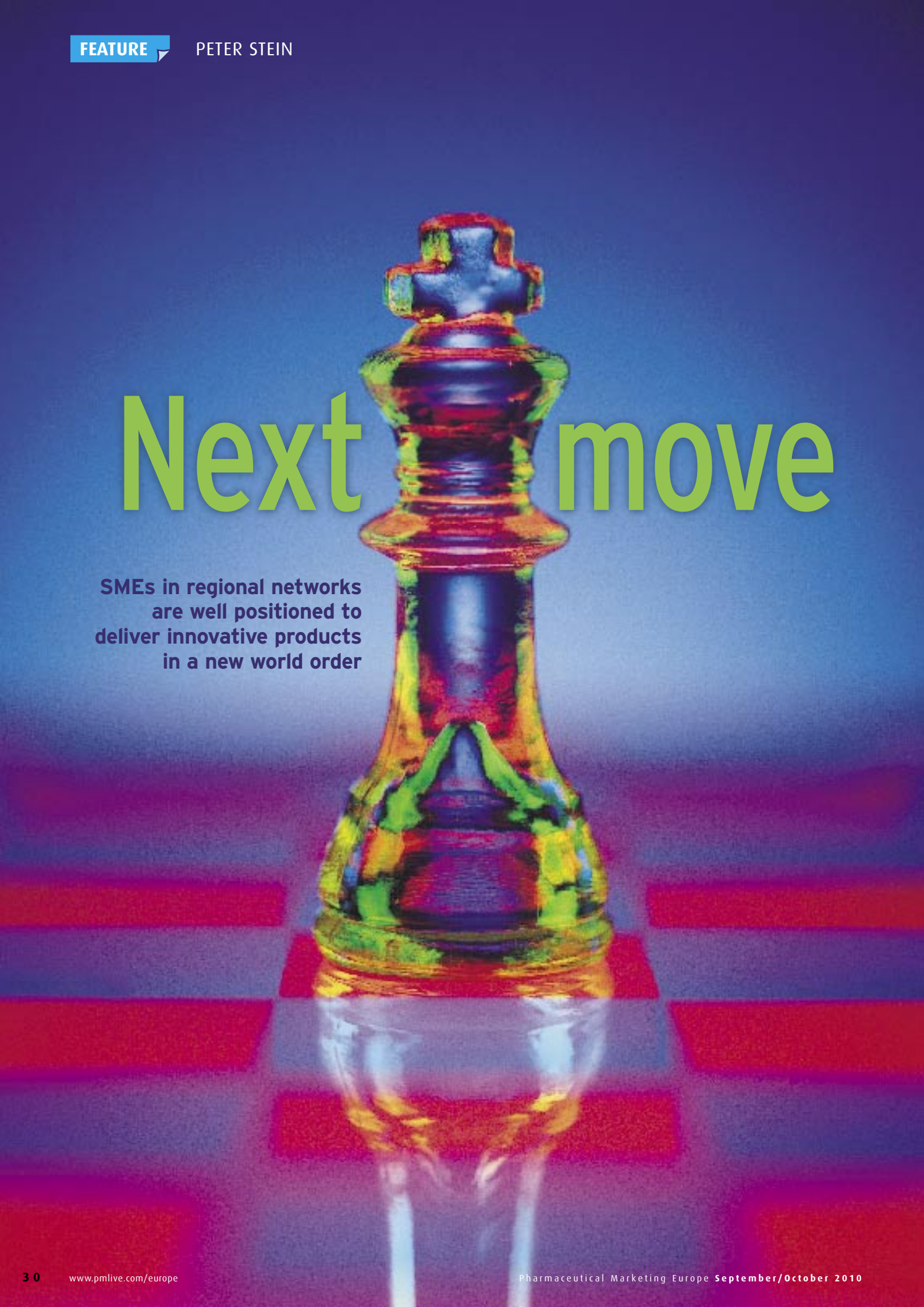
Next move

SMEs in regional networks are well positioned to deliver innovative products in a new world order



As the pharmaceutical industry emerges from at least the first phase of the global financial crisis, it knows that companies and shareholders can no longer be assured that it will be a safe haven during a financial storm. Indeed, its vulnerable period really begins now, as governments beset by towering debts – hundreds of billions in euros, pounds or dollars – strive to bridge the fiscal chasm stretching across the public purse. No politician ever lost majority backing by proposing to force pharmaceutical companies to reduce their prices.

Downward pressures created by the financial crisis will heighten the price sensitivity of healthcare delivery systems, virtually guaranteeing that the next few years will see an accelerated transformation of the pharma industry. With the pricing environment in the 'old world' - defined as Europe and other developed economies - constrained by budgetary pressures, global pharma can look forward only to the somewhat forced emergence of a new world order. So what are the options?

A common choice in recent years has been to depart troubled shores and to set sail for the apparently more welcoming 'pharmerging' markets, much admired for their growth potential by various trend analysis and consultancy groups. It is beyond doubt that the emerging markets have enormous potential for growth and that they will increase, in both value and unit terms, at a pace which eclipses that of the old world markets.

There is another school of thought, however: that a good deal of this much-trumpeted opportunity proves to be a mirage on the horizon. Though the elite may pay modest premiums for an original brand, over time, society must strive to spread the benefit of healthcare provision to the wider population. That can only be afforded if these markets focus principally on the most cost effective delivery of healthcare products and services, which, in turn, requires access and pricing solutions that suit a higher volume, lower price model.

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It is also difficult to see why the healthcare systems in these pharmerging markets would include provision for the mainstay big pharma model in its chief form today; that is, the delivery of premium priced Me2NCEs (me-too 'new' chemical entities), which, while patented, do not necessarily offer significant proven benefit over existing therapies. The evidence is now incontrovertible that the traditional R&D model of global pharma has been unable to deliver true innovation at a rate sufficient to sustain the growth of the industry.

While there will always be a major opportunity for true innovation - the first H2 blocker, PPI, statin, ACE inhibitor etc – neither the old world nor the new will have an appetite to pay premium prices for the umpteenth drug in the class. Pharmerging markets may prove to be a useful distraction for a couple of years to deflect shareholders' attention from the core problems of the pharma model, but there is no escaping the fact that such markets are each complex, difficult to access and subject to precipitous change, not to mention somewhat alien for firms built from the ground up to service European and US-style thinking and business models.

Of course there is an ethical obligation for the industry to make products available in developing markets, but it would be prudent for global pharma to be wary of basing its business growth prospects too heavily on the alleged untapped potential of 'pharmergence'. Global pharma is not designed as a commodity seller in markets where prices are low and the required infrastructure is nascent.

SURVIVAL OF THE FITTEST?

Away from the pharmerging markets, the financial crisis has also largely eliminated funding for the creation of new pharmaceutical companies. An unfortunate consequence of this new world order, in which there will be fewer and smaller product launches, is that the availability of capital for new companies seeking to establish commercial operations will remain sparse. This is particularly true in Europe, where lower pharmaceutical prices combined with higher complexity and operating costs have proved a barrier to the creation of profitable new commercial entities.

The intricacies of complying with a pharmacovigilance system spanning 25 countries and almost as many languages are not insubstantial and is perhaps the best illustration of the differences between the US and Europe. Organisations without a critical mass face the circular problem that it is difficult to build a compliant European infrastructure without a significant sales base across the region, yet attracting or buying new products without that infrastructure is equally problematic. The budget crisis currently biting governments and healthcare systems will accentuate this situation, with smaller domestic companies finding it increasingly difficult; partly because the entirety of their business is exposed to systemic effects in a single market but also because licensers are increasingly recognising the necessity of partnering with a single European licensee.

Those few companies with established and cash flow-positive operations spanning Europe should be in a comparatively strong position to attract new partnerships. However, the nature of these regional alliances is evolving too. Common

standards for new product registration and ever higher requirements for post marketing surveillance are driving companies to earlier, closer cooperation in which a handful of partners (at most) covers both the major markets and the largest emerging markets. In this new scenario, ensuring that the partners share a long-term vision for a product and a therapy area is critical to the selection of a licensee, which is where the doors open for Europe's small-to-medium-sized enterprises (SMEs).

> "By building networks focused on a number of products or therapy areas with other regional specialists, SMEs can compete with big pharma"

By building networks focused on a number of products or therapy areas with other regional specialists, the SMEs can compete effectively with big pharma, as they are more likely to be able to integrate and apply existing scientific knowledge to develop solutions to unmet needs, ie small products that add real value to carefully defined sub-groups of patients. The clear result of recent trends is that a product that has a demonstrable advantage for a specific sub-group of patients will be priced according to the value of that proven advantage, but its use will be limited to that sub-group. However, these smaller products, adding real value to carefully defined sub-groups of patients, can still sustain the growth of a SME.

The relatively lean cost structure of SMEs also enables these networks to develop new products more cost effectively. In an environment where health economic benefit must be proven before launch, cost effective development programmes focused on moderate-sized therapeutic targets are more likely to generate a positive return on investment, while not placing an undue burden upon the healthcare system.

In contrast to many in big pharma, Europe's SMEs are not only avoiding the distractions of uncharted pharmerging territory, but remain focused on delivering innovations that make a difference for patients and thereby add value for healthcare systems. Groups such as Norgine, for example, delivering meaningful incremental innovations and with an established footprint across Europe, will seek to commercialise products profitably from their R&D pipelines through a network of regional partnerships around the world. Conversely, the existing European infrastructure makes these firms attractive for other regional commercial companies, as well as those focused solely on new product development.

> "Europe's SMEs are... avoiding the distractions of uncharted pharmerging territory"

However, it is not surprising to see a spate of consolidations among the smaller SME players without the European coverage or critical mass. This will produce companies more able to compete effectively through participation in global networks.

Regarding big pharma too, it is a commonly held view that another round of mega-mergers will - once again - be the industry's salvation. While these big pharma mergers facilitate cost-cutting and therefore can delay the day of reckoning, the combination of two dinosaurs is unlikely to yield a dynamic pharmaceutical development engine. In order to succeed, companies must remain focused on the industry's core mission: the development of innovative products to improve the provision and quality of healthcare outcomes.

AFFORDABLE INNOVATION

For SMEs to benefit from their position, however, they must continue to search out innovation, while the definition of that innovation has itself evolved. Some would argue that innovation has, in the past, been measured (by the global industry and some of its representative associations) by the number of patents protecting a product, rather than the benefit a product conveys to the patient or the healthcare provider; but times are changing. By the new definition, true innovation comes from providing a proven benefit in healthcare outcome, however that advance is delivered.

Unfortunately, there are still examples of products launched today without well-designed active controlled studies against the best existing therapy, but increasingly these will become the exceptions. At the same time, there is growing potential for cost effective research programmes, which apply existing scientific knowledge and, in certain cases, even well established chemical entities, to solve unmet medical needs.

The European model still has to face the challenge of how the recognition of incremental innovation can be preserved so that improvements in the use of established molecules can offer effective competition to prevent unnecessary use of the latest Me2NCE. In their drive towards use of generics in existing product categories, governments are, in effect, locking these established medicines in a time warp, with their regulatory status, formulations and clinical support frozen in time. This, in turn, allows more highly priced NCEs to penetrate markets at the expense of older, better value medicines.

While the future is uncertain, one certainty is that the global financial crisis has elicited a greater degree of 'consumer mindfulness'. SMEs that are both entrepreneurial and open to collaboration will therefore find the path to continued successful development via the smart solution of regional partner networks, sharing the risks and rewards of delivering the affordable and worthy innovations Europe's patients seek.

The Author

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