

Appropriate Governance of the Life Sciences - 5

Health Innovation for the world's poor: Who are the players and what is the game?

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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.

A variety of public private partnering arrangements and innovative financing mechanisms has begun to change the neglected disease landscape over the last decade. How significant are these public-private partnership (PPP) arrangements? Are these players likely to endure? Do they deserve the continued support of development donors? How do they relate to broader shifts in the pharmaceutical sector landscape and the changing 'rules of the game'?

Our analysis is that these arrangements constitute very important 'social technologies'¹ providing a framework through which to solve intractable problems within neglected disease product development much in the same way as genomic technology is revolutionising medical care. However, these social technologies need to be looked at in the context of overall changes and constraints on change in the pharmaceutical industry. Whilst they may be part of a set of changes that is transformative and discussions are often poverty and disease reduction focused, they may get caught in the same set of influencing factors which maintains the status quo in the pharmaceutical sector overall. This brief draws on work carried out by Innogen researchers on the partnerships themselves and on a study carried out by Innogen for the OECD on future scenarios in the pharmaceutical sector.

Fundamental change seems increasingly inevitable, but at the same time increasingly unimaginable.

What are PDPs and what have they contributed?

PPPs dedicated to product development are termed 'Product Development Partnerships' (PDPs). They bring together public, private and not for profit organisations to develop new drugs and vaccines for neglected diseases or to create new avenues for access to existing or modified medicines by the world's poorest and most in need populations. Over the last decade they have raised millions of US dollars and have been supported by a range of development and industry donors¹. Moreover they have been very involved in policy initiatives such as the Global Alliance for Vaccines and Immunization (GAVI) and the International Financing Initiative on

¹ By 'social technologies' we mean new sets of organisational and institutional arrangements which aim to foster the creation of new physical technologies.

immunisation (IFFIm) which have brought much more significant amounts of money into addressing neglected diseases.

Chris Elias, head of the Program for Appropriate Technologies for Health, PATH, a well-known non-governmental organisation supporting PDPs, describes them in the following way:

“[PDPs] provide a creative means for the industry to participate in solving some of the world’s most important problems – vaccines for malaria and other neglected diseases, new tuberculosis drugs, and specialised diagnostics and delivery devices – while remaining true to its commercial purpose. These partnerships take many forms and typically involve highly creative approaches to management of intellectual property rights, negotiation of affordable access, and shared risk taking”ⁱⁱⁱ

Early assessment of PDP activities rated them very positively against a range of criteria (Chataway and Smith, 2006). They scored well against traditional public and private sector organisations in the following categories: amount of activity in drug development; performance metrics including quality of output; speed of drug development; and cost. They also contributed positively to science and technology capacity in developing countries. Despite governance criticisms levelled against PDPs, when measured in terms of the effectiveness of drug development efforts likely to produce new drugs relevant to the needs of the poor, a number of PDPs scored highly.

PDPs score well in assessments against more traditional public, private and international actors but do they break the mould of a system that fails to deliver to the world’s poorest people?

Successful examples of PDPs

PDPs do not all work in the same way or have the same structure but for the majority the starting point of their activity has not been basic science. The International AIDS Vaccine Initiative (IAVI) for example has until recently made it clear that it exists to channel funding into clinical trials. So unlike a traditional formula whereby a public research institute or university funds initial work and then hands it over to private sector players, IAVI aimed to fund and organise work through clinical trials, setting up sites and activities in a range of developing countries to conduct this work.

In this way it played a similar role to some pharmaceutical companies in the general product development value chain. Some of its own staff and a number of observers began to describe IAVI’s approach as the creation of a ‘virtual pharmaceutical company’. The difference however is that IAVI’s focus was clinical development first and foremost as the way in to product development activities. Thus it has set up offices in a number of developing country locations and has worked closely with developing country partners in its clinical trial work (Chataway, et al, 2007).

An AIDS vaccine has proved more elusive than predicted and as a result IAVI has been pulled increasingly in the direction of basic science, but importantly it retains its conviction that it must work across the supply chain, from bench to patient in Africa, Asia and other developing countries, if it is to

PDPs are not uniform. They are a collection of organisations and institutions that work in different ways. But they will all be faced with critical decisions about their strategic roles over the next few years.

be successful in its mission. IAVI, which was one of the first of this new breed of PDPs has always been adamant that an integrated approach to policy, advocacy and science is core to its approach.

The Malaria Vaccine Initiative (MVI) similarly supports clinical trials for new vaccines. MVI has products in Phase IIb and III trials and plays a leading role in organising trial sites, bringing on board the donors and stakeholders necessary to trialling products and, if successful, delivering them to patients. MVI however has a different institutional history from IAVI, as a programme within a broader health systems development oriented NGO (PATH) rather than a stand alone PDP with a private pharmaceutical business ethos. While developing out of alternative 'cultures' both MVI and IAVI have emphasised combining the needs of product development innovation with the needs of social development around clinical trial sites.

While they have proved themselves in many respects, PDPs are currently faced with a difficult situation: the financial crisis is likely to put them under increased pressure; there is a feeling that the science is not moving quickly enough (particularly in the field of HIV/AIDS work) and this may impact negatively on funding from some development donors; and there is increasing pressure from some who feel that PDPs remain under the control of powerful actors in the 'North' and have not made enough effort to really engage Southern partners in leadership roles.

They will be forced to make a number of critical decisions about their future direction and how they continue to bridge innovation and development activities. It is extremely unlikely that one model will emerge as PDPs reposition themselves, but the process will highlight the need to develop new evaluation methods and tools which are sorely lackingⁱⁱⁱ. Less evident but equally important are the ways in which PDPs are shaped, influenced and constrained by broader factors in the pharmaceutical industry as discussed in our scenario report for the OECD International Futures Programme.^{iv}

New players in an old game or something different?

Innogen was asked to write the scenario report to consider pathways that health biotechnologies could follow, the future bio-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. Our report has as its 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. It is exactly these same regulatory structures that make PDPs necessary but may also be limiting the scope for changes they might bring about. In some respects it is because of the need for clinical trials that many PDPs exist.

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. It has done much less well of course in serving the needs of the world's poorer people and countries. Under challenge from an increasingly complex range of biotechnologies and because of a range of economic, social and political factors, fundamental change seems increasingly necessary and even inevitable, but at the same time increasingly unimaginable.

Using a 'no change scenario' and a 'radical change scenario' the OECD report looks at what sorts of developments are likely or possible under various sets of conditions and if different sets of decisions are taken. In the first of the OECD scenarios PPPs, and particularly PDPs, continue to play a role and some do achieve important but rather minor contributions to addressing neglected diseases. Overall, the picture in terms of health inequalities remains and perhaps even deteriorates. In the radical change scenario, based on networked health care, PDPs become much more established figures, fitting well into a model which focuses on portfolios of health care technology providers and service delivery. The radical change scenario is based on new mergers and joint ventures between IT and pharma companies, introduction and development of a set of new technologies and change within regulatory regimes which favour intensified innovation.

PDPs work within a context that is in need of fundamental change.

In the radical change networked health care scenario China and India become important providers of health care technologies and India's success in project management of complex IT operations is adopted and echoed in pharmaceuticals. Companies and governments are able to respond more effectively to political pressure to act effectively to reduce health care inequalities across the globe.

The radical change model allows for PDPs to come into their own as core players in a very different industrial model. They would be significant new 'social technologies' which would promote intensified innovation favouring the poor in a changed landscape.

Conclusion

PDPs have already contributed significantly to the truly terrible lack of health care provision which exists for the majority of the world's population. However, they are likely to come under new sources of pressure. Given a no-change scenario they will remain as important sources of creativity both in terms of physical and social technologies and political pressure but will not be able to embrace fully their potential as harbingers of greater equality in health care. They can only achieve that in the context of a broader set of changes such as those outlined in the OECD report. This new role however also depends on PDPs deciding not to totally turn back towards science at the expense of their wider international development objectives. Unfortunately, in these uncertain times, even this is difficult to predict.

ⁱ Including the International AIDS Vaccine Initiative (IAVI), the Malaria Vaccine Initiative (MVI) and others included in Innogen's Health Partnerships Database (see www.health-partnerships-database.com).

ⁱⁱ Elias, C. (2006) pp 540-541

ⁱⁱⁱ A new Open University and Innogen initiative entitled 'Technologies for Health Systems Strengthening' (THeSys) will be developing new methodologies to address this deficit.

^{iv} Innogen Policy Brief. Appropriate Governance of the Life Sciences – 4. Pharmaceutical Futures: Health Biotechnology to 2030

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