DFID HEALTH RESOURCE CENTRE

GHP Study Paper 3:

GLOBAL HEALTH PARTNERSHIP IMPACT ON COMMODITY PRICING AND SECURITY

This paper forms part of the 2004 DFID Study: ***Global Health Partnerships: Assessing the Impact.***

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The DFID Health Resource Centre (HRC) provides technical assistance and information to the British Government's Department for International Development (DFID) and its partners in support of pro-poor health policies, financing and services. The HRC is based at IHSD's UK offices and managed by an international consortium of five organisations: Ifakara Health Research and Development Centre, Tanzania (IHRDC); Institute for Health Sector Development, UK (IHSD Limited); ICDDR,B - Centre for Health and Population Research, Bangladesh; Sharan, India; Swiss Centre for International Health (SCIH) of the Swiss Tropical Institute, Switzerland.

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1 EXECUTIVE SUMMARY

This report, commissioned as part of a series evaluating Global Health Partnerships (GHPs), focuses on identifying the impact of structures embedded within GHPs on pricing and security of commodities that meet global health needs in developing countries. The report identifies the market structure within which the different GHPs are operating, traces the various functions performed by each GHP, unpacks what effect these functions have on the intermediary variables of supplier cost, competition and purchaser leverage, and finally, identifies what outcomes have been achieved in terms of commodity pricing and security.

The variables of pricing and commodity security can be in conflict. Indeed, one of the greatest GHP challenges is to assure that static access to medicines, which may be enabled by single-firm contracting or reduced short-term prices, does not preclude dynamic access, made possible by manufacturers continuing to provide a secure supply of existing products, to invest in R&D for future products, as well as by the development and maintenance of competitive markets, facilitating price reductions.

The GHPs that are most effective in balancing static and dynamic access adapt their supplier approach to the product and market characteristics. GHPs operating in an environment where product competition is already present design their functions to bring about price reductions and enhanced security primarily through their impact on purchaser leverage, achieved through bulk-purchasing for example. The Global Drug Facility for tuberculosis drugs is a good example of such a GHP that successfully creates and pools demand, helps to standardise treatment regimens, and provides grants; the result is a 33% average price reduction in an already competitive market as well as increased commodity security, especially in cases where local procurement or financing systems have failed.

Other GHPs are operating in an environment where products are available only through single sources. In this environment of unilateral dependence of the purchaser on the supplier, the effective GHPs attempt to increase purchaser leverage via creating a situation of relative bilateral dependence, achieved through advance purchase firm contracting, for example. In such situations, GHPs must also think about tailoring contract terms and length so as to encourage a longer-term competitive environment. Some GHPs have proactively sought to encourage new supplier entry. The Global Alliance for Vaccines and Immunization (GAVI) and the Green Light Committee (GLC) for multi-drug resistant tuberculosis (MDR TB) have found effective ways to do this, when the supply has been single-source. The GLC in fact operates in a situation where drugs for MDR TB are both single and multi-source, and it tailors its supplier approach to the market situation. GLC's strategy has increased supply security and decreased the price of quality-assured MDR TB drugs, achieving reductions of 85 - 99% on US prices of the 14 products procured for GLC-endorsed projects.

The less effective GHPs take a less comprehensive or a more short-sighted approach, failing to think about how to enhance purchaser leverage or competition. The obvious example is the WHO Accelerated Access Initiative for supply of ARVs. Questions are also arising about the degree to which the WHO/Coartem partnership facilitates a longer-term competitive market for ACTs, and thus, dynamic access. Based on the analysis throughout the report of how and whether GHPs adapt their functions according to what the market and product characteristics call for, a normative framework is proposed for how GHPs should approach suppliers. DFID is encouraged to support GHP-related structures that can demonstrate that they have successfully set up their functions to achieve both static and dynamic access to medicines.

2 INTRODUCTION

This report, part of a larger series commissioned by the Global Health Partnerships team at DFID and focused on evaluating Global Health Partnerships (GHPs), is aimed at identifying whether and how GHPs have had an impact on commodity pricing and security, with some consideration on incentive impact for research and development (R&D) as well.[1]

2.1 Format and scope and of the report

This report relies primarily on secondary data available on GHP functions and commodity pricing/security. The GHP functions are described, their impact on the intermediate parameters of supplier cost, competition, purchaser leverage are analysed, and their effect on the outcomes of commodity pricing and security explained. The final sections of the report draw the evidence together to develop a normative framework for how best to approach suppliers in different market contexts.

2.1.1 Definition of GHPs

There are many initiatives aimed at reducing prices and increasing commodity security, not all of which are GHPs. Examples include the MSH International Price Guide and the Médecins sans Frontières (2002) "Untangling the Web of Price Reductions: A Pricing Guide for the Purchase of ARVs for Developing Countries", MSF, Geneva. These initiatives make pricing more transparent, having a positive effect on competition and purchaser leverage, and therefore commodity pricing. This report does not cover the entire range of initiatives of relevance to commodity pricing and security; it limits coverage to those initiatives that are *structures within or linked to GHPs* that are widely recognised to be focused on commodity security and pricing.

2.1.2 Pricing

This report focuses on source prices, rather than prices to the end-user, since very few GHPs have influence on retailer prices, taxes and tariffs[2], dispensing fees, or distribution mark-ups, and the TOR request for pricing, security and R&D implies a focus on source prices.

2.1.3 Commodity focus

Due to time limitations, this study focuses the following drugs and vaccines: ARVs for AIDS, ACTs for malaria, vaccines, and TB drugs. Some of the normative conclusions drawn in later sections may not be accurately extrapolated to health commodities generally, such as bed-nets for malaria or contraceptives. The drugs studied have also been limited to those with a price, therefore drugs for the most neglected diseases and made available by donations, were not covered.

2.1.4 Security

UNICEF defines security of supply as: 'Uninterrupted, sustainable supply of affordable quality medicines'[3] and this study provides data, where available, on the following:

[1] A larger study focused on the R&D side has also been commissioned as part of this series. See Gingerich et al.

[2] The Roll Back Malaria Partnership is one exception; it was successful in lobbying for tariff elimination on ITNs in 16 countries. Other GHPs have also advocated that newly introduced drugs are added to national drugs lists and hence exempted from import taxes and tariffs.

[3] Steve Jarrett, UNICEF Supply Division, presentation to World Vaccine Congress Montreal 2003

Uninterrupted: lead times and (time between grant and approval process) with sufficient buffer stock to ensure that stock outs do not occur.

Sustainable: ensuring that the market is attractive enough to maintain current capacity as well as induce additional producers to invest in capacity[4] so that competition is maintained or enhanced.

Quality: Meeting internationally accepted quality standards

2.1.5 R&D

It was not necessary to cover this subject on a GHP by GHP basis, because the effect of GHPs on R&D incentives can be summarized quite simply, as follows. If there is global demand for a product, for which the public market is a small fraction in value terms, then developing country public sector procurement activities will have minimal negative effects on incentives for R&D for future products of a similar nature. However, if the developing country, public sector funded market is a large proportion of the overall market in value terms, then consideration must be given to how the GHP affects R&D incentives, and 'push' or 'pull' incentives for R&D will likely need to be created. For example, the single most important factor cited by vaccine manufacturers regarding their investment in R&D of new vaccines geared specifically for developing countries, is the ability of those countries, with support from UNICEF, WHO, and the Gates Foundation, to accelerate the introduction and ensure the sustained use of vaccines.[5]

2.1.6 Challenges

There are several challenges in interpreting data related to GHPs and commodity pricing/security:

- The lack of an alternative scenario: to compare drug price without GHP versus with GHP
- The difficulty of attribution: i.e. to isolate the effect of the GHP on price, versus changes in market conditions or the impact of other GHPs operating at the same time
- To isolate which aspect or function of the GHP has been the most influential on price and security: i.e. is it related to increased volumes made possible through demand creation and standard harmonisation? To pooled demand linked with financing? To better buying practices? To measures that increase the competitiveness of the market?
- Some of the data available, especially on vaccines, unpacks the variety of influences on price, allowing a reasonable interpretation of GHP impact. However, most of the data remains patchy and suggestive rather than definitive. Nevertheless, the data available do make it possible to draw some conclusions about which approaches with suppliers are more likely to be successful in balancing affordability and security, in various market conditions, and this is the focus of the final sections of this report.

[4] E.g. pre-qualifying developing country suppliers, or WHO (as GDF partner) performing normative function of certifying manufacturers via the white list

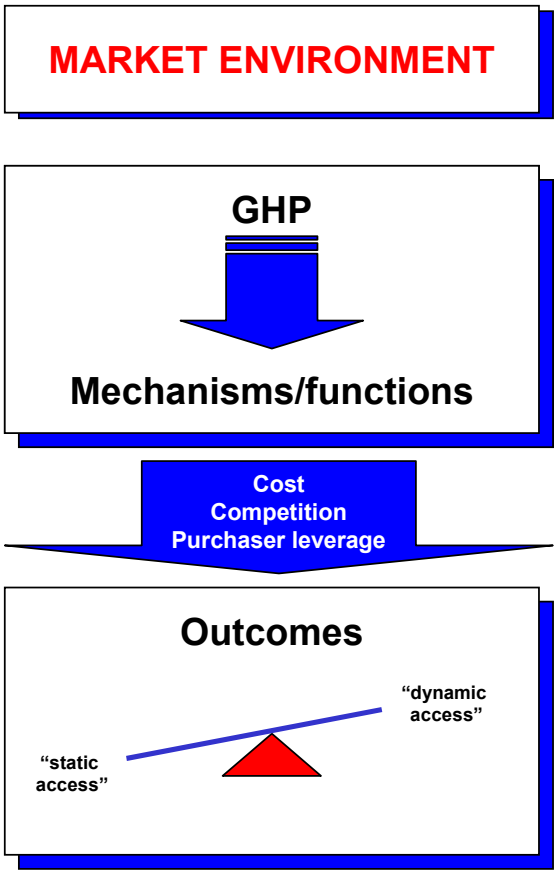
[5] United Nations Children's Fund memo to address Item 6 of the provisional agenda for the 21-25 meeting of the Executive Board, 21 December 2001. E/ICEF/2002/6

3 FACTORS THAT AFFECT PRICING AND SECURITY

GHPs use various mechanisms or perform various functions, through which they attempt to influence supplier cost, competition and purchaser leverage, with consequent effects on price and security.

The diagram illustrates the following:

1) GHPs operate within a larger market environment, having its own underlying effects on price and security, irrespective of GHP impact.



2) The functions that GHPs perform do not directly impact pricing and security, but do so via their effect on the intermediate variables of supplier cost, market competition, and purchaser leverage.

3) There can be a tension between static and dynamic access to medicines. Static access to medicines may be facilitated by reduced prices, for example, as well as single firm contracting when the supply is single-source. Dynamic access is reliant on such factors as the market remaining attractive enough for additional producers to invest in product development and invest in and maintain manufacturing capacity as well as the development of competition. If the GHP influences market dynamics too much in favour of static access, longer-term security and competitive pricing may be compromised.

3.1 Cost

Costs for drug manufacture may be grouped into R&D and production costs. R&D cost is a significant proportion of new drug costs, and R&D costs may be growing as new technologies, especially gene-based and conjugate vaccine technologies, are increasingly deployed. Production costs are comprised of fixed and variable costs. Pharmaceuticals are characterized by high fixed costs (fixed production and fixed R&D costs) and low variable costs (e.g. materials, labour), making tiered pricing according to ability/willingness to pay feasible where there is a wealthy market from which the fixed costs can be recouped.

When a producer is able to make maximised use of existing capacity, this reduces cost, but a significant upsurge in demand will create the need for new investment in capacity, and this can cause a surge in costs. For example, in the early 1990s, the Universal Child Immunization initiative drove demand beyond production capacity worldwide. Industry invested in new infrastructure and this was given as the main reason for the 22% average price increase charged to UNICEF and PAHO between 1991 and 1992 (although a drop in competition, as producers consolidated, and increased R&D costs have been cited as likely factors as well).

From the supplier's perspective, engaging in bulk purchasing and competitive tendering (which is a major function that most of the GHPs provide) can lower supplier costs (e.g. economies of scale and reduced transaction costs in dealing with a single, large purchaser). Assuring purchase through forward contracting can also allow better production planning, reduction in inventory costs and reduction in the risk of capital equipment investment.

It is important to note that pharmaceutical producers do not price based on cost, but rather, based on what the market will bear. The cost can be thought of as the price floor, while the value in the customer's mind, relative to competitors, is the price ceiling. Increases in cost can only be passed on to the consumer in an environment of limited competition. Conversely, the degree to which any cost savings is translated into reduced prices depends on the purchaser's bargaining power. This is a function of the competitiveness of the market and the purchaser's financial credibility, market knowledge, and purchasing size.

3.2 Competition

Competition is affected by the number of producers in the market, and their capacities, relative to demand. Competition changes as a product advances through its life cycle. Typically, newer products are offered by fewer if not a single supplier, due to smaller demand, patent/IPRs, technological difficulty, capital requirements and other barriers to entry. Older products have an established demand that, given high fixed costs, means the production cost has reduced with increased economies of scale. More importantly, competitors enter the market as a product matures and this is a major reason for price decreases.

GHPs can influence the competitiveness of the market in many ways: procurement procedures that foster competition; pooled demand and predictable forecasting (lures competitors into market); estimating international reference standards for products and facilitating quality compliance of manufacturers (especially important for ACTs and for developing country manufacturers), for example, through WHO pre-qualification.

Dynamic competition is enhanced when GHPs have systems set up to monitor supply and demand changes in the market, in order to determine whether the market remains healthy enough for multiple suppliers to enter into and maintain manufacturing capacity, and to develop new products for that market. GHPs can help lure additional suppliers into the market through various mechanisms, creating and pooling demand being two important ones. Demand can be enhanced when GHPs help countries understand epidemiological need or they influence government, providers or patients in terms of the timing and uptake once the product is available. GHPs may also provide technical assistance to countries to support evidence-based policies and strategies or to provide financing for product. Once demand has been created, some GHPs focus on signalling predictable demand, hoping to influence the suitability of the product being supplied (e.g. profile, price) and the supplier market structure (e.g. number of firms, developed versus developing country suppliers). Some GHPs guarantee financing for a product (so called 'pull' mechanisms), and this is aimed at mitigating downstream market risk, encouraging product development and securing supply.

3.3 Purchaser leverage

There are also certain actions GHPs can take to allow purchasers greater leverage to negotiate terms and pricing with suppliers. For instance, GHPs can:

- Collect and disseminate transparent pricing & quality information which allows purchasers to compare suppliers;
- Offer professionally managed procurement services;
- Compile and share country experiences and best practices in policy change, procurement, financing, subsidies and delivery;
- Pool demand: the fewer the buyers and the larger their percentage of the total market in value terms, the greater their influence in negotiating prices with producers. A less fragmented purchaser base can also make the market more predictable, and predictability is conducive to more cost-efficient manufacturing, the savings of which may be passed onto buyers in certain circumstances.

4 MALARIA

4.1 Market context for malaria drugs and the need for a GHP

Until fairly recently, there were no partnerships taking a total market approach to deal with the shortage of supply for ACTs.[6] Part of the reason for this may be that the scientific basis for significant ACT use has not been fully established until recently.[7]

It is estimated that there are 300-500 million cases of malaria in SSA and, assuming 60% of these cases are appropriate for artesunate therapy (Abt Assoc), there is a large gap between supply and potential demand (based on health need), since enough raw material is available today to generate 20-30 million treatment doses.

A recent RBM meeting[8] determined that the lack of pooled procurement is not meeting countries needs for ACTs. Manufacturers are not producing sufficient quantities of ACTs, because of demand uncertainties. These uncertainties create barriers to entry for manufacturers who might otherwise enter production of ACTs. Supply, and consequently competition, is reduced, resulting in higher prices and less stable supply for ACT combinations. Experience from other disease control initiatives (e.g. STOP TB and GAVI) indicates that some method of pooled procurement is needed to stimulate market entry for production of ACTs, increase competition, reduce prices and increase stability of supply.

The market characteristics for ACTs indeed suggest that a GHP with procurement and financing functions could have a beneficial impact on ACT pricing and security. Production lead times are long,[9] there are few manufacturers currently[10] and lack of GMP is also a major hurdle that could be lowered by an appropriately focused GHP. It has been estimated that 80% of ACT cost is tied up in the active ingredient stage[11], so this should be a particular area of focus for any GHP focused on ACT access.

4.2 GHPs focused on malaria drug pricing/security

4.2.1 WHO/Novartis Partnership

Until recently, the only partnership that might be considered to be a GHP with impact on commodity pricing and security of malaria drugs might be the WHO/Novartis partnership to provide Coartem (artemether-lumefantrine) at 'cost' pricing. In this partnership, WHO reduces risks and costs for Novartis by providing expert reviews (reduces scientific risk); providing funding and technical assistance to make the product better suited for target markets (e.g. appropriate packaging, partial funding of Phase IV trials to determine appropriate dosage); monitoring leakage; assisting with

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[6] At the time of writing, 90% of ACT demand is for Coartem (artemether/lumefantrine), therefore this section refers primarily to the particular context for this ACT product.

[7] In fact, the scientific basis is still under scrutiny in some circles. Dr. Suzanne Hill, consultant to RBM, personal communication, October 2004.

[8] Tyson, S. 'Strategies to Increase Access to Artemisinin Combination Therapy (ACT) Columbia University, New York, meeting note, April 29-30, 2004.

[9] Largely due to the fact that the drug is reliant on natural plant cultivation

[10] 6 producers of raw materials (3 in Vietnam, 2 in India, 1 in China) and 12 producers of ACT finished product of differing combinations (4 in Europe, 7 in Asia, 1 in Africa) JM Kindermans, unpublished data quoted in 'Expert Consultation on the Procurement & financing of anti-malarial drugs'.

[11] Guimier, J., Lee, E., Grupper, M., Processes and issues for improving access to medicines: The evidence base for domestic production and greater access to medicines. A Paper for the Department for International Development, June 2004.

collecting pharmacovigilance and post-marketing surveillance data; and by reducing the transaction costs Novartis would otherwise incur from managing the business relationship with multiple purchasers. WHO also forecasts demand and provides a credit fund to help countries pay for Coartem.[12] The extent of WHO's contributions allows them greater purchaser leverage than they would otherwise have with a monopoly supplier.

The price of Coartem versus its counterpart sold in wealthy markets is certainly concessionary,[13] however, it is difficult to know what the alternative pricing/security scenario might have been, if the partnership were never to have evolved, and generic producers currently supplied the product.[14] Whether the partnership is a good thing for dynamic access is also a question – i.e does the partnership lay the ground for a competitive market in the longer term?

4.2.2 GFATM

The GFATM is the largest financial supporter of ACTs in countries. A total of US$30 million was committed over the full 5-year life of GFATM Board-approved proposals from African countries for the purchase of ACTs in three proposal rounds. However, the cumulative total approved was enough to treat only 6 million patients annually,[15] a small fraction of the 180 to 300 million estimated to be eligible for treatment. Procurement forecasts, from countries that have changed, are changing, or are expected to change to ACTs in 2004 and 2005 are in the range of 131 million for the year 2005-2006. In GFATM round 4, there was a sharp increase in approvals of applications that included funding for ACT treatments, and 122 million treatments have been approved for funding in Round 4[16]. The primary problem seems to have shifted from one of financing shortage to one of supply shortage, as noted earlier.

4.2.3 Malaria Medicines Supply Service (MMSS)

The MMSS service has recently been formed in WHO to try and address the challenges present with ACTs. MMSS will incorporate the following functions:[17]

Financing

MMSS plans to work with countries to get firm support for virtual pooling of funds through pledges and other means; to explore other options to negotiate concessionary pricing or other favorable terms from suppliers using a bilateral negotiation/firm contracting approach similar to GLC/Coartem; establish a resource mapping exercise and, if necessary, explore a time-limited purchase fund for ACT (preferably within existing structures), given the critical need for market stimulation and rapid expansion.

Supply chain management

[12] Grace, 2003. See: http://www.who.int/medicines/library/par/equitable_pricing.doc

[13] Novartis has agreed to provide drug 'at cost' through WHO for 10 years – US$2.40 for adult treatment, whereas the UK equivalent costs more than $40.

[14] Artesunate is not patent protected, although the artemether-lumefantrine combination formulation is.

[15] Clive Ondari, EDM/WHO, March 2004 presentation 'Access to anti-malarial medicines'

[16] GFTAM presentation on Round 4 Approvals, Eighth Board Meeting Geneva, 28 – 30 June 2004

[17] Source: Clive Ondari, EDM/WHO, March 2004 presentation 'Access to anti-malarial medicines'

MMSS plans to offer the following functions related to supply chain management: demand forecasting, support for fast-tracking in-country registration, pre-qualification of manufacturers/products, a database on sources and prices; and technical support on procurement planning. MMSS does not necessarily plan to offer an actual purchasing service, although it can do so through its partners if countries require this service. MMSS also plans to work with other donors to advocate that all products financed by them are pre-qualified or conform to WHO specifications.

Technical tools

MMSS will work with RBM and partners to offer a number of technical tools, including preparing a database of tools and guidelines (reflecting best practices) in areas relevant for access to medicines and other essential supplies for malaria; disseminating and promoting such tools and guidelines; MMSS will not undertake advocacy as this responsibility of the RBM Partnership Secretariat. The following tools/practices/guidelines may be offered by MMSS: forecasting supply and demand; selection of appropriate anti-malarial medicines/supplies and for new product introduction/transition; registration with relevant national authorities; procurement planning and practices, including tenders, negotiations and financing considerations; management and distribution practices; pricing and subsidy policies; quality assurance (e.g., GMP, drug management, combating counterfeits).

Provision of global information products

Potential information services that MMSS can offer include: demand forecasts for medicines and supplies; market intelligence on sources and prices of medicines, raw materials and supplies; a database of pre-qualified products and suppliers of medicines and diagnostics; a database of country indicators, showing progress on new policies and access to treatment; a database for consultants in procurement and supplies management; specifications for products and packaging for medicines and supplies; a database to track global flows and use of medicines and supplies; a database tracking anti-malarial drug/insecticide resistance; data systems to support distributed work groups.

MMSS Impact

As the MMSS initiative is not yet operative, impact on pricing and security is not known. The economic conditions of the ACT market are certainly favourable for a GHP of this kind. Global pooled procurement would help increase purchaser leverage that could result in reduced prices, more secure supply, ensured quality, and an influence on product norms. Meanwhile, demand creation activities to bring forth latent demand, along with provision of finance, could help to lure new suppliers into a market that has a large unmet latent demand. MMSS is certain to be an improvement upon the current WHO GHP for ACT, which is effective at achieving a concessionary price, but perhaps at the expense of dynamic access that could be obtained through market entry, particularly of lower cost developing country suppliers, resultant competition and lower prices.

5 TUBERCULOSIS

5.1 Global Drug Facility for STOP-TB[18]

5.1.1 The global market structure for TB drugs

In order to determine what impact the GDF has had on drug prices and predict possible future effects, it is necessary to understand the market context. A few statistics: in 2000, the Global Alliance for TB Drug Development reported that the world spent $470 million on TB drugs (first line and drugs for MDR-TB combined). An estimated 30% of that was in the public/tender market, and 13% in international donor assistance. Any initiative that can bring together the 30% disaggregated demand is bound to gain more leverage with suppliers, and therefore price reductions, and this is exactly what GDF attempts to do, at least until demand is created and country systems are in place to professionally manage a procurement process.

Looking more specifically at first line TB drugs - the focus of the GDF - a WHO/Stop TB Drug Market Survey conducted by the GDF in 2002 revealed that the total market size for first line anti-TB drugs is in the range of US $341- $384 million, and the value of the global anti-TB drug public/tender market is approximately $66 million so about one-sixth (the GDF procured value would be a smaller fraction of the $66 million).[19]

The market for first-line TB drugs is competitive, for the most part. Therefore it is primarily through increased purchasing leverage that GDF can have its impact. This involves creating and pooling demand, helping to standardise treatment regimens, and in combination with financing. And since the market is already competitive, the price reductions that GDF can achieve are understandably less than what can be achieved by programmes focused on increasing access to drugs supplied by few or single sources.

5.1.2 GDF functions

The GDF bundles global pooled procurement with pooled financing and a network of partners to provide technical assistance to support grants. TB drugs are procured through a contractual partner on a centralized, pooled basis and shipped to countries. The GDF claims that its success rests on its bundling of grants,[20] procurement and technical assistance into a single package. A 2003 review of the GDF[21] agreed that a separate or unlinked system would not have the same impact as the GDF because it would not encourage standardization of products and price reductions through bulk procurement.

GDF claims that it achieves prices that are, on average, a third less than previous international tenders.[22] A recent evaluation revealed that the combined approach of pooled financing and commodity purchase has been key for the GDF to meet some of its goals, and the primary benefits of the facility have been: expansion of access to

[18] Kumaresan, J., Smith, I., Arnold, V., Evans, P. The Global TB Drug Facility: innovative global procurement, International Journal of Tuberculosis and Lung Disease 8(1):130-138, 2004. See also McKinsey, 'Evaluation of the Global Drug Facility (GDF), Presentation of Interim Report to the Coordinating Board Brasilia, April 4, 2003.

[19] Moore, T., Global Anti-TB Drug Market Survey, Stop TB/GDF. 2002.

[20] Grants increase the leverage of GDF and the Stop TB network to mobilize government and partner commitment.

[21] Evaluation of the Global Drug Facility, McKinsey & Company, 2003.

[22] Kumaresan 2004.

high quality TB drugs; facilitation of DOTS expansion; and system level benefits that have resulted in drug price reductions.

With the combination of GDF grants, the WHO link, and the procurement function, GDF is able to guarantee sufficient demand to encourage manufacturers to produce the drugs and formulations recommended by WHO, and this is what brings about reduced prices, the promotion of standardisation/innovations, and to a lesser extent, security of supply.

As far as drug security, GDF alleges that GDF grants linked to procurement reach countries faster than through separate granting and procurement processes, and with fewer 'leakages'. Similarly, the McKinsey evaluation of GDF noted, 'GDF can help address some drug shortage issues via procurement alone, but having an impact on non-drug bottlenecks is dependent on the 'carrot' of providing grants and the 'stick' of post-grant M&E.' The India country study, another in this GHP series for DFID, found that GDF's commodity grant-making and commodity security service is more important than its demand pooling and price reduction service;[23] the GDF's primary use in this context has been as a back-up procurement mechanism when local procurement mechanisms have failed and a finance provider when resource gaps have presented. Despite these benefits, some past reports have highlighted the need to improve performance in terms of lead times and other aspects of order completeness, which have fallen below target.[24]

Interestingly, it is anticipated that the GDF will phase out its grant-making function over time. This, plus the advent of GFATM monies, may threaten the basis on which GDF has achieved its gains, since GDF would lose financial leverage to encourage DOTS expansion, ability to promote standardization of TB treatments. GDF was initially scheduled to phase out the grant making function over 3 years, but GDF is concerned to consolidate gains achieved before phasing out, so the grant making function may continue for 6 to 9 years.[25]

5.1.3 GDF Price Impact

Although the GDF generally claims achievement of prices that are 33% lower than previous international tenders, the McKinsey evaluation found that GDF prices were 40-50% lower than the prices on the MSH International Price Indicator Guide and 20 - 45% lower than previous tenders in Kenya.

5.2 Green Light Committee for multi-drug resistant tuberculosis (MDR TB)[26]

5.2.1 The market context for MDR TB drugs

Unlike drugs for first-line TB treatment, many drugs for MDR TB originate from single sources, making competitive tendering an impractical option for securing price reductions. For single source drugs, the only short-term options are increasing the leverage of purchasers and/or securing differential pricing agreements.

[23] Druce and Sadanandan, GHP India Country Study.

[24] Pearson, M. Unpublished report, IHSD relying on data from GDF monitoring reports.

[25] Peter Evans, GDF, personal communication, September 2004.

[26] Haak, H. Improving the affordability and financing of artemisinin-based combination therapies, WHO 2003.

5.2.2 GLC functions

The GLC originated from a Working Group established by WHO, which recommended consolidating the buying side of the market and promoting access to drugs at negotiated prices to projects with adequate technical capacity. GLC pools demand, structures partnerships and negotiates on behalf of countries in a situation where demand is small and extremely fragmented. The GLC also provides technical assistance so that the quality of the MDR-TB treatment is improved; consequently demand for drugs has been stimulated and the delivery system for treatment improved.

Recognising the differing market structures for MDR TB drugs, GLC tailors its supplier approach to the particular market situation. For drugs that can be competitively sourced, a GDF type bulk purchasing approach is used. For drugs that are single-sourced or patented, a negotiation approach is used, based on quality and price criteria, whilst longer-term, more competitive supply options are sought. To maintain a competitive marketplace and ensure sustainable supply, GLC awards a large percentage of its tender to the quality-assured company with the lowest-priced drug, and a proportional percentage to one or a few of the remaining quality manufacturers. GLC also looks for opportunities to induce new suppliers into the market, thereby increasing competition. This was done successfully with capreomycin and cycloserine, both formerly exclusively produced by Eli Lilly, as well as with a third drug called PAS.[27]

5.2.3 GLC Impact

GLC's strategy has increased supply and decreased the price of quality-assured MDR TB drugs. GLC has managed to achieve 85 - 99% reductions on US prices of the 14 products procured for GLC-endorsed projects. Drugs for an entire 2-year course of therapy now cost US$ 500 - 1500.

27 Grace, C. 'Equitable Pricing of Newer Essential Medicines for Developing Countries: Evidence for the Potential of Different Mechanisms', page 26.

6 VACCINES

6.1 GAVI's functions

GAVI shares some common features with GLC in that the market for many products it supplies is oligopolistic or even monopolistic. Through its partner organizations[28], GAVI works closely with the suppliers, attempting to align their interests with those of GAVI. This approach is necessary due to the limited number of vaccine suppliers and the fact that many products are single-source or patented. To secure price concessions and supply, GAVI enhances the overall attractiveness of the vaccine market by stimulating demand in developing markets, strengthening vaccine delivery infrastructure, and guaranteeing future purchasing of the product, at least in the short term.

A project management team, overseen by the GAVI Board, and made up of parties from UNICEF, WHO, and The Vaccine Fund, performs the following functions: demand forecasting on a country-by-country basis; influencing the timing of the introduction of new vaccines; reviewing the availability of finance; monitoring the market situation - global supply as well as supply to UNICEF.

GAVI's approach aims to accomplish two things: through the project management team, to help reduce the manufacturer's risk of investing in research and production capacity that might otherwise end up idle, and to increase the bilateral dependence between GAVI and suppliers, thereby increasing GAVI's bargaining power with the suppliers.

6.2 The market context

Several studies unpack the variety of factors that have influenced vaccine prices over the years, many of which have been outside GAVI and UNICEF's control.

Pre-1990s purchases by UNICEF at low prices were effectively made possible by industrialized countries' procurement of the same products[29]. However, in the 1990s, industrialised countries began to use a different set of vaccines than those used in most developing countries. For example, although most developing countries continue to use whole-cell pertussis as part of the DTP combination vaccine (DTwP), higher-income countries have changed to the acellular pertussis vaccine (DTaP).

From this divergence of immunization programmes and vaccine types, emerged the poorest countries as a distinct market for vaccines. But since the higher priced DTaP vaccine has lower yields than the whole cell vaccine, introduction on any scale in developing countries would require significant increases in production capacity, increases which manufacturers will only be wiling to make at a price that covers opportunity cost.

Besides the divergence between poor and wealthy countries vaccine usage trends, other market factors have led to insecure vaccine supply. In the late 1990s, many large pharmaceutical companies have pulled out of the low-margin vaccine business;[30] the number of players shrunk from 26 in 1967 to 8 in 1996 and finally to 4

[28] UNICEF's supply division procures vaccines under the umbrella of GAVI. Approximately 25% of UNICEF's effort goes towards forecasting demand.

[29] The presence of a wealthier market means that manufacturers can recoup their fixed costs from those with ability to pay, making it feasible for them to offer marginal cost pricing to GHPs serving poorer markets.

[30] Mercer Management 2002

players in 2003.[31] The reasons include price controls, liability fears and opportunity costs.

In 2001, when UNICEF was reliant on two manufacturers for 65% of its traditional vaccines, the availability of DTwP, BCG and measles vaccines was at its lowest levels since early 1990s. This point in history demonstrated the higher risk to vaccine security when availability becomes near to, or falls short of, demand. This crisis in security was well illustrated with DTwP. Before 2000, UNICEF only needed to buy one-fifth of the available vaccine. The availability of vaccine dropped dramatically in 2000, and the number of doses UNICEF needed to buy fell within 5% of the number of doses offered to UNICEF. The closeness between supply and demand meant that there could be no allowance for variable yields, batch failures, slow regulatory processes - all common difficulties with the production of biological products. It also meant that there was no ability to negotiate on price. In fact, prices of all basic vaccines increased between 2000 and 2001 (DTP by 15%, BCG by 27%, measles by 10%, and TT by 23%).

This story illustrates that GHPs are limited in their scope for bringing about price reduction – the entire context needs to be taken into account. The levers used by GHPs currently are unlikely to influence the R&D industry's commercial and strategic decisions related to mergers and product positioning in low-price and high-price markets.

However, GHPs seem to have more leverage with emerging market producers; in recent years, many more developing country firms have entered the vaccine market, lured by strong demand for vaccines and their competitive cost structures.[32] On the manufacturing side, 60% of UNICEF's requirement for EPI vaccines is fulfilled by India, Indonesia, Cuba, and Brazil; and the Serum Institute of India is believed to be the world's largest manufacturer of DPT vaccines.[33] The price per dose of plasma-derived HepB vaccine dropped suddenly from $15 -$30 to less than $1 when two Korean manufacturers new to the market tendered an international bid for Indonesia. PAHO also attributed the decline in most EPI vaccine prices in 1995 to the entry of new Asian manufacturers into the international market. However, technological complexity (e.g. conjugate technology used to make the Hib and pneumococcal vaccines), high development costs and IPRs all serve as barriers to entry for the most novel products. Meeting GMP standards is another important hurdle to developing country producers, thus the WHO pre-qualification programme is an essential initiative to lowering entry barriers and ensuring competition.

6.3 GAVI/UNICEF/Vaccine Fund Impact

According to the 'Report from the 12th GAVI board meeting *Lessons learned from the Pilot Phase July 02-October 03',* 43 products were offered from US, European and emerging market suppliers in the latest procurement round; GAVI was noted to have been successful in stimulating the entry of new manufacturers in the production of HepB, Hib and Yellow Fever vaccines for low income countries, in particular DTP HepB.

[31] See http://biospectrumindia.com/cgi-bin/printer.asp?id=54364

[32] On average, one-fifth of the cost structure of MNCs. See page 18 of Grace 2004:

http://www.dfidhealthrc.org/shared/publications/Issues_papers/ATM/Grace2.pdf

[33] Mercer Management 2002 and see http://biospectrumindia.com/cgi-bin/printer.asp?id=54364

6.3.1 Recent trends in pricing/security of newer vaccines

HepB

The price of monovalent HepB has continued to decrease; weighted average price per dose decreasing from $0.32 in 2003 to $0.28 in 2004. Monovalent Hepatitis B is considered to be the 'text-book' case of a maturing product with continuing price reduction expected of 22% between 2003 and 2006, to a price of $0.26 in 2006.

DTP

In contrast, prices for DTP-based combination vaccines are increasing, with a price jump between 2003 and 2004 of 10% for DTP-Hep+Hib and of 27% for DTP-HepB. Compared with 2001, dose prices in 2006 will increase from $3.50 to $3.60 (3%) for DTP-hepB+Hib and from $1.10 to $1.29 (15%) for DTP-hepB.

Hib

Currently, 20 million doses of pentavalent vaccine are procured annually. This does not represent a significant market to vaccine manufacturer; market competition and price reductions will only come if demand increases.

Yellow fever vaccine

Due to change in vial size from 20ml to 10ml, the price per dose of this vaccine increased from $0.34 in 2002 to $0.80 in 2004, and to $0.97 in 2006 (the price of 10d vials was $0.63 in 2002).

Comment

The combination products preferred by countries became commercially available specifically for GAVI and are still early in their lifecycle. Significant and sustained price reductions are not likely to be seen until competition has been established – and this will happen with DTP-HepB before DTP-HepB+Hib, with 2 additional producers of DTP-HepB expected to enter market with pre-qualified products in 2006.

Some price concessions for DTP-HepB and DTP-Hep+Hib vaccines have been achieved via firm contracting, involving making advance commitments to vaccine purchase and sharing risks with producers. Around 40% of the total GAVI vaccine value is scheduled for firm contracting. The prevailing monopoly situation for combination vaccines, with several buyers vying for limited supply, may be limiting the price concessions achieved; the main benefit of firm contracting in this environment is seen to be ensuring security of supply. 'Significant price reduction for combination vaccines are not likely to be seen until competition is established. GAVI partners should ensure that conditions remain favourable and stimulate competition in the period leading up to the next round of procurement. Current prices for combination vaccines should serve as solid incentives for suppliers to enter into and remain in production .'[34]

GAVI is currently exploring the potential to use the International Finance Facility, as a mechanism of creating greater predictability of funding flows.[35] This finance

[34] The VPP pilot evaluation.

[35] IFF would allow increased funding security because governments could commit funding for up to 15 years, for example, beyond the terms of the current government. How GAVI would balance vaccination of existing children, versus subsequent generations, remains a question though. The idea is that the commitments to be paid over 15 years would be front-loaded, theoretically bringing forth investments from industry that would induce competition and

predictability could result in new suppliers being lured into the market and/or in the ability for GAVI to enter into longer-term and more secure advanced purchase contracting with suppliers. As noted, sharing risks with suppliers increases purchaser leverage and may result in greater commodity security or reduced prices during the contract period. However, in order to encourage dynamic access, the contract terms will need to be carefully defined and the market monitored to encourage new supplier entry during subsequent contracting rounds.

6.3.2 Recent trends pricing/availability of traditional EPI vaccine market

UNICEF reports that the availability of BCG, DTP TT and measles vaccine has recently increased, but prices for several have also increased. The limited number of manufacturers for some products remains a concern, especially for measles. Broadening the supply base is necessary. Many basic paediatric vaccines (BCG, DTP, TT and measles) compete for filling or liaphilization[36] capacity, therefore UNICEF supply division, in agreement with suppliers, organized the procurement of basic paediatric vaccines for 2004-2006 together with the tender for GAVI/VF supported products.

However, significant price increases for all the basic paediatrics still have occurred and prices are expected to remain at this level in the medium term. For example, average UNICEF procurement prices for DTwP vaccine were well under $0.10 per dose throughout 1990s. However, weighted average price for DTP will increase from $0.08 per dose in 2003 to $0.12 in 2004, and $0.14 in 2006. This reflects the demand in excess of supply.

drive down prices that would benefit subsequent funding agencies (e.g. bilaterals, developing country health budgets).

[36] Liaphilization is the freeze-drying process used to create the powder for injections

7 ARVS

7.1 Accelerated Access Initiative (AAI)

The intention of AAI is to provide developing countries with access to ARV medicines at the lowest possible prices and to technical support for the implementation of national access programmes for ARV treatment. The launch of the UNAIDS initiative resulted in participating companies reducing their prices for triple ARV therapy from US $12,000 to US $7,000 per year per patient. Around the time when AAI moved to WHO, negotiations resulted in further reductions to US $1,200. At this point, the Indian generics industry began production and offered the same combination for US $600. When Côte d'Ivoire announced that it was ready to accept the offer from the Indian manufacturer Cipla, Bristol-Myers Squibb and Merck made a further price reduction to US $800.

7.2 Impact of AAI

The ARVs offered through the six AAI participating companies remain more expensive than the prices offered by generic companies and the cost of ARV treatment still exceeds the annual GDP per capita of many LDCs. As of April 2002, the lowest generic price for triple combination therapy was US $209,[37]and the Clinton Initiative has negotiated even further reductions, available only under certain circumstances.

7.3 Market for ARVs

AAI has claimed responsibility for the ARV price reductions that occurred during its lifetime. However, concurrent developments in the global and national access arena were likely to have had a more significant impact, most notably pressure from investors, governments, activists and civil society as well as competition from generic manufacturers. A 2002 study looking at ARV procurement prices in Brazil and in 13 African countries, in which 1030 transactions were observed, provided empirical evidence that increased competition, more than international support in the AAI negotiation process, has been the driving force for ARV price decreases.[38]

It is important to note several upcoming changes in the external environment – most notably TRIPS and the impact from increases in ARV funding - will have significant, and opposite, effects on the market structure for ARVs.

With South Africa scaling up its ARV efforts, made partly possible through GFATM funding, a shift in the market dynamics for ARVs is about to take place. Approximately 900,000 people are currently on ARV therapy world-wide (developed and developing countries), 500,000 of whom are in developed countries.[39] Indian firms currently supply the API or the finished product for less than half of the total, but for a large percentage of the patients in developing countries. However, approximately 100,000[40] new patients are expected to be started on ARV therapy by

[37] Médecins sans Frontières (2002) "Untangling the Web of Price Reductions: A Pricing Guide for the Purchase of ARVs for Developing Countries", MSF, Geneva.

[38] Lucchini S, Cisse B, Duran A, de Cenival M, Comiti C, Gaudry M, Moatti JP. Decrease in prices of anti-retroviral drugs for developing countries: From political "philanthropy" to regulated markets? In: Economics of AIDS and Access to HIV/AIDS Care in Developing Countries, Issues and Challenges, International AIDS Economics Network, 2003:169-212.

[39] See: http://www.avert.org/aidsdrugsafrica2.htm

[40] 100,000 is a rough benchmark between the announcements made by public officials of 53,000 and the public tender document's request of enough ARVs for 120,000 new patients (including paediatrics).

2005 in South Africa alone, and the API for this supply will come from India in the near-term, with Chinese and South African suppliers on the horizon.[41] Therefore, because of the scaling up of treatment in South Africa, suppliers from India, China and South Africa will soon become more important sources of API and/or ARV finished product supply globally. This will make the marketplace more competitive generally, at least for the older ARVs.

On the other hand, the market for newer ARVs is likely to become less competitive over time, since TRIPS implementation in major producing countries like India will make generic copying of patented products illegal. The result is likely to be bifurcation of the market for ARVs, with single-source products for newer ARVs on one hand and competitively supplied older ARVs on the other.. The GHP approach to these two markets should therefore be tailored to these very different market structures.

7.4 AIDS Medicines and Diagnostics Service (AMDS)

The AMDS is a welcome addition to the GHPs aimed at securing reduced ARV prices and increased security. Its approach to suppliers is more appropriate to the bifurcated market structure, and it therefore has greater potential, as a GHP, to increase competition or help purchasers gain leverage for reduced prices or secured supply. Begun in December 2003, the AMDS is currently helping around 20 countries in procurement and/or distribution of medicines and/or diagnostics, and this number is expected to rise to 50 countries by the end of 2005. The AMDS offers the following functions:

- Selection of core ARVs, national acceptance, e.g. via country-level technical support to promote clinical guidelines
- Patent status and licensing: information provision and legal guidance
- Registration and quality assurance, esp. strengthening drug regulatory agencies in dealing with ARVs (registration, inspection, importation, local production and combination products).
- Product specifications
- Prequalification of ARVs and diagnostics
- Market intelligence on sources, prices, raw materials
- Procurement of core ARVs and diagnostics
- Import taxes and margins
- Supply management and monitoring
- Local production and quality assurance: Guidance on GMP and TA to National Drug Regulatory Authorities

[41] I am grateful to Stavros Nicolaou, Director Aspen-Pharmacare, for this information

8 ANALYSIS

8.1 Pricing and Security

By analysing how and whether GHPs adapt their functions according to what the market and product characteristics call for, we can start to develop a normative framework for how GHPs should approach suppliers. Diagram A provides a normative framework for the approach a GHP should take according to different market contexts and Diagram B plots the actual approach of various GHPs. The GHP's box position in Box A, B, C or D denotes the market situation for the particular product(s) with which the GHP deals, whilst the arrows indicate the direction into which the GHP tries to nudge the market, via the functions it performs. The areas of mismatch to note are 1) between older ARVs (for which a competitive market has been emerging) and the AAI and 2) until fairly recently, the lack of effective GHP(s) focused on securing gains in ACT security and pricing, despite the fact that the market conditions call for a GHP with such functions (i.e. the Coartem PPP versus MMSS)..

DIAGRAM A

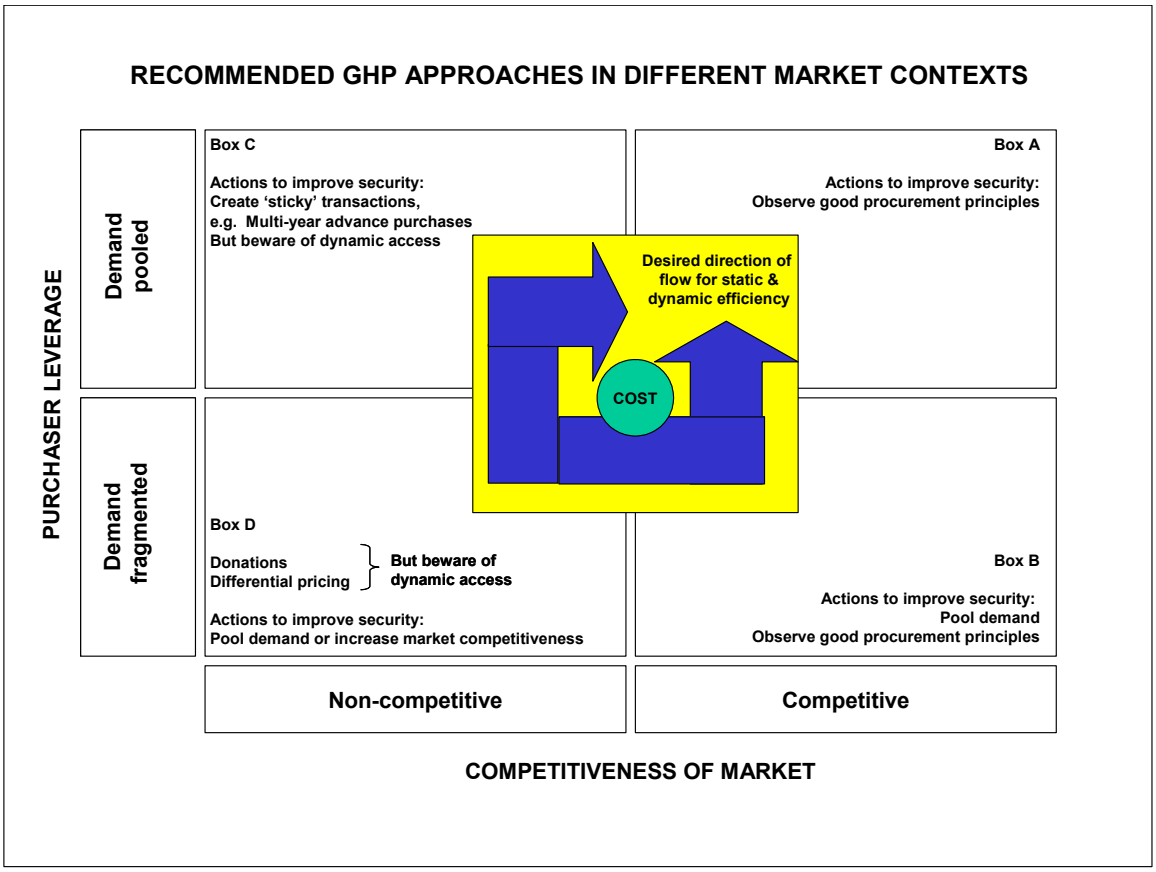
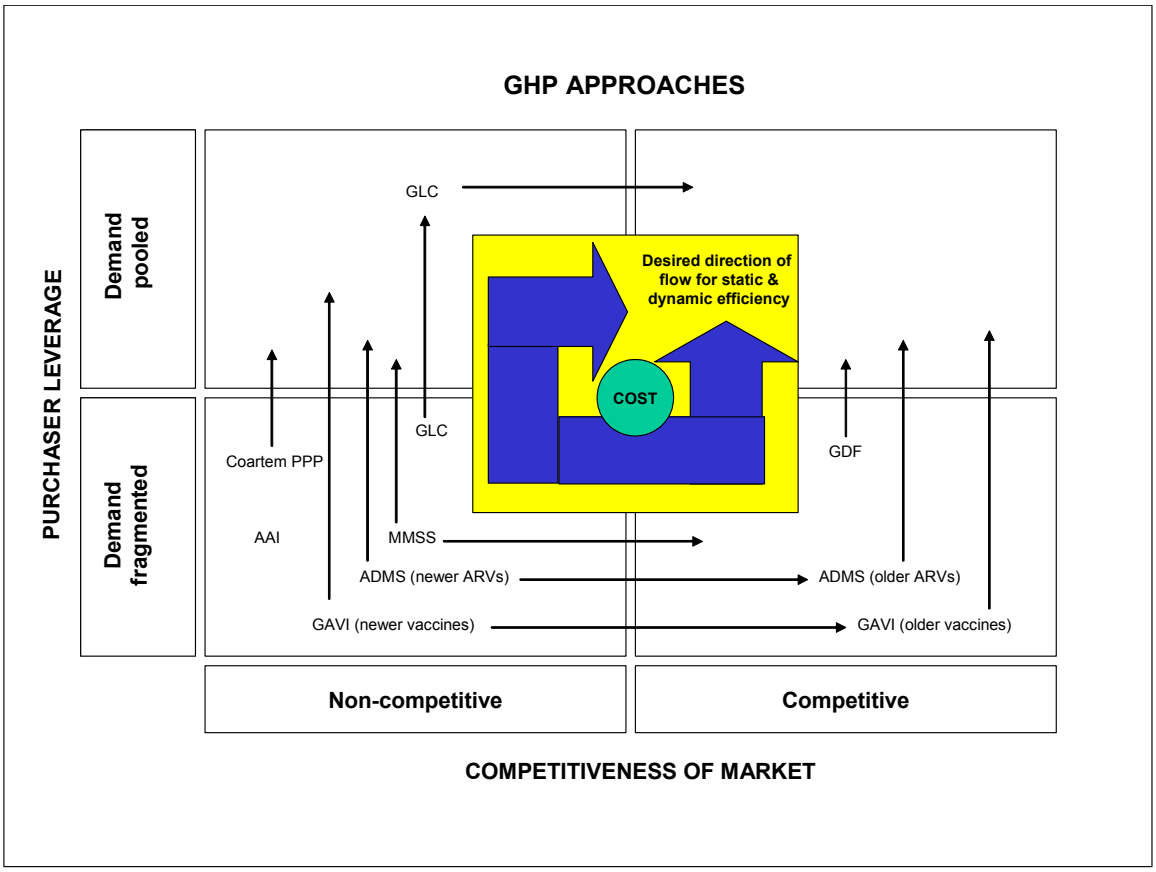


DIAGRAM B



The approach of AAI might be appropriate if all ARVs were single source and if the GHP were focused on encouraging the development of a longer-term competitive market (i.e. ensuring that entry of new firms is not impeded). However, the market for ARVs is increasingly bifurcated, and any GHP focused on gains in ARV security and pricing should be tailored to take account of this fact.

On the ACT side, donors should definitely be encouraging the MMSS, as the large unmet need for ACTs has potential to be met through, for example, GDF, GLC and GAVI market stimulating approaches. The WHO/Novartis partnership to provide Coartem at a differential price does not directly deal with the problem of dynamic access, for example through estimating, financing and pooling demand, and encouraging more suppliers into the market. However, WHO is attempting to deal with the ACT crisis via other functions it performs – e.g. technical support to RBM meetings on the issue, the pre-qualification process and more recently, establishment of the MMSS.

8.2 R&D

R&D incentives for HIV/AIDS medicines, at least for strains also prevalent in the developed world, are unlikely to be negatively affected by GHP actions; the same is true of vaccines that are marketed in wealthy markets and TB drugs which can be used to treat indications prevalent in wealthy countries. Attention must be paid to

how GHP actions affect R&D incentives for drugs for neglected diseases (including malaria), however the GHPs currently existing for these drug categories are likely to have a positive, if any, impact on R&D decisions.

9 CONCLUSIONS

Reduced commodity prices and increased security can be best achieved via adapting the approach to the supplier in accordance to the product and market characteristics. Where the supply is single sourced or patented, the purchaser may be able to gain some leverage via stimulating demand, pooling demand or locking the supplier into supply contracts so as to create a degree of bilateral dependence, where there would otherwise be unilateral dependence. In situations where the public market is a tiny fraction of the overall global market, as with many ARVs and now with some newer vaccines, there will be little hope of creating any purchaser leverage whatsoever, at least from a direct commercial perspective. In this case, differential pricing may be the only alternative and the leverage in this case, perhaps the more indirect benefits a company receives in the eyes of investors and activists, for engaging in such agreements.

However, there are risks with strategies that rely on firm contracting or corporate philanthropy, the primary one being the possibility that dynamic access suffers due to possible heightened barriers to entry that decrease competition and therefore prevent future price reductions. GHPs focused on direct negotiations and locking in suppliers must have systems in place to monitor the market – changes in demand, new product approvals, capacity changes – so as to ensure that any short term agreements do not impede longer term commodity security or market entry and competition. The economic characteristics will differ product by product, therefore this requires quite detailed and ongoing investigation, raising transaction costs.[42] The optimal situation in terms of securing supply, best prices and reduced transaction costs would therefore be to encourage competitive markets.

[42] There has been some question raised about whether it is best to have the structures focusing on securing commodity security and pricing within one organisation or separated by disease area, as is the situation currently. Whilst the potential for cross-disease learning is acknowledged, the economic rationale for having these functions carried out by disease-specific organisations include:

- There is little supplier overlap between diseases, so efficiency savings would not come from consolidating supplier relationships. Even where a single firm holds AIDS as well as malaria products in its portfolio (e.g. GSK), the people with whom the GHP would negotiate would differ.
- The scope of work involved in engaging in either single-firm contracting or bulk purchase tendering is transaction-intensive. 'Transaction' costs here refer to those costs that firms or individuals undergo in the process of using the market system/building a contract. Examples of these costs include: a) search costs, i.e. the cost of discovering contractors and the relevant prices b) the contracting cost itself, that is, the cost of negotiating and concluding a separate contract for each transaction. Other examples of transaction costs include setting up and running costs associated with structures to oversee/govern the agreement, measurement costs of collecting information used to monitor, haggling costs when parties disagree over contract terms, and 'maladaptation' costs (when agreements cannot be reached and one party holds up/ refuses to continue with the contract). Transaction costs are also incurred when the GHP must monitor changes in suppliers' capacity and emerging new suppliers that might be encouraged to enter the market. The reason why transaction costs are high is because of the incomplete contracting environment, with the firms having more information about costs than the purchasers.
- The scope of work of many GHPs includes not only the aspect of dealing with suppliers and markets, but also, of promoting better disease management and demand forecasting at country level. This is transaction-intensive as well and many GHPs (including AAI and GLC) have argued that they not sufficiently resourced to meet the demand for this service at present.

Despite these economic reasons of continuing with the status quo of GHPs being focused on securing commodity supply only within their disease-specific area, it is recognised that there are important cross-disease lessons to be learnt about working with suppliers, creating optimal contracting structures and about promoting better disease management at country level.

10 IMPLICATIONS

The following recommendations emerge from the findings in this report:

- GHPs' (and by implication, donors') primary focus should be directed towards encouraging competitive markets, as this is where the best gains are made in security and pricing and transaction costs are relatively lower than with firm contracting. Support should be given to price information sources and to competitive procurement.
- Similarly, donors could more proactively seek to lower barriers to entry for developing country suppliers, since their lower-cost structure makes them more obvious and sustainable partners for publicly funded programmes concerned with cost. Support of the WHO pre-qualification project is one important means of lowering barriers to entry for developing country firms as is support to a pro-public health interpretation of the TRIPS Doha Declaration.
- Differential pricing of essential medicines should be supported only insofar as such arrangements do not impede the development of longer-term competitive markets.
- Where a competitive market does not exist in the short-term, public purchasers have a variety of options aimed at increasing their leverage with suppliers, including direct negotiation and advance purchase. However, such agreements must be entered into with caution, and a view towards creating/ensuring a longer-term competitive market. Periodic re-tendering would be important, so that the sanction of losing the tender serves as at least partial incentive to offer good price/service, and so as to provide incentives for new firms to enter the market. Market surveillance is also necessary in order to gauge when and if other suppliers can be induced into the market. Supply awards can also be offered in such a way so as to encourage dynamic access, e.g. offering a high percentage of the tender to the best bidder and a lower percentage to competitors.
- For most of the product types covered in this report, DFID funds for drug purchase should be allocated via larger partner agencies (UNICEF, GFATM, UNICEF, GDF, trust funds at international institutions) and pooled procurement encouraged with these funds, so as to allow for increased purchaser leverage with suppliers. DFID funds for drug purchase should include long-term commitments in order to lure producers, increase competition, lower prices, increase security of supply and increase incentives for R&D. Where product markets are more competitive, sufficient scale exists at country level to achieve maximum price reductions via national level procurement, and efficient national procurement capacity exists, then DFID funding to country level for procurement (e.g. budget support) may be appropriate.