Appropriate Governance of the Life Sciences - 4

Pharmaceutical Futures: Health biotechnology to 2030

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This policy brief is one of a series describing Innogen's research on strategic innovation issues in life sciences, the governance and regulation of innovation and the resulting innovation trajectories determining which products are developed and which companies take the lead in developing them.

Innogen was asked to write a scenario report for the OECD International Futures Programme to consider the pathways that health biotechnologies could follow, the future trajectory of the bio-economy in the context of human health and the likely societal, economic and policy impacts of these projected outcomes, focusing on the period 2015 to 2030[i]. We chose as a starting point a world health care system that, *from the perspective of potential impacts of biotechnology*, has been mainly under the influence of the innovation model of the multinational drug companies. To date the scope and inventiveness of this model has been constrained by the expensive and lengthy regulatory systems that act as a barrier to entry for small companies that could challenge the industry status quo and our report focuses on the need for regulatory change as a prelude to the emergence of a new, more radically innovative, health care sector[ii].

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The present structure of the pharmaceutical sector, closely coupled to a complex interacting set of markets and regulatory systems, has served public health care needs in the developed world reasonably well for the last fifty years. However, under challenge from an increasingly complex range of innovative biotechnologies, fundamental change seems increasingly necessary and even inevitable, but at the same time increasingly unimaginable. However, if one finds the right levers, and is able simultaneously or sequentially to align other system components to be sufficiently flexible, change can take place dramatically and surprisingly rapidly. This does not imply a lowering of safety standards, but the development of 'smarter' approaches to the regulation of pharmaceuticals so as to be more receptive to new discoveries in life sciences.

SCENARIO BUILDING FOR THE PHARMACEUTICAL SECTOR

Attempting to predict future technology and policy developments, and their influence on complex systems, is a highly uncertain exercise – outcomes will be determined by interactions among drivers and actors in complex and unpredictable ways. Timing is often the most important factor – changes that occur simultaneously can have powerful mutually reinforcing effects or they may cancel one another out; changes that are separated by a period of years can build on one another in a synergistic manner or alternatively the time lapse may mean that the opportunity for an impact has been missed.

Building on the presumption that the key to constructive change in pharmaceutical innovation systems lies in the regulatory system, we developed two alternative scenarios: '*No change scenario*' and '*Radical change scenario – Networked Health Care*'.

NO CHANGE SCENARIO

Where companies and regulatory bodies have resisted *fundamental* change, but have embraced *incremental, piecemeal* change, the pharmaceutical sector will probably still be populated by highly competitive companies seeking to maximise the short term advantages from life science innovation to their own organisations. In normal circumstances these are admirable survival tactics but the failure to embrace radical change when the timing is ripe can mean that, when the inevitable change does happen, it is highly disruptive for all concerned. By 2030 or earlier, the pharmaceutical sector will begin to experience the following difficulties:

- increasingly intense competition between major companies gives rise to practices that are portrayed by public groups as unethical;
- narrowly focused thinking leads to localised conflicts and tensions;
- continued and increasing difficulties in finding innovative products to fill product development pipelines;
- lack of funding for new technology;
- the sector consists increasingly of commodity producers with a diminished R&D component in company strategies;
- numerous missed technology-based opportunities and dysfunctional competition between and within companies;
- company relationships with regulators tend to be adversarial rather than collaborative; and
- legal actions by health care providers and patients against companies and regulators are increasing in number and in cost.

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This outcome is seriously sub-optimal, although not disastrous. In 20 years' time the sector could be characterised by a general atmosphere of low-level aggression and bad temper, and a pervasive concern that this could erupt rapidly into very damaging levels of conflict, with no clear strategy for preventing it. The rigidity in both regulatory systems and companies was a classic case of inability to see the opportunities to become part of a new, more collaborative global innovation environment. Despite the recognised need for an over-arching vision of how to reach this goal, key players were unable to bring together the right combination of expertise and influence to generate a window of opportunity for radical change.

RADICAL CHANGE SCENARIO – NETWORKED HEALTH CARE

An alternative scenario could give rise to dramatic and fundamental change in the pharmaceutical innovation system, enabled by a sequence of equally fundamental changes to regulatory systems, involving the development of new, smarter approaches to drug development. If industry, regulators and stakeholder groups can collaborate to enable such changes to take place, the prize could be healthcare systems that, while remaining profitable, deliver a more equitable distribution of benefits and a more cost-effective translation of innovative developments "from bench to bedside".

In this scenario, thinking about fundamental change in the sector was stimulated partly by innovative thinking about new business models and radically new structures for the health care sector as a whole. Expertise was brought in from the information and communications technology (ICT) sector to contribute experience of operating in a more open, networked environment with active collaboration with consumers.

We suggested that these discussions about new business strategies led to the formation of a joint company involving a major pharmaceutical multinational and a

major ICT firm in order to gain first mover advantage in what they perceived was the way forward for the sector – a new co-ordinated mode of operation which became known as Networked Health Care (NHC). The backing of the two parent companies was reinforced by the support and active participation of two other major players, the private health care insurance industry, particularly in the United States, and the re-insurance industry.

The industry was no longer acting as a technology gate-keeper, inhibiting (with the unwitting aid of regulatory systems) the development of innovations that did not contribute to a drug-based approach to health care.

Health care under this model became predominantly a service industry. Its business was to co-ordinate the activities of a range of public and private sector providers to deliver drugs, information, services, treatments, and other health care-related products to patients. The new type of company was able to harness a wide range of global networks, bringing together new technology, new types of expertise, surmounting regulatory barriers to innovation, and embracing new competition models. As nanotechnology, information technology and biotechnology became increasingly convergent at the scientific discovery and innovation levels, their business models also began to converge, enabling new insights to be combined to deliver better health care faster.

An important aspect of the NHC approach was the involvement of several different types of company and product within the same networked organisation. The key to the NHC profit model was that the most powerful industry partner was no longer acting as a technology gate-keeper, inhibiting (with the unwitting aid of regulatory systems) the development of innovations that did not contribute to a drug-based approach to health care. While the profit base of any individual item in the portfolio of a NHC-based company was not comparable to that of a block-buster drug, the co-ordinated delivery of a range of drugs and therapies, each with a more modest profit base, proved to be a more viable and resilient approach in the long term.

The success of this initiative meant that companies involved in drug development were increasingly obliged to operate on the basis of the NHC model. Those that resisted change either became targets for take-over by the more successful NHC based group of companies, or concentrated on generic drug markets.

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The fact that the route to market for health care products was increasingly mediated and brokered via the NHC-based companies meant that contributing companies could succeed financially with a much wider range of innovation strategies than was previously the case. The fruits of public and private investment in life sciences began to emerge in new and often-unexpected ways, stimulated by new types of partnership bringing together companies and individuals with biochemical, chemical, IT, physics and engineering expertise.

By 2030 the long term winners were the companies that, faced with a need for creative change, had been able to re-structure their innovation models, even if it meant making many current products and processes redundant. Companies that aggressively defended the status quo in a rapidly changing environment gained in the short term but did not retain their dominance in the long run.

A change in stakeholder attitudes was seen at an early stage in this scenario. Collaboration with the ICT sector, and the speeding up of delivery of innovations through new regulatory approaches, defused the “anti-big pharma” public mindset that had become increasingly apparent. The perception that “something important was happening” meant that patient groups and most members of the public who took an interest in such things switched from critical mode to being increasingly positive collaborators.

CHANGE IN REGULATORY SYSTEMS

Strategic change in the innovation system could not have taken place without equally fundamental change in regulatory systems. Instead of seeing themselves as passive responders to events, regulators began to see their role as being more

proactive. The challenge was to ensure the continued safety, quality and efficacy of new drugs but to do this within a regulatory system that was responsive to the new opportunities being presented by life science innovation. Drug failures in late stage clinical trials, rather than being seen as a failure of industry innovation models, began to be reappraised as a mismatch between:

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- the nature of new life science innovations;
- the nature of the companies that could best exploit these innovations;
- public and patient expectations of new drugs and treatments; and
- regulatory systems that were designed around 20th century models of drug development.

The key to change, showing how it could be done, not merely recognising that it was needed, came from interaction with the ICT sector that freed up thinking about health care policy and regulation in a way that was seen as non-threatening even although it involved radical change. The resulting products, while not cheap, were more affordable than previous generations of products and were developed more rapidly thanks to the revised regulatory arrangements.

TIMING OF DEVELOPMENTS

Achieving major change in large scale entrenched systems like the pharmaceutical industry or regulatory agencies has been described as “turning round an oil tanker”. However, even once you have turned the oil tanker round, it is still an oil tanker. The challenge in this case was equivalent to converting the oil tanker into a smaller, more multifunctional mother ship in charge of a fleet of smaller faster vessels capable of taking off in many directions while remaining well connected with one another.

Achieving the outcome in the second scenario would depend on good judgement by key thinkers in companies and regulatory agencies backed up by good luck, particularly in the timing of important changes. Change managers would need to be open minded and able to think creatively across disciplinary and sectoral boundaries, with the ability to recognise the need for systemic change and to appreciate the advantages that would accrue to the first movers in making this change. They would also need to have the authority (as a group) to implement the required changes.

The willingness of regulators to consider innovative approaches to regulation, and of senior pharmaceutical industry managers to discuss issues in an open environment were necessary for a successful outcome, followed closely by the willingness of key players in the ICT sector to take up the opportunity to engage in such discussions. If only one of these elements had been missing, this scenario would have been much less likely to emerge. Likewise, if one of these players had attempted to dominate the outcome, the chances of an optimal resolution would have been much less.

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[i] J. Tait (with D. Wield, J. Chataway and A. Bruce) (2008) Health Biotechnology to 2030. Report to OECD International Futures Project, “The Bio-Economy to 2030: Designing a Policy Agenda”, OECD, Paris, pp 52; http://www.oecd.org/dataoecd/12/10/40922867.pdf.

[ii] See Innogen Policy Papers: Appropriate Governance of the Life Sciences-1, *Multinational Company Innovation Strategies*, Joyce Tait; Appropriate Governance of the Life Sciences-2, *The Case for Smart Regulation*, Joyce Tait, Joanna Chataway and David Wield. http://www.genomicsnetwork.ac.uk/innogen/publications/policypapers/