PDP Pricing Discussion Paper

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Abstract

All Product Development Partnerships (PDPs) have as part of their core mission ensuring that the products they develop are affordable and will be accessible to their target populations. Price is usually seen as a surrogate measure for affordability, although the definition of price is important to ensure that the correlation is adequate. Overall PDPs have not developed detailed strategies for pricing and to guide their negotiations with their development partners. This is due to a lack of case histories in setting suitable pricing strategies to guide this process (as most of the projects are still early in the development process). PDPs have historically been reluctant to be too specific in their approach to pricing in order to reassure development partners from the private sector that they are not going to be tied into uneconomic pricing agreements. With a couple of exceptions, pricing has been agreed using the Cost Plus method. PDPs are seen as having increasing leverage with their partners as development progresses and uncertainties about the final product and its cost are reduced. Because of the few products that have made it to the market so far, it has not been possible to develop measures of success by which pricing strategies and methods can be judged. However such measures of success must recognise the two key parameters of ensuring access and sustaining supply. Challenges faced by PDPs over pricing include the development of detailed pricing strategies and their evolution through the development process, partner concerns and education, collection of market intelligence, ensuring sustainable supply, and the role of complementary interventions. PDPs could benefit from collaboration and information sharing on choices of pricing methods, collection of market intelligence, cost calculation methodologies, and auditing of partner's costs.

Paper Objectives

All PDPs involved in the development of this paper have as part of their core mission ensuring that the products that are developed with their financing and involvement are available and acceptable to the appropriate target populations in adequate quantities at an affordable price.

The objective of this paper is to examine the various approaches taken by a selection of PDPs to establish pricing of new products with their partners. After describing the possible options that have been identified, the paper outlines the chosen options and the role of endemic countries and third parties in deciding on the chosen approach. It outlines the challenges that the PDPs have identified in price setting and negotiations with their partners, and finally some ideas for collaboration between PDPs to improve their price setting methods.

The paper is based upon interviews and written responses to questions with the following organisations – Bill & Melinda Gates Foundation (BMGF), Department for International Development (DFID), DNDi, IAVI, IVCC, MVI, MMV, and TB Alliance. As such it covers drugs, vaccines, and insecticides but does not discuss diagnostics. It should be read in conjunction with the PDP Economics and Financing Discussion Paper.

Strategies

All the PDPs interviewed for this paper stated that their objective is to ensure that the products they are co-developing with private sector partners are affordable to their target market and that supply of their products are sustainable over the long-term. All PDPs also used price as a surrogate for measuring affordability, although IVCC was most aware that the definition of price and the

[1] Prepared by Ian Boulton (TropMed Pharma Consulting) based on interviews conducted by Yvette Madrid on behalf of the PDP Access Steering Committee, which is made up of the following organisations: Aeras, Concept, DNDi, FIND, iOWH, IPM, IVCC, MMV, MVI, PDVI, and TB Alliance.

relationship between the price of an intervention and the total cost of delivering the intervention would have an important impact on how affordability could be measured and comparisons drawn between different interventions.

All PDPs built pricing commitments into their agreements with product development partners and manufacturers from the start of each project. In general, the commitments are kept vague in the early stages of product development, and the commitments are firmed up as the product comes closer to the market. This reflects the increasing knowledge both about the costs of manufacture of the product and the market dynamics into which the product will be launched.

The funding organisations interviewed were concerned that the PDPs were not clearly setting out their pricing strategies. In particular they felt that there was a lack of clarity about how the strategy would evolve as a new product moved through development. PDPs seemed to be concerned to keep their options open for as long as possible during the development process. In part, this reflects the lack of case histories for many PDPs to fall back on in dealing with the complexities of pricing negotiations with private sector partners. It also reflects the uncertainties inherent in the early stage of product development that their projects are currently at. The PDPs with the most well articulated pricing strategies are those involved in drug development. This is because of their more mature portfolios, the length of experience of both PDP and manufacturer management teams in negotiating pricing, and the reasonably well defined relationship between price, affordability, and sustainable supply for pharmaceuticals.

It is of value for PDPs to start with a clear statement of their strategy for pricing. It should be a statement of key over-arching principles that will guide the development of individual pricing agreements for individual products. This may be kept for internal guidance or shared publically depending on the approach favoured by each individual PDP. The advantage of a clear statement of strategy is that it ensures consistency between projects and can be communicated simply to all relevant staff. The exact components of a good pricing strategy for the PDP should be agreed through discussion within the PDP and with its key stakeholders (including funders). The possible components of a pricing strategy are discussed later in this paper.

All PDPs have in their pricing strategies the possibility of not moving forward with projects if they look as though they will fail to deliver affordable products. Some projects may not be entered into at all if the technology is considered to be so inherently expensive that it has no role in fighting diseases in the poorer parts of the world. In other cases, the inability of the project to bring down costs as originally forecast to an affordable level during the development process has been the cause of projects being terminated[2]. Every project was considered on a case-by-case basis.

PDPs interviewed were not explicit about whether they intend to actively develop a competitive market for the new product, or if they will let this develop passively. PDPs all have the view that increasing the number of players manufacturing and distributing a particular intervention will result in the price falling due to the impact of competition. Also increasing the number of manufacturers should reduce the risk of interruptions in the supply of a new product. This element of the strategy will depend crucially on issues of intellectual property ownership relating to each product. However, PDPs may consider explicitly stating in their pricing strategies what is their approach to encouraging multiple suppliers of a given product and if they plan to be active or passive on this. It will remove concerns and a possible source of mistrust with private sector partners. PDPs can also consider the impact on potential manufacturers of developing robust demand forecasts for a new intervention to encourage multiple supply sources if the demand supports this.

[2] And therefore potential prices, as price must at least recover costs.

Methods

A variety of theoretical methods to set pricing or pricing guidelines were identified by PDPs and external experts in this field. These were then used in the interview process to help the PDPs interviewed clarify their thoughts on the actual methods they are adopting with their development partners. They can be grouped together as follows:-

Method (with possible variants)	**Objective**
Cost-based • No profit / no loss • Cost Plus	To drive product price as close to its marginal cost of manufacture as possible without removing incentives to the manufacturer to invest and maintain supplies.
Target-based • Benchmarked • Price ceiling	To use information on pricing already available from the marketplace to establish an appropriate price.
Health Outcomes based	For second or later new product entrants to a market segment to show increase value for money to payers of the new intervention.
Volume-linked • Specify price and minimum supply quantity • Price explicitly linked to quantities purchased	To assure adequate supplies of a product or to stimulate a normal demand/supply response of falling prices as demand increases.
Competition-based • Creation of substitute products • Passive IP access (PDP makes IP freely available) • Active IP access (PDP actively seeks manufacturers)	To create a more competitive market and use market forces to drive down prices.
Market Incentive • Profits vary with degree of commercial investment • Advanced Market Commitment or similar initiative	To stimulate commercial interest by accelerating product availability through predictable pricing and donor assurances to fund purchases of a predetermined volume related to the level of the supply commitment.
Market	Leave the setting of prices to pure market forces with no involvement from PDP.

There is potential for overlap between the various methods. For example the Market Incentive approach may include elements of Target-based pricing. Also different methods may be more appropriate to certain market segments or sectors, or to the priority of a disease and hence its associated level of funding.

Challenges with Different Methods

Each of the methods identified have issues and drawbacks that must be considered when choosing a suitable approach to adopt in a particular case. None is ideal and therefore PDPs should investigate a range of options before settling those that are most appropriate for their particular situation or project:-

Method	Challenges
Cost-based (Includes Cost Plus)	• Information on costs is mostly held by co-developer/manufacturer and is not readily available to the PDP. This puts the PDP at a disadvantage in discussions on pricing based on cost. • Cost is usually uncertain until production scale batches are actually manufactured. Pilot scale production is not always a good guide to final cost. • Cost-based pricing does not incentivise the manufacturer to undertake process development to bring down cost of manufacture. • Forecasts of costs will depend on forecast sales volumes. These are usually very uncertain for novel interventions. This drives conservatism by the manufacturer on cost forecasts.
Target-based	• Requires good understanding of the dynamics of the market in question, especially demand side. • Needs benchmarks based on existing alternatives. Getting agreement on the appropriate comparator intervention package may be challenging. • Needs knowledge of total costs of comparator interventions to establish appropriate target price. This might include data on comparative costs of delivery, of storage, of complementary interventions. • Targets set at too low a level may cause supply shortages. There may be inadequate incentives for adequate capacity to be made available before the market has stabilised (*e.g.* recent challenges with ACT supply).
Health Outcomes based	• More important for second entrants to a given market. • May require specific data collection during development studies. This may be a major challenge in developing country situations where most PDP-develop products are designed to be used. • Almost certainly will be country or context-specific. Economic benefits will depend on the nature of the health system and disease pattern in a given situation.
Volume-linked	• In the absence of good demand forecasts, not possible to negotiate with any degree of confidence that the quantities will be realistic. • Requires opportunities to revisit agreements if the volumes forecast are found to be significantly out-of-line with reality (both above and below). • No incentives to reduce costs if required price reductions with increasing demand keep total return to manufacturer constant. • May require separate agreements with every possible manufacturer if development partner is not expected to meet the entire demand (at least initially).

Method	Challenges
Competition-based	• Needs a competitive market situation to be feasible. If there are no competing interventions being used by the target customer base then there are no market forces to establish the price the market will bear. • First to market products will usually expect a period of exclusivity to earn the required return on investment. Creating a competitive market quickly may be a disincentive to the PDP's partner to either get involved at all or to take the product finally to market. • Creating a competitive market artificially by sharing IP may be difficult if the technology also underpins products in more commercially valuable diseases.
Market incentive	• Requires confidence that the funding will still available at the end of the development programme. • Uncertainty on costs during development makes it difficult to establish profit incentive to be offered. • "Pull" incentive – most PDPs are operating on the basis of "Push" incentives.
Market	• Pure market approaches can only work if there is adequate IP to be used by a wide range of participants. IP in this arena is politically difficult. In many target countries IP is either non-existent or unenforceable. • The PDP has no control over the prices being charged. This can lead to prices too high to ensure access by the patient population the product has been developed for. • Market imperfections will impact prices actually being charged.

It is advisable to ensure that the prices arrived at by any of the above methods are ceiling prices. This allows for the forces of competition to work to reduce prices over time and to give an incentive for process innovation.

Methods Currently Adopted

Most of the PDPs interviewed only use the Cost Plus method to agree pricing with their partners. This was because this was felt to be the one method that was transparent in showing that the price was as low as possible while allowing some return on the partner's investment. Some return is necessary as an incentive to continue to supply[3]. Usually data on cost of manufacture is also the most readily available. PDPs usually have some form of auditing rights that allow them to use independent financial specialists to confirm that the manufacturer-supplied information accurately reflects the costs of manufacture. This auditing principle predates most PDP agreements as it formed part of the 2001 Coartem® agreement between Novartis and WHO, and has been used for over 30 years by PATH.

The exceptions to the general use of Cost Plus are the PDPs involved in vector control and anti-malarial drugs. Here there is some experience in using Target-based approaches. In the anti-malarial market, the 2001 agreement between Novartis and WHO on the price of Coartem started a process in the market that set a generally accepted target price for first-line oral Artemisinin-based Combination Therapies (ACTs) of US$1 / adult treatment and US$0.50 / child treatment. It is now the target price for any new first-line treatment for *P falciparum* malaria. However, outside this specific antimalarial market segment, a mixture of Cost Plus and Target-based pricing methods are used in setting pricing agreements with development partners and potential manufacturers.

[3] In some cases, major manufacturers of drugs are pricing on a no-profit/no-loss basis. These are pharmaceutical manufacturers who have adopted this for marketed products and maybe extending it to newer products being developed with PDPs. However this is an exception to the general rule of requiring some return on investment.

In the area of vector control, the insecticide actually makes up a small proportion of the total cost of the intervention (Long-lasting Impregnated Nets [LLINs] or Indoor Residual Spraying [IRS]). Typically the insecticide cost is only 5 – 10% of the total cost of manufacturing and distributing an LLIN. The customer for the insecticide is not the ultimate buyer of the net but the manufacturer of the net. Therefore it makes more sense to use the Target-based approach using benchmarking of the projected price of the insecticide against the currently marketed insecticides.

Market Segmentation

All PDPs interviewed recognised that the market was segmented in various ways and that this needed to be recognised in their approaches to pricing and the agreements with potential suppliers.

The usual segmentation identified was between the income level of countries, as defined by international organisations like the World Bank or the OECD. All PDPs sought to have strong pricing agreements in place for supplies to low or low-and-middle income countries. High income countries are usually left to pure Market-based pricing and to the commercial decision of the manufacturer. The decision on which level of country segmentation is to be adopted depends on precedent, the attitudes of both the PDP and partner's managements, and the geographical incidence of the disease. Multiple segments based on relative income levels of different countries (tiered pricing) are coming under increased scrutiny from global financing agencies (*e.g.* Global Fund). They are identifying anomalies in multiple tiered pricing structures, especially when there is a wide disparity in access to healthcare and its affordability. This is adding to pressure to segment only between developed and developing countries. However manufacturers are resisting this trend as they see this as a threat to their overall business in the faster developing countries (like India and Brazil), where conceding the principle for products primarily aimed at the poor would be used to attack their prices on major profit earners.

All PDPs recognised that the market could be segmented between public and private sectors. The relative importance of each sector depends on the intervention in question. Thus the private sector may assume greater importance for the supply of drugs, especially antimalarials. However the public sector may be more dominant in the supply of interventions like nets, spraying, and vaccines. In many Neglected Tropical Diseases (NTDs), the public sector is also the dominant purchaser of drugs. This distinction would guide the amount of interest a PDP takes to agreeing pricing with a manufacturer for the private sector. All PDPs are deeply involved in agreeing pricing for the public sector.

It is sometimes sensible to distinguish between a "premium" private market and a "normal" private market sector in low and low-to-middle income countries. The premium private market supplies drugs in particular to the wealthy upper and upper middle class urban patients who have the money to buy branded products from international manufacturers. The wider private market supplies the less well-off urban and rural populations, often using generic drugs supplied by local manufacturers. PDPs, if they do make this distinction, leave the "premium" private market to the manufacturer to price freely on a Market-based approach. Initiatives such as the Affordable Medicines Facility – malaria (AMFm) – hosted by the Global Fund – is attempting to widen access of ACTs to the private sector through a Target-based approach and co-payment mechanism. In this situation, the *ex*-manufacturer price is set to be the same as the public sector price, and whatever pricing methodology was used to establish the public sector price is applied.

It is also possible to segment the market (and therefore the approach to pricing) on the indication for the product. Again this is best seen in malaria. The use of antimalarials and the potential use of malaria vaccine to prevent malaria in travellers is a market mainly restricted to the high income countries. This market segment can be left again to the manufacturer to adopt a Market-based approach. Use in endemic countries for treatment or prevention is the area where the PDPs can negotiate pricing agreements with their partners.

Third Party Involvement

Interviewed PDPs were asked about the extent that they could rely on their own internal resources to set and implement their pricing strategies, and to what extent they required the assistance of external or third party people or organisations.

Overall PDPs did not see much involvement of third parties in:-

- setting their pricing strategies;
- selecting the methods to be used in a particular collaboration;
- in supplying a "running commentary" on the performance of the PDP on pricing.

Apart from concerns over the lack of clarity of PDPs on their pricing strategies, the funders interviewed were happy to take a hands-off approach to PDPs over pricing. The funders recognised that they were not in a position to properly understand the issues and particularities of each market. They expected the PDPs to have the necessary expertise to manage this appropriately for each development project. There was a general recognition that it was also difficult for funders to comment on the appropriateness of the pricing method adopted until the product is marketed and access and affordability can be measured directly, even if this was too late to do much about the situation apart from learning for the next time.

Historically PDPs have not involved endemic countries in the setting of pricing strategy or the choice of pricing method. Governments have in general been supportive of the role PDPs can play in minimising the cost of novel interventions to their healthcare budgets. They see that PDPs have more leverage with the manufacturers during the development phases, as the PDPs can negotiate at a global level. In the past, countries have tried to intervene for marketed products to encourage local manufacture of existing products. A variety of tools – such as preference for local manufacturers, compulsory licensing of IP, tariff barriers – have been used. For new products emerging from PDP collaborations, they may look at applying similar approaches once the products are marketed and have established their value in disease prevention and control. This supports a Competition-based approach to pricing if the relevant government can get it to work properly. However the government runs the risk of finding that it is tied to one or two local manufacturers and has lost the competition from the global players. This approach is not relevant to pricing agreements for interventions still in development (for the reasons stated above). There are a few examples of governments using cost-effectiveness in their choice of interventions. This is a trend that is still in its infancy and most interventions do not have the necessary information to make such an analysis possible.

In general PDPs have internal business development groups who are responsible for negotiating and managing the pricing agreements with partners. External consultants are involved from time-to-time when specialist knowledge is needed. This is mostly on manufacturing issues when there are problems meeting the target costs/prices or to understand complex new technologies. Some PDPs also use third parties to collect market intelligence.

Measures of Success

Funding agencies and PDPs would welcome objective measures of success for their chosen pricing methods. However in nearly every case the projects are not yet marketed and so there is no information on access and affordability from which success can be judged. Success needs to be measured on two key parameters of how well the price has ensured:-

- Level of access to appropriate treatment in the target population
- Sustainability of supply over the long-term

Some suggestions have been made about more sophisticated ways of measuring "affordability", but these ultimately serve to answer the two key measures of success noted above.

Challenges

Strategy Development

As mentioned above, the main concern of the funders with PDPs' approach to pricing is the absence of clear strategies. However the challenge to the PDPs is to understand exactly what the funders mean and what are the components of an acceptable strategy. In addition, it may not be sensible to have the same detailed strategy for all products in a PDP's portfolio. It should be possible to agree a set of over-arching strategic principles within the PDP and with its key stakeholders. These can then be adapted to each individual project as necessary. Such a set of principles is outlined below. They are distilled from the interviews and the consultant's view of best practice in this area. They should be applied as far as possible throughout a project's life and in most cases will be the same for all projects supported by an individual PDP:-

Target Markets or Segments:

- What are the target countries to which the pricing strategy will be applied (*e.g.* only low income countries)?
- Will there be different strategies for different types of target market (*e.g.* one for low income and one for middle income countries)?
- Will there be different strategies for the public and private sectors?
- What will happen in segments or countries not covered by the PDP's strategy (*e.g.* allow partners a free hand to decide their own strategies)?

Ensuring Affordability:

- How will affordability be defined? Does this differ between market segments?
- Does affordability only apply to directly comparable interventions (*e.g.* only other similar vaccines) or does it include the total cost of delivering the intervention?

Ensuring Sustainable Supply:

- Will this apply to all market segments, or only to a priority selection (*e.g.* only supply of vaccines to public sector general vaccination campaigns)?
- Will this apply to all countries or only to a specific target segment (*e.g.* only low income)?
- Does the PDP plan to be proactive in developing a competitive market to ensure sustainable supply or not?
- How will IP issues be handled to ensure that the PDPs strategy on ensuring sustainable supply can be effective?

Ensuring Partners' Return on Investment:

- What is the PDP's attitude to a development and/or manufacturing partner earning a return on its investment? Does this differ between public and private sectors, or between different countries segmented by income levels?
- How will investment of the partner be defined for this purpose?

Evolution of Strategy:

- How frequently will the pricing strategy for a particular project be reviewed? Annually or less frequently?
- When will the pricing method to be adopted for a particular project be finalised?
- At what stage(s) in product development must the pricing commitments be firmed up and the partner's commitments on cost and price become specific (*e.g.* end of Ph II, end of Ph III, prior to launch)? Will there be intermediate checkpoints along the development path where loose commitments given in the early stages can be made firmer but still allow for some flexibility?

Other components can be added as necessary, especially to meet any specific needs of the funders and other key stakeholders.

Partner Education

In many cases, PDPs are engaging with private sector companies that have limited experience and understanding of the market dynamics of products targeted at the poorer parts of the world. Often the partners need a considerable amount of education about the behaviour of the markets, the major players and their expectations, the dynamics of working with a PDP and closely with the public sector. Potential partners are understandably concerned about being tied into pricing agreements that put them in position where they fear they could lose significant amounts of money. For example, IVCC has to work with insecticide manufacturers who are comfortable with the agricultural sector but may have little or no experience of working in the healthcare sector.

Partner Concerns

The motives and concerns of the manufacturer with whom the PDP is in partnership to develop a particular intervention can have a significant effect on the details of the pricing method agreed for a particular project. Such issues include:-

- Corporate reputation — Here the manufacturer is only interested in ensuring that it covers the costs of its involvement while its primary motive is to improve its corporate reputation. This is most obviously seen with the international pharmaceutical manufacturers (*e.g.* Novartis, sanofi aventis) and their no profit/no loss commitments on supply of antimalarials.

- Return on investment — Here the manufacturer expects a defined return on its investment in supplying the product, even if its investment in developing the product has been covered by the PDP. The challenge is what level of return is acceptable. The pricing approach must ensure that there is a sustainable supply of the product without allowing "undue profiteering" from the sales of the new product. The challenge is how this is determined in pricing negotiations with the manufacturer.

- Distribution system — A key component of ensuring access to a new product is ensuring that there is a distribution system in place to get the product to the people who are in need of it while maintaining affordability. If the manufacturer is expected to develop a new distribution system (beyond one that it currently uses) to make the product available, then it may be reluctant to proceed. Large pharmaceutical companies often have pre-existing distribution systems they can use. Similarly interventions delivered predominantly through a public sector channel (requiring only institutional sales to a central government purchasing body) may not require any investment from the partner. However PDPs need to work with partners to ensure the costs of building and maintaining a suitable distribution system are covered adequately in the agreed pricing strategy for an intervention.

Market Intelligence

All the PDPs and the funding agencies interviewed felt that they needed more information on the markets into which the products being developed would be launched. The more a target market can be understood, both from the demand and the supply side, the less the uncertainty associated with predicting how a new intervention will perform. By reducing uncertainties, the PDPs and their partners feel they will be more confident in addressing the challenges of setting prices.

The information needs ranged over all aspects of the marketplace. Information needs could be readily defined for products being launched into established markets (*e.g.* pharmaceuticals). Information like target customers, existing product pricing, market shares, payer behaviour, public sector funding, *etc.* is available if sometimes difficult and/or expensive to collect. However completely novel interventions (*e.g.* malaria vaccine, HIV vaccine) are breakthrough technologies with no pre-existing marketplace. It is therefore a challenge to identify and collect the appropriate market information needed to inform decision-making. A wider range of market intelligence might allow PDPs to consider other pricing methods than Cost Plus. For example, an understanding of the total cost of delivering an existing interventions compared to the new intervention would help to inform using Target-based pricing. If a malaria vaccine could remove the need for bednets, then the target price of the vaccine plus costs of delivery through and EPI programme could be set against the target of the costs of delivering bednets and replacing them on a 3-5 year cycle. Similarly a better understanding of the potential demand for a novel treatment for Human African trypanosomiasis might allow a Volume-linked approach to be adopted.

Most development programmes undertaken by PDPs and their partners do not collect proper cost-effectiveness information. This means that a proper cost-effectiveness approach to setting the price of an intervention relative to its competitors is not possible. The challenge is to be able to accurately to collect information on the associated costs for such an analysis in healthcare environments where such information is not readily available.

Stage of Development

The major challenge to agreeing pricing with partners is with early stage development. Here the uncertainties around cost of manufacture are very high, especially where the technology being used is novel. As the development project moves through its various stages, the exact costs of manufacture and delivery become clearer and uncertainty is reduced. This allows for a more specific and detailed pricing agreement to be negotiated. The PDP has increased leverage with the partner as the uncertainty is reduced and can use this to ensure an appropriate price is agreed. At an early stage, PDPs usually feel it is better to keep options open (within broad affordability parameters) to keep partners engaged and work with them to refine the pricing over the course of the development process.

Complementary Interventions

In the range of interventions covered by this paper, there are considerable differences in the role of complementary or supportive products and of additional costs of distribution and administration. These costs may be a significant part of the overall cost of the intervention to a healthcare purchaser. The most extreme example identified is vector control where the cost of the insecticide is a very small percentage of the total cost. Vaccines and anti-TB drugs also have significant costs associated with administration that may exceed the costs of the intervention under development. The role of diagnostics in malaria is being promoted in order to reduce the treatment of non-malarial fevers with antimalarial drugs. This may significantly reduce the volume of malaria treatments needed. The impact of this on the target price of new antimalarials to public healthcare budgets has yet to be determined. The cost of diagnostic reagents may be only a small part of the total cost of a diagnostic method, and it is more sensible to consider the total cost to the healthcare system of the test (including instrumentation).

To-date the PDPs interviewed in general did not report having taken much interest in the role of complementary products when choosing pricing methods and setting prices for interventions under development. In the case of anti-TB drugs, the widespread use of fixed dose combinations (FDCs) has meant that the TB Alliance has assessed the costs of the other components of potential new FDCs. Similarly MMV and DNDi have been involved with the costs of artemisinin derivatives to be used in their ACTs.

PDPs need to take a holistic view of the entire cost of the intervention (including costs of diagnosis, administration, distribution, *etc.*) in order to properly judge the affordability of a new intervention, and hence to set its desired price. For example, setting the appropriate price for a single dose treatment for malaria administered following use of a rapid diagnostic test would need to factor in not only the reduced costs of distribution from the single dose treatment but also the additional cost to the healthcare budget of the diagnostic. Similarly a novel treatment for human African trypanosomiasis has to factor in the cost of diagnosis, the cost of supply to remote populations, and the cost of training of suitable healthcare workers to administer the drug. This has been addressed in more detail in the paper on Economics and Financing.

Ensuring Sustainable Supplies

PDPs must tread a careful line between insisting on low prices and ensuring that the prices are not so low that manufacturers have no long-term incentive to supply the product in question in the quantities needed. Most PDPs interviewed have some form of "walk-in" rights to ensure that there are adequate supplies of the product if the development partner is not able to meet the demand. But there also need to be adequate incentives and returns for the alternative manufacturers to be interested in getting involved in the product's supply. In addition, there will be a time lag in getting a new manufacturer up-and-running.

Earlier in this paper, attention has been drawn to the concerns of manufacturing partners about the pre-existence or not of in-country distribution systems. PDPs mission are to develop products that meet the needs of all people (irrespective of income level) affected by a particular disease. Therefore in negotiating agreements with manufacturers on supply, the geographical spread of supply needs to be aligned with the need. However, insisting on a specific group of countries that a manufacturer must supply to may be a disincentive for collaboration if there is no pre-existing network. PDPs need to treat this issue flexibly and work with the manufacturing partner to overcome any problems in this area.

Impact of Partner's Actions

It is important that the PDP and all its partners stay aligned on the pricing strategies being adopted and send consistent messages to the external community. It is especially of importance when a PDP is negotiating with other companies. There have been examples of manufacturers making announcements about pricing strategies without consulting the PDP concerned, with the possibility that their messages are at odds with those of the PDP's or may adversely affect the PDP's negotiations with other partners.

Some PDPs face the challenge of trying to manage the impact of one partner's actions over pricing on the market and other partners (actual or prospective). For example, the pricing strategy adopted by the major antimalarial manufacturers is to supply on a no profit/no loss basis. A possible development partner for a new antimalarial may be reluctant to become involved if they see no opportunity to earn a return due to the precedent established by the major companies. The majors' investment is already paid for and they only seek to improve their reputation.

Potential Areas for Collaboration between PDPs

All PDPs are on a learning curve on the best way to establish prices to ensure access and affordability. Some are further along the learning curve and may be able to share their experiences with others less far advanced. It is clear from the various discussions that have already taken place within the PDP Access Steering Committee that the members have seen value in such sharing of experiences.

In the area of pricing, because of the commercial sensitivity of the subject and external rules around price fixing and cartels, collaboration between PDPs can be difficult and must be handled carefully. However there are several areas where collaboration could be of use:-

Choice of Pricing Method

Without going into specifics of individual agreements, there is still room for PDPs to discuss their choices of pricing methodologies and to develop case studies for others to learn from. In particular, it would be of interest to share experiences on the evolution of approach across the product development cycle, when to change from a generalised "ensuring affordability" objective to more specific price levels, and when to change from one specific pricing method (*e.g.* Cost Plus) to another (*e.g.* Target-based).

PDPs will also benefit from discussions around how to segment their target markets and the choice of pricing method most appropriate for each segment. This is especially true for country segmentation. Some say they are only focusing on low income markets while others say their focus is on both low and low-to-middle income ones. There seems to be a lack of consistency among PDPs in how they approach this type of segmentation. Terminology is often used loosely and so it is unclear which definition of income levels are the targets for each PDP. More alignment of approach and consistency of terminology here would enable clearer pricing strategies to be developed and aligned messages to be sent to the global community by the PDP community.

It was not possible from the data collected in this exercise to identify whether there was any agreement between PDPs on the best way to establish pricing strategies or select pricing methods. The questions posed focused more on the collection of information about current practices and did not explore in detail PDPs perceptions on better ways to proceed in the future.

Collection of Market Intelligence

Although every market segment and product marketplace is different in detail, there are many areas where common information is of value. Size of government healthcare budgets, levels of external funding (*e.g.* from Global Fund grants), and systems in the public sector for vaccination & bednet distribution are some examples of where common information could be shared among PDPs to save on cost and to ensure a level of shared learning. Also experience in the collecting cost-effectiveness data to help drive cost-effective arguments for setting prices could be shared to mutual benefit.

Sharing of Experience with Individual Companies

Many PDPs work with the same group of companies. Without breaching commercial or contractual confidence, it would be of benefit for PDPs to share their experiences with each company. This shared learning would allow PDPs to ensure some consistency in their dealing with a particular company. By trying to maximise consistency across different diseases and market segments for a particular company, PDPs will increase their opportunities to maximise the benefits of working with the company in question. Also understanding any differences in approach needed between diseases and market segments or between different partnerships will improve PDPs overall understanding of the workings of the marketplace.

Cost Calculation Methodologies

It is well established in accounting circles that the definition of "cost of manufacture" is not simple and there are many factors that can be included between pure marginal and fully absorbed cost of manufacture. PDPs could benefit from sharing information on the cost calculation methodologies they have used and the pitfalls that may arise in this area. This will also be a cost saving to some PDPs who will reduce their need for specialist accounting or financial advice in this area when negotiating with development partners.

PDPs can also benefit from sharing experiences of dealing with the additional costs of an intervention on top of the pure cost of the product – distribution, diagnosis, complementary products, *etc.*. For example, it would be of interest to be able to share successful cases of how the higher cost of a novel intervention with a shorter duration of treatment or higher efficacy could be offset by reductions in the cost of delivery of the treatment or reducing the overall cost of treatment (including treatment failures). Similar the costs of delivery of a novel vaccine could be justified by the reduction in overall costs of the disease in question to the healthcare system. Experience of using such information in developing a pricing strategy for a particular intervention would be valuable to share.

Cost Auditing

PDPs can also benefit from sharing experiences of auditing the actual costs of their partners' manufacturing and how to avoid pitfalls in this area as well. It should also be possible to identify which auditing firms are best qualified to undertake this type of work and any that should be avoided.

Annexes:

List of People Interviewed:

The following people were interviewed either in writing, by telephone, or a combination of both on the basis of an interview guide. Agreed responses to the interview guide are available.

Bill & Melinda Gates Foundation (BMGF)	Patricia Atkinson	Senior Program Officer
Department for International Development (DFID)	Saul Walker	Senior Policy Adviser, Access to Medicines
Drugs for Neglected Diseases Initiative (DNDi)	Pascal Boulet	IP & Regulatory Advisor
	Florence Camus-Bablon	Senior Access Advisor
Innovative Vector Control Consortium (IVCC)	Tom McLean	Chief Operating Officer
International AIDS Vaccine Initiative	Labeeb Abboud	Senior Vice President & General Counsel
	Rachel Belt	Executive Assistant, General Council
	Claire Pharoah	Associate Council
Malaria Vaccine Initiative	Alex Adjagba	Program Officer
	Carla Botting	Director, Product Development and Access
	Alan Brooks	Senior Program Officer, Policy & Access
Medicines for Malaria Venture (MMV)	George Jagoe	Executive Vice President, Global Access
TB Alliance	Elizabeth Gardiner	Vice President, Market Access
	Gerald Siuta	Consultant, Business Development
	William Wells	Director, Market Access

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Authors Biographies

Ian Boulton
Ian Boulton is Managing Director of TropMed Pharma Consulting (TMPC), a small consultancy working with organisations active in the fields of malaria and neglected tropical diseases. He is also a Trustee of the Malaria Consortium (Malaria Consortium is one of the leading specialist organisations operating in communicable diseases, especially malaria), a member of the Market Dynamics & Commodities Committee of the Global Fund, and has advised the Global Fund, Roll Back Malaria Partnership, the Bill & Melinda Gates Foundation, and the Medicines for Malaria Venture. Before setting up TMPC, Ian spent 34 years in a variety of roles in the pharmaceutical industry, including 20 years in the Far East. In his last role, he was one of the leaders of GSK's Diseases of the Developing World Initiative and was also a Board Member of the Roll Back Malaria Partnership for 4 years.

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Yvette Madrid
Yvette Madrid is an international health consultant whose work centers upon the economic and supply chain aspects of sustainable access to health products in developing countries. These include financial considerations affecting research and development; process economics; financing, supply, and pricing of new products; innovative financing mechanisms; links between financing mechanisms and efficient supply chain; and the optimization of supply chains in the face of escalating and changing needs.

Her international health experience spans over fifteen years, including positions with the World Health Organization (Essential Medicines, Vaccines and Immunization) and contracts with organizations such as IAVI, IFPMA, and PATH. Prior to her work in public health she was employed by a multinational pharmaceutical firm with responsibilities in clinical development and marketing.

Yvette holds degrees from the Massachusetts Institute of Technology and the California Institute of Technology.

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