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LIFE SCIENCES TOWARDS 2012: NEW DYNAMICS, NEW LEADERSHIP ROLES, NEW STRUCTURES

A new era dawns – Economics takes centre stage

One out of two commercialised medicines is now a biopharmaceutical drug, putting biomedicines at the heart of better targeted therapeutic responses and greater efficiency in medical treatment. While the prospects for personalised therapies are highly encouraging, they represent a significant financial risk for the pharmaceutical industry and huge costs for healthcare systems.

Healthcare budgets around the world are under increasing pressure from the increase of 'civilisation' diseases such as Type II diabetes in mature economies and cardiovascular disease in emerging markets, as well as ageing Western populations. "This will intensify the economic evaluation of all healthcare approaches, including the use of drugs and their overall effectiveness," says Christiaan Lebbink, Global Practice Leader Life Sciences and Healthcare at Boyden. "Healthcare products will have to compete in a global environment and withstand comparisons with medical devices or other therapeutic approaches across each of their vested interests."

Global issues are among the primary concerns of CEOs who run life sciences companies. In a study by IBM on 'The Enterprise of the Future'[1] the 40 participating life sciences CEOs express concern over three core areas: first, managing change; second, recruiting and retaining the right people; and third, the need for major business model innovation.

1. Managing Change

Some of the biggest changes in life sciences are being driven by technology: for example, digitising medical records which will improve medical care; genome sequencing; personalised medicine delivered by mobile handsets; and continuing empowerment of patients. Ajay Royyuru of IBM articulates the effect of this as "the transformation of biology into an information science from a discovery science."

But changes are also forced upon the industry from outside, as "from early-stage clinical development through manufacturing and marketing, life science firms are facing greater scrutiny, stronger political headwinds, and heightened public skepticism than ever. All companies are attempting to make difficult go or no-go decisions as early as possible to preserve capital, cut losses, and avoid downstream legal challenges," says John Cornille, Managing Director, Boyden New York.

Other changes, high on the CEO agenda, include building truly multicultural organisations, globalising brands and products, and optimising operations worldwide. Such major issues are driving the development of new leadership and management roles – increasingly, the main focus for conversations between Boyden and the board.

2. Recruiting and Retaining the Right People

In the current climate, the need to address cost issues in clinical development is shining the spotlight on two main issues: achieving better integration of scientists with commercially-focused executives in specialised disciplines such as market access and risk assessment, and creating more commercial, global roles.

For example, "New approaches necessitate greater technical and scientific expertise of the sales leadership and sales team," says John Cornille. "With companies emphasising product 'cost effectiveness' as a major value proposition to the customer, solution selling is becoming more important than feature-and-benefit sales," he adds.

In terms of global roles, the marketing function is at the forefront of change, with a more commercial approach that

focuses on strategically identifying new products and market opportunities. Mr. Cornille comments, "There is growing recognition and need for life science product marketers who can fully participate in early-stage technology assessment, and have strategic marketing capabilities to supplement traditional tactical marketing skills."

Market Access Prompts Radical Changes in Sales and Marketing

Marketing will therefore undergo a significant shift, with both sales and marketing reduced in favour of market access. "Achieving an optimal market access prior to product marketing is becoming key to a successful launch," says Christiaan Lebbink, adding "Marketing might even split up into Market Access and Marketing Support of Sales."

The industry will require visionary market access candidates with good leadership qualities to turn market access from an administrative role into a leadership role. Signs of this are already apparent, with many companies creating a Chief Marketing Officer role at the corporate level, rather than relying on divisional marketing expertise. John Cornille explains, "This is to assign and hold accountable a senior executive marketing resource to the design and development of the global strategic marketing plans of the company rather than merely the product marketing and product management roles typically found in the operating divisions."

Risk-Sharing Trend Sees Greater Role For Risk Officer

Nevertheless, drug development will always be risky. "We are already seeing the first risk-sharing agreements between the industry and third party payers," Cornille points out." The industry has a vested interest in developing the department of risk evaluation, and the role and function of the risk officer. "This role will be suited to econometrists – as in the insurance industry – people who can evaluate early on the chances of obtaining public funding for a new approach, either in terms of reimbursement, or being accepted as valuable treatment by organisations like NICE or Medicare. They will also be required to judge risk-sharing deals," observes Lebbink.

More Commercial, Global Roles Blur the Lines Between Biotech and Big Pharma

In an industry driven by scientific and technological advances, there has typically been a divide between biotech companies – nurturing an innovative, scientific and technical skill base – and big pharma, with executives better suited to the commercial aspects of late-stage product development and having the financial leverage to do so.

However, the costs involved in new product development and innovation, coupled with an unfavourable economic climate, are bringing a commercial tipping point into sharper focus. The impact of this is a major shift in hiring practices, with commercial expertise required at an earlier stage in scientific development, blurring the lines between biotech and big pharma.

The need for more commercial reflection at an earlier stage across the scientific development spectrum is creating global hubs, currently in Western economies. Here, global leadership roles in big pharma are increasingly concentrated, due to their more commercial talent pools.

"Big pharma in Sweden has moved many global jobs outside the country, e.g. Pfizer (previously Pharmacia) and AstraZeneca, most notably global marketing roles, comments IngaLill Forslund Larsson, Boyden associate, Malmö Sweden. Still though the big pharma scientific part is kept close to the big Universities in our country. Most recently some of the big pharma Nordic/Scandinavian Commercial Operations also merged into one single Scandinavian organization, which has reduced the commercial roles in the Nordic countries significantly, of course with the aim to reduce costs."

However, the industry needs to acknowledge greater involvement of fast-developing markets such as India and China, particularly the latter on the R&D side. Many pharma companies have already established a research base in China, most popularly in Shanghai.

"As for biotechs, they have a huge need for early commercial expertise in order to position and communicate their science and products in an effective way. This is barely recognised at present, one of the barriers being cost, but those biotech companies that hire executives with strategic commercial expertise will have an enormous competitive edge," says Forslund Larsson.

Commercial and Health Economic Insight Must Be Part of R&D

This will involve a fundamental change in the structure of R&D teams. Forslund Larsson explains, "R&D teams need early commercial input, in addition to clinical input. Many biotech companies are so focused on scientific development that they fail to explore the potential demand for new products, and whether or not consumers will be prepared to pay when the new technology is fully developed. This is where market access and health economics are crucial and these disciplines must be integrated into the R&D team."

The more progressive biotech companies are addressing this by hiring executives from big pharma. Forslund Larsson points to the effectiveness of such transfers, which allow biotech companies to access commercial expertise which builds greater direction and vision into the development stage.

How is this effectiveness achieved? Forslund Larsson explains, "The big pharma executives who successfully integrate into a biotech company are those unhappy with the bureaucracy of big organisations. They want to be seen and to have an acknowledged impact on final outcomes, which is much easier in smaller organisations."

3. Business Model Innovation

As we acknowledged earlier, the concerns of the 40 life sciences CEOs in IBM's study include building truly multicultural organisations, globalising brands and products and optimising operations worldwide. All this leads to a consensus that they will plan major business model innovations in the near future.

With financial pressure now intensifying the picture, Christiaan Lebbink believes that new budget demands on authorities, which could easily require doubling the drug budget, will be unfeasible. He comments, "With the current

Extract from *In Vivo*: will pay-for-performance boom in UK?

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Can we look for more risk-sharing discounts for pricey drugs in the UK? If the government's new pharma pricing scheme is any indication, yes we can. In the wake of several high-profile arrangements – think Johnson & Johnson's pay-for-performance Velcade deal, under which the company rebates the drug's cost if a patient doesn't respond; or Roche's rebate on Tarceva, which brings its cost in line with rival Taxotere, made by Sanofi-Aventis — the PPRS is codifying risk-sharing deals.

Since the PPRS was released a few months ago, the UK health authorities have been in talks with several companies about new pricing schemes for their costly drugs, *In Vivo* reports.

Thing is, the risk-sharing schemes to date were spawned by a "No" from the National Institute of Clinical Excellence. NICE said Velcade wasn't worth the cost, so J&J offered the rebate for patients who don't respond. And so on. Now, NICE says it wants drugmakers to propose those sorts of deals up front, rather than as a last resort.

Obstacles? It's already complicated to administer rebates and track outcomes, as *In Vivo* notes. If every high-priced drug has different terms and conditions around it, then how will NHS and drugmakers keep track? NICE may have to come up with a few standardized deal templates to get a sizable number of pharma companies to play.

economic climate, there will be no money available, so we will see an increase of Risk-Sharing-and Outcome-agreements, such as that closed by J&J or Roche in the United Kingdom."

In addition, given the flood of patent expires in the near term, the difficulty will be in getting innovation and its risk accepted by the public and the authorities. "Today, there will be no payment for therapy based on historical facts, but on the economic realities of tomorrow," says Lebbink.

This is exacerbated by continued pressure on pricing from national account agreement renewals and Group Purchasing Organisations, as well as competitive product offerings which are spurring continuous improvement and cost reduction programmes to manage potential margin erosion.

In a nutshell, the objective will be to avoid development of a drug which has a therapeutic value insufficient to be accepted by society for economic reasons.

Changing Dynamics in Big Pharma and Biotech

Both pharma as well as biotech will be in continuous transition for the next few years. More immediately, we will see the battle between big and small. On one hand, there is pressure on big pharma – some mega-mergers, like Pfizer and Wyeth or Merck and Schering-Plough will lead a next round of consolidation and will put pressure on the followers. Also, many pharma companies are diversifying by acquiring and adding generic companies to their portfolio, for example, Sanofi-Aventis acquiring Zentiva and Laboratorius Kendrick or Pfizer with the Aurobindo deal. "This diversified model has been pioneered by Novartis, being active in specialty, generic, vaccine and consumer health business and now appears to attract followers throughout the industry," says Lebbink.

On the other hand, there is also pressure on small biotech. "The biotechnology industry is under pressure on two levels; attracting capital and attracting talent," says Geneviève Grandjean, Senior Vice President & Partner, Boyden France. Biotech companies are constantly searching for capital in order to support the development of their medicines, particularly in the current financial crisis. Compelled to find new investments or other means to survive, increasingly they are taking the initiative by turning to big pharma – which is on the lookout for external innovations, often in order to compensate a portfolio lacking in new medicines and establish therefore strategic partnerships with biotechnologies. The most recent reverse choice was made by Roche pursuing the remaining participation in Genetech. Another recent example is the acquisition of MedImmun by AstraZeneca.

"However, if biotechs want to preserve their autonomy, they need to remain attractive for investors, and should increase their credibility by endowing themselves with an executive team composed of strong scientific, managerial and entrepreneurial talent," says Mrs. Grandjean.

Attracting World-Class Talent

In addition to capital, attracting the right talent at an early stage is the other major challenge for biotechnology companies. Start-ups are often hampered by poor visibility in the market, making them less attractive to world-class executives.

"Management is very important to the success of these start-ups and must combine rigour, an entrepreneurial approach, risk-taking, audacity, but also creativity and reactivity. The ideal profile of executives for these companies is

exceptional. Capturing this kind of talent is often neglected at the start-up stage due to limited financial means and reputation. However, the building of a highly-skilled team in this phase strengthens the project credibility in the eyes of investors and eases capital inflow. The bottom line is always the same – it is the quality of human resources that makes the difference in a competitive environment," says Genevieve Grandjean.

An Industry in Transition

"Given the significant changes at both the macro-economic level and individual company level, we can expect fundamental shifts in the structure of the industry," says Forslund Larsson.

What sort of structural shifts? First, "fewer early stage companies are pursuing an IPO strategy," says John Cornille. "Instead, they are focusing on the successful development, commercialisation and potential acquisition of new or differentiated products by a more established player in the market".

Second, Christiaan Lebbink expects the economic model to change. "Although very difficult, because of the uncertain nature of drug development, the economic model for the industry will change from a sophisticated cost plus model to an economic model with a determined added value for the individual and society. More quantitative measures such as Quality Adjusted Life Years, or QALY as it is known, will be used to establish 'added value'."

Third, it is likely that different entities will be created. At present, pharma and biotech companies are looking to market access and healthcare economics, going from justification of a therapy and price, to integration of the healthcare advantage and the healthcare economics in the very early phases of drug development. "This is currently being achieved by including a commercial focus earlier on in the development stage," says Forslund Larsson. "However, given that health economics should be integrated early on in the process, independent outside health economic agencies could emerge."

Fourth, industry dynamics will change how companies evolve. "Market access and health economics have a large part to play in the future development of companies," says Grandjean. "Healthcare lacks and cannot have an open market mechanism, as the third party payer principle still strongly distorts a real-market mechanism and healthcare is not currently considered a consumer good."

What is the real impact of this? Quite simply, the issue is public and private funding. Due to budget constraints and closed budget approaches, health economics and market access become increasingly important in determining whether an innovation will find an economically sustainable place in the market. "This is why we are working with companies to develop new roles that are more aligned with health economics and the crucial role it will play in the future," concludes Lebbink.

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[1] 'The Enterprise of the Future' is IBM's third biennial Global CEO Study, 2008, which draws upon 1,130 interviews with CEOs, General Managers, business leaders and public sector heads. The life sciences view is taken from the 40 participating CEOs running companies that represent every aspect of the life sciences industry worldwide.

Hiring In the Current Climate

1. The short-term impact of the economic downturn is the lack of executive mobility, with individuals staying in their current positions and delaying retirement plans. However, new thinking and new leadership is needed to drive the changes required to combat market conditions, competitive pressures, and to initiate new strategies.
2. The growing number of global roles is a challenge for the industry, faced with executives who are reticent to relocate and manage family 'dislocation.'
3. Global roles will be filled less by expatriates on archaic expatriate packages and more by 'multi-country,' global executives with extensive experience in the markets being served.
4. Individuals expect a significant compensation 'upside' in new opportunities, offsetting personal and professional risk. Senior executives accept new positions on condition of specific employment agreements or extended severance agreements.
5. In terms of leadership progression, senior executives need to demonstrate more global experience, including turnaround situations in their careers.
6. Integrating senior, commercial talent is often neglected when companies are formed, due of limited financial means and reputation. However, the building of an excellent leadership team in the early stages strengthens the project credibility in the eyes of investors and eases the flow of capital.
7. A strong and proactive management team with the ability to engender trust and confidence in their people is critical today. Leaders need communication skills to truly 'lead' rather than dictate, leaning more towards the 'player-coach' relationship.
8. Better talent management makes it easier to attract and retain the best executives. The investment of time in the identification and development of talent within an organisation is a major indicator of the quality of the organisation.
9. Enlightened healthcare providers and insurance companies are beginning to seek marketing executives from the consumer products industry, focusing on success based on consultative, solution-oriented selling and an emphasis on financial benefit to the customer, as well as improved and quantifiable quality outcomes.
10. Commercial expertise is paramount, emerging from the initial entrepreneurial stage through development and clinical trials. This requires a changing skill set in the organisation from an R&D focus to a sales, marketing and commercialisation focus.