

Barriers to access: An assessment of stakeholder risks and incentives in the value chain for Artemisinin Combination Therapy (ACT) treatments

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Background

Artemisinin combination therapy is being widely advocated as a first line treatment for malarial in Sub-Saharan Africa and other parts of the world where traditional chloroquine therapies are no longer effective. Today, donors are committing almost \$885 million annually to fight this disease; this is projected to more than double over the next two years to almost \$2 billion annually (Figure 1). In a ten-year period, funding for malaria will increase ten-fold - a dramatic scale-up by any standards.

Half of malarial funding is projected for treatment, primarily through ACTs. Various bilateral and multilateral donors assist countries in procurement of treatments, but serious barriers prevent increase in patient access. These barriers are related to the dysfunctional global health value chain of ACTs and by the risks and incentives faced by a range of stakeholders in this value chain, from manufacturers to health service providers. This analysis uses value chain expertise to examine the ACT market by systematically analyzing how risks and rewards are shared among stakeholders in the public sector value chain for ACTs and proposes ways to correct imbalances which will result in increased access to these life saving drugs.

Methods

We identified a set of common risks faced by key stakeholders in the value chain using standard economics and value chain analytic frameworks as our starting points. We categorized major risks into four main groups: supply-side risks; demand side risks; regulatory and quality risks; and logistical risks.

To assess the risks and incentives faced by each stakeholder, we interviewed key decision makers in a variety of organizations engaged in the value chain, such as the WHO, the Global Fund, the World Bank, Roll Back Malaria Partnership, Novartis, Sanofi-Aventis, Medicines for Malaria Venture, using quasi-structured phone and in-person interviews.

Based on these interviews we created risk and incentive maps which were validated with a diverse group of 26 global health experts through the Global Health Forecasting Group, convened by the Center for Global Development.

Findings

1. The ACT value chain consists of a large number of uncoordinated stakeholders, and this environment is rapidly becoming more complex. This increases risk and uncertainty for individual manufacturers and other global players, making it costlier for them to stay in the market.
2. A map of the risks faced by key stakeholders shows a sharply skewed risk distribution resulting in suppliers and patients bearing a disproportionate share of market risks and the consequences of these risks. This results in a situation where the parties that suffer the most are not in the best position to act, while the parties in the best position to act do not suffer enough to invest substantially in addressing the problems.
3. The skewed and lopsided risk distribution leads to misaligned incentives resulting in an inefficient market that does not maximize access to ACTs.

Policy Implications and Recommendations

Funding agencies and national buyers must actively contribute to reducing overall market risk and sharing in the remaining risk. This can be done through the creation of a Global Health Infomediary which will help to reduce overall uncertainty in the market, and through the adoption of risk sharing contracts between suppliers and buyers. Ultimately, there is a need for more sustainable funding and fundamental changes in the willingness of funders and technical agencies to assume risk and effectively intervene in the market.

Conflict of interest

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Introduction

More than 1.2 million people die each year from malaria, most of them children under the age of six.¹ The global community has recently awoken to the tremendous avoidable suffering caused by this disease, and today the fight against malaria is garnering significant donor funds. In 2002, donors committed approximately \$200 million annually to fighting malaria. Today, that number is estimated at \$885 million and is projected to more than double over the next two years to almost \$2 billion annually (Figure 1). In a ten-year period, funding for malaria will increase ten-fold - a dramatic scale-up by any standards.

Almost half of the monies targeted for malaria will be focused on treatment, specifically through the purchase of Artemisinin Combination Therapies (ACTs), the drug of choice recommended by the World Health Organization (WHO). This drug replaces chloroquine-based and other therapies, which, due to resistance, are no longer effective in large regions where the disease is endemic; ACTs are a preferred formulation to artemisinin-only formulations, which are likely to induce the development of resistance more quickly than the combination therapy. While funding, and therefore potential market purchasing power for buying ACTs, has dramatically increased, access to ACTs on the ground has been much slower than expected. In 2004, the WHO projected that 120 million treatments of *Coartem*®, the only WHO pre-qualified ACT, would be needed by the end of 2006. The number actually ordered by countries till the end of 2006 was only half of this.² Given logistics, wastage and distribution bottlenecks, considerably less quantities of the drug have actually reached the patients who need it. The recent performance monitoring report of the Global Fund to Fight AIDS, TB and Malaria (Global Fund), currently the largest funding source for purchase of ACTs, shows that grants focused on providing anti-malarial treatments reached only 77% of their targets. This falls well below achievements in the corresponding indicators for TB, (which achieved 101% of targets) and HIV/AIDS, (which achieved on average of 89% of targets.)³ Procurement and distribution of ACTs is specifically cited as an area of weakness in this report.⁴

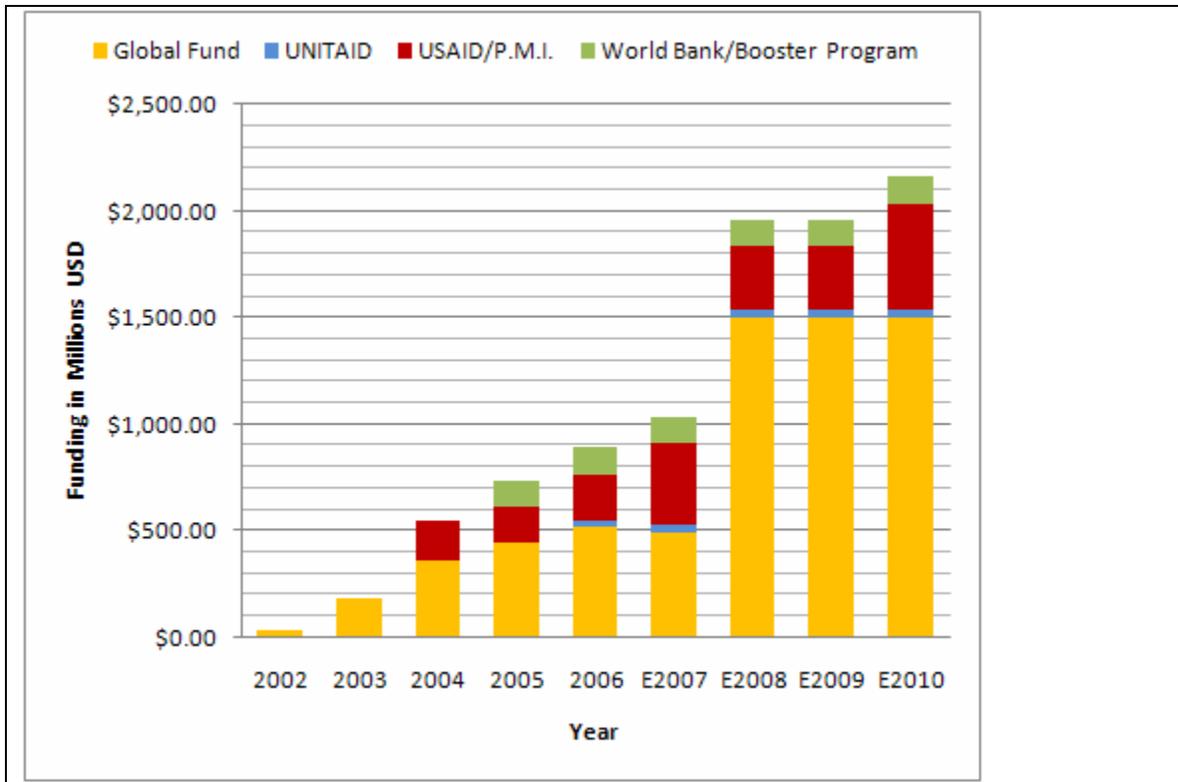


Figure 1: Historical and Projected Levels and Sources of Malaria Funding^{5, 6, 7 and 8}

It is difficult to know how much of the lag between funding and scale up can be attributed to the relative newness of the market, because the global health community has a limited understanding of how the market for anti-malarials in general, and ACTs in particular, actually functions. Past analyses of bottlenecks in achieving access to therapies have focused on individual aspects of the problem such as slow procurement processes, lack of skilled health workers, or poor drug quality.⁹ Lacking is a systematic review of the underlying distortions in the *value chain** caused by misalignments in risks and incentives, which must be addressed in a coordinated manner to ensure that monies being committed to treatment save the maximum number of lives.

This analysis uses value chain expertise to examine the ACT market by looking at the way in which risks and rewards are shared among the stakeholders in the public sector value chain for ACTs.

* We define value chain as the set of interrelated activities that are involved in developing, manufacturing and delivering the product or service to the customer (i.e. from product development to retail distribution logistics.)¹⁰

The analysis focuses on the global players in the market and does not examine how the value chain works within individual countries. This focus allows us to identify ways in which global actors, such as funders and technical agencies, can alter the balance of risks and incentives to drive faster and wider access. Because of their considerable leverage, the operational policies and guidelines of these agencies have a significant impact on improving ACT access on the ground. This is of particular relevance since a new global subsidy for ACTs is being considered which is expected to call for large, new funding commitments, and will rely on even less well understood, private sector markets for increasing access.¹¹

The allocation of risks in a value chain determines its effectiveness, efficiency and long term sustainability.¹² A cornerstone of research on the performance of multi-agent systems is the relationship between risks and incentives¹². A poor allocation of risks leads to misaligned incentives, which in turn lead to behaviours by individual stakeholders that compromise effective delivery across the entire system.

We define risk[†] as an event that has some uncertainty of occurrence (a probability of occurrence between zero and one) and usually a negative consequence of occurrence.¹³ An underlying tenet of fair risk allocation suggests that the actor who is in the best position to manage or mitigate a risk should assume that risk. If the stakeholder who bears the greatest risk is the one least able to manage it, or if those who are in the best position to act do not suffer enough risk to invest in mitigating it, then misalignments occur which result in poor performance of the value chain.¹⁴

We define an *incentive* as an explicit or implicit reward obtained by an agent for engaging in a specific activity, usually designed to encourage the agent to perform that activity. While each stakeholder is influenced by both implicit and explicit incentives, implicit incentives are indirect and require that the stakeholder exert effort (often considerable effort) to engage in a behaviour that is not directly supported by an explicit

Supply Side Facilitators fund late-stage research, provide information pertaining to long term market potential, fund clinical trials, help the manufacturers to obtain better rates from Contract Research Organizations and facilitate relationship of smaller manufacturers with international regulatory and technical organizations.

Manufacturers are responsible for the production and sale of ACTs to the mass market. Qualified manufacturers have products that are PIC/S approved and non-qualified manufacturers currently do not have PIC/S approval for their products.

Quality Regulators are responsible for ensuring the quality of the drug. In this category, we also consider internal quality standards of funding agencies that guide which manufacturer recipient countries can buy from. In addition to being approved by a quality regulator, many buying countries have their own national registration process in which drugs must be registered by a national entity.

Global Technical Agencies are responsible for setting treatment norms and guidelines.

Funding Agencies give grants and loans to malaria control programs.

Donors are comprised of countries and philanthropic foundations that give money to funding agencies.

Procurement Agents assist countries in ordering and purchasing ACTs.

Logistics Providers handle shipping and transport of ACTs from the manufacturer to the buying country, and assist in distributing it throughout the buying country.

National Public Buyers are the government entities responsible for purchasing ACTs for the public sector.

[†] Risk remains an elusive concept and various definitions with varying degrees of formal rigor continue to exist. We choose to work with a definition that is general and perhaps easier to comprehend.

reward. For example, while everyone would like to see a decrease in risk for malarial morbidity and mortality, it is explicit incentives that drive decisions about whether an individual stakeholder will take on additional risk to achieve or contribute to this objective. While implicit incentives can motivate behaviour, they are more likely to influence the behaviour of particular individuals rather than systematically influence the behaviour of an organization. For example, strategic heads of agencies may be motivated by implicit incentives for social responsibility but in the absence of supporting explicit rewards for this behaviour, tactical and operational decision makers may not be willing to commit resources and time, to this goal.¹⁵

A system with many independent stakeholders, functioning in a loose network, works well in achieving its objectives if the incentives of all parties are aligned, towards a common goal.¹² In the case of ACTs this means that the risks, costs, and rewards of doing business should be distributed fairly across the network towards the common goal of improved access. Each stakeholder should have an explicit incentive to engage in activities that support the goal of increased access.

This is particularly critical in the complex and often confusing global health environment which consists of donors who are subject to a multitude of national political pressures; funders such as the Global Fund, who rely on annual funding rounds and must balance the conflicting objectives and political priorities of multiple donors; countries who don't pay directly for products but take multiple actions to get access to money and drugs; manufacturers who often sell their products at cost and therefore participate in the market more for public relations than for profits; and a host of technical agencies and intermediaries who play multiple, sometimes ill-defined roles in the value chain. Access to treatments is further constrained by dysfunctional country health systems spending a few dollars per person on health care and delivering care to the poor and most vulnerable. In this environment, creating a well functioning market is a particular challenge.

The first section of this paper defines the methodology used to conduct the analysis, the second outlines key findings, and the final section proposes actions that could be undertaken by policy makers to correct underlying incentive misalignments.

Methodology

A study to enhance access of ACTs to patients needs to be based on a careful understanding of the stakeholders in the ACT value chain, the role of each stakeholder, stakeholder's ability to mitigate the risks in the value chain, and their explicit incentives to improve access.

We began our analysis by identifying a set of common risks faced by key stakeholders in the value chain. A study of the existing literature did not reveal any widely accepted risk classification for analysing global health markets. Hence, we developed a simplified classification that could be easily understood by the multi-disciplinary groups involved in global health, using standard economics and value chain analytic frameworks as our

starting points. We categorized major risks into four main groups: supply-side risks; demand side risks; regulatory and quality risks; and logistical risks.¹⁶

In analysing incentives, we focused on *explicit incentives* i.e., those in which a stakeholder clearly achieves better results on its key performance indicators by carrying out a particular activity.

Using this framework, we mapped risks and incentives by stakeholder using a “risk and incentive audit”. A similar methodology has been used in previous studies of health care value chains.¹⁷ Private sector companies across various industries with disintegrated value chains and multiple stakeholders also use these of audits to better understand poor performance in their chains.

To assess the risks and incentives faced by each stakeholder, we interviewed key decision makers in a variety of organizations engaged in the value chain, such as the WHO, the Global Fund, the World Bank, Roll Back Malaria Partnership, Novartis, Sanofi-Aventis, Medicines for Malaria Venture. We used quasi-structured phone and in-person interviews rather than formal surveys because these provide greater flexibility, allowing the respondent to bring up new issues; such flexibility is much more likely to yield new hypotheses which is important for this type of analysis.^{18, 19, and 20}

In total we conducted 19 interviews over a period of 3 months between October 2006 and January 2007.[‡] Interviews lasted from 30 to 90 minutes as the respondents were not required to stay within the standard questions and were permitted to include other related responses if these were perceived by the interviewer to be beneficial to the research. Respondents were asked to identify the role of their organization in the area of malaria treatment with specific emphasis on ACTs. Questions were framed to infer the nature and extent of risks undertaken by each constituent. To avoid errors and inconsistencies, all interviews were conducted by the investigators themselves with at least one of the investigators being common to each interview. Whenever possible, responses were cross validated in subsequent interviews, and with other stakeholders.

Based on these interviews, we classified the risks undertaken by each constituent in each category, into four levels; no risk, low risk, moderate risk and high risk. This risk allocation was then used to determine the incentives for key activities that were considered fundamental to improving access. The initial risk and incentive maps were validated by the Global Health Forecasting Working Group consisting of over 26 individuals with a range of expertise from industry, public-private partnerships and funding agencies.²¹ Based on the feedback, the risk and incentive maps were modified to improve comprehensibility and, in some cases, to better reflect perceived risk allocation.

[‡] A list of interviewees can be obtained from the authors upon request. It is not included due to space constraints.

Findings

Our analysis yielded three major findings.

- 1.) **The ACT value chain consists of a large number of uncoordinated stakeholders and this environment is rapidly becoming more complex.** In the past four years, the public sector market for ACTs has been relatively simple, with one large funder (the Global Fund) providing 60-70% of purchasing power for ACTs, one pre-qualified producer (Novartis with the drug *Coartem*®) and one large procurement agent (the WHO). This landscape will change dramatically over the next 24 months with more manufacturers entering the ACT market, a diversity of new funders, several new procurement agents who will be able to obtain the drug on behalf of countries, and an array of new intermediaries (Figure 2).

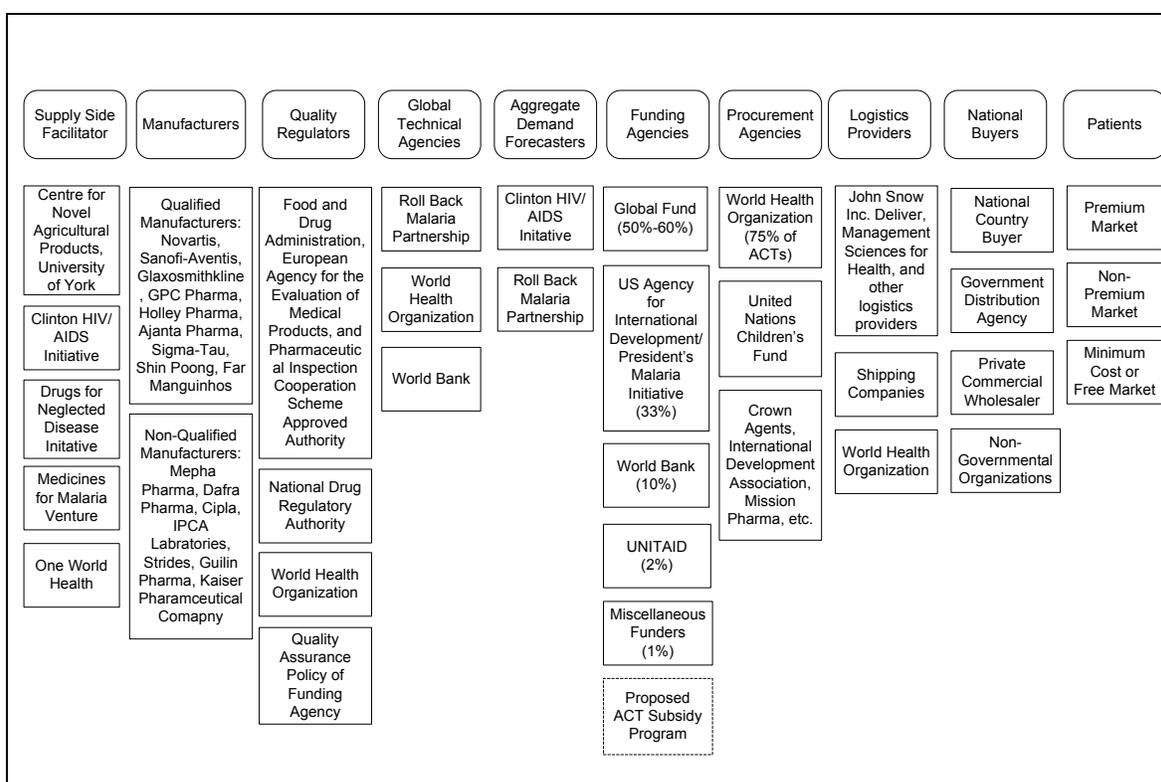


Figure 2: Projected Stakeholder Map of the ACT Value Chain

This change is driven on the supply side, by various product development partnerships (e.g. Medicines for Malaria, One World Health), which have been investing in R&D for new malarial drugs that will shortly be coming on the market. It is also the consequence of a maturing market where suppliers see the potential of investing and funders see the opportunity to make progress against a leading cause of mortality. However, with these additional choices comes greater uncertainty in demand and supply, increasing the underlying risks for individual suppliers and buyers.

2.) A map of the risks faced by key stakeholders shows a sharply skewed risk distribution resulting in suppliers and patients bearing a disproportionate share of market risks and the consequences of these risks. This results in a situation in which the parties suffering the most are not in the best position to act, while the parties in the best position to act do not suffer enough to invest substantially in addressing the problems. Figure 3 provides a risk allocation map by key stakeholder. The map can be read in several ways: looking across the rows shows the extent to which each stakeholder bears a particular risk. Looking down the columns gives a picture of which stakeholders are bearing the greatest risks across the spectrum. The darker the square, the greater the risk borne by that stakeholder. Fair risk allocation means that the party in the best position to control a risk should bear the greatest burden for that risk.²²

| | No risk | Moderate Risk | | | | | | | | |
|-------------------------------------------|----------|---------------|--|------------|--------------------|---------------------------|------------------|--------------------|------------|------------|
| | Low Risk | High Risk | | Suppliers | Quality Regulators | Global Technical Agencies | Funding Agencies | Procurement Agents | Buyers | Patients |
| SUPPLY-SIDE RISKS | | | | | | | | | | |
| Excess Inventory Risk | | | | ██████████ | | ██████████ | ██████████ | | | |
| Excess Capacity Risk | | | | ██████████ | | ██████████ | | | | |
| Shortage Risk | | | | | | | | | | |
| Financial | | | | | | | | | | |
| Morbidity and Mortality | | | | | | | | | | ██████████ |
| Reputational | | | | ██████████ | | | ██████████ | | | |
| DEMAND-SIDE RISKS | | | | | | | | | | |
| Change in Price Risk | | | | | | | | | ██████████ | |
| Grant Approval & Disbursement Timing Risk | | | | ██████████ | | | | | | ██████████ |
| Sustainability of Funding Risk | | | | | | | ██████████ | | | ██████████ |
| REGULATORY AND QUALITY RISKS | | | | | | | | | | |
| Counterfeit Product Risk | | | | | | | | | | ██████████ |
| Safety of Approved Drugs Risk | | | | ██████████ | ██████████ | | ██████████ | | | ██████████ |
| Lack of Approved Drugs Risk | | | | | ██████████ | | | | | ██████████ |
| LOGISTICAL RISKS | | | | | | | | | | |
| Non-Timely Delivery Risk | | | | | | | | | | ██████████ |
| Losses and Leakage Risk | | | | | | | ██████████ | | | ██████████ |

Figure 3: ACT Value Chain Risk Map

Looking at the map by stakeholder shows that most of the risks in this value chain fall to suppliers and patients. Suppliers bear the greatest burden of financial risks for excess capacity because under current contracting arrangements they do not receive purchase commitments, but must have inventory available to fill orders as they are placed. The consequences of excess supplier capacity are higher prices, due to greater capital and operating costs.

In the case of shortages, patients ultimately bear the greatest risk of increased morbidity and mortality. Suppliers bear a significant reputational risk for shortages, which can have a strong negative impact on their sales and profitability. Research shows that companies face decreasing sales due to adverse publicity.²³ Specifically for pharmaceutical manufacturers, a tarnished social responsibility image may lead to greater pricing pressures from consumer groups, an inability to recruit patients for

clinical trials, poor prescribing behaviour from physicians, and damaged relationships with national and international regulatory authorities. These factors together can lead to plummeting shareholder value.²⁴

On the demand side, the most acute risks are for public sector buyers, who assume risk for mismatches between the timing and disbursement of grants on one hand and the needs of patients on the other. They also bear the greatest risk for sustainability of donor funding. In the case of malaria treatment, timing issues may be just as important as overall sustainability because of the seasonality of malaria, the short shelf life of ACTs (often less than 18 months by the time they reach the country) and the long manufacturing cycle which requires that accurate orders are placed well in advance of expected usage.

In the area of regulation and quality, we find that risks are lopsided. Quality regulators are at a much higher risk if drugs they approve turn out to be unsafe than if drugs are not moved quickly through approval processes. This dampens market competition, making higher costs and shortages more likely.

Notable in this risk allocation is that funding agencies bear very little risk. Unlike funders in developed markets who share risk with suppliers through purchase guarantees and other contracting mechanisms, in general in the global health value chain, funding agencies and intermediaries such as procurement agents, bear virtually none of the risks. By contrast, in a typical pharmaceutical value chain in developed countries, funders (such national healthcare payers), wholesalers (e.g. procurement agents), and buyers share more equally in the financial and reputational risks of the market.

The consequences fall to patients and communities, who suffer the health impact of unbalanced risk sharing.

3.) **The skewed and lopsided risk distribution leads to misaligned incentives resulting in an inefficient market that does not maximize access to ACTs.**

The goal of the ACT value chain is to provide patient access to a steady supply of quality products. The incentives map (Figure 4) shows whether each stakeholder has a definite incentive, a clear disincentive or neither one, to engage in a particular behaviour that will promote this goal. It is important to note that this map depicts only the *explicit incentives* of each stakeholder. We recognize that implicit or indirect incentives may be inducing a particular stakeholder to engage in activities that promote access; however, we only consider these as incentives if they explicitly link to the risks assumed by that stakeholder.

| | Suppliers | Quality Regulators | Global Technical Agencies | Funding Agencies | Procurement Agents | National Buyers | Patients |
|-----------------------------------------------------------|-----------|--------------------|---------------------------|------------------|------------------------|-----------------|----------|
| SUPPLY-SIDE | | | | | | | |
| Maintain a competitive/ efficient supply market | ↓ | - | - | - | - | - | - |
| Invest in accurate forecasting | ↑ | - | - | - | ↑ | - | - |
| DEMAND-SIDE | | | | | | | |
| Keep retail ACT prices low | - | - | ↑ | ↑ | - | - | ↑ |
| Improve predictability of grant approval and disbursement | ↑ | - | - | - | - | ↑ | - |
| Enhance the level and sustainability of funding | ↑ | - | ↑ | ↑ | - | ↑ | - |
| REGULATORY AND QUALITY | | | | | | | |
| Plan and anticipate changes in treatment guidelines | - | - | - | - | - | - | - |
| Ensure regulatory compliance and safety | ↑ | ↑ | - | ↑ | - | ↑ | ↑ |
| Expedite regulatory approval of new drugs | ↑ | - | - | - | - | ↑ | - |
| LOGISTICS AND DISTRIBUTION RISKS | | | | | | | |
| Ensuring cost effective and timely delivery | ↑ | - | ↑ | ↑ | ↑ | ↑ | ↑ |
| | ↓ | Disincentive | | - | Indifferent | | |
| | ↑ | Incentive | | - | Potential Misalignment | | |

Figure 4: ACT Value Chain Incentives Map

Major misalignments are shaded. As the map shows, suppliers have a disincentive to maintain a competitive and efficient supply market because, as illustrated in the risk map, they bear all the financial risk of overcapacity and are keen to protect their investments. On the other hand, while a stable and healthy supply market for ACTs is in the broader interest of funding agencies and global technical agencies, there are no clear reward structures for them to exert effort to increase market competition. Access would be better served if stakeholders had positive incentives in this area or, at the very least, if suppliers could pass on some of their risk for excess capacity to other stakeholders, reducing some of their strong negative incentive.

Accurate demand forecasting is crucial for ACTs because they have a long production cycle (14 months) and it takes almost three years to ramp up manufacturing capacity for these drugs. A short shelf-life further amplifies the need for accurate forecasts. However, the incentive map demonstrates that most stakeholders do not have explicit incentives to invest in generating accurate forecasts of demand primarily because none of them bears the financial risk of overcapacity or shortages. Demand forecasters, in particular, bear no risk for poor forecasts. This may be one cause of the inaccuracies observed in the forecasts for *Coartem*®, which resulted in shortages in 2004, followed by large surpluses and excess inventory in 2005 and 2006.²⁵

On the demand side, national buyers do not have explicit incentives to keep the retail (at the point of treatment) price of ACTs as low as possible, because they often rely on cost recovery from drugs to fund their health systems delivery capacity. Also, the risk they bear for patient safety means that in the absence of clear guidelines on the safety of self diagnosis and treatment of malaria, they are hesitant to encourage the low cost distribution of ACTs, particularly through private sector retailers.

Another critical area of misalignment is the absence of a clear incentive for funding agencies to make the timing of disbursements more predictable. Many interviewees attributed inaccuracies in global demand forecasting for ACTs and the resultant mismatch of demand and supply to uncertainty in the timing of grant approvals and

disbursement. Clearly, the number of grants approved and disbursed in a given time period are key performance indicators for funding agencies, and they have an explicit incentive to increase the number of well-performing grants awarded. However, since they do not bear any of the risks arising from poor matching of demand and supply, they have no explicit incentive to improve the predictability and timing of grant disbursements to better match country supply needs. The same is true of technical agencies as they work with countries to anticipate and plan for changes in treatment guidelines and essential drug lists. Providing clearer incentives in both these areas would be of great benefit to countries in ensuring adequate supply to achieve access targets.

Finally, as pointed out in the risk map, quality regulators are at much higher risk if the drugs they approve turn out to be unsafe than if the drugs are not moved quickly through the approval and pre-qualification processes. This lop-sided risk results in their not having an explicit incentive to expedite regulatory approval of newer forms of ACTs or quickly pre-qualify new manufacturers for existing drugs. Balancing the risks in this case could result in greater access and lower prices.

Conclusions and Policy Implications

Ensuring access to medicines requires more than money—it requires a market in which incentives are aligned so that each stakeholder acts to maximize the chance that the right drug will be provided to the patient at the right price, when and where it is needed. Aligning incentives for greater access, in turn, requires that risks in the market are more evenly shared among stakeholders. In the long run, stakeholders who bear disproportionate risks but are not adequately compensated will either leave the market or engage in behaviour that will threaten its viability.

The structural complexities of the ACT value chain and the asymmetrical distribution of risks create incentive misalignments that work against the goal of enhanced access to ACTs. The magnitude of these misalignments requires practical solutions to remedy the adverse incentives of each stakeholder, as a first step in improving access.

If the global health community expects manufacturers to provide their products at low or zero margins, and guarantee access to products when and where they are needed, it is important that funding agencies and national buyers contribute to reducing overall market risk and sharing in the remaining risk. Some solutions, such as improving the timing of disbursements and sustainability of funding will require essential reform by the donor community. Others, such as sharing of information for demand forecasting and for other key activities among all stakeholders, can be accomplished through the creation of a “Global Health Infomediary”.²¹

An ‘Infomediary’ would serve as a neutral third party to collect and disseminate essential data across the value chain. This would not be limited to data on malaria or ACTs, but would cover a wide range of health products. The primary function of the infomediary would be to serve as a central repository of all data on relevant demand and supply by collecting, synthesizing and disseminating information that individual organizations may

be unwilling or unable to share independently. The Infomediary model has been successfully used in a variety of industries and is accepted practice in developed pharmaceutical markets. Open sharing of information and analyses would go a long way in reducing the uncertainty in global health product markets.

The risk that remains must then be reallocated more equitably. Sharing some of the excess financial risk born by suppliers can be corrected through straightforward, if not simple, changes in contracting mechanisms by funders. Contracting methods that share risk are frequently used in developed markets and across various industries. They include minimum purchase commitments, quantity flexibility contracts, buyback contracts, revenue sharing and real options contracts.²⁶ Rather than focusing on any one of these contracts, a range should be considered as an effective way to better share risk.

Undertaking new contracting arrangements requires funding agencies to make longer, multi-year commitments to both suppliers and to buyers.²¹ A major shift in how aid is provided has already begun with the United Kingdom Department of International Development (DFID) moving to 10 year commitment horizons.²⁷ This trend and more reliable financing streams such as UNITAID will make sustainability easier.

The greatest responsibility for risk reduction and risk sharing ultimately falls to funding agencies for a number of reasons.

- First, funders supply the true purchasing power in the market. By ensuring greater sustainability of funding through multi-year commitments and better matching the timing of approvals and disbursements to country needs, funders can reduce a key area of uncertainty and market risk for suppliers, buyers and patients.
- Second, funders have the greatest leverage in the system. As the gorillas in the value chain, funders can influence the availability and price of products on one hand, and the purchase patterns of buyers on the other. They also have the ability to create incentives to share some of the risk they bear with intermediaries such as procurement agents, creating a more equitable distribution of risks.
- Third, funders have the ability to pool risks across countries. An individual country faces much greater volatility in demand, and in funding for that demand, than a funding agency. Funding agencies can better manage volatility both because their funding streams are much more stable²¹ and because aggregating demand across countries can smooth short-term ordering fluctuations, which benefits suppliers.

The misalignments described above, and their consequences, are pronounced in the case of ACTs, but are not unique to this product. The structural complexities of the global health market, combined with the asymmetrical distribution of risks, impede access to much needed medicines across a variety of drugs and technologies. While the study is not exhaustive, it provides a framework on which to base future analyses of value chains for a wide range of health products. This approach offers a deeper understanding of how the value chains for health products work, going beyond symptoms to identify underlying distortions.

Ultimately correcting misalignments may require a fundamental change in how bilateral and multilateral funders, international regulatory and post-regulatory authorities like WHO, and procurement agents such as UNICEF, perform their roles in the value chain. Traditionally, these agencies have been subject to a set of organizational and legal imperatives that conflict with taking action to assume risk and effectively intervene in the market.²¹ Their Boards and member states have consciously shielded them through elaborate legal contracts that place risk on suppliers and recipients, not on the agency. This must change if the large amounts of new monies are to have the maximum impact on saving lives.

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