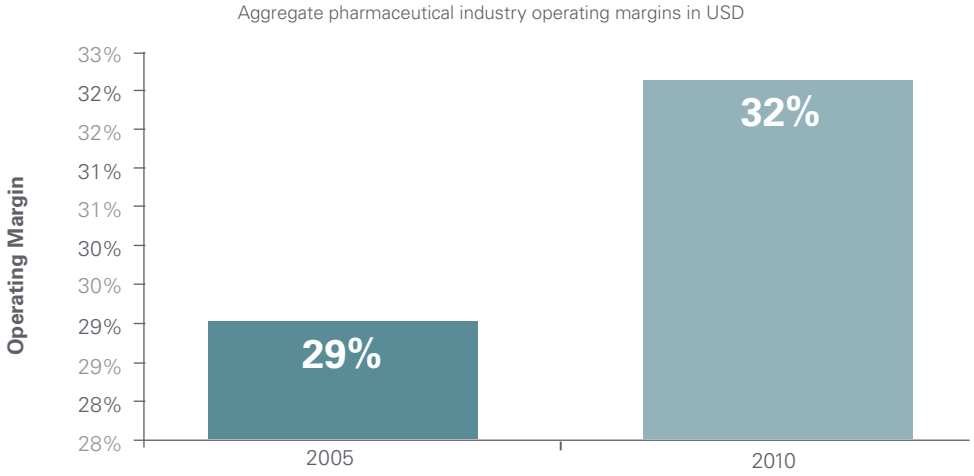
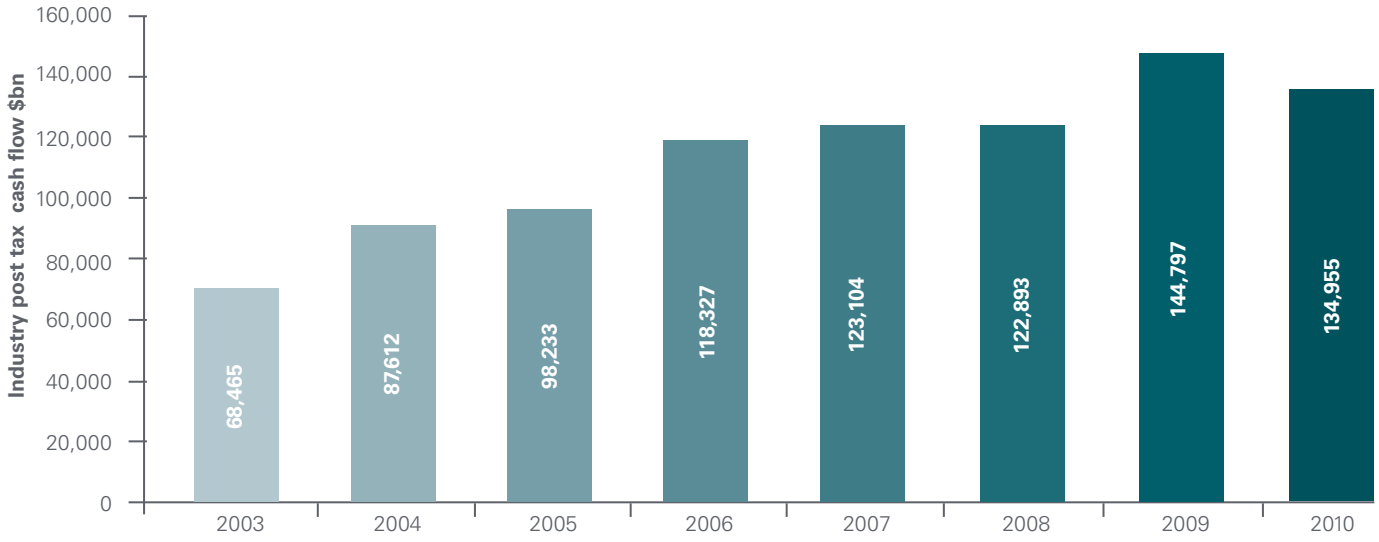


Figure 6

Pharmaceutical Industry post Tax cash flows

Source: KPMG estimates



We believe that over the next ten years the pharmaceutical industry could deliver growth in line with real GDP (3-5%), which is respectable and merits a higher market value than that of today. We see a real opportunity for the industry to redefine itself in the minds of shareholders, stakeholders, consumers and governments.

This will require a shift in how the industry operates, particularly regarding how it spends its shareholders funds and how it communicates the value its products and delivers its services. The industry has to demonstrate that it can deliver better returns on investment than in the past by changing many aspects of how it operates.

This is likely to be uncomfortable but will be, we suspect, a continuation of a process which has already started. Novartis management has made a step in the right direction by discussing cash flow return on invested capital, and how it planned to improve it for each division, at its November 2010 Strategy & Innovation Forum[1].

[1] http://www.novartis.com/downloads/investors/presentations-events/pipeline-update/2010/2010-11-17-generating-financial-returns-from-the-portfolio.pdf

Challenge 2

Low Growth Business Environment

Revenue growth modestly slowing in 2010-2015

The pharmaceutical industry is facing a future with lower growth prospects than in the past. IMS forecasts global spending on medicines will reach $1.1 trillion by 2015 but the revenue growth rate will slow from 6% between 2005 and 2010 to 3-6% between 2010 and 2015.

The impact of $120bn of product revenues losing patent protection in major Western Markets from 2010-2015 will be largely matched by on-patent brand growth, leaving Emerging Market growth and generic spending as the main drivers of global spending. Per IMS the combined US and EUR share of spending will shrink from 61% in 2005 to 44% by 2015 and Emerging Markets will grow from 12% in 2005 to 28% by 2015.

Policy changes seen in 2010 in the US, Japan, Europe and China are unlikely to be the last made as governments struggle with growing budget deficits and look for ways to spend more effectively on healthcare, further pressurising growth.

Major therapeutic classes driving brand growth between 2010 and 2015 are expected to be Oncology (+5-8% annually to $75-80bn), diabetes (+4-7% annually to $43-48bn) and autoimmune diseases (+6% to circa $30bn), with continuing if slower growth for asthma/COPD (+2-5% to $41-46bn), angiotensin inhibitors (+1-4% to $28-33bn) and platelet aggregation inhibitors (+4-7% to $18-22bn), both for cardiovascular disease (Figure 7).

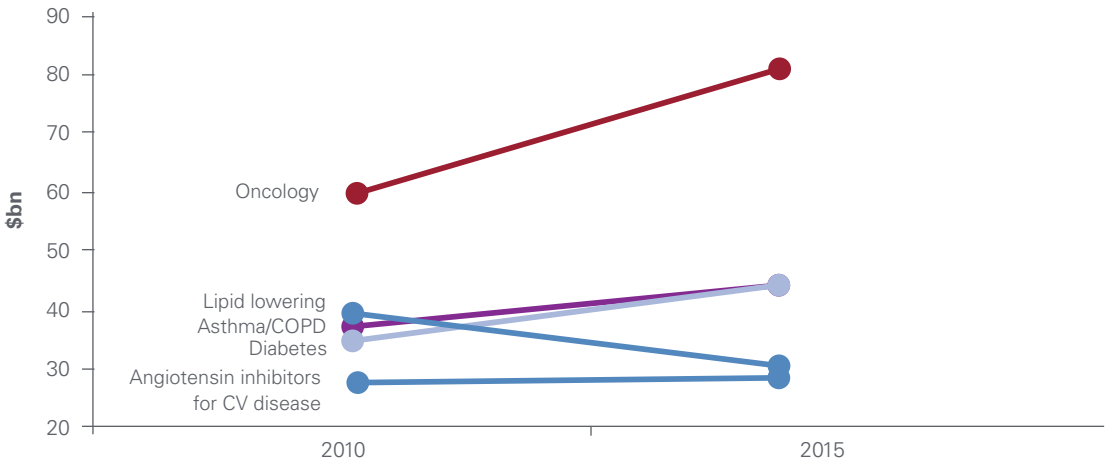
Biologic therapies as a class are a major growth contributor, forecast to grow from $138bn in 2010 to $190-200bn by 2015, or an increase from 16% of global drug spending to 18%.

The impact of $120bn of product revenues losing patent protection in major Western Markets from 2011-2015 will be largely matched by on-patent brand growth, leaving Emerging Market growth and generic spending as the main drivers of global spending.

Figure 7

Forecast Therapeutic Class Growth 2010-2015

Source: IMS Health



[2] The Global Use of Medicines: Outlook Through 2015. IMS Institute for Healthcare Informatics May 2011

Aggregate Emerging Market revenues are forecast to grow at a compound 14% between 2010 and 2015.

If Western Market stagnation/decline continues and Emerging Market growth slows to around 10% per annum then global revenues would grow on average 4% per annum between 2015-2020 (Figure 8).

If the pressure on US and EU market lessens post the patent expiration cliff and low levels of growth return (say 3%) then global growth would be 4% between 2015 and 2020.

Figure 8

Pharmaceutical Industry 2010 to 2020 by Major Geographic Market

Source: 2010, 2015 IMS Health; 2020 KPMG estimates

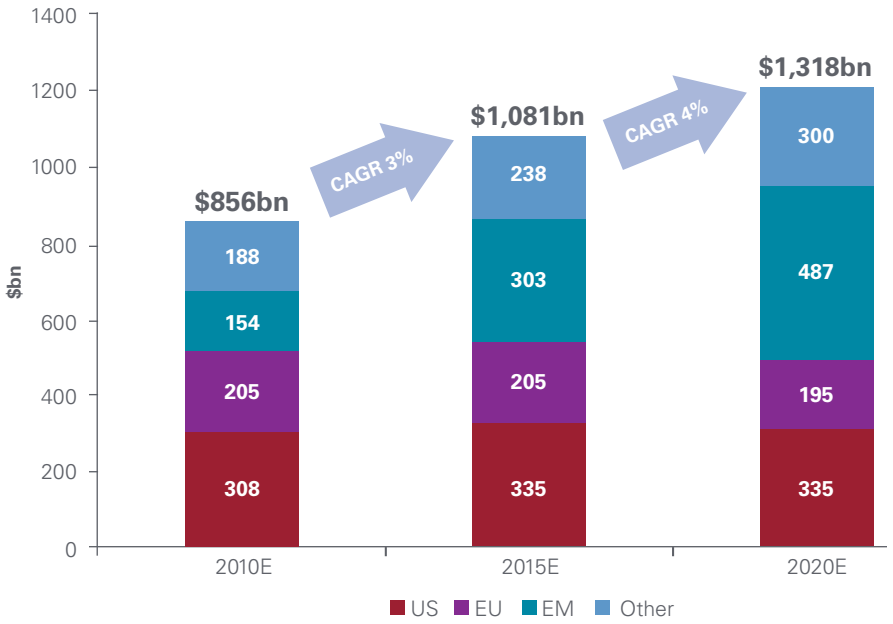


Figure 9

Estimated Industry Cost and Margin breakdown

Source: KPMG estimates

Operating Margins Peaking and Set to Decline

We believe that the pharmaceutical industry currently achieves close to 50% pre-R&D operating margins, on average.

	2010E
Revenues	100%
Cost of sales	-25%
General and administrative costs	-7%
Marketing & sales	-20%
R&D	-16%
Operating profit	32%
Pre R&D operating profit	48%

Challenge 2

Low Growth Business Environment

Figure 10

Estimated 2010 Geographic Contribution to Global Pharmaceutical Sales and Profits

Source: IMS Health; KPMG estimates

Based on data from various industry sources we have estimated the contribution by major geographic region to industry pre-R&D operating profit **(Figure 10)**.

This table highlights the lower margins available in Emerging Markets.

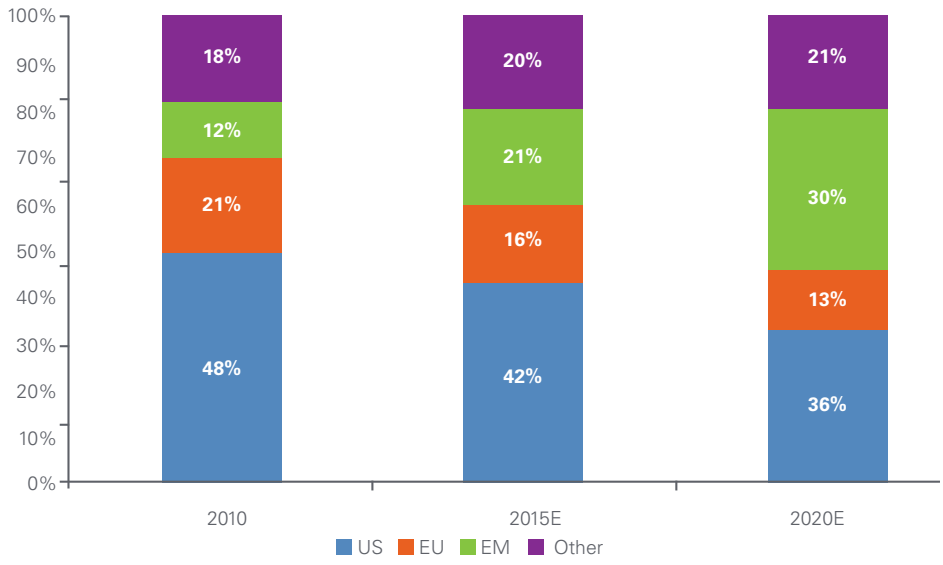
Region	% 2010 global revenues	Revenues $bn	Est Pre-R&D margin	Pre-R&D op. profit $bn
US	36%	308	65%	200
EU	24%	205	43%	88
EM	18%	154	33%	51
Other	22%	188	40%	75
Total		856	48%	415

Figure 11

Changing Geographic Contribution to Global Pre-R&D Operating Profit

Source: 2010, 2015 IMS Health; 2020 KPMG estimates

Growth of Emerging Markets could result in these countries together contributing as much to global profits as the US by 2020 **(Figure 11)**.



Using the assumptions shown in (**Figure 12)** we conclude that global margins will inevitably come under pressure as the contribution from lower margin Emerging Markets continues to grow rapidly relative to the mature Western Markets. We find that the pre-R&D industry operating margin could decline from an estimated 48% in 2010 to 43% by 2020 **(Figure 13)**.

The importance of Emerging Markets and the pressure on margins we believe merits a wholesale review of the marketing and sales investment in both growth markets and those in decline, the personnel talent required to manage these businesses and above all the R&D portfolio being developed to supply appropriate products that payors will fund in these different markets over the next 10 years.

We find that the pre-R&D industry operating margin could decline from an estimated 48% in 2010 to 43% by 2020.

Figure 12

Assumptions of Compound Annual Revenue Growth and Geographic Margin 2010-2020

Source: IMS Health; KPMG estimates

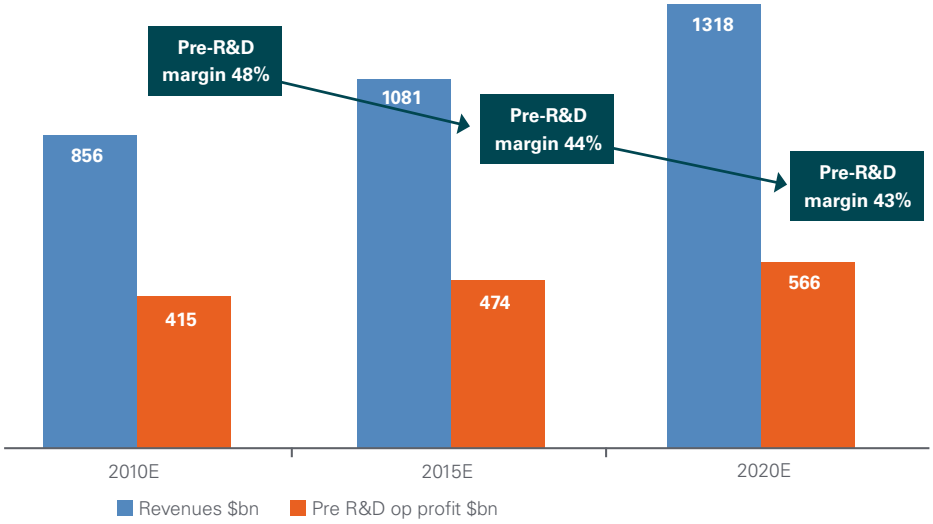
	2010-15 Revenue CAGR	2015 Pre-R&D op. margin	2015-20 Revenue CAGR	2020 Pre-R&D op. margin
Assumptions				
US	2%	60%	0%	60%
EU	0%	38%	-1%	38%
EM	14%	33%	10%	35%
Other	5%	40%	5%	40%
Global	5%	45%	4%	43%

Figure 13

Pre-R&D Profit Margins Pressured due to Emerging Markets

Source: 2010, 2015 IMS Health; 2020 KPMG estimates

This figure illustrates the profit margin impact of the growth of the industry in Emerging Markets.



Challenge 3

R&D Productivity

Over the past decade the number of applications for approval of new medical entities being made to FDA has averaged 30 per year. However, in 2010 only 23 applications were filed, the second lowest number in a decade (Figure 14).

Poor R&D productivity

The number of new medical entities (excluding line extensions) being approved in the US has not shown any trend change **(Figure 15)** over the past decade. It is hard to correlate application numbers with approvals because of the difference in approval times. FDA data indicates that between January 2006 and October 2009 61% of new medical entity applications were approved. Comparative data for the equivalent European authority, the EMEA, indicates 68% were approved in the same period[3].

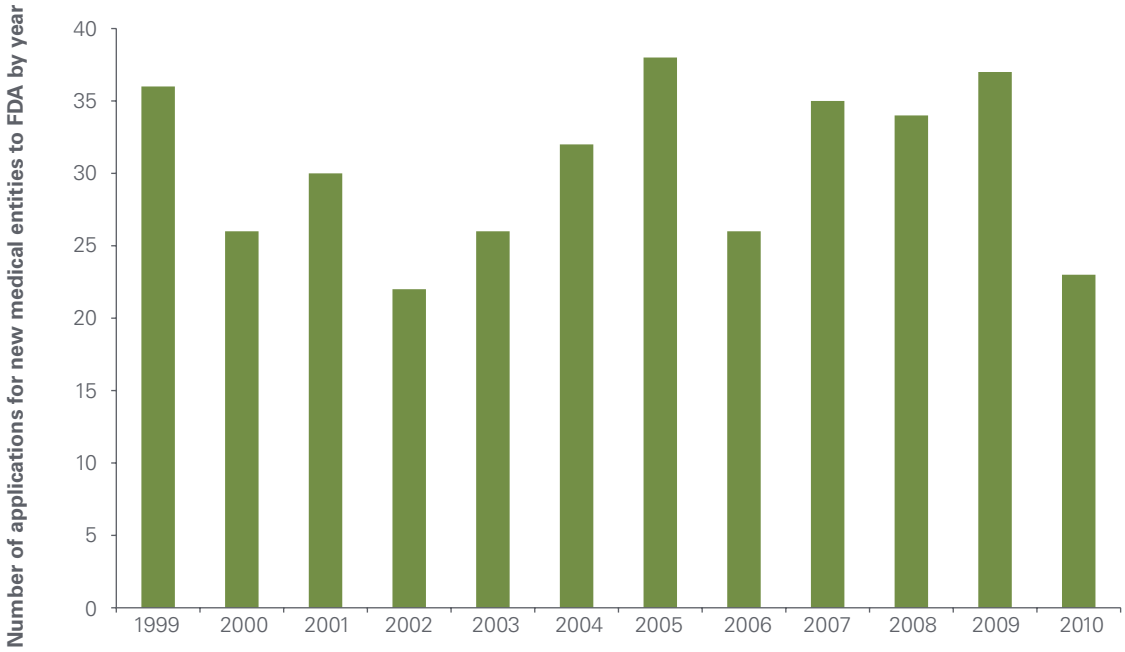
2011 is looking a lot better than 2010 and could be an above average year.

So far this year (through 7th July) 20 new medicines have been approved compared with 21 in the whole of 2010[4]. This looks like the pattern of 2005 and 2009 being repeated. There is no basis to assume the overall number of approvals is on a long term up trend.

Figure 14

Number of Applications for New Medical Entities to FDA

Source: FDA



[3] http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/UCM192786.pdf

[4] http://www.firstwordpharma.com/node/886309

R&D productivity based on numbers of approvals relative to R&D spending is worsening.

R&D spending has, however, been climbing inexorably, running at a compound annual growth rate of 10% 1999-2007, although there has been a significant slowdown since 2007 (CAGR 1%). These calculations are based on data for member companies of the Pharmaceutical Manufacturers Association of America and therefore understate global R&D spending.

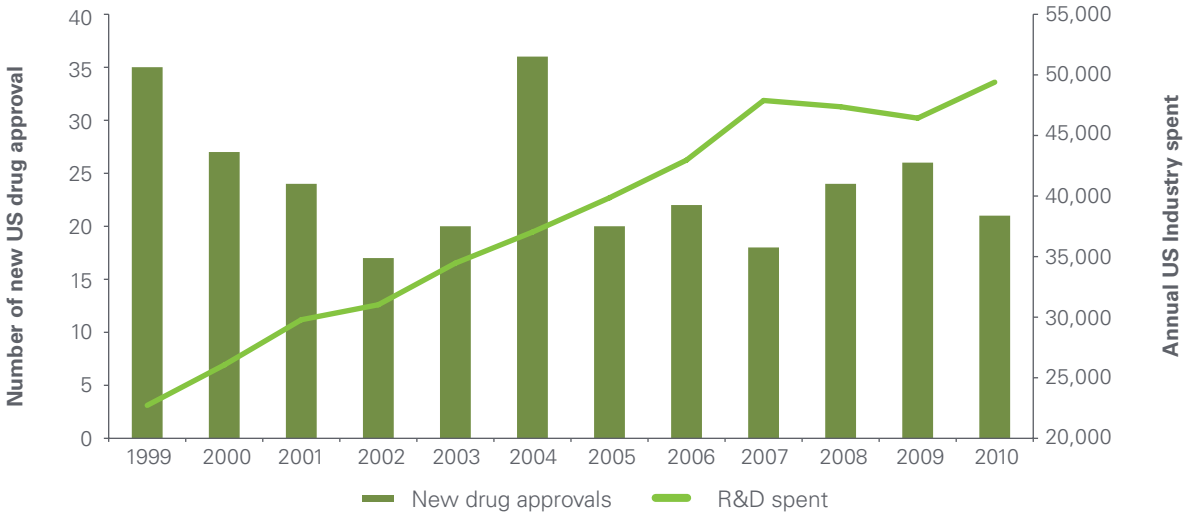
R&D productivity based on numbers of approvals relative to R&D spending is worsening.

Looking at R&D productivity another way, industry success rates in bringing a drug from research to market was just 4% between 2005 and 2009[5]. This is clearly an unsustainably low rate.

Figure 15

New Medical Entity Approvals and Annual R&D Spending 1999-2010

Source: PhRMA and FDA



[5] Linda Martin KMR, Bernstein R&D Conference 2011, cited in Roche 1H2011 results presentation

Challenge 3

R&D Productivity

R&D returns have nearly halved over the last 10 years.

Return on R&D falling

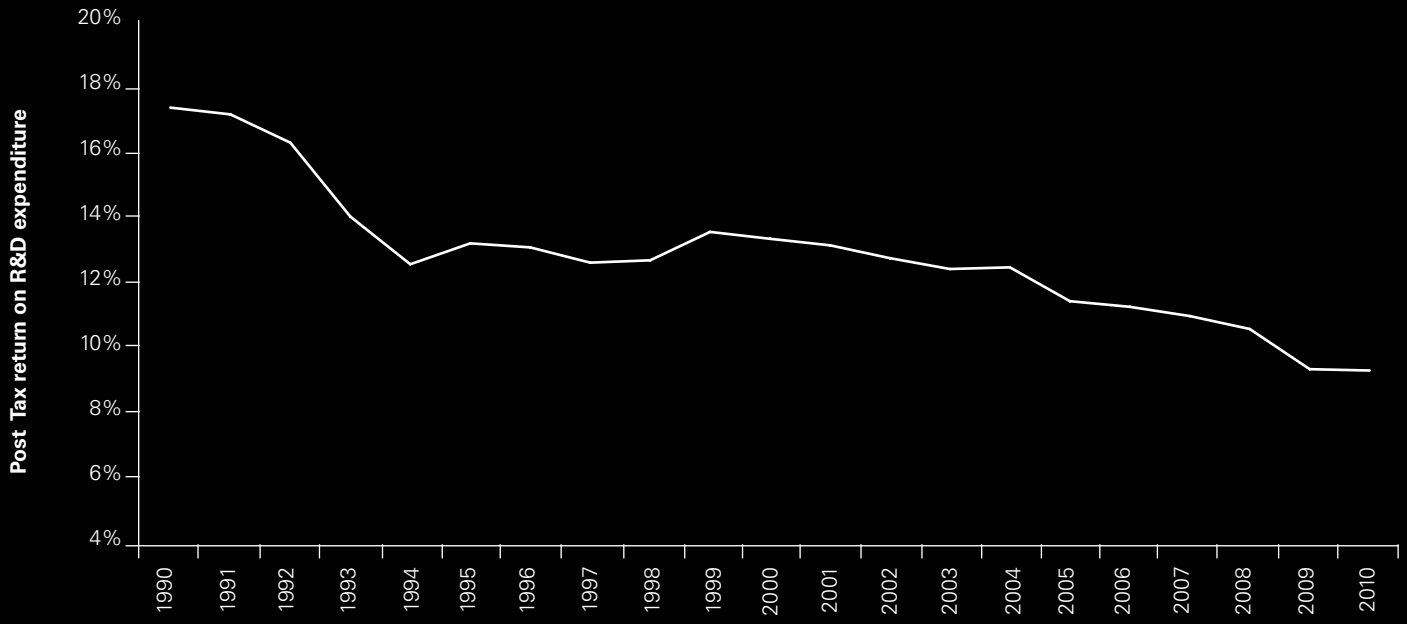
We have made an illustrative calculation of the post-tax return on R&D spending over 15 years **(Figure 16)**.

The steady decline over the past 20 years is no surprise, but it illustrates the need to address the expectations of future returns from current spending both from a peak sales perspective and from a cost of marketing and sales support point of view.

Figure 16

Illustrative Post Tax Return on R&D Expenditure

Source: PhRMA data; KPMG estimates



Challenge 3

R&D Productivity

A predictable delivery of new drugs over a multi-year period is the most likely means for companies to capture an element of their pipeline value in their market capitalisation.

R&D Productivity Ineffectively Assessed

Industry focuses on numbers of projects in R&D, not returns, nor forecasts

Corporate presentation of the value of R&D tends to focus on numbers of product candidates in development. Mention of how much was spent rarely features prominently in the annual report to shareholders and we could find only one company, GlaxoSmithKline, among the industry majors that highlights its target return on R&D spending.

Phrases that industry participants use to describe their R&D pipelines include:

- 'strongest'
- 'one of the best'
- 'one of the most innovative'
- 'strongest and most productive'
- 'uniquely broad'
- 'peer-leading'

The subjective nature of these descriptions is not unreasonable. There is little numerical basis for comparison with other companies whose needs for future growth may be smaller or greater. The recent history of the industry would suggest that hubris is to be avoided at all costs. The point is that these comments and the detailed explanations of the individual development projects give no information about why the companies believe that spending on these projects will give shareholders a return greater than the cost of capital for the company. Or put another way, why these projects will result in a reversal of the long-term trend illustrated in **Figure 16**.

We believe that there is little or no value being ascribed to pipelines, based on current market capitalisations and the cash flow value of on market drugs. Some value should be allocated, although not too much given the inherent unpredictability of medical research. A predictable delivery of new drugs over a multi-year period is the most likely means for companies to capture an element of their pipeline value in their market capitalisation. However, in the shorter term, exposition of an understandable assessment of the returns that have been achieved and indications of why the future returns will be better would also help.

A systematic explanation of why product candidates failed or why products had to be withdrawn from the market and what was learnt from these failures would help show that the R&D process is more considered than in the past and that past mistakes are not being repeated.

Some measure of scientific quality is also needed. The best science is not always conducted in large-capitalisation pharmaceutical companies as illustrated by the industry seeking new ways to partner with academia[6].

[6] 2 March 2011 | Nature 471, 17-18 (2011

Challenge 4

Rising Risks and Loss of Trust

Staying close to government thinking will be critical to securing a continuing strong position in the industry.

Rising scientific risk

In the information age it is reasonable to assume that everyone knows everything, and therefore that competitors may be working on similar biological targets with similar chemical or biological entities. In the recent past the speed with which several companies have simultaneously developed new chemical entities is testament to this. We see it as key to understand the end game at the start: integrate information on what value a new drug or new drug class could bring and the attitude of those that will pay for the medicine as early as possible into the development process.

We were very surprised to find that only 5/13 (38%) of major companies include a Board committee with an explicit mandate to provide assurance to the Board about the quality, competitiveness and integrity of the Company's R&D/scientific activities. This would seem an essential check and balance on the path to greater rigour in agreeing R&D expenditure given the importance of innovation.

Rising political risk

Political risk in the US and the European Community is well understood and will be part of all companies' planning process. There are probably no expectations that pressure from governments to reduce the cost of medicines and of treating chronic disease is going to reduce. The industry is cash generative and relatively cash rich. Working with governments to promote innovation, while achieving adequate commercial returns, will be important.

We think that a systematic approach to the changing nature of government policy in Emerging Markets is key to reducing long-term political risk. In a majority of Emerging Markets, the consumer pays for prescription medicines, but governments influence the price paid to varying degrees. Staying close to government thinking will be critical to securing a continuing strong position in these markets.

Rising legal risk

In spite of extensive risk management input to Board audit committees, there has been a rise in the number of settlements for violations of a variety of laws as exemplified by data from the US over the past twenty years with a very rapid rise since 2003 **(Figure 17, Figure 18)**.

The industry needs to reverse these trends to begin to win back confidence and trust from consumers and governments alike. This is no small task.

We suppose that the rate of increase in these settlements could be viewed by some as a positive, because the decks are being cleared and historic long running litigation risk is being reduced. We see this as stretching the point.

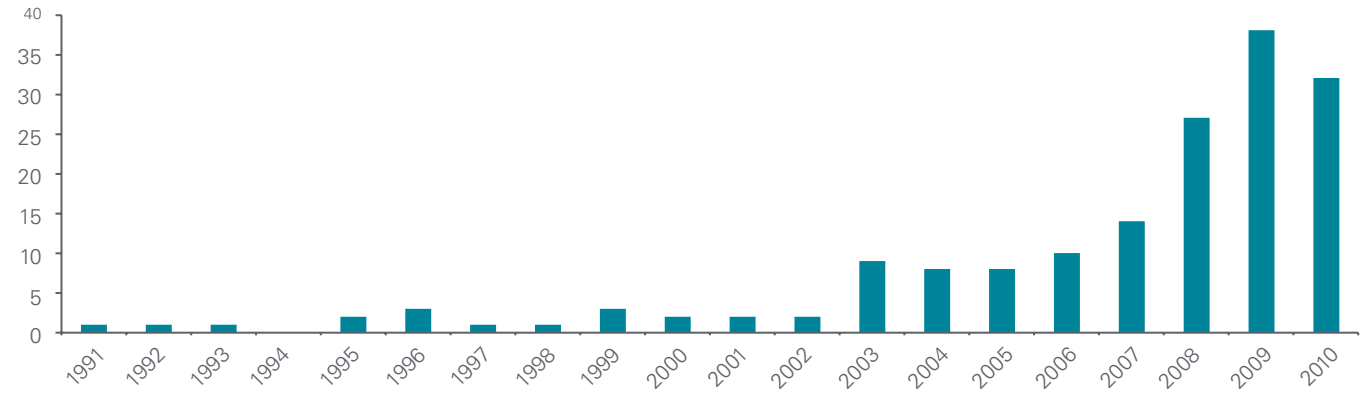
Challenge 4

Rising Risks and Loss of Trust

Figure 17

Number of Pharmaceutical Industry Settlements with US State and Federal Government 1991-2010

Source: Public Citizen

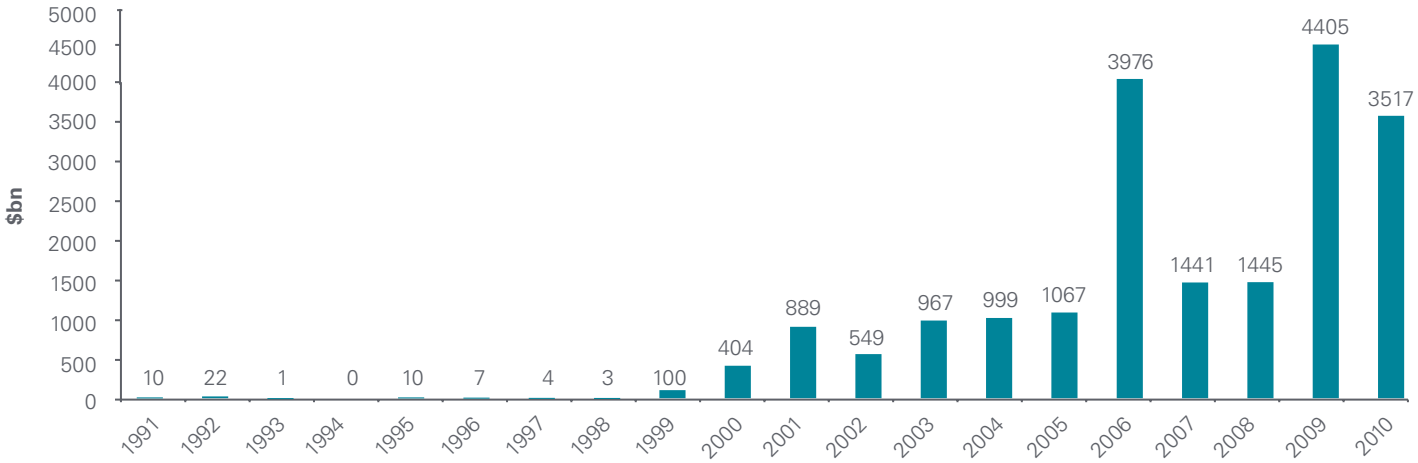


The value of these settlements has also risen dramatically over the past decade.

Figure 18

Value of Pharmaceutical Settlements with US State and Federal Government 1991-2010

Source: Public Citizen



Rising personnel risk

The changing nature of the growth drivers within the pharmaceutical industry and the cultural shift in how the industry spends money, suggests to us that there is rising personnel risk. Risk because the best qualified staff may be tempted by competitors, or by opportunities for career development. Risk because the wrong staff may be retaining key management positions for too long. Risk because senior management has not asked the hard questions of its employees frequently enough. It could be argued that Boards of Directors and executive management should put in place plans to increase the diversity of senior talent to match the evolving needs of the global healthcare market. In addition a review of management structures would also seem essential to the growing importance of Emerging Markets not only as growth drivers, but also as important sources of scientific and medical research talent.

Loss of Trust

Pharmaceutical companies have created the perception that they put their commercial goals above the interests of governments, payors, prescribers and patients and lost the trust of these stakeholders. Investors too remain sceptical of the longer term outlook in the wake of serial R&D pipeline disappointments. Justified or not, the pharmaceutical industry faces a sceptical audience regarding the integrity of its commercial operations. Golden parachutes that reward executives in spite of poor performance exacerbate the situation. Fines, court cases and product withdrawals are all prevalent and serve to draw attention to the industry's weaknesses. This situation can be changed as part of a series of transformational steps in both the operations and culture including better internal and external communication of corporate priorities, corporate responsibilities and of the risks that the company is prepared to take and why.

> **Stakeholders need a clear understanding of the risk profile to which they are exposed either as employees, shareholders or both.**

There are many new relationships to develop with government agencies in the growth markets, in addition to increasing complexity in relations with governments and payors in established markets. Improving these relationships and avoiding the creation of new risks can best be achieved by adopting better standards of governance at all levels of the industry.

A Vision of the Pharmaceutical Industry in 2020 and Beyond

A Vision of the Pharmaceutical Industry in 2020 and Beyond

Companies that can demonstrate the value their products (and services) bring to patients will be able to access broad patient populations in both Western and Emerging Markets.

Having laid out some of the key challenges that we believe the industry is facing, we outline a vision of the how the industry might look in 2020 and beyond. We believe that to be successful in ten years' time companies will need to be different from today in the way that they are organised and operate. (Fig. 19)

Companies that can demonstrate the value their products (and services) bring to patients will be able to access broad patient populations in both Western and Emerging Markets. Scale will still be important but marketing muscle alone will not be sufficient.

Companies with the courage to price according to ability to pay and not solely wedded to a global high Western based price will reap the volume benefits, as for example GlaxoSmithKline has reported following an Emerging Market price cut for anti-allergy medication Avamys.[7]

In addition, the pharmaceutical industry has a significant opportunity to play an important role in the broader healthcare "ecosystem" as the pressures to reduce cost, improve quality, and increase access to care impact nearly all countries' healthcare systems. Payment for healthcare products and services, which has historically been based on unit or episode, is expected to move to a new economic system that rewards demonstrably better health outcomes and lower costs. In this scenario, the interests of the pharmaceutical industry would converge with those of healthcare providers and payers in increasingly integrated delivery and financing models. Given pharmaceutical companies' deep knowledge of testing and measuring quality outcomes and related costs, the industry can play a significant role in the evolving, broader healthcare enterprise.

Figure 19

Future Industrial Success Factors

Source: KPMG estimate

Bases of competitive advantage today		Bases of competitive advantage in 2020
Development resources, sales and marketing scale		Value of products and services, distribution strength
Global high prices, restricting access		Pricing based on ability to pay driving volume uplift
Multiple competitors in major therapeutic areas, scale permitting success		Fewer competitors in a broader range of diseases
Multi-billion dollar drug revenues covering high fixed costs		More products with lower revenues and lower costs
End to end operational capabilities for "self-sufficiency" strategy		Significant outsourcing of operations such as manufacturing and support functions
Acquisitions of technologies and products to augment product pipeline		Greater collaboration with academia, biotech and peers
Focus on mature Western Markets		Focus on Emerging Markets

[7] http://www.gsk.com/investors/presentations/2011/Abbas-Hussain-10March2011.pdf

A Vision of the Pharmaceutical Industry in 2020 and Beyond

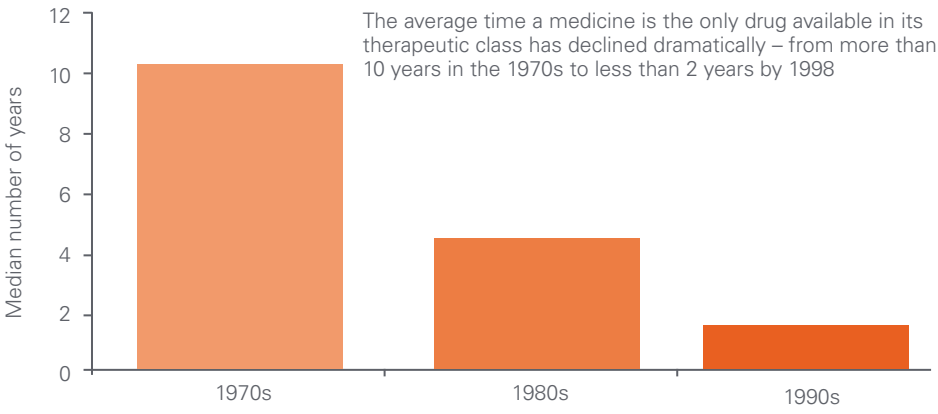
Historically, companies have faced competition at an ever increasing pace because markets have sustained multiple products with little or no differentiation **(Figure 20)**.

We see this trend slowly reversing because of the need to focus R&D spending on the most differentiated products. The growth of biopharmaceuticals is also likely to have an impact on the number of competitors per disease. New biological targets are being identified for less common but debilitating or life threatening disease for which no treatments exist, including rare diseases. In these areas we expect fewer competitors.

Figure 20

Competing Medicines Race for Approval

Source: Tufts Center for the Study of Drug Development; PhRMA



We think that by 2020 there will be more products selling less on average than today as a result of more targeted therapies and the genericisation of many of the major primary care therapeutic areas. But new products should have better returns on capital thanks to more efficient development spending, fewer failures and much lower levels of marketing and sales investment.

The scarcity of new product opportunities has driven up the price to in-license development stage compounds. But the problem is that the failure rates have been rising for all late stage compounds and are higher for in-licensed compounds than for in-house projects.

According to a recent report from the Centre for Medicines Research there were 55 phase III drug terminations during 2008-2010, more than double the number of terminations during 2005 – 2007; and in addition the number of drugs entering phase III clinical trials fell by 55 per cent in 2010[8]. We see a growing trend for large pharmaceutical companies to bypass the small biotechs and forge collaborations directly with academia. We see leaner organisations with networks of academic collaborations and small company partnerships fuelling the research process and more focused development organisations using genomic profiling allowing smaller clinical trials to be conducted with more power and at lower cost. Companion diagnostic tests will be much more common and will be integral to development, market access and penetration. More risk sharing with other industry participants should help improve research productivity. The creation of ViiV Healthcare by GlaxoSmithKline and Pfizer, should provide both companies with a better outcome for their HIV therapies than either going it alone and is a good example of how to retain intellectual capital on the one hand and access a commercial platform for a development assets on the other. Companies will need to maximise the return on differentiated research skills and avoid losing intellectual capital.

[8] CMR 2011 Pharmaceutical R&D Factbook

A predictable delivery of new drugs over a multi-year period is the most likely means for companies to capture an element of their pipeline value in their market capitalisation.

Companies in the industry have already started unpicking, to various degrees, their long-established network of internal capabilities that were built up during the heady days of free pricing and less competition. We see this trend accelerating, with the potential for significant portions of not just primary manufacturing being outsourced. It is of note that the markets to which many capabilities are being outsourced are the very same Emerging Markets that are driving industry growth.

Emerging Markets will be the drivers of industry growth and successful companies beyond 2020 will have deep local relationships including significant investments in R&D facilities, as well as the already growing manufacturing investments in these key markets.

We believe that there is a significant opportunity for creating shareholder value by rebalancing the risk that shareholders perceive they are taking with more predictable rewards from better organised and governed companies.

Returns need to be more predictable and with the optional upside from serendipitous discoveries not based on the need to be creative to order.

Shareholders need to see an explanation of the returns on historic R&D spending and the criteria for future returns to believe that R&D spending is worthwhile. Boards of directors need to believe this even more and sooner.

Successful companies in 2020 could pursue either a diversified or a specialist business model; the key will be to maximise the individual company's strengths, to improve internal processes and to understand if the company's product offering and future product offering deliver sustainable value to its customers.

Clear articulation of the strategy both to access Emerging Market growth while not missing opportunities in mature markets will be needed to persuade shareholders that companies have moved on from the old pharma model. Trust needs to be restored. Visibility and honesty will be key to achieve this. Simpler, less complex businesses will make this easier.

Figure 21

Potential Success Factors in Creating Shareholder Value

Source: KPMG estimates

Bases of competitive advantage in the past / Today		Bases of competitive advantage in 2020
Serendipity and scale drive returns from R&D		More predictability and efficiency drive returns
Number of R&D projects the basis for a "strong pipeline"		Portfolio with range of IRR forecasts based on historic track record
Emphasis on earnings per share growth		Emphasis on volume/revenue growth
Inadequate articulation of systemic risk		Risk better governed and managed
Unintended complexity		Transparent and simpler business model – easier to understand

A Vision of the Pharmaceutical Industry in 2020 and Beyond

Scientific and medical research is unpredictable and serendipitous discovery will continue to occur. However, the competitive nature of the business now (likely to be even more so by 2020) means that in our view a greater element of predictability needs to be introduced to regain investors' confidence in the value the sector can deliver. Show regular and steady growth. Minimise business surprises.

R&D in 2020 will be a much more numerically driven process than today. We cannot see any way to justify the spending needed without better measures of the historic return on capital based on IRR. The seeds of a new approach are being sown, for example at Pfizer[9], Novartis[10].

The dominance of Emerging Market economies by 2020 could result in a shift back to volume growth as a key measure of performance, with earnings growth following. Improving efficiency is the right strategy, but until it is accompanied by sustainable revenue growth it is not likely to see the industry's valuation expand, all other factors in the stock market being equal. While returning cash to shareholders through share repurchase or enhanced dividends is a positive use of excess free cash flow, it is not likely to be rewarded by a high valuation.

We think successful companies in 2020 will have a more dynamic approach to risk reporting, with greater disclosure of potential and actual risk. The industry will be perceived to be better governed as a consequence.

Lastly, we see an industry in 2020 that will be simpler for investors to understand not because it will be structurally simpler; developing new medicines will be an ever more complex process. But because the geographically diverse nature of its business will increase with the growth of Emerging Market influence, the pharmaceutical industry could take on the appearance of a high value consumer products industry to its shareholders.

[9] http://www.pfizer.com/files/investors/presentations/barclays_capital_031711.pdf

[10] http://www.novartis.com/downloads/investors/presentations-events/pipeline-update/2010/2010-11-17-changing-the-practice-of-medicine.pdf

5 Strategies to Accelerate the Transformation of the Pharmaceutical Industry by 2020

Strategy 1

Reassess Product Strategy

The driver of industry growth is Emerging Markets. While these markets are currently being driven by the growth of classic primary care products for major diseases – the very therapeutic categories that are being genericised in western markets, this situation is unlikely to persist. There is therefore a strategic dilemma because most companies do not possess an ideal Emerging Markets portfolio.

To what extent should investment in today's needs be made versus the longer term? Because in the longer term, the key Emerging Market consumers and governments will want access to the very best medicines, but it is inconceivable that they will be prepared or able to pay the prices currently paid in the US or even in Europe. The volumes and therefore the costs would simply be too high. There could be twice as many people with income above $10,000 in the top 13 Emerging Markets compared with the US and EU combined[11].

The recent volume increases reported by some companies for products for which prices have been substantially reduced indicate in our view the path the industry must pursue in the long term although balancing the need for affordable prices with the risk of commoditisation. Value delivery must be demonstrable.

Products must take into account the needs of consumers in Emerging Markets.

Emerging Markets offer largely blank slates; the continuing application of an adapted "old Western" model of the drug industry, which is currently ongoing, will miss a significant opportunity to redraw how the industry interacts with patients and governments.

There is an argument for focusing business strategy on delivering high value modern medicines to Emerging Markets at much lower prices than have been accepted in Western Markets. This would underpin a root and branch reassessment of the costs of bringing these medicines to market, the marketing and sales support required and the risk of counterfeiting and parallel trade.

This should drive strategy in clinical development, location of trials, marketing plans, sales infrastructure and manufacturing investment. The opportunity for biologic therapies for cancer for instance is very large, providing the right pricing strategy can be developed[12].

Emerging Market governments are moving rapidly to increase medical consumer spending. The "established" branded generic Emerging Markets growth route could run out of steam as generics become commoditised. This suggests that every possible opportunity to drive consumer/OTC business in Emerging Markets should be explored in addition to a focus on speed to market, lowering the costs of development and efficient delivery of appropriate, differentiated quality prescription products.

[11] http://www.gsk.com/investors/presentations/2011/Abbas-Hussain-10March2011.pdf
[12] http://www.roche.com/investors/ir_agenda.htm?tab=2 Sanford Bernstein Conference 1st June 2011, p10

Strategy 2

Invest in the Marketing and Sales Infrastructure of 2015 and Beyond

Accelerate the modernisation of selling and marketing in mature markets

New technology has come relatively slowly to the pharmaceutical industry. Now the challenge for the pharmaceutical industry is to balance innovation and creativity in its use of new technology against perceived value and the cost of creation. The key is mapping the new technology opportunity with the business in a sustainable and updatable way.

Integrating flexible technologies such as QR barcodes as a means for doctors to communicate with the industry using smartphones is one example of how technology investment could make a sales force more efficient. It provides a more rapid and flexible response mechanism for a physician to contact the pharmaceutical company than simply ticking a box or even filling in an online form.

Partnership with technology companies could be a route to more rapid integration of modern technology platforms. Potentially partnership with consumer companies might also reveal opportunities for greater efficiency.

Many companies have started to address the need to reduce marketing and sales infrastructure in mature markets of the US and Western Europe. However, we think the pace of change could be accelerated and may be a key component of preserving margins in the face of increasing pressure on price. New technology, such as the iPad, is enabling greater efficiency according to several companies including Novartis[13], Otsuka[14]. Pfizer launched an iPhone app to encourage doctors to send questions directly to the company[15] and AstraZeneca has an iPhone, iTouch and iPad app to help educate healthcare professionals with genetic testing for lung cancer[16] . AstraZeneca also recently launched a live click-to-chat function on its US Crestor and Nexium consumer websites[17].

The basis for assessing marketing and sales effectiveness needs to be addressed.

We see communication of evolving corporate strategy in the face of the rapidly changing industry as essential. This is no straightforward or simple task and merits a major commitment from executive management.

Focus on the longer term in Emerging Markets

Emerging Markets are not going to replicate the development of the Western pharmaceutical markets of the last 25 years but will take new paths defined by the pressures from large populations, rapid growth of both personal and national wealth but also the clear need for individuals and governments to balance spending on healthcare with multiple other demands.

Business leadership in key growth Emerging Markets needs to develop a plan for investment in the markets that these key countries will become, not those that they are today. Merely adding more and more sales reps on the ground in a traditional model does not seem an appropriate strategy for the future. It could be valid to build a presence but the pace of change is such that plans should be regularly reviewed and realigned.

[13] http://www.pharmalot.com/2011/03/novartis-the-ipad-35000-more-visits-to-docs/

[14] http://www.bloomberg.com/news/2010-06-08/ipads-to-help-otsuka-pharmaceutical-sales-force-market-drugs-to-doctors.html

[15] http://www.pharmalot.com/2010/06/one-more-way-to-minimize-the-sales-rep/

[16] http://www.astrazeneca.co.uk/Media/latest-press-releases/2010/FIRST_IAPP_TO_HELP_EDUCATE_HPa_ON_EGFR_GENETIC_TESTING?itemId=12167029

[17] http://astrazeneca-us.com/about-astrazeneca-us/newsroom/all/12379170?itemId=12379170

The diverse nature of Emerging Markets merits a careful refinement of investment strategy; while Brazil, Russia, India, China, Mexico and Turkey may contribute half of Emerging Market sales, dozens of other smaller markets make up the other half.

One recent example of the need to plan for change can be found in China. An important element of the historic growth experienced by most international companies has come from branded generics, where the manufacturer's name is a proxy for high quality. Branded generics have enjoyed higher prices (referred to as separate pricing) than local equivalents that are limited to a lower maximum price (known as general pricing). A new price list issued in November 2010 reduced separate pricing on nearly 50 drugs out of 200 on the Essential Drug List. It is believed that separate pricing could be reduced or eliminated across the board over the next 4 years.

At the same time there is likely to be a government push to increase use of OTC drugs sold at retail pharmacies. These moves by government will very likely result in material changes in the Chinese market and will need different infrastructure from 2011 to maximise long term returns.

Accelerate development and integration of social media and mobile-health policy

The pharmaceutical industry has lagged other major industries in its use of social media. At face value this is understandable given the high levels of regulatory scrutiny imposed on all aspects of the industry's interaction with patients, prescribers and payors.

Since 2009 there has been a significant investment in social media.

From a survey of the websites of the 13 companies that we define as the large capitalisation pharmaceutical industry, 15% have a blog, 54% are on Facebook and 77% are now on Twitter.

However it is clear that there is an opportunity not only to lead the regulators and help develop regulatory policy but, for internal planning purposes, being prepared to use social media might be a key competitive advantage in many markets.

For instance Emerging Market penetration of social media use is higher than in Western markets, with over 70% of the population of the Philippines and Malaysia for example as active online users.

Figure 22

Social media use by Fortune 100 Companies in 2009

Source: Burson-Marseller: Social Media Use by Fortune 100 Companies 29th July 2009

Industry	Percentage with a blog	Percentage on Facebook	Percentage on Twitter
Telecommunications	75%	100%	100%
Computer, office equipment	67%	100%	67%
Specialty retailer	50%	50%	100%
Food and drug stores	17%	33%	50%
Pharmaceuticals	33%	0%	33%

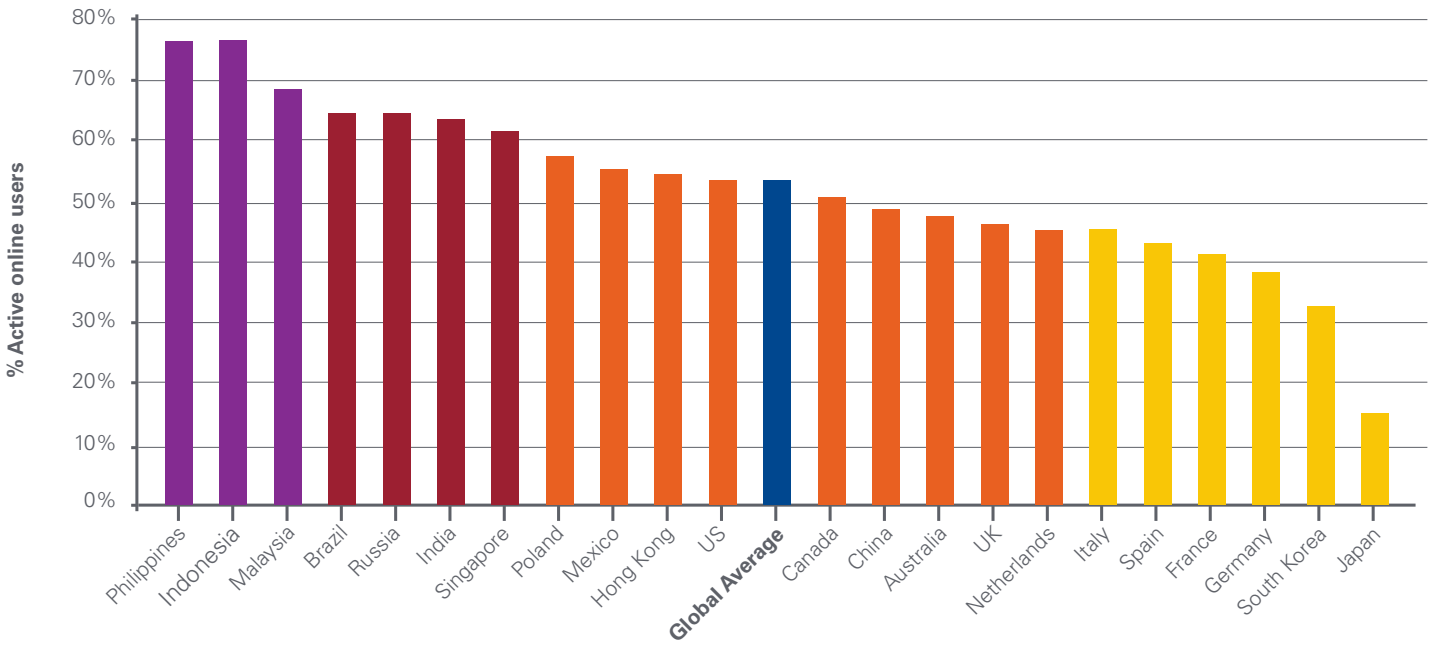
Strategy 2

Invest in the Marketing and Sales Infrastructure for 2015 and Beyond

Figure 23

Global Social Network Penetration

Source Global Web Index



Source Global Web Index

The rising power of patient groups in the data age will continue at pace. If the past five years has seen the industry focus on regulatory and reimbursement outcomes then the next five years should see a greater emphasis on how to improve the outcome for patients. The spread of social media use seems certain to be giving patient groups a greater voice and empowering individuals, with a potential impact at all levels of healthcare provision and delivery. The use of social media offers the industry a route to restoring trust with patients from its current low ebb[18].

The industry needs only to look back in history at the power exerted by organised patient groups (e.g. in the fast-tracking of the first AIDS drugs).

Patient groups are becoming more organised, better informed, and connecting across borders using social media. Greater interaction with such groups in a structured way should benefit all aspects of the pharmaceutical development process and the safe and appropriate use of medicines once marketed.

[18] Financial Times 12th March 2010, Patients' groups distrust 'big pharma'

Strategy 3

Acquire more Talent and Experience from other Industries

The growth markets of the future look more like consumer brand driven markets than the traditional pharmaceutical markets of the 20th century. This begs the question of what leadership talent will be required to capture the opportunities presented by these new markets while maximising the most efficient returns from mature Western Markets.

Our research indicates that in aggregate less than 20% of executive team members within the industry have come from outside the pharmaceutical industry within the last 5 years, within a range of 0%-50%. The most common role now filled by individuals with industrial experience from outside the pharmaceutical sector is that of chief financial officer. The impact of the attendant fresh thinking has been visible on how individual companies spend shareholder funds and the scale and speed of efficiency programmes.

More diversity of talent throughout any given organisation should enhance and strengthen the business.

This could cover all major business areas. Manufacturing and administration are areas in which new talent has been recruited by some companies but the need for greater urgency is pressing. Even in R&D there have been some very successful hires of highly skilled academic researchers to lead drug discovery.

We believe that senior management in the industry should actively seek talent and experience from outside the traditional group of pharmaceutical competitors.

However, it could be argued that looking for fresh approaches to key account management in the changing world of marketing and sales is the business activity with the greatest need, given the shifting nature of both traditional Western and Emerging Markets. In particular regional and country management would benefit from having experience from other sectors, as opposed to just from the pharmaceutical industry. With the old "sales rep calling on doctor" model now being gradually consigned to history, we believe that the industry should look to import key account management techniques from other sectors, notably in the consumer space.

Strategy 4

Use Internal Rate of Return to Prioritise and Rationalise the R&D Portfolio

Research spending is the minor part of industry R&D investment (circa 30%). It should be reviewed for how and why spending is taking place but also scrutinised as to who is doing the spending i.e. the quality of the individuals leading the projects.

This scrutiny, which could be along the lines of "is this best biology/best molecule/best target and are these the best people", begs the question of how do you know that you have the best of anything?

Patent applications filed, scientific papers published (and the proportion in the prestigious journals, such as *Nature and Science*), and the number of times scientists working in research have been cited by their peers all spring to mind as potential measures of quality. Assessment by an independent panel of experts is a further possibility.

Development spending and the post launch investment needed to deliver acceptable returns is the big issue.

We believe all companies should have a standardised approach to be able to show on an ongoing basis what internal rate of return (IRR) has been achieved on past investment and an internal perspective on what range of returns is forecast from the current investments, and what assumptions are used in these projections.

Such analyses should also include off balance sheet funding through partnerships and minority investment in third party companies (typically development stage biotechnology companies).

We believe this type of IRR based information could transform the investment decisions recommended by senior management in the industry and signed off by boards of directors.

If more efficient development can be achieved, and marketing and sales practices are modernised, lower peak revenue numbers will still permit internal rates of return well above the industry's cost of capital.

There is also a need to be clear about the true cost of capital for any individual company.

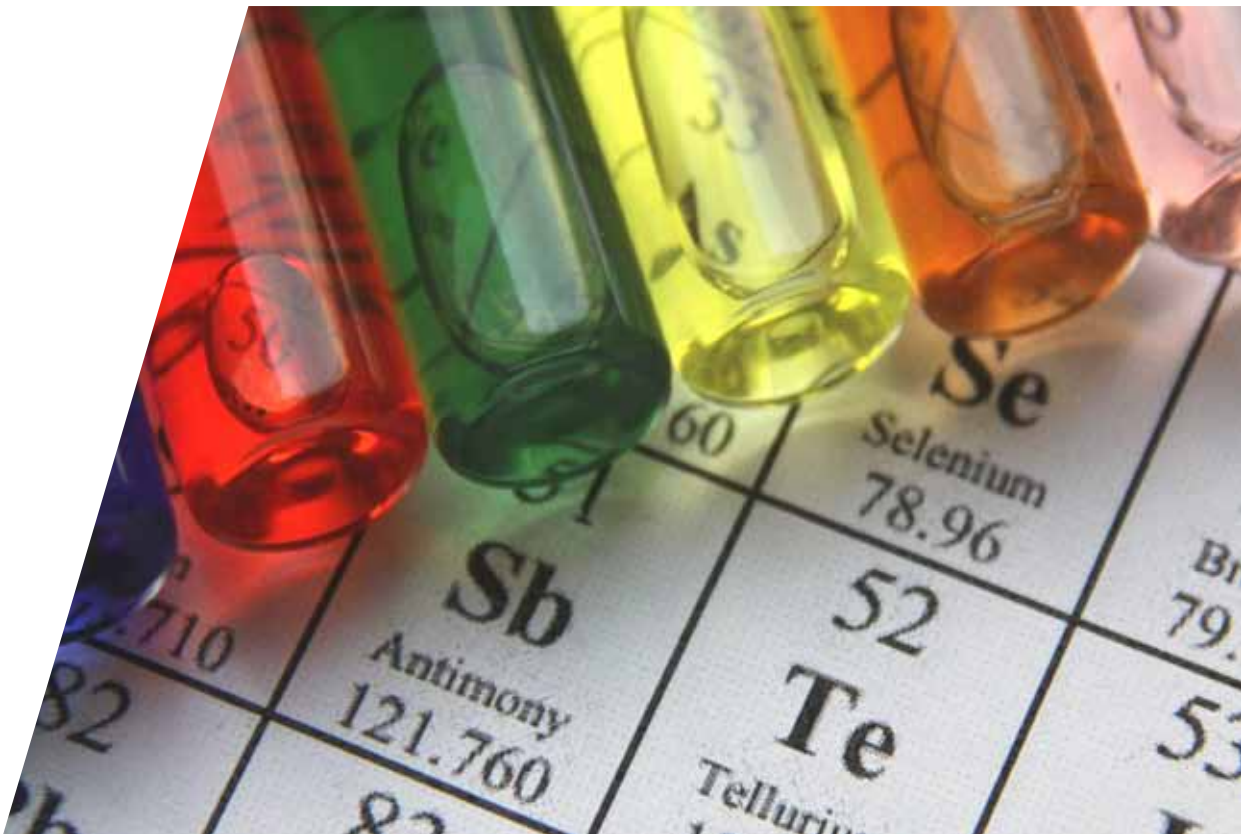
It is hard to believe that every late stage portfolio in the industry is optimal and that none of the projects carries a potentially marginal or negative return. We recommend re-evaluation of the value proposition of all phase II, phase III and registration assets on an IRR basis.

This review should include a detailed review of the assumptions that supported development of these assets. Consideration could be given to whether the forecast returns could be improved by partnerships or co-marketing arrangements.

We think that the most successful companies have complemented their scientific agenda with business performance management goals and an integrated approach to R&D Finance. R&D Finance is key to reducing operational obstacles that slow the progress of product candidates to market by timely analysis and financial review through the introduction of early warning indicators and go/no go checkpoints based on financial analysis and evaluation.

We also recommend the following actions as part of the R&D review:

- Set up an R&D team with the express role of working out how to beat the company's key innovative compounds - an internal fast follower team
- Assess whether the compounds with the highest potential return are optimally funded to bring them to market as rapidly as possible with the best possible label
- Consider introducing an external perspective to this process
- Host an internal R&D day for all R&D employees worldwide to showcase their research to each other and drive higher levels of collaboration
- Clearly articulate policy on collaborations, both with academia, with biotechnology companies and smaller pharmaceutical companies as well as with peers
- Look for ways to maintain a return on the intellectual capital built up during a periods of success in any given therapeutic area. Too often companies discard this intellectual capital once patents have expired



Strategy 5

Review and Revise Governance Standards

Change should start at the top. It could be argued that the industry is still perceived poorly by consumers and some parts of government. The aim should be to revise and improve Board governance standards to not only a higher level than any industry competitor, but to the best practice levels seen in any industry.

Companies need to conduct a root and branch review of governance and enterprise risk management across the entire value chain – to understand better the activities, appreciate the impact from speed of change and the increasing pressures on each link of the chain– from early research and development, through late stage development, manufacturing to sales and marketing.

We see using a specialist approach as the best way to deal with these new risks, whereby personnel are employed in specialist risk/governance roles, together with a three-step approach:

1. Internal independent checks and balances where people review each stage and have a reporting line outside of that area's particular vertical with direct access to c-suite executives.
2. Give power and credence to internal audit groups and focus on their outputs.
3. Use completely independent and external experts who are allied with ethics, risk and governance as a final check and balance for each element of the value chain.

We expect all companies in the sector will have in place robust and modern employee appraisal systems. We think a thorough review of all senior management job descriptions should be a component of the review of the product portfolio and the investment in marketing and sales support described earlier.

Changing elements of the value chain where we see these new pressures include:

- Increased (volume and value of) research collaborations to source innovation
- New social media use leading to exponential growth in data collection and storage
- Changing IT landscapes (e.g. cloud computing)
- Doing business in Emerging Markets (e.g. competitive landscape, "the way things are done around here", anti-bribery and corruption, intermediary risk)
- Regulators all gaining teeth – regulators tend to regulate – rules not going to get any easier going forward
- Increasing use of third parties (e.g. CROs in late stage development, CMOs in manufacturing, IT organisations)

Change should start at the top.

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