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Where are Product Development Partnerships (PDPs) headed and how can THeSyS help them get there?

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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.

What are PDPs?

PDPs as 'social technologies' and 'development brokers'

The last decade has witnessed a flourishing of new approaches to financing and addressing neglected diseases including Product Development Partnerships (PDPs). Many PDPs have taken root with funding by the Rockefeller and Gates Foundations, some bi-lateral funding agencies and a range of other public and private donors. Most are not-for-profit. They use public private partnerships arrangements to develop new drugs and vaccines for neglected diseases.

As new 'social technologies' PDPs aim to create new physical technologies and medicines or provide access to existing medicines. They bridge innovation and development activities by acting as 'development brokers' (working alongside other development agencies on clinical trials, access to medicine issues and a range of policy and advocacy problems associated with neglected diseases) and 'innovation integrators' (working with public and private sector industrial and scientific actors to bring new drugs to market). They have contributed a great deal to addressing the acute problem of neglected diseases over the past decade.

Avoiding an 'innovation pile-up' is important

PDPs are now coming under pressure however. While it is not the case that funding is drying up in the short term, some are very likely to find it much more difficult to finance themselves and their activities over the medium term. They will also need to focus increasingly on health systems development so that new drugs can be absorbed. PDPs will need to adapt to changing environments.

Based on previous and ongoing work by Innogen researchers this Policy Brief puts forward the argument that there is scope for differentiation amongst PDPs with some needing to move in the direction of development actors and others moving towards integrator activities. The crucial thing is that they retain a capacity to span activities and engage with tools to help them assess their future activities. Using a range of qualitative and quantitative techniques Innogen is pursuing a stream of work under the banner of Technologies for

Health Systems Strengthening (THeSyS) to assist with this.

What have PDPs achieved?

PDPs sit on a spectrum between being generators of new innovations, sometimes looking like and indeed describing themselves as virtual firms and knowledge brokers working to bring together a range of different stakeholders involved in addressing neglected diseases around common agendas. Most have not assumed they know what poor people need and have rather taken very seriously the need for real engagement with developing countries and poor people to understand what is needed and the best routes for product development. Their unique contribution as 'social technologies' has been in this effort to harness new technology development efforts to concrete needs of poor people in developing countries.

Decentralising laboratory research

For example, the International AIDS Vaccine Initiative (IAVI) funds promising new vaccine candidates through clinical trials. It has taken a portfolio approach funding a range of different candidates based on a variety of scientific lines of attack. Rather than just take the scientific work involved in early clinical trial work which could have been largely carried out in developed country laboratories, IAVI established well resourced laboratories in a number of developing countries. It carried out very significant training of scientific and technical staff and worked closely with local partners to carry out trials.

Early assessment of IAVI's work and the work of other PDPs indicated that they achieved more than traditional public and private sector organisations and that developing country partners enjoyed significant capabilities as a result of partnering activity (Chataway *et al* 2007[1]).

IAVI also invested heavily in a whole range of community based and educational work connected to prevention, treatment and clinical trial preparation work. This paved the way for smooth running of clinical trial work which received significant local support. It also meant that while early funding from the Gates Foundation was critical, IAVI was able to diversify its funding base and as a result of support from developing country governments currently receives the majority of its funding from bilateral development donor agencies.

As already noted, in order to gain maximum buy in and support from developing countries IAVI invested heavily in developing countries and devoted very substantial time and effort to building advocacy, policy, scientific and innovation work in developing countries.

PDPs as innovation integrators

However, the science involved in the creation of an HIV/AIDS vaccine has proved more complicated than predicted. IAVI has moved to establish itself as a leading innovation integrator but has also concentrated more and more effort on upstream scientific activities. Its particular scientific focus is on

[1] Chataway, Joanna and Hanlin, Rebecca (2008) Sustainable (vaccine) development: the International AIDS Vaccine Initiative (IAVI) and capacity building . Health Partnerships Review. Global Forum for Health Research. www.Globalforumhealth.org

neutralising antibodies and it has recently established a world leading laboratory in New York to work in this area.

As PDPs consider their future strategies, it is important to keep in mind that they are not following one model and a variety of approaches may need to be adopted. Some, like the Malaria Vaccine Initiative (MVI), which has had relative success with clinical trials, seem to be favouring an approach which consolidates their knowledge broker activities. They are innovation integrators, organising clinical trials and engaging deeply in issues of distribution and manufacturer but they themselves tend not to lead on scientific and technology development directly.

Different approaches for different PDPs

Unlike IAVI, the MVI is expanding its clinical trial activities where prospects for new vaccines look promising. For MVI then the challenges are different. MVI will need to find new ways to contribute to the development of health systems which can handle new treatments in developing countries.

As Chris Elias[2] from Program for Appropriate Technology in Health (PATH) puts it:

"Recent investments in new technology development have not yet been matched by similar efforts to strengthen health systems in resource poor settings. The danger is that new innovations will not move smoothly into widespread use, even in places where they are desperately needed, because of weaknesses in health systems, such as shortages of health workers, fragmented or corrupt procurement and supply chains, poor quality assurance, and lack of sustainable financing. Failure to bring new products into use could also become a disincentive for the creative partnerships that drive the development of innovations for the poor?" (Elias, 2006)

What are the sources of pressure and what is needed?

The sources of pressure confronting different PDPs include the following:

PDPs are under pressure to deliver

- Pressure for financing is likely to increase as a result of the combination of the current financial crisis, disillusion from some donors about the slow pace of scientific progress in come areas and increased competition between different PDPs and PPPs;

- PDPs which are moving upstream into more basic science will need to show that they are still maintaining active and useful links to developing countries and maintaining their unique positions as bridges between innovation and development actors;

- In areas where PDPs and others have had success in developing and adapting medicines and pipelines are full of new drugs, there are new challenges in the manufacture and distribution of drugs. Weak health

[2] Chris Elias (2006) Can we ensure health is within reach for everyone? Lancet 368: 540-541.

[3] Another Innogen Policy Brief, 'Health Innovation for the World's poor: who are the players and what is the game?' can be found on the Innogen website at …... as No. 5 in the 'Appropriate Governance of Life Sciences Policy Briefing Series.

systems may well be overwhelmed.

- PDPs will increasingly be under pressure to show they can contribute effectively to health systems strengthening. They will need to develop intelligent tools based on quantitative and qualitative measures of performance. They will need to show they can act as useful members of the product development communities (PDCs).

Conclusion: A new THeSyS?

Room for new THeSyS?

PDPs constitute breakthrough social technologies. They have contributed significantly to research on neglected diseases with policy and advocacy work and some have had considerable success in developing new physical technologies. As PDPs move into a new era, our Technologies for Healthy System Strengthening (THeSyS) work will focus on developing new analytical frameworks and methodological tools to assist them, their partners and donors to make good decisions this will include:

- Analytical frameworks based on the understanding of these actors as social technologies developing physical technologies;
- Using value chains and innovation systems analysis to examine the ways in which these social technologies contribute to innovation and production capacity and address constraints in emerging systems;
- Mapping PDPs on a development broker and innovation integrator spectrum;

Importance of understanding the multiple contexts in which the PDPs operate

- Modelling the contribution of new technologies to healthcare systems;
- Contextualising PDP activities in a broader understanding of the pharmaceutical as a whole to push forward broader policy change[3];
- Scenario planning and other futures based activities to help in determining productive pathways for social and technology innovations and systems development.

Social science research in the ESRC Genomics Network (EGN) interprets the field of genomics broadly, including plant, animal and health related innovations in life sciences. The Network ranges across five of the UK's leading universities, and involves over a hundred researchers, administrative and support staff, and international visiting research fellows. It is one of the largest social science investments in the ESRC's current portfolio, and is becoming the largest concentration of social scientific research on life sciences in the world.

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