SUMMARY ANALYSIS OF ACCESS COSTS[1]

December 2011

Introduction:

The purpose of the costing analysis was to explore the structure, nature, and size of the costs associated with access to new tools following marketing authorization. The analysis used a series of case studies covering a variety of new interventions supported by Product Development Partnerships (PDPs). The PDP Access Steering Committee selected four case studies to give a range of different situations:-

Coartem Dispersible®	• Pediatric line extension of marketed drug for malaria treatment • Two party collaboration between the PDP (Medicines for Malaria Venture; MMV) and major pharmaceutical company (Novartis)
MenAfriVac®	• Novel meningitis vaccine • Multipartner collaboration including the PATH Meningitis Vaccine Project (MVP)
GeneXpert®	• Novel machine-based TB diagnostic • Two partner collaboration between the PDP (the Foundation for Innovative New Diagnostics; FIND) and developer (Cepheid) • Multipartner collaboration on introduction coordinated through Stop TB Partnership
Paromomycin	• New use of an existing antibiotic for treatment of visceral leishmaniasis • Not yet launched so responsibility for introduction costs not yet decided

TropMed Pharma Consulting in consultation with three members of the PDP Access Steering Committee carried out the project over a six month period (July – December 2011). The methodology used involved the following steps:-

1. Each PDP identified a contact person for the project. They were then contacted by the consultant using a questionnaire. This asked for details of the nature and history of the project in question (to give context to the analysis) and for a detailed breakdown of the costs associated with introduction of the product. The breakdown of costs was aligned as far as possible with other analyses carried out for the Steering Committee.

[1] This paper was prepared by Ian Boulton (consultant) together with PDP leads Carla Botting (MVI), Elizabeth Gardiner (TB Alliance) and Claire Pharoah (IAVI) on behalf of the PDP Access Steering Committee which is now comprised of the following organizations: Aeras, Concept, DNDi, DVI, FIND, IAVI, iOWH, IPM, IVAC, IVCC, MMV, MVI, Population council , TB Alliance, & TBVI

2. The consultant then followed up with a telephone interview with the PDP to clarify any concerns from the PDP and to explore in more detail aspects of the project and its costs that were of interest based on the questionnaire responses.
3. The PDP was asked to identify key organisations that they had partnered with in establishing access to the product in question and a contact person in that organisation. The consultant then followed up with each of these partner organisations using the same questionnaire, and a follow-up telephone contact if that was thought to be necessary.
4. This process was continued with other relevant organisations being identified and the questionnaire and telephone contact was used to gather further information on the costs associated with each of the four cases.
5. TropMed Pharma Consulting presented the four case studies for discussion at the PDP Access Steering Committee's December 2011 meeting. This enabled the group to discuss costing beyond the four cases presented.

Conclusions

- The four projects presented an excellent opportunity to explore the diversity of costs. Due to the challenges noted below, the detailed costs are not presented here. However, the study did illuminate a number of important points related to costing; these are detailed below.
- Partnership structure and responsibilities are key drivers of access costs to the PDP. Partners may be close to 100% responsible for market introduction or the PDP may carry greater responsibility at launch, with the resulting cost implications. PDPs have different partnership structures for access, and even for a single PDP, the partnership structure can be different for different products. The cost of access is not generalizable as there are too many different roll-out models and variables to consider.
- The level of detail asked for on costs and timing of costs proved to be a major barrier for nearly all the PDPs and partner organisations. Many of the costs were the responsibility of the partners and did not come from the PDPs' own resources. Partner organisations were not prepared to spend time in detailed analyses of their costs and referred the consultant to published documents which either did not provide information in an easy to analyse way or covered costs not relevant to the project (such as development). Certain costs (*e.g.* Ph. IV trials or pharmacovigilance) were a particular problem where organisations were not prepared to share the actual costs. Confidentiality was also a barrier.
- The classification of cost elements both within the PDPs and the partners was not aligned and different PDPs classified cost elements differently between access and development.
- Under a partnership model, a key element of access costs for a PDP is staffing because management of the access partnerships is a critical role for PDPs. Important access elements such as advocacy on policy change, trouble-shooting at the country level, and other managerial roles have small cost implications beyond staff time and travel. Often PDP access staff work across multiple products, so allocation of time is another challenge when conducting a costing exercise. Although PDP staff costs were identified as an important consideration for access, PDPs have very small access staff costs relative to other organizations involved in access (e.g. CHAI has 500 people working on access).
- Although the PDP Access Steering Committee recognizes that many access activities take place in preparation for launch (i.e. prior to market authorization; see Timelines paper at http://pdpaccess.org/downloads/projects/full-papers/PDP%20Access%20Timelines%20Paper.pdf), this analysis focused on costs incurred *after* marketing authorization as this is a less well documented component of access costs.

- In one case (paromomycin), the product had not been launched and so the costs being incurred were maintenance costs to ensure the product was available for this market until it could be launched. While all PDPs are certainly planning for success, it's important to remember that delayed introduction also has costs.
- The costs collected in preparation of these case studies were actual costs. However PDPs might have been able to accelerate introduction if more resources had been available. This possibility was not investigated further in this study.
- Costs do not always reflect responsibility. Budgets may be housed in a partner, but the PDP may be responsible for ensuring quality execution of those activities. The PDP might be involved in managing elements of the access budget, but they were not in a position to claim a leadership role as this is often given to another partner (often WHO) that might have more global reach than a PDP.

Author Biography

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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