PDP Economics and Financing Discussion Paper

October 2010

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Abstract

Economics and finance issues are important, though often overlooked areas of a strategy to improve access for PDPs. By exploring the economic and financing aspects of a product during the earliest stages of its development, PDPs can improve the chances that an optimal product will be brought to market, demanded by countries and financed by donors.

Affordability is a critical component of economics and financing, driving adoption rates in countries and the likelihood of financing, both from countries and external donors. While pricing is dealt with in a separate paper, in practice, it is part of the economics and financing considerations, namely: (1) Is it worth the expense?; (2) Is it affordable?; and (3) How will countries pay for it?. While PDPs were unanimous in their message that affordability is the first priority, it is in fact intertwined with the effectiveness of the product, and the availability of resources to finance it.

A variety of additional factors will influence the adoption of product in target markets and need to be factored into economic and financing strategies. For middle-income countries, cost-effectiveness is particularly important, as these countries often finance the product domestically. In all markets, product financing is supported by early stage advocacy, demonstration projects and awareness-building with key policy-makers. In the poorest countries, global funding bodies often finance all, or a significant portion, of the purchase, making these partnerships the focus of PDP efforts. Lastly, a number of the activities herein could benefit from PDP collaboration, particularly those working in the same disease area to demonstrate the benefits of multiple interventions.

Paper Objectives

PDPs are understandably focused on bringing their products to market, the core of their mission. With resources stretched, this often means focusing on financing research and development costs, to ensure clinical trials can go forward, rather than worrying about the financing of a product that may be ten years out. Additionally, studies on the economics of a product often seem murky when so many of a product's attributes remain unknown. As a result, many PDPs delay both economic and finance activities until they are closer to market and the specifics of the product have been determined.

While a PDP's economic and financing strategy will evolve as the product is developed, consideration of these aspects need to begin in the earliest stages of a PDP's work. Economics and financing issues are key drivers of eventual product use and need to be considered in every

[1] Prepared by Andrew Jones (consultant) and Lois Privor-Dumm (IVAC) on behalf of the PDP Access Steering Committee, which is made up of the following organizations: Aeras, Concept, DNDi, FIND, iOWH, IPM, IVCC, MMV, PATH MVI, PDVI, and TB Alliance.

stage of work. In the context of this paper, economics encompasses work that deals with the relative value of the product. In other words, in a context of scarce resources, countries and donors cannot do everything. They must make choices, and prioritize among different interventions and products based on a balance of the benefits of the product relative to its cost. In doing so, the ability to secure financing for the product is critical. Financing encompasses the mechanisms and incentives that support the purchase of the product.

For example, waiting until the product is being licensed to begin financing discussions is often too late. These discussions need to begin early with associated activities such as advocacy and knowledge building to raise awareness of the disease and the potential impact of the product under development of a PDP. Then, a few years later, as proof-of-concept is demonstrated, and the cost of the product becomes clearer, more concrete funding discussions can go forward. One intervention will usually not solve the disease. Rather, a host of interventions, combined together will make the most impact. Approaching financing in this way is also an effective way to go forward, demonstrating the total impact on a disease with a host of several interventions, recognizing that in some cases interventions will be additive, while in other situations they may replace a current intervention.

Likewise, economic analysis, done right, can support effective prioritization in countries and in donors, ensuring the best value interventions are financed. In the early days of product development, this analysis seems far off. Nonetheless, analysis can be carried out under a range of scenarios. In addition, it can be an effective tool for pricing and negotiations with manufacturers. Analysis may show that at certain price ranges the intervention is very cost-effective, likely increasing demand and uptake, assuming that other criteria are met to establish need. At other higher price points, this may not be the case. In effect, CEA's of hypothetical products can also help define the minimum criteria a product should have to be considered worthwhile. In addition, the broader cost of many diseases, particularly as it relates to morbidity is often poorly communicated, but can be a very effective tool to support financing and uptake. Studies that provide this broader economic impact data can be very useful. In examining economics and financing issues, this paper had two objectives:

Economics: How do the various PDPs consider economic data around their product and what role does it play in introduction and access?

Financing: How have different PDPs approached financing of their product and what challenges have they encountered?

Overview of PDP Access Strategies

Economics

When PDPs tackle economic issues, they need to consider both product-specific cost-effectiveness (CE) data, and broader economic impact data (return on investment, impact on country health budget, ability to increase economic growth). The relative importance of these types of economic analysis is the subject of some debate. The majority of PDPs feel that countries have a limited interest in cost-effectiveness data, both because affordability concerns are paramount, and because the ministries often do not fully appreciate the value of such analyses and may dismiss the validity if performed by those outside of the country or if it does not contain locally gathered data. In many cases, PDPs believe data is more important to donors, who use the information to prioritize their decisions about which PDPs and products to finance. Some PDPs use it in a similar way, helping it drive prioritization amongst their product pipeline

in light of scarce R&D resources. It is also the case that CE analysis necessarily brings in an element of competition among interventions. All global health stakeholders would likely agree that increasing the overall funding envelope is the best way forward, but even with increased funding, choices must be made. Comparisons may also become a source of contention when studies are done using varying assumptions and are not directly comparable. CE analyses may also hold more value when used to evaluate various strategies (e.g., using a bundle of interventions or investing in particular programs) rather than to evaluate an individual product.

The lack of accurate cost or effectiveness data early on in product development means that proper analysis must wait until closer to licensure. PDPs have dealt with this by carrying out early broad analysis, which spans a range of cost and effectiveness values where possible and then, as effectiveness becomes clearer, developing models that span a range of possible prices, potentially as a tool to drive pricing discussions with industry. In addition to some of the specific work on cost-effectiveness, some of the PDPs have carried out activities to build capacity in country by developing regional centers of excellence, building interactive cost-effectiveness frameworks and supporting the development of decision-making tools.

Financing

At a very broad level, there is a debate within the PDPs as to the extent of their role in securing financing for their products. The majority of PDPs have focused on their main role of product research and development, carrying out activities to bring the product to market, including financing. Product financing strategies are divided into two categories: middle-income countries, where much of the product will be financed by the national governments, and low-income countries, where the product will need to be financed to varying extents by external donors. The majority of PDPs have had discussions with multilateral and bilateral donors to raise awareness of their disease and relevant product, sometimes in concert with others, although few have progressed into concrete funding discussions. Several PDPs however are considering a host of associated activities, which can lay the groundwork for financing. These activities include advocacy, rigorous demand forecasting, market research, demonstration projects and willingness-to-pay studies. In some cases, advocacy needs to start at a very broad level, as some policy-makers are completely unaware of some interventions. In general, the PDPs have focused on traditional types of financing rather than exploring innovative financing mechanisms.

What specific strategies have PDPs used?

PDPs interviewed had products in different phases of development; some were licensed or close to licensure, whereas many were only in early research. While the PDPs have employed a variety of strategies, based upon the type of product, it is useful to think about activities carried out at different times, based upon the development status of the product in question. In the section below, a proposed series of activities are grouped by timing, providing a "roadmap" for PDPs to consider these issues.

Early development (more than 6-10 years out from product availability):

Focus on price early: Almost all of the PDPs cited the primacy of affordability. For many countries, incremental cost-effectiveness can be important, but if the product is priced high relative to other interventions (even if it is more effective) this can be problematic. If a product is going to be significantly higher priced than other benchmark products, advocacy to build value needs to start earlier as it is not always feasible to achieve lower pricing for products that

require significant investment to develop. Early on, PDPs should carry out demand and market assessments and willingness-to-pay studies with policy-makers and/or the public (may still be important in private markets or middle-income countries to demonstrate that families value the intervention) that can set benchmarks and provide a framework for pricing. These types of studies also need to be quantitative, rather than many of the current qualitative assessments of price. These will also help frame discussions with manufacturers and donors.

Consider broader impacts of the product: Diseases such as malaria and TB have enormous societal impacts, causing lost work days, reduced economic productivity and act as a brake on poverty reduction. In most cases, analyses that consider these broader economic impacts have been done by recognized experts in the field, and the PDPs have used these analyses as supporting tools for highlighting the potential impact of their product. This includes work by STOP TB and Roll-Back Malaria. Although governments may be concerned more by direct costs than societal impact, they can often be used to build public support from stakeholders outside of the health sector.

Use cost-effectiveness internally as a decision-making tool: Several PDPs have used cost-effectiveness analysis primarily as an internal tool to prioritize between different products. Both MMV and IVCC have used the tool to evaluate their product pipeline and allocate resources effectively to support the best product.

Clarify the end goal for the PDP in product financing: Some donors stated that simply bringing a product successfully to market was not sufficient, and that underlying financing needed to be arranged to ensure the product would be effectively used in countries. Individual PDPs have approached this in different ways, but a strategic decision needs to be taken early to determine what the end goal is for financing so that the strategy and specific activities can be tailored appropriately. In some cases, an investment case was developed by the PDP (IVAC/PneumoADIP) to clearly define what was needed, the return on investment and what needed to happen support realization of demand, supply and financing.

Start planning the product financing strategy early and integrate it into R&D financing strategy: R&D financing impacts product financing. Many PDPs with products early in the life cycle (such as IAVI and IPM) are focused on securing the needed financing to complete clinical trials. In some cases however, PDPs noted their concerns about donors declining to support product financing if they have already financed development, necessitating a strategy that considers trade-offs and the need to consider the implications early on when deciding which donors to approach and how. An affordable price and a cost effective product may not be sufficient – a clear plan outlining demand generation and supply assumptions and potential impact may also be needed to convince donors of the need to fund. Target product profiles should also be communicated to manufacturers early. Ideally, this should be determined with country, donor and expert input to ensure that the minimum levels of critical product attributes are achieved and that the understanding if not achieved, financing would not be likely.

Pre-licensure (3-6 years from product availability):

Commission preliminary cost-effectiveness estimates and refine those estimates once phase 3 data are available: Doing this right usually involves commissioning the appropriate experts, often at universities, who have experience in carrying out economic evaluations on health products. PDPs should ensure the right strategies are being compared. In considering cost-effectiveness properly, it is not simply a matter of comparing the product in question to a "null"

strategy, but rather the current treatment. That is, what is the incremental cost and benefit to the new product over and above the status quo? In some cases this can be a challenge. IVCC notes that comparing insecticides to other forms of intervention against malaria can be difficult because the mode of use is so different. In addition, collaborating with other partnerships can be an effective way to increase the number of reviewers as well as potentially defraying costs. Aeras has worked with STOP TB on their taskforce that looks at economics and product profiles to share thinking and seek input on approaching these issues. Moreover, many interventions are not used in isolation, but rather are part of a series of interventions (i.e. for malaria one would use bednets plus vaccine plus spraying of insecticides) as the sum of the interventions is likely to produce a much more significant impact on the morbidity and mortality than taken individuals. Therefore, cost-effectiveness can be considered for a group of interventions, in addition to the product in question.

- **Ensure accurate effectiveness data**: There are two issues to be considered here: (1) effectiveness data is often not available until late in the product development cycle; and (2) effectiveness data needs to reflect real-world usage. The TB Alliance, in their consideration of new treatments, recognizes the importance of adherence. New treatments will have a shorter treatment course, which is likely to increase adherence and real-word effectiveness. Nonetheless, clinical trial data, however, do not reflect these realities: patients are blinded to the duration of treatment (so do not adjust their adherence behavior accordingly) and numerous additional interventions are in place to maximize adherence in both control and experimental arms. FIND has related issues; a new diagnostic for detecting TB will be more accurate, but only if used properly, so a significant part of effectiveness will depend on the training of healthcare workers. Sensitivity analyses can be particularly important to underscore the contribution of adherence on outcomes, particularly if effectiveness is highly dependent on proper use.

- **Ensure accurate cost data:** Many PDPs have products in early development where cost is unknown (TB Alliance, IPM) or uncertain (Aeras, MVI, IVCC, TB Alliance). In these cases, carrying out cost-effectiveness studies over a wide range of prices can help compensate for the uncertainty (this was done with pneumococcal vaccine). The product may include associated costs, such as the need for diagnostic services with a new tool (FIND) or the cost of administration of treatment (TB Alliance). Quantifying associated program costs becomes essential in understanding the full picture for financial planning purposes as well[2]. In addition, cost-effectiveness data needs to consider the costs averted through treatment such as saved hospital visits, additional drugs and associated costs. This data can be difficult to gather, and is difficult to quantify. For example, models sometimes consider that all cases will seek and receive full treatment, which is often not the case. This would have the effect of making the

[2] Possible costs to be considered beyond R&D include regulatory costs of preparing, submitting and managing dossiers for submission and managing market authorization, pharmacovigilance and other reporting requirements to regulatory bodies, phase IIIB/IV research and other regulatory clinical commitments program costs including shipping, distribution, storage, social marketing, ongoing market research and operational research, training, etc.

treatment appear more cost-effective than it actually was.

Ensure good strategic demand forecasts and clear target product profiles: Strategic demand forecasts are a critical component of securing financing, for without a clear rigorous estimate of anticipated demand, it is difficult to get manufacturers to make pricing commitments and for donors to evaluate the likely impact of their investments in terms of lives saved. These strategic demand forecasts should start earlier, as noted in the previous section, and it is critical they are tied to target product profiles that have been the basis of CE analysis and willingness to pay studies.

Develop different financing strategies for low and middle-income countries: While the product pricing varies between products handled by the PDPs, in many cases, it is unlikely that the poorest countries can fully finance the product in question. Many middle-income countries however may be able to finance the product if sufficient political will is generated. The result suggests an approach that is directed at external multilateral and bilateral donors for the poorest countries and at national governments for middle-income countries (MICs). Lower-middle income countries (LMICs) pose a particular challenge as they are often too poor to finance the product, but not resource constrained enough to receive support from external donors.

Engage early in policy discussions with key global financiers: For the poorest countries, there are often specific global financing bodies that could finance the product such as the Global Drug Facility, UNITAID, GAVI and the Global Fund for AIDS, TB and Malaria. PDPs have focused on discussions with these organizations, although many of the PDPs are at a very early stage. MVI early on determined that the poorest countries would need external financing for a malaria vaccine and engaged in a policy dialogue with GAVI and the Global Fund. They proposed a process of GAVI and the Global Fund to discuss principles of support for interventions that potentially could be funded by either organization.. In the coming year, MVI anticipates supporting a a series of steps between the two organizations to formalize the collaboration between them on financing of "shared" interventions. MVI initiated these policy discussions based upon phase 2b safety and efficacy data, and prior to the start of phase 3.

- **Innovative financing for health looks limited:** Some of the PDPs have explored innovative financing arrangements such as the AMC (Aeras and MVI). Others are waiting on the work that the Gates Foundation has funded with Research for Development that is looking at various policy solutions for innovative financing. Several experts (CGD, World Bank) however think that significant new innovative financing for health products is limited.
- **But emerging economies may be future donors:** New donors from emerging markets may play more of a role in the future financing. The AMC was unique in gaining financial support from Russia and the IFFIm from South Africa, in addition to traditional donors. Over the next decade as many of the PDPs bring new products to market, many of these countries will become wealthier and may be potential donors for new products.

Licensure and post-licensure (from 3 years before availability through the initial use of the product)

Build capacity to use cost-effectiveness analysis in countries: The TB Alliance noted that while some country decision-makers stated they would use CE data when making an introduction

decision, the survey indicates it has not been used as a key factor in the past. One of the options is to carry out capacity building and training in countries to inform and educate policy-makers (MVI & PneumoADIP/IVAC). IVAC used both an online Pneumococcal vaccine tool, open to all, developed by the University of Medicine and Dentistry of NJ and Johns Hopkins, and a model they supported for PAHO (PROVAC cost-effectiveness model), developed by the London School of Hygiene and Tropical Medicine. There are currently discussions to create a cost-effectiveness tool for Africa and Asia. Although there is value in determining the cost-effectiveness of an intervention, there may be even more value in the process itself which provides an evidence-based framework. MVI's framework (see annex) provides a useful framework to develop decision-making tools.

- **PDPs should develop and support country tools that provide a framework for evidence-based decisions on introduction:** Building capacity for countries in making evidence-based introduction decisions can provide a framework for securing financing. PneumoADIP/IVAC, MVI and FIND have carried out versions of these activities. External donors are more likely to provide financing if they feel a country has made an informed decision about the introduction of the product in question. Furthermore, ministries of finance can often respond better when they have a clear set of evidence, and a process by which the ministry of health has reached a decision on the need to introduce this product. Ensuring that local evidence is available for the context at hand is also important. The TB alliance is considering whether demonstration projects in 3-5 countries would be necessary to show that the product and new regimen could work.

Work with national governments to secure financing for procurement: Most PDPs have done very limited work that supports national governments in securing financing. PneumoADIP/IVAC has engaged in advocacy with key opinion leaders and decision-makers in country, MVI has supported the development of a decision framework, FIND has engaged with some countries specifically, such as Uganda, to help it find ways to support a regional east Africa lab project.

Bilateral donors can provide additional targeted support: Many of the bilateral donors support the global financiers mentioned earlier, but in some cases, specific associated support can be achieved through bilateral donors. FIND is working with donors including the CDC to support the related facilities for effective use of a diagnostic such as standardized labs. Given the technical nature of these investments, finding appropriately knowledgeable people at donors is difficult, and collaborating with others, such as WHO, to build awareness and understanding of the critical need for these facilities is important.

Explore financing of the product through the private sector: For malaria and TB treatments, this is a significant issue. The private sector for TB treatment is a particularly significant channel in Asia. If PDPs want to improve access globally, in particular regions, they will need to find ways to consider the specific challenges of distribution of products through the private sector.

- **Consider mechanisms to ensure marginalized populations have access to the product through the private sector:** With malaria treatment, the creation of the Affordable Medicines Facility for Malaria (AMFm) provides a subsidy to the manufacturer that reduces the patient cost from $6-$10 per course to about $0.20 to $0.50 per course. While in the public sector, this treatment may be provided free to the patient, in many cases, patients pay directly for the treatment themselves through the private sector. By reducing the price to patients, this mechanism increases access to the drug for the poorest people. The effectiveness of this mechanism is unclear, and currently being

studied by MMV and others. A similar mechanism for TB may not be advisable for drug sensitive TB, as private sector TB treatment is characterized by poor adherence, lack of monitoring and variable regimens of uncertain efficacy. (In addition, immediate access to treatment through the private sector is more essential for malaria than for TB). Adherence is not a real issue with malaria since it is only a three-day course. Should the global community be willing to recognize the private sector as a legitimate channel for TB treatment, it could improve adherence through the use of an AMFM type mechanism. For vaccines this is less of a challenge in low-income countries that may have access through universal programs. Lower-middle income countries have a particular problem, since they often have an income that puts donor financing out of reach for many of them. Those that have the highest rates of disease are generally least able to afford vaccines in the private markets.

Challenges PDPs face in addressing these issues

In broad-ranging discussions with the PDPs and other stakeholders in the field, a few challenges stand out. For economics, until national governments have greater capacity to analyze and consider cost-effectiveness data, this will remain primarily a "box-check" rather than a substantive input for decision-making. Some governments will not accept data that are not generated locally. The lack of cost and effectiveness data for early stage products is also a problem. For financing, many PDPs consider it difficult to work on securing financing for their product when proof-of-concept has yet to be demonstrated. Collaborating between PDPs to secure financing for their products remains a challenge given the potential for competing interventions. Increased evidence and advocacy is clearly needed to support a multi-pronged approach to fighting disease. Few if any diseases will be addressed by a single "magic bullet" and a unified approach when addressing donors may be helpful. Coordinated "asks" for funding must include treatment, prevention, diagnosis and system improvements. Another challenge is influencing donor priority. When such a situation exists, as in the case with Pneumonia, additional communication and education efforts may be beneficial to gain support of high-level actors (e.g. All Party Parliamentary Group on Pneumococcal Disease Prevention) and demonstrate the scientific community's support for the priority.

Feedback from donors and others

Conducting cost-effectiveness and other economic assessments were not thought to be the niche of PDPs. Rather donors felt that it was more appropriate that other appropriately skilled stakeholders carry out this work. But this should not be a reason to ignore CE data. Instead, PDPs, individually or in collaboration should track this information and commission it where needed, particularly collaborating with stakeholders in country to build capacity for this type of exercise. If there are considered to be significant gaps that could slow the introduction of the product into countries, then PDPs should consider commissioning the work, but it should not be a primary focus of the PDPs. Moreover, as the PDPs themselves noted, the issue of affordability and pricing was the primary driver, and needed to be the critical focus through a series of activities to ensure pricing that can promote access. Donors felt that many PDPs could do more extensive work on affordability that encompassed proper market and demand assessments. For TB in particular, the consumer perspective was cited as important. PDPs also need to recognize that CE analysis is a prioritization tool, and that informed decisions by countries on the basis of

CE and other evidence may result in some governments deciding the product is not appropriate for their setting.

With regard to PDP financing, particularly research and development, financing tends to be narrowly based on a few key donors and not sufficiently diverse. The diversity of the funding base needs to be a larger focus of PDPs. Moreover, understanding the business models of manufacturers better was cited as an area that PDPs could better analyze. In addition the concept of a target product profile should include issues such as cost-effectiveness and pricing, so that the product produced fits within a reasonable framework. More broadly though, donors spoke of the opportunities for PDPs to collaborate in constructive ways more regularly and more substantively. While discussions have taken place for some time, concrete joint activities beyond information sharing are somewhat lacking.

Potential future activities

While a detailed description of future activities is beyond the scope of this paper, and is specific to the different PDPs depending on the stage of their product, this paper suggests a few activities should be considered. For several of these activities, PDPs may be best served by combining their efforts. PDPs need to support capacity in developing countries through the training of policy-makers on CE models as well as decision-making tools (MVI). It may be worth considering the use of broader tools that look at the potential impact of an intervention in country (such as the LiST tool at Hopkins) which can be part of an approach to financing, by clearly delineating the benefits of the intervention in question – and, supporting evidence based decision-making. Incorporating broader economic benefits into the analysis is something that is gaining increasing traction. Working with others in the field, PDPs can pool resources to support studies that have a greater emphasis on societal benefits, including productivity and the impact on education. A workshop that looks at strategies for carrying out CE analysis with a range of possible cost and effectiveness data may help many of the PDPs that have products in early development. Furthermore, a series of workshops that develop strategic approaches to donors examining a disease-based approach that considers a range of interventions as a package may help increase the overall size of resources for these new interventions. In addition, coalition building may be appropriate to reduce inherent conflict between interventions and gain agreement that multiple approaches may be needed. Lastly, depending on the outcome of the Affordable Medicines Facility for Malaria (AMFm), PDPs may wish, through workshops or engaging with appropriate consultants, consider studies on how it might be used for other products.

Annexes

List of people / organizations interviewed
Formal Interviews (transcripts provided):

- William Wells (TB Alliance)
- Elizabeth Gardiner (TB Alliance)
- Lew Barker (Aeras)
- Peg Willingham (Aeras)
- Vicki Chen (Aeras)
- Alan Brooks (PATH Malaria Vaccine Initiative
- Holly Wong (IAVI)
- George Jagoe (MMV)
- Thomas Mertenskoetter (IPM)
- Tom McLean (IVCC)
- Damian Walker (IVAC, formerly PneumoADIP)
- Patricia Atkinson Roberts (Bill and Melinda Gates Foundation)
- Guy Stallworthy (Gates Foundation)
- Evan Lee (FIND)

Informal discussions:

- Ruth Levine (was CGD, now USAID)
- Susan McAdams (World Bank)
- Michel Zaffran (WHO/PATH)
- John Wecker (PATH)
- Logan Brenzel (World Bank)
- Orin Levine (IVAC, Johns Hopkins)
- Lois Privor-Dumm (IVAC, Johns Hopkins)

Economics and Financing Panel Discussion at PDP Access Meeting:

- Lois Privor-Dumm (IVAC, Johns Hopkins)
- David Evans (WHO)
- Tania Cernuschi (GAVI)
- Tom MacLean (IVCC)
- Alan Brooks (PATH Malaria Vaccine Initiative)
- Patricia Atkinson Roberts (Bill and Melinda Gates Foundation)

Additional background on cost-effectiveness

Economic issues around a drug, vaccine, insecticide or diagnostic are focused primarily on efficiency, namely, does the product represent an efficient investment? There are two broad approaches: cost-benefit and cost-effectiveness analysis. Cost-benefit studies are constrained by the challenges in measuring health benefits. Trying to quantify health benefits with regards to economic productivity can be difficult; although increasingly there are efforts to look at issues such as lost work time, lost school time and corresponding economic productivity, but these are not carried out by the PDPs but other partnerships (i.e. STOP TB, Roll Back Malaria). In its purest sense, cost-benefit analysis would allow the comparison of health interventions to other sectors, through the use of a single number, representing the cost-benefit value of an intervention. In reality, while some of these broader economic benefits are being measured, the achievement of true cost-benefit analysis in health is unlikely to happen soon. However, some of the PDPs interviewed are considering ways to measure these broader economic benefits as part of their efforts.

Cost-effectiveness analysis looks at a specific medical condition and examines the costs of alternative forms of treatment. While this avoids the need to measure benefits, evidence on the effectiveness of many treatments is limited, particularly for the PDPs in question, since trials are ongoing, and in many cases, effectiveness has yet to be determined. Cost-effectiveness is often expressed as either QALYs or DALYs, so that effectiveness can be quantified through a consistent measure. Decision-makers look at the marginal cost-effectiveness of a new treatment versus an existing one, which is to say how much MORE effective will a treatment be than the old one, rather than simply looking at a new treatment versus nothing, which will not provide an accurate measure of its cost-effectiveness. While determining effectiveness is a complex task, the cost of the intervention can often be unclear in early trials. For some of the PDPs, the manufacturing cost of the end product is simply unknown. Part of this can be dealt with through appropriate sensitivity analysis, carrying out cost-effectiveness analysis over a wide range of potential costs. The WHO uses the benchmark of GDP per capita, as compared to year of life gained. When the cost per year is less than GDP per capita, the product is highly cost-effective; when it is between one and three times GDP per capita, it is cost-effective; and when it is more than three times GDP per capita it is not cost effective.

In general, vaccines, as compared to drugs, are much more cost-effective, since they prevent an illness from occurring through a simple early event, rather than treatment which tends to take place over a longer time period, and includes issues of adherence, which differ markedly from a clinical trial setting to the real world. Diagnostics are more complex. In practice, this means that cost-effectiveness studies for diagnostics and drugs are more complex and potentially more critical in making a decision.

For information on IPM's / LSHTM modeling work microbicides please see:

http://www.ipmglobal.org/pdfs/english/ipm_publications/2008/IPM_PolicyReport%28English%29.pdf

For PneumoADIP's Online tool for cost-effectiveness see:

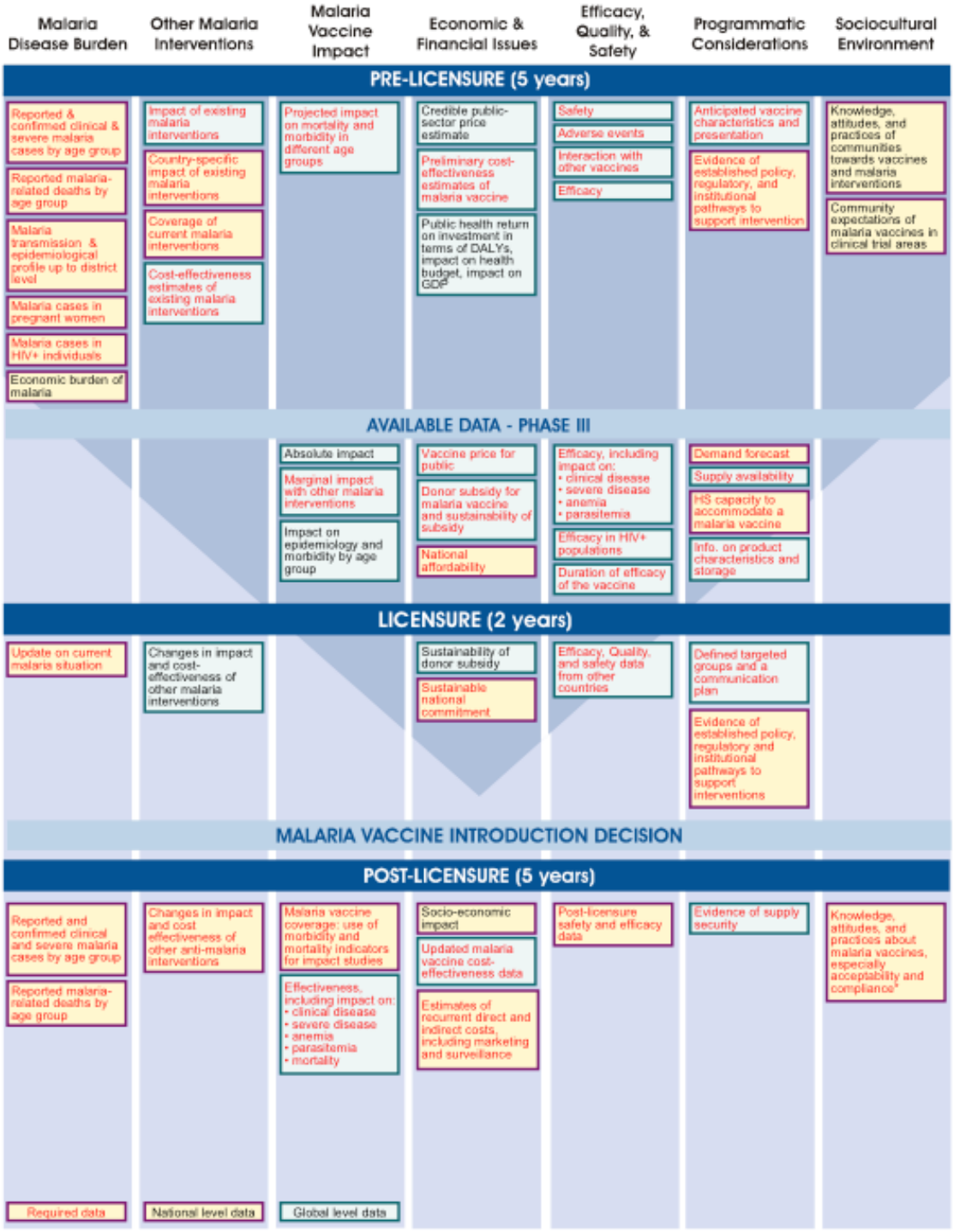
http://preventpneumo.org/data-tools/Cost_Effectiveness_Model.cfm

MVI decision-making framework

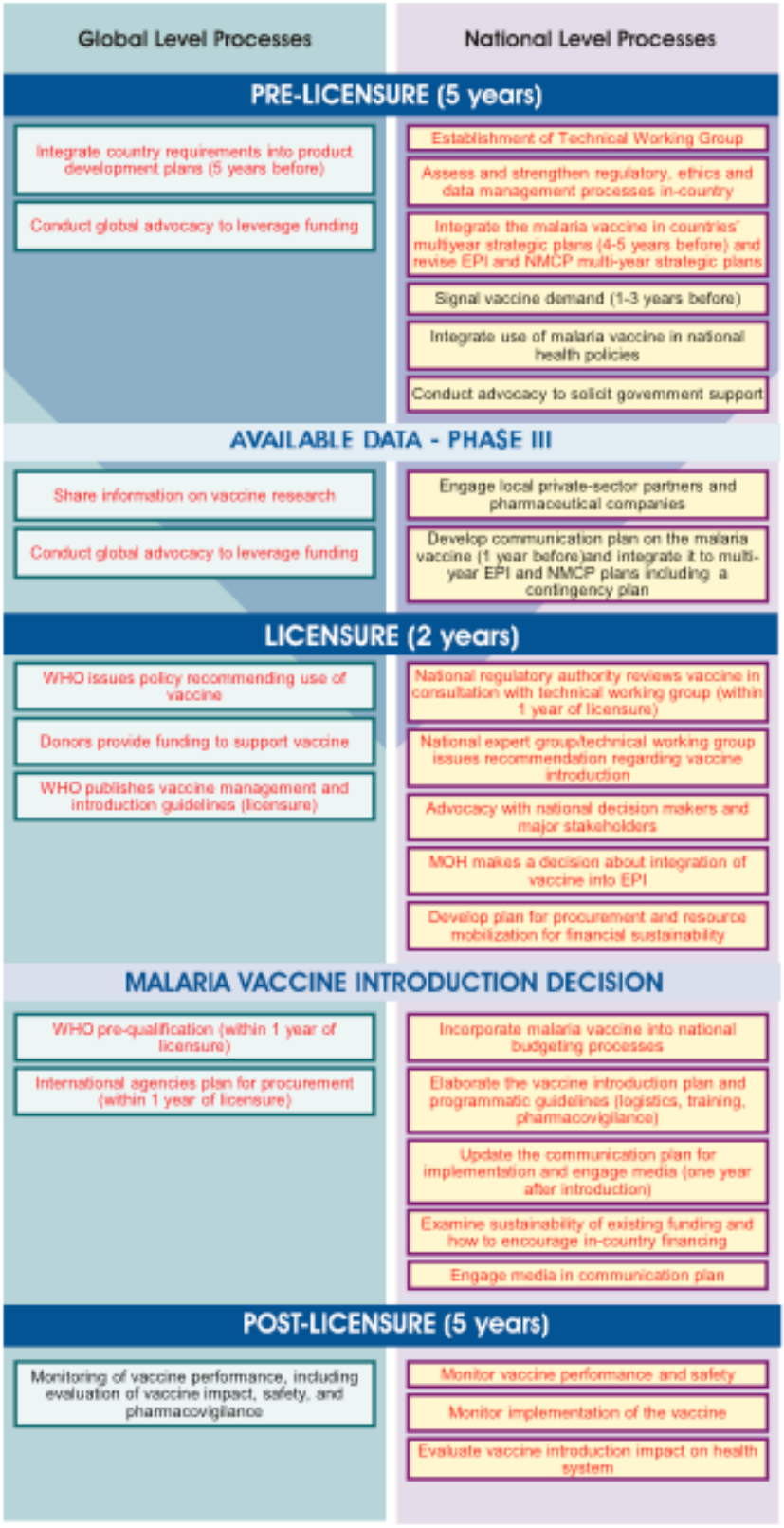
See next page, particularly section marked in red.

(Source : http://www.malvacdecision.net/)

Regional Malaria Vaccine Decision-Making Framework – Data



Regional Malaria Vaccine Decision-Making Framework – Process



Authors Biography

Andrew Jones is currently the Manager of Malaria Financing at the Clinton Health Access Initiative (CHAI). In this role he oversees a team of analysts working in four countries that have been successful in controlling malaria at low levels. This work is supporting Ministries of Health and Finance to cost out their malaria program and develop financial sustainability plans that provide a roadmap for financing malaria control programs in these countries over the next ten years. Using new sources of financing, including domestic sources, and combining them with innovative mechanisms, the aim is to diversify and stabilize malaria program financing. These plans are being put forward at the African Leaders' Malaria Alliance summit in September in New York.

From 2008 to 2010, Andrew was a director at Adeni Consulting, Inc. carrying out consulting projects within the international public health area, with a focus on vaccines and immunization. This has included includes work with industry to look at the options for financing a flu stockpile, developing a strategic plan for the WHO Immunization and Vaccines Research team, working with the Gates Foundation to look at how to ensure effective introduction of rotavirus and pneumoccal vaccines and working with MSF on a strategy to influence the vaccine markets.

Previous to joining Adeni Consulting, he worked for five years at the Global Alliance for Vaccines and Immunization (GAVI) where he worked on health policy issues, focused on new vaccine introduction. Jones' initial work with GAVI was on innovative financing instruments and he played a key role in GAVI's work to develop and launch the International Finance Facility for Immunization. He has worked on Advanced Market Commitments (AMC) with the World Bank, taking the initial work of CGD and others into a pilot for a pneumococcal vaccine. In addition, he coordinated the work of GAVI's supply strategy group and was the focal point for vaccine supply and procurement activities at the GAVI Secretariat.

Before GAVI, Jones worked for the Canadian International Development Agency (CIDA) on health systems and immunization issues as a health policy adviser. This included work on community-based financing of healthcare as well as leading a corporate initiative to ensure that social development funding remained an integral part of CIDA programming.

Jones also worked as an adviser to one of the senior government whips in the U.K. House of Commons, where he provided policy advice on healthcare issues. Jones' original background is in science research where he did graduate work on human genetics. Following that, he completed a joint master's degree with the London School of Economics and the London School of Hygiene and Tropical Medicine in health policy planning and financing.

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