8. New approaches to promoting innovation

8.1 Public-Private Partnerships and Innovation

See Background Paper 8.1 (BP8_1PPPs.pdf)

In the 2004 Report, public-private partnerships (PPPs) were identified as a promising solution for addressing challenges in pharmaceutical innovation. Since then, there has been considerable progress in the development of PPPs and in particular in the product development partnerships (PDPs). The current challenges in drug development require the mobilization of significant resources from a wide variety of stakeholders, PPPs can help facilitate this process and capitalize on the benefits of new approaches such as ‘open innovation’.¹

Public-private partnership can be defined as any informal or formal arrangement between one or more public sector entities and one or more private sector entities created in order to achieve a public health objective or to produce a health-related product or service for the public good. In a PPP, the partners share certain risks and may exchange intellectual property, financial, in-kind, and/or human resources in any mutually agreed upon proportion.

There are several reasons for establishing PPPs. They include the need to:

- Increase scale: pooling of resources can help to address issues that cannot be addressed by a single entity (for example, because the knowledge or expertise that is needed to answer a question is not available in a single company or institute, or the scale of the activities required is too large).
- Share risk: by sharing risks (for example, through government involvement), projects can become of interest to potential partners who, without a subsidy or support, would be unwilling to get involved. An example of such a project would be the repurposing of existing drugs.²
- Focus R&D priorities: by defining a strategic research agenda, in consultation with stakeholders, resources can be focused on issues of particular public health interest.
- Optimize the use of available knowledge and resources: in order to make progress in many areas, there is a need to bring together data or expertise that resides with different parties. In addition, PPPs can be used to create a research infrastructure for future work (networks, biobanks, research databases etc.) Research on the performance of PDPs for neglected diseases showed that industry working alone and public groups working alone performed less effectively overall than public–private collaborations.³
- Foster a more competitive private sector to promote economic growth: governments that support PPP research may also aim to support new R&D activities within their region or country. In this way, PPPs can both address a medical need and help generate new forms of economic activity. Therefore PPPs are an important factor for innovation and business models in the life sciences (such as the ‘open innovation’ paradigm).⁴
Address topics that require a neutral/multi-stakeholder environment: to make progress on some issues, a neutral environment has to be created. A partly publicly-funded consortium can be an appropriate vehicle for this. An example would be topics in the regulatory arena in which regulatory authorities (should) play a role, but where input from industry is also needed.

Against this background, different types of PPPs can be identified, based on their focus on different parts of the medicines development pipeline:

**Research partnerships:** supporting (early stage) innovation or creating technology platforms in high priority disease areas. Examples of this type at the EU level are: the Top Institute (TI) Pharma in the Netherlands, which was launched in 2006 with total funding of €260 million and which has used the 2004 Priority Medicines Report as the foundation for its research programme; and the Innovative Medicines Initiative (IMI), which was launched in 2008 with total funding of €2 billion. Both these examples are discussed in more detail in Background Paper 8.1. This type of PPP is a relatively new model for collaboration in the development of medicines. All such partnerships face a challenge in that funding time-lines are often short and it can take a long time (five to 10 years or more) to see the impact that such research partnerships can have on the development of drugs or diagnostics that reach patients. Efforts will be needed to reconcile the issue of long-term funding commitments if these partnerships are to fulfil their great potential. This means that evaluating intermediate outcomes is of critical importance. For those projects that focus on tools and method development, intermediate outcomes should be identified that fit this goal.

**Product development:** focus product development activities on concrete products, in many cases to address diseases that occur mainly in low- and middle-income countries. Examples in this area are the Medicines for Malaria Venture (MMV), the Foundation for Innovative New Diagnostics (FIND) and the Drugs for Neglected Diseases initiative (DNDi).

Partnerships concentrating on the development of medicines and diagnostics for tuberculosis and neglected tropical diseases (including malaria) have had considerable success. While the 2004 Report warned that these partnerships may face challenges in relation to the sustainability of funding, the current outlook for many of these PDPs is reasonable, despite the impact of the financial crisis.

**Concept development and overall systems strategy:** PPPs can also play an important role in overall discussions and contribute to systems reform. Many broader issues in pricing, market authorization or sustainable models for innovation can only be addressed in projects that involve all stakeholders. Such ‘system innovation’ projects, appear promising and should be further monitored and expanded. These kinds of projects could potentially have a broader scope and also involve global players (e.g. the EU, Japan, the United States and emerging market economies).
There are several additional forms of public-private collaboration, such as Public Supply Partnerships. However, these are not discussed here as they fall outside of the scope of this report.

PPPs face a number of challenges, irrespective of their overall goal. These are more prominent for PPPs involved in research partnerships such as the IMI and TI Pharma as experience in this area is more limited.

These challenges include:

- **Time-lines and sustainability:** PPPs generally receive tranches of funding for a three to five year period. In view of the long time-lines in drug development, this amount of time may be insufficient to achieve the development of new compounds and targets.

- **The role of small and medium-sized enterprises (SMEs) and large companies:** the need to ensure the appropriate engagement of SMEs is especially important in efforts to achieve economic targets (e.g. nurturing new companies, job creation). The conditions for the participation of SMEs differ from those for large pharmaceutical companies or academic institutions. This aspect of economic development is important to the EU and many other countries.

- **Consortium leadership and project management:** managing partnerships requires a different set of competences and skills than managing regular research projects. Capacity building for this skill-set is of critical importance for the success of any PPP.

- **The role of the central entity:** a well functioning central entity or ‘office’ is essential for any PPP. This can play a role as a neutral entity, trusted third party or honest broker. An appropriate and balanced role for the central entity is also critical in building and maintaining trust in the PPP from participants and society as a whole.

- **Intellectual Property (IP) structure:** the goal of many PPPs is to generate innovative insights into diseases and their diagnosis or treatment. This means that the way intellectual property is handled in the consortium is of key importance and provides an important reason for partners to participate or not.

- **Performance measurement:** one of the major challenges for partnerships is to measure the added value that the partnership provides. This is important for public funders, companies, and academia from the perspective of the efficient and responsible allocation of their different resources. There is currently a requirement for investments in this area.

For future research, there is a need to learn more about what are the most successful models for PPP collaboration. This is an area where industry, governments and academia have much to contribute, in particular by the sharing of information and experience. Knowledge about what are the most useful indicators (structural, process, output or outcome) of successful partnerships would be beneficial for all those involved.
The growth of knowledge about what constitutes a successful partnership (apart from better prioritization) will help facilitate more realistic assessment of what can be achieved within a given time-frame with the resources invested.

Another area for research is the important issue of stakeholder involvement in PPPs and how patients and citizens can best be involved in the decision-making process. Chapter 8.5 contains a number of research recommendations that are also relevant for PPPs: build models or frameworks for meaningful patient and citizen involvement, research methods for capacity building and assure standard indicators for assessment of initiatives that involve patients and citizens.

References


