DFID HEALTH RESOURCE CENTRE

INDUSTRY GOVERNMENT FORUM ON ACCESS TO MEDICINES (IGFAM)

London, Oct 12th 2009

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October 2009

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SUMMARY [1]
UK kick-starts the differential pricing debate for developing world
13 October 2009
Elizabeth Sukkar

The UK Department for International Development (DFID) hosted a meeting yesterday with pharmaceutical industry leaders to encourage them to think of practical ways to implement differential pricing to make medicines more accessible to poor people in developing countries and emerging markets.

The meeting, the first Industry Government Forum on Access to Medicines (IGFAM), looked at the key challenges facing differential pricing, including cross-country price referencing and the diversion of goods to richer countries. It also addressed the complexities of the supply chain itself, in that companies do not have control over additional mark-ups which can be added to the price of a product. Differential pricing is not always access improving, the meeting heard.

"The causes of poor health outcomes in developing countries are complex – but the inability to access life-saving medicines plays a major role. And price is, of course, a major factor," Mike Foster, DFID's parliamentary undersecretary of state, told the meeting.

DFID is funding a study into differential pricing, which it hopes will "move companies into action", Dr Prashant Yadav, professor of supply chain management at MIT-Zaragoza International Logistics Program and author of the study, told *Scrip*.

"A single price is inequitable and inefficient... choosing a single price reduces the manufacturer's potential to expand into [emerging markets]," Dr Yadav said as he presenting his early findings from the study.

He stressed that for differential pricing to work it required "separable markets", but that "market separability falls apart very quickly due to informational arbitrage". He also pointed out that reference pricing (or cross country referencing) undertaken by some low middle income countries further limited companies' ability to engage in differential pricing.

[1] This summary is the text of an article in Scripnews by Elizabeth Sukkar. Our thanks are due to her and Scrip for permission to reproduce this. The original article is available at: http://www.scripnews.com/therapysector/UK-kick-starts-the-differential-pricing-debate-for-developing-world-178512

"Historically, companies have differentially priced (either between countries or intra-country), but that has been mainly driven by the buying power of the buyer. So for example, if the buyer buys a large volume they are given a certain price. But companies have never questioned whether this lower price is reaching the lower income segments [of the population]," he told *Scrip*. He believes that companies should sign up deals with organisations, not based on their buying powers, but on how they reach certain low income people.

Dr Yadav also believes that the risk of diversion of products to richer markets is not as huge as some have stated in the past: "In reality what we see is small volumes of diversion." However, he does recommend that companies find the right partners to help prevent diversion.

He pointed to the Novartis's Coartem (artemether plus lumefantrine) programme which has the Global Fund and World Bank as partners, so that the risk of leakage of products to the private sector or rich countries also presents as a reputational risk to the financing agency.

To date, differential pricing by companies has generally only been applied to treatments for infectious diseases, such as antiretroviral and antimalarial drugs, with little extension to non-communicable diseases in developing countries, ie, mainstream pharma products. Dr Yadav would like to see companies provide differential pricing to treatments for chronic diseases.

still in its infancy

Adrian Towse, director of the Office of Health Economics, says differential pricing as a concept has been around for many years, but that it is only now taking off. "We have seen some growth in differential pricing, but it is still very much in its infancy."

He argues that when critics of the industry say that differential pricing isn't working, his response is that "for most products for most markets", differential pricing has not actually been tried. This is because companies are concerned about cross-country reference pricing and the risk of diversion.

"It is very important that if we are to have differential pricing across world markets and within some countries, that we don't have some countries say, 'they are paying are lower price, so I want that price'. That will mean that the lower price will be withdrawn for the other country and at the end of the day, patients are worse off."

He believes there is a need for political leadership on the matter, as the UK government has already said it will not reference price its drugs to lower and middle income countries. Richer countries should tell middle income countries to follow this lead, and not insist on the same prices as the very poor countries, he says.

In terms of providing intra-country differential pricing, Mr Towse points out that richer segments of countries, such as the middle-classes, may object to paying higher prices than the poorer sectors, which can then create political problems for governments.

diversion a concern

"Diversion is a big problem within countries and across countries. It is one of the issues that is discouraging companies from going down that route [differential pricing]. We don't know how much of an issue diversion in practice will be because we have not had enough differential pricing to make diversion sufficiently attractive. We have had one or two celebrated cases," says Mr Towse.

Michael Rabbow, involved in HIV policy and public affairs for Boehringer Ingelheim, which provides tiered pricing for its ARV nevirapine, believes "infections disease is the starting point" for companies on differential pricing. "Differential pricing is one way around the access to medicine issue, but voluntary pricing with no royalties is another route."

Abbas Hussain, president of emerging markets for GlaxoSmithKline, which is often seen as one of the top companies addressing the access to medicine issue, told the meeting that there was no simple solution and that it was not just about pricing.

He cited India as an example, where there are in excess of 10,000 pharmaceutical manufacturers who make copy products, but there is also a huge part of the population without access to medicines.

He pointed out that his company has addressed the access to medicine issue through its R&D (it has a dedicated centre for diseases of the developing world and a specialist R&D group for emerging markets), neglected diseases patent pool, its pricing (not-for-profit prices on ARVs have been reduced five times), partnerships and voluntary licences. It has also made some significant technology transfers in some key emerging markets, which will help improve access. Mr Hussain said GSK plans to roll out tiered pricing to all of its pharmaceuticals for all emerging markets.

Ponni Subbiah, vice president of global access in emerging markets for Pfizer, was concerned about supply chain issues and how to ensure patients actually got the treatments, highlighting the company's work with its partners including the Clinton Foundation on a TB drug.

Wim Leereveld, chair of the Dutch-based Access to Medicine Index, which rates companies on how well they tackle the access to medicine issue, told *Scrip* that pricing was very important, but that it was only part of the solution.

investor view

Investors too are keen to see companies introduce differential pricing as part of improving access to medicines.

Marieke Samson, senior advisor for responsible investment for Dutch pensions' asset manager, PGGM, which invests in all major pharmaceutical companies, told *Scrip*: "We consider responsible investment as strategically important. In our focus area "access to medicine": we ask for "proof" – if possible results, otherwise indications that there are policies and activities – that indicates that companies take all elements that determine access to medicine into account. Pricing is one of the very important but also complex elements that determine if somebody with medical needs will get the treatment they are entitled to."

But she too sees barriers to implementing pricing policies, mostly because of the complexity of the "on the ground" situations.

"Every market is different and local managers do not yet have sufficient tools to make the right decisions. However, determination to proceed and new concepts such as 'differentiate not on geographical level, but on the basis of income of patients' will help the industry to go ahead. An important driver is the conviction that good results in emerging markets and in poor patient populations in general will add to the long term valuation of the business," she says.

Whether or not companies introduce differential pricing, it is interesting to note that the policy does not always improve social outcomes or access.

A key study by Brenda Waning et al, published this year by the WHO's bulletin, assessed ARV purchase transactions. For 15 of 18 products, differentially-priced drugs were 23-498% higher than generics. "Differential prices are not immune to market forces: [they] fall when generic competitors enter the market," Suerie Moon, research fellow at the centre for international development at Harvard University, told the meeting.

Session 1

Opening the forum, **Mike Foster, Parliamentary Undersecretary, DFID,** spoke of the contrast between the situation in the UK, where debates about access to medicines concern cancer drugs costing tens of thousands of pounds, with the situation in much of Africa, where life-saving drugs for malaria or antibiotics which cost pennies are either not available at all, or not affordable.

The causes of poor health outcomes in developing countries are complex, but the inability to access life-saving medicines plays a major role, and price is a major factor in this. Especially since most poor people in developing countries rely on their own resources to purchase medicines.

The most effective way to improve health is by supporting stronger national health systems, and it is developing country governments which must lead the way in this. Between now and 2015 the UK will spend £6bn to improve health systems in developing countries.

Decisions made by pharmaceutical companies about which products to promote, how much to invest in research and development (R&D) and which diseases to focus on make a huge difference to people in developing countries. By 2020 sales in emerging markets are likely to exceed current sales in the USA and Europe combined. Our challenge is to ensure that the poor as well as the rich benefit as the pharmaceutical market expands. Generic competition from producers in India, as well as initiatives by international brand name companies have helped to drive down the price of anti-retrovirals for HIV in developing countries. However, as more people need more sophisticated 'second-line' treatments for AIDS, prices are rising again. DFID is supporting UNITAID's efforts to create a global patent pool for anti-retrovirals to address the urgent need for cost reduction, and to help create the fixed-dose combinations (FDCs) which are needed in developing countries.

The evidence suggests that for the great majority of drugs, differential pricing has not really been tried. Companies - both brand-name and generic - concentrate their efforts on the better-off and often sell at prices little different from those in developed countries. That is why we need new business models, which many pharmaceutical companies are already

exploring. Mike Foster noted GSK's initiatives, such as the patent pool to promote research on neglected tropical diseases (NTDs), and that Pfizer has set up a Global Access Strategy Unit. With the Bill and Melinda Gates Foundation, DFID is funding the new Access to Medicines Index, which ranks companies on the quality of their policies on access to medicines.

By working together, industry and government, along with stakeholders from across civil society, can change the way we all do business and make a real difference to the lives of millions of poor people around the world.

Abbas Hussain of GSK said that in 20 years in the pharmaceutical business, he had never seen such a degree of consensus among different stake-holders that something should, and more importantly could, be done to improve access to medicines. But the problem is multifaceted, and there is no simple solution.

For a company such as GSK there are three reasons to respond to this new situation: There is an ethical imperative; it is good for GSK's image and reputation; and there is a sound business rationale.

The key to the company's strategy is partnership; with other companies, with NGOs, and with governments. GSK has set up a dedicated research centre for diseases of the developing world (DDW), and a specialist R&D group for Emerging Markets. They have formed a joint venture with Pfizer to achieve scale on HIV R&D. The company has the world's leading malaria vaccine, and one third of its vaccine pipeline is for DDW. GSK has also promoted a patent pool for neglected tropical diseases, and has partnership agreements with companies such as Aspen in South Africa and Dr Reddy in India. It is transferring technology related to pneumoccocal vaccine to Brazil.

GSK's approach is becoming less 'product' and more 'patient' focussed. Its view of markets is now 'bottom up', seeing emerging markets not as peripheral but as major market opportunities which are currently constrained by lack of purchasing power.

Abbas Hussain argued that access is not just about pricing - in India there are thousands of manufacturers marketing multiple versions of every drug, almost all at very low prices - but there are still lots of people without access. Affordability is not just a function of price: A pack

of 60 tablets may be too expensive for someone who can only afford to buy 15 at a time, so re-packaging can make a drug more 'affordable'. GSK is committed to tiered pricing: It has reduced the price of its ARVs for not-for-profit customers five times; and 75–90% of its vaccines go to developing countries at prices lower than those GSK charges in rich countries. By the end of this year all GSK products in all its markets will be offered at tiered prices.

Ponni Subbiah of Pfizer agreed that price is not the only barrier to access, nor is there is a single solution to the problem – the barriers are multiple and need a comprehensive approach. She noted that 'developing countries' is not a useful category for this discussion, as it covers such a diverse range of countries and sub-populations within them. Differential pricing can work, for certain products in certain circumstances, but we do not yet have a satisfactory framework to predict when it will be an appropriate solution, and for how long and at what levels. She explained how Pfizer believes that corporate philanthropy, however generous, is not enough to solve the problem; positive and sustainable impact on patient health can only be achieved by partnerships between different sectors. She warned participants not to assume they understand the real needs and perspectives of the poor; we have to listen to the people, and work with those who themselves work closely with them.

We need a new model, and her division of Pfizer is exploring a number of options. Each product in each country is different, and the company is not yet clear whether it can have an over-arching approach. For example, in health-financing Pfizer is working in Bangladesh with a subsidiary of the micro-finance pioneer Grameen Bank; in Colombia it is exploring a more commercial model of cardiac care with a Health Management Orqanisation (HMO). This includes discounting the price of Pfizer's drug Lipitor, and extending the HMO's work into training doctors and health education. In Africa Pfizer is working with the Clinton Foundation, not only to cut the price of Rifabutin (for TB and HIV), but also to develop paediatric formulations and to obtain a single 'regional' registration for these, which will cover 11 countries. With PATH and USAID it is trying to improve its three-month injectable - Depo Provera - while for its ACT it has partnered with an Italian company. At the global level, it has opened up its library to WHO, which is screening it for anti-parasitic molecules.

Rajeev Venkayya from the Bill & Melinda Gates Foundation (BMGF) said the Foundation's mission is to ensure that life-saving advances in health are developed and shared with those who need them the most. He noted that whereas in the US new products

reached patients in a very short time, many products took years or decades to achieve significant coverage in developing countries. Many critical health interventions have historically faced slow uptake and achieved low coverage - and it is always the poor who are the ones not covered. One example is the Hep B vaccine, which has been available for 27 years and yet coverage is still only 60%.

We need to address the causes of the slow uptake of new drugs, to avoid the same delays happening with newer interventions such as pneumococcal and rotavirus vaccines. In this regard, he stressed the importance of partnering with other agencies. BMGF has identified five barriers which have to be overcome:

1. First get the right product, and launch it quickly;
2. Second, have optimized regulatory and policy processes so that it gets into all the markets as fast as possible;
3. Third, ensure there is sufficient funding and that the money is properly applied;
4. Fourth, enhanced delivery platforms to make sure that the benefits reach everyone, not just urban areas or the better-off;
5. Lastly, leadership and accountability: All the above will only work if there is leadership, and if all those involved and fully accountable for their actions.

The foundation is funding partnerships in all five of these areas. He said that measures and incentives intended to stimulate faster access needed to consider the impact on innovation. Involuntary measures (such as compulsory licensing) could adversely affect innovation whereas voluntary measures and incentives specifically designed to spur innovation would have a positive impact.

Discussion

Opening the discussion of the first session, **Andrew Jack of the Financial Times** asked the minister how difficult it was to sell the access to medicines agenda inside government at a time of financial crisis. Noting that 'it is not the poor who caused this crisis', Mike Foster explained that the UK was not just sticking to the ODA target of 0.7%, but proposing to make it a legal commitment. He said that one 'great prize' of increased attention to climate change would be that the related but neglected subject of 'water and sanitation' should receive

higher priority, especially in Africa. Like others, DFID is convinced that partnerships are the way forward - indeed the only way forward.

A member of the audience praised DFID for working so closely with civil society on the proposed UNITAID patent pool for antiretrovirals, and argued that neither differential pricing nor philanthropy would achieve the scale needed to overcome the barriers which stop poor people accessing the medicines they need. She asked what the pharmaceutical companies were doing to collaborate with UNITAID. Abbas Hussain of GSK explained that GSK's proposed patent pool was different to UNITAID's in that it was intended to facilitate research on neglected diseases which, in their view, did not include HIV.

Session 2

Opening the second session, **Prashant Yadav of MIT Zaragoza** posed the question 'Is access to high quality affordable medicines for all income groups necessarily incompatible with maintaining incentives for industry to develop new drugs?' Industry and governments are both keen to achieve the two objectives by building on the existing system rather than reconstructing it. Changing the way we pay for R&D is often proposed as a solution, and many different models have been proposed. However, completely changing the architecture of paying for the costs of R&D requires a system overhaul, which is risky as it is based on a new and untested model.

He argued that differential pricing does not change the system of pharmaceutical R&D. The absolute size of the market in low and middle income countries has grown, presenting new opportunities for businesses such as pharmaceuticals to do 'landscape pricing'. Product Development Partnerships (PDPs) are new because the scale of funding from donors such as the Bill and Melinda Gates Foundation is now big enough to have real influence.

He suggested that the example of contraceptives was a useful one. In most markets there is not only dual-pricing - with subsidised and full-price versions of the same product on sale in the same markets - but also dual-branding; with social marketing agencies actively promoting a cheaper brand (of the same pill) alongside the originator brand. The social marketing agencies make sure their cheaper version is not diverted into parallel markets.

He pointed out how dual-pricing is easier if products are bundled with some degree of service. UNICEF can buy vaccines at a price lower than that charged in Europe or the USA, because they end up being delivered by the MOH or NGOs, not as products alone but as part of a vaccination service. (The cold chain also makes diversion difficult). Drugs for HIV/AIDS are in demand in rich, middle-income and poor countries, whereas the market for malaria drugs is only in poor ones. In the case of HIV/AIDS there is a real risk of leakage from one market to another, but with malaria drugs it is possible to have two or even three-tier pricing, to meet different needs of different segments of the market.

Suerie Moon of Harvard University suggested there were five key questions on differential pricing: how to maximize access to medicines; how to pay for R&D; who pays; how much; and who decides.

There are many factors involved - economic, logistical, scientific and technological, and political. Governments are ultimately responsible for protecting the right to health, and if we accept this point medicines are global 'public goods'. She suggested that having single prices in a segmented market will always be inequitable and inefficient: inequitable if the price is not affordable to some; inefficient if the price is much greater than production cost; and ineffective if the price does not recoup R&D costs. Competitive production and marginal/average cost pricing leads to more efficient and more equitable markets. Markets are also more effective if those who have invested in R&D get a fair return.

The evidence suggests that differential pricing does not always improve social outcomes or increase access for the poor. Brenda Waning's 2009 analysis for the Global Fund of more than 7000 ARV purchases between 2002 and 2007 found that for the majority of products (15 out of 18), differentially-priced drugs were more expensive than generics, with the difference varying from 23% to over 400%.

Differential prices are clearly not immune to market forces - they fall when generic competitors enter a market. If companies offer 'internal' differential pricing (as suggested by GSK), how equitable is the public/private market segmentation? It depends very much on which disease and which product market you are looking at. For example, the TB treatment market in Brazil and South Africa is mostly public-sector, but in India and the Philippines it is mainly a private sector market. Likewise for malaria, most people with fever seek treatment outside the public sector. AMFm intends to 'de-segment' markets, to increase access, and will provide highly subsidised ACT in private as well as public markets.

Today's business model includes branded drugs, with low volumes and high margins. These compete on efficacy and safety, and have limited sales in developing countries; and generics, which sell high volumes (especially in developing countries) at low margins, and where competition is mainly on the efficiency of production.

Tomorrow's model could see production separated from R&D, with competitive production for developing country markets providing some return to R&D through tiered contributions

via fees or royalties. These might be based on income, inequality, disease burden, cost-effectiveness of product or the like. One example of this is Gilead's Tenofovir (TDF), which was (voluntarily) licensed in 2006 to more than 10 generic firms, each paying a 5% royalty. Three years later Gilead itself was still selling Tenofivir at $365 (reduced to $207 for governments) while the generic licensees were selling it for $100, mostly to developing countries.

Differential pricing may be very useful when competitive production is not feasible (because of small volumes, for example), or when rapid access is required. Costly production will encourage technology transfer as part of a transition to competitive generic production.

Key questions on differential pricing include:

1. How to pay for R&D (royalties or fixed fees);
2. Who pays (all share burden of global public goods finance);
3. How much do they pay (a fair price = production costs + R&D contribution);
4. And perhaps most important of all, who decides (companies, governments, civil society).

More empirical research is needed on a number of topics. First, to establish how equitable, feasible and efficient internal market segmentation really is; whether so-called 'informational arbitrage' and 'physical arbitrage' are just conjecture or real (and if the latter, what is the evidence?).

Secondly, we need analysis of past experience (including the risks) of comparable products, such as hormonal contraceptives, vaccines and AIDS drugs, and of the role played by international norms in this.

Discussion

The idea of separating R&D and production was taken up in the discussion which followed these presentations. It is not as simple as its sounds, at least for the multinational research-based pharmaceutical companies on the platform, who do not look at their R&D as individual products. Rather they look at them as a portfolio which is itself in constant flux as progress is made or promising avenues encounter set-backs. It is not always obvious what disease a given bit of research will help, as work on one product can deliver unexpected benefits for another.

It was suggested that, in fact, two distinct forces were at work in this market: New international funding from donors, and competition from manufacturers of generics. Ponni Subbiah of Pfizer said that that it is large volumes rather than high prices which delivers return on R&D – if donors such as UNITAID commit to a large order, the developer has confidence that its investment will yield a return. Suerie Moon was not sure this was the case with Tenofovir, as the volumes remain small, so the price of generic versions has also remained high. Economies of scale do not necessarily lead to lower prices. It may be that only the manufacturer has the advantage of scale, in which case they can charge a very low price and drive out the competition, then charge a higher monopoly price.

Andrew Jack noted that even very competitive markets are not necessarily transparent – he himself had recently tried to buy a new mobile phone in the UK, and was baffled by the complexity of the bundles and the variety of contractual terms, and the unpredictability of the charges.

Abbas Hussain of GSK liked what he called the ‘Robin Hood approach’, whereby profits from one market segment subsidise lower prices for another. He pointed out that working in one division of a global company such as GSK, he cannot ‘see’ what the exact cost of production of Drug X or Y are for his own division, as these costs are spread across all the whole company. Most R&D is done on products for wealthy markets, and the divisions which serve those markets then bear the costs of paying the internal ‘dividend’ on the R&D investment. Even if the product is sold in poorer countries, over the life-cycle of the product the great bulk of the R&D pay-back comes from sales in richer ones.

The way companies organize their internal financial and performance reporting provides incentives (and disincentives) for managers to pursue different public-private partnerships. The internal P&L account for divisions such as his, which covers emerging markets, would look terrible if they included the R&D costs described above. It makes sense for a country manager in his division to make profits from sales in the private market, and achieve volumes by selling at a lower price to the MOH. Ponni Subbiah agreed that separating R&D and production was not a simple step, and said that Pfizer was looking at similar issues of how the company's internal responsibilities and accounting could provide the right incentives for encouraging greater access to medicines.

Rajeev Venkayya of Gates noted that the pharmaceutical industry was not an undifferentiated monolith – what might be a disincentive for one sector, such as the research-based multinationals on the platform, might be an incentive for another, such as a small research company in India. (It was suggested that DFID should be inviting generic companies to this forum, so that the voice of all sides of the industry could be heard). More work is needed on how to operationalise different incentives across the industry, so that publicly-financed R&D by Gates or UNITAID can be applied where it will have most impact.

One NGO representative argued that companies are, by definition, accountable only to their share-holders. Internal cross-subsidies such as those suggested by GSK may work to some extent but they cannot be a large-scale sustainable solution to ATM. Similarly, UNITAID may try to solve market failures, but there is little they can do if there is only one supplier of a product.

Prashant Yadav pointed out that differential pricing had not succeeded in making many drugs accessible. Several of those which have been available for years and are still not widely accessible have long had lower prices for developing countries, and the R&D costs have been recovered long ago.

Abbas Hussain of GSK argued that differential pricing may have been around for a long time, but it has still not been fully tested. With the right mix of circumstances, differential pricing works well. For example GAVI and UNICEF have achieved high vaccination coverage in most of Africa, but coverage remains low in India. The pharmaceutical industry is only taking DP seriously now because emerging markets have become big enough to be of interest to them. The issue is not the separation of R&D from production, but rather 'where

does the R&D money come from'. For example, the Gilead model seems to work, with high revenues from patented drugs and low revenues from non-patented ones. This raised two questions – if low-income countries get especially low prices, will middle-income countries insist on having the same price? And will middle-class people in poor countries pay a higher price than the subsidised price available to poorer people in public or NGO clinics?

Gates is bringing together the CEOs of pharmaceutical companies and trying to open channels of dialogue about pricing and several other barriers to wider ATM. Making it easier for companies to register products, by countries accepting a single regional registration, is an example of a non-price barrier where progress has already been made. The new CEO of GSK, Andrew Witty, is driving a change of culture in the company as well as a change of strategy. For example, country directors used to be given a product and a price by HQ and told to go out and sell it, but now in a country such as Brazil the local GSK country director is much more empowered to take his or her own decisions on how to market a product, including what price to charge to different segments.

Rajeev Venkayya said that Gates and DFID want to understand how best to partner with each other on Access to Medicines. Barriers other than price which they are looking at include weak capacity for clinical trials in poorer countries, and the lack of regulatory harmonization.

One participant observed that it is not always possible to separate 'public' and 'private' sector and markets. She was concerned that few if any of the interventions so far have achieved the scale needed to really improve access. Many of the drugs highlighted as having been very slow to achieve coverage have actually received massive support to get as far as they have done. Even in Tanzania the ADDO programme to strengthen the drug shops on which most poor people rely has only just reached a significant scale, after ten years of work.

Rajeev Venkayya agreed, and noted that one of the lessons they have learned from looking at these timelines from innovation to coverage is that overcoming each one the barriers does not work on its own, it needs a multi-faceted assault on all of them. What GAVI funding has achieved with rotavirus and pneumococcal vaccines is impressive but they are still not reaching the millions of rural poor in northern India. No amount of innovation or obstacle-crushing can succeed without a functioning EPI system. He also noted that AMFm is an

experiment, albeit on a large scale, and we will learn a lot about how it works from the operational research which Gates is funding.

Another participant agreed that there had indeed been a 'sea-change' in the debate over ATM and in many companies' attitudes, but she still hears investors talking about 'mature markets' and ignoring the markets emerging elsewhere. It is investors who are the obstacle, as much as or more than company managers. Abbas Hussain of GSK agreed that investors are wary of emerging markets, but it is 'horses for courses' – GSK has partnerships in Brazil and South Africa, and with Dr Reddy in India. He pressed for recognition of the importance of the work the industry has done over the years to create an effective worldwide distribution system. It is this which actually delivers access to cheap generic medicines for most people in poor countries. He agreed with the suggestion that generic manufacturers should be at this forum in the future.

A participant from PATH noted that some of his agency's most productive partnerships were not with US or European pharmaceutical companies but with those in developing countries themselves, where people are investing their own money in R&D and developing products for their own and other emerging markets. There is an opportunity to create new models, such as Merck's collaboration with an Indian company on vaccine development.

Suerie Moon said that most analysts of ATM agreed that both collaboration and competition are needed. Too much collaboration carries the risk of becoming anti-competitive – she noted that the South African competition authority had queried GSK's deal with Aspen and required GSK to license four other companies as well.

In conclusion, Andrew Jack asked the panelists what they would propose if they had to name one single initiative to improve ATM:

- Suerie Moon opted for the separation of production from R&D (and the maintenance of competition in both);
- Ponni Subbiah from Pfizer opted for more and stronger public private partnerships;
- Abbas Hussain from GSK chose 'leadership and staying the course';
- Rajeev Venkayya said donors must insist on global access provisions being included in all PDPs;

- Prashant Yadav urged that before going further we really need to understand the distribution and delivery channels in developing countries, as we currently know very little about how they work.

Annex 1: List of Attendees

Arma	Ahmad	Fleishman Europe
Amanda	Atkinson	GlaxoSmithKline
Nick	Banatvala	Department of Health
David	Borrow	UK Member of Parliament
David	Brickwood	Johnson & Johnson
Kalipso	Chalkidou	National Institute for Health & Clinical Excellence
Jay	Chavda	MSD UK
Charles	Clift	DFID
Derek	Cutler	National Institute for Health & Clinical Excellence
Nel	Druce	HLSP
Lesley	Edwards	The Bill & Melinda Gates Foundation
Chris	Elias	PATH
Catherine	Fletcher	London International Development Centre
Mike	Foster	Parliamentary Undersecretary of State, DFID
Graham	Fry	Eisai Co Ltd
Alexandra	Fullem	PATH
Neil	Gerard	UK Member of Parliament
Isabelle	Girault	MSD UK
Len	Gooblar	Abbott
Charlotte	Heyes	Intellectual Property Office, UK
Abbas	Hussain	GSK
Claire	Innes	DFID
Andrew	Jack	Financial Times
David	Jefferys	Eisai
Mohga	Kamal-Yanni	Oxfam UK
Panos	Kanavos	London School of Economics
Megan	Kell	
Anila	Khan	DFID
Wim	Leereveld	ATM Index
Femke	Markus	ATM Index
Diarmaid	Mcdonald	Students Partnership Worldwide
Afshin	Mehrpouya	Risk Metrics
Geoff	Mitchinson	GlaxoSmithKline
Chris	Mockler	Fleishman Europe
Suerie	Moon	Harvard University
Geraldine	Murphy	DFID
Veronica	Oakeshott	All Parliamentary Group on AIDS
Susan	Pearl	
Jon	Pender	GlaxoSmithKline
Greg	Penlington	MSD UK
Ben	Price	DFID
Michael	Rabbow	Boehringer-Ingelheim
Marieke	Samson	PGGM Investments
Azusa	Sato	London School of Economics
Philippa	Saunders	Association for Progressive Communications
Robyn	Scott	ATM Index
Rebecca	Stevens	Novartis
Ponni	Subbiah	Pfizer
Elizabeth	Sukkar	Informa Healthcare
Sophia	Tickell	SustainAbility
Catriona	Towriss	

Adrian	Towse	Office of Health Economics
Luke	Treves	Department for Business, Innovation and Skills
Sotirios	Vandoros	London School of Economics
Rajeev	Venkayya	Bill & Melinda Gates Foundation
Maria	Vigneau	Roche
Johannes	Waltz	Pfizer
Nicola	Watt	Department of Health
Steve	Waygood	Aviva Investors
Andrew	White	ESG Consulting Services
Guy	Willis	International Federation of Pharmaceutical Manufacturers & Associations
Paul	Woods	Department of Health
Freddie	Woolfe	Hermes Fund Management
John	Worley	DFID
Ian	Young	Department for Business, Innovation and Skills

Annex 2: Perspectives on Access to Medicines - GSK Presentation

12th October 2009
IGFAM Launch Event, London

Perspectives on Access to Medicines

Abbas Hussain
President, Emerging Markets, GSK

GSK's Response

- **Community investment**
  - 1 billion tablets donated to the LF elimination programme
  - Programmes on HIV/AIDS, malaria and diarrhoea
  - 50 million doses of pandemic flu vaccine donated
  - £50m commitment over 10 years to new Positive Action for Children Fund
  - Reinvestment of 20% of profits in LDCs
- **Commitment to innovative partnerships**
  - Product development PPPs
  - Disease strategy groups
  - 8 voluntary licences for ARVS in Africa
  - Joint ventures in Emerging Markets
  - Pfizer/GSK HIV Joint Venture

The Developing World Challenge

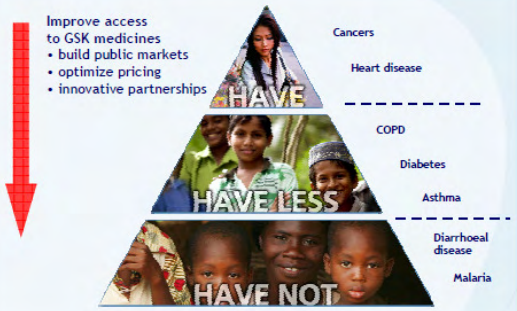
- A global healthcare crisis
- A complex and multifaceted problem with no simple solution – poverty reduction is vital
- Much has been achieved but more needs to be done
- Partnership will be essential

Why respond?

- Ethical imperative
- Image and reputation imperative
- Business imperative

GSK Emerging Markets business

Improve access to GSK medicines
- build public markets
- optimize pricing
- innovative partnerships



GSK's Response

- **Research & Development**
  - Dedicated research centre for diseases of the developing world (DDW)
  - Specialist R&D group for Emerging Markets
  - One-third of vaccine pipeline for DDW
  - World's leading malaria vaccine
  - NTD patent pool
- **Improving affordability**
  - Not-for-profit prices on ARVs reduced 5 times
  - Tiered pricing - 75 – 90% of our vaccines go to developing countries
  - Capping prices in LDCs
  - Creating the right portfolio

The over-arching priority …

Focus on the Patient

Annex 3: Differential Pricing of Medicines - Presentation

Differential Pricing of Medicines:
How to Maximize Access and Pay for R&D?

INDUSTRY GOVERNMENT FORUM ON ACCESS TO MEDICINES
UK DEPARTMENT FOR INTERNATIONAL DEVELOPMENT
12 OCTOBER 2009
SCIENCE MUSEUM

BY SUERIE MOON
RESEARCH FELLOW & DOCTORAL CANDIDATE
SUSTAINABILITY SCIENCE PROGRAM,
CENTER FOR INTERNATIONAL DEVELOPMENT
KENNEDY SCHOOL OF GOVERNMENT, HARVARD UNIVERSITY
SUERIE_MOON@HKSPHD.HARVARD.EDU

Key Questions & Factors

Key Questions on Differential Pricing:
1. How to maximize access to medicines?
2. How to pay for R&D?
3. Who pays?
4. How much?
5. Who decides?

Key Factors:
1. Economic
2. Logistical
3. Scientific & Technological
4. Political:
   1. Medicines as global public goods → demand for access
   2. Governments ultimately responsible for protecting right to health

Single prices vs. Market segmentation

1. Are they *always* inequitable and inefficient?
   1. Inequitable: if price is not affordable
   2. Inefficient: if price much greater than production cost
   3. Ineffective: if price does not recoup R&D costs
2. Competitive production → Marginal/average cost pricing (efficient & more equitable)
3. Fair contributions to R&D (effective)

Differential Pricing: some evidence

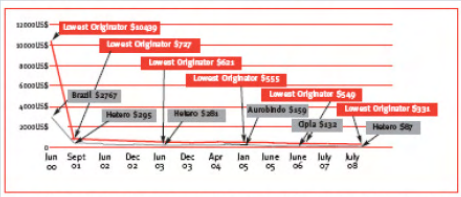
"Differential pricing is not always social outcome/access improving"

Waning et al (2009):
• >7000 ARV purchase transactions (2002-2007)
• For 15 of 18 products, differentially-priced drugs were 23-498% higher than generics

Source: Brenda Waning, Warren Kaplan, Alexis C. King, Danielle A. Lawrence, Hubert G.Leufkens, Mathew P. Fox. (2009). Global strategies to reduce the price of antiretroviral medicines. Evidence from transactional databases. *Bull World Health Organ* 2009;87:520–528 | doi:10.2471/BLT.08.058925

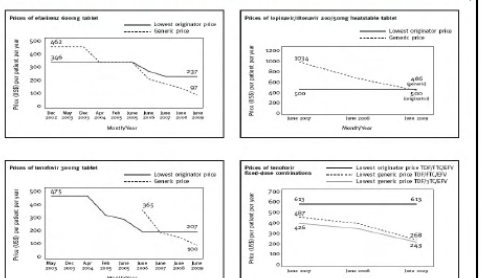
Differential pricing & Generic competition

• Differential prices not immune to market forces: fall when generic competitors enter market



Source: Medecins Sans Frontieres (MSF). (2008) Untangling the Web of Antiretroviral Price Reductions, 11th edition. Geneva: MSF Campaign for Access to Essential Medicines.

Differential pricing: trends over time



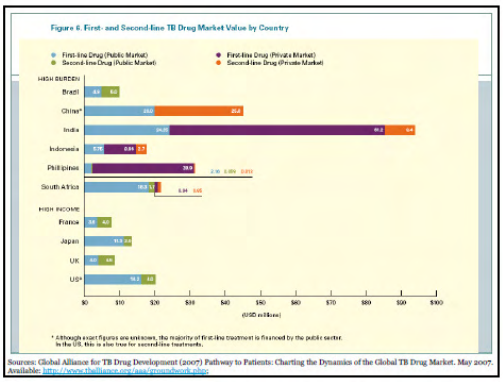
Source: Medecins Sans Frontieres (MSF). (2009) Untangling the Web of Antiretroviral Price Reductions,: Pre-publication price analysis , upcoming 12th edition, July 2009. Geneva: MSF Campaign for Access to Essential Medicines.

Internal differential pricing:
how equitable is public/private market segmentation?

Depends on:

1. Disease & product market:
   - Tuberculosis:
     - Brazil & South Africa: mostly public-sector market
     - India & Philippines: > 70% private sector market
   - Malaria:
     - ~50% in WHO Africa & Western Pacific, seek care outside public sector
     - 78% in Southeast Asia region, seek care outside public sector
     - AMFm intended to de-segment markets to increase access
2. Capacity of public health system:
   - Rural areas = Lower income, but Rural areas ≠ Public healthcare
3. National policies
   - South Africa delayed public treatment for HIV/AIDS

Sources: Global Alliance for TB Drug Development (2007) Pathway to Patients: Charting the Dynamics of the Global TB Drug Market. May 2007. Available: http://www.tballiance.org/aaa/groundwork.php; World Health Organization (2008) World malaria report 2008. WHO/HTM/GMP/2008.1. Available:http://www.who.int/malaria/wmr2008/



Sources: Global Alliance for TB Drug Development (2007) Pathway to Patients: Charting the Dynamics of the Global TB Drug Market. May 2007. Available: http://www.tballiance.org/aaa/groundwork.php;

Business model of the future?

- Today's model:
  - Brand: Low volume & high margin; compete on drug efficacy & safety; limited developing country sales
  - Generic: High volume & low margin; compete on production efficiency, high developing country sales
- Tomorrow's model?:
  - Separate production from R&D
    - Competitive production for developing country markets
    - Tiered R&D contribution from developing countries via fees or royalties (e.g. based on income, inequality, disease burden, cost-effectiveness of product, etc.)
  - Gilead: tenofovir (TDF):
    - 2006: Voluntary license to >10 generic firms, 5% royalty
    - 2009: Gilead $365/$207 vs Generic $100
    - 2009: Most developing countries buying generic

For further discussion of de-linking production from the cost of R&D, see work by James Love, Tim Hubbard, Ellen 't Hoen, Michelle Childs, Joseph Stiglitz, WHO Global Strategy and Plan of Action, and others.

Summary

Differential pricing: when?

- Very useful when competitive production *infeasible*
  - Rapid access required
  - Small volumes
  - Costly production
- Encourage technology transfer to transition to competitive generic production

Key Questions on Differential Pricing:

1. *How to maximize access to medicines?*: equitable & efficient cost pricing via competitive production
2. *How to pay for R&D?*: royalties or fixed fees
3. *Who pays?*: all share burden of global public goods finance
4. *How much?*: Fair price = production cost + R&D contribution
5. *Who decides?*: Companies, Governments, Civil Society

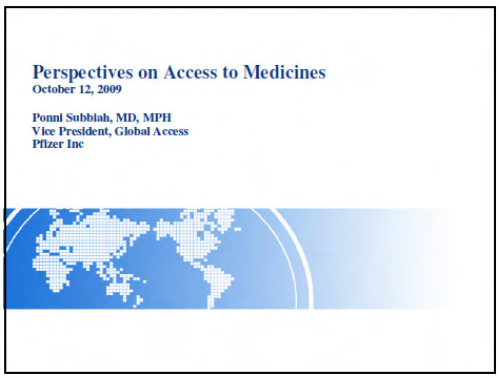
Empirical Research Needed

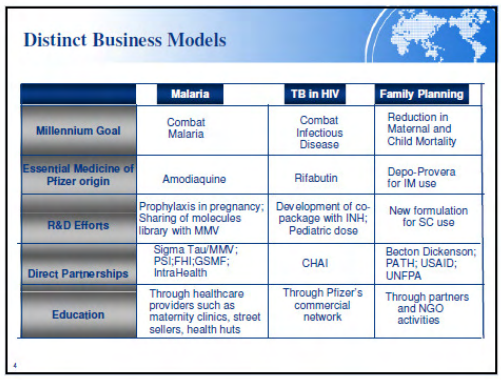
- Internal market segmentation:
  - How equitable is it? Feasible? Efficient?
- Informational arbitrage: conjecture vs evidence
  - What is the risk? Experience? What has occurred with contraceptives, vaccines and AIDS drugs? What role played by international norms?
- Physical arbitrage: conjecture vs evidence
  - What is the risk? Experience? For internal and internationally segmented markets?

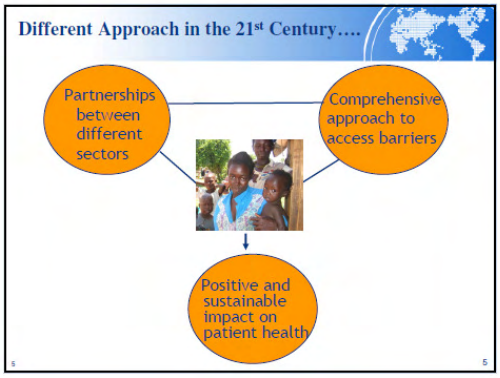
Thank you

SUERIE.MOON@GMAIL.COM

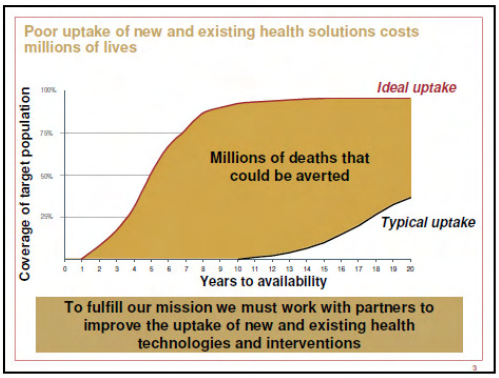
Annex 4: Perspectives on Access to Medicines - Pfizer Inc Presentation

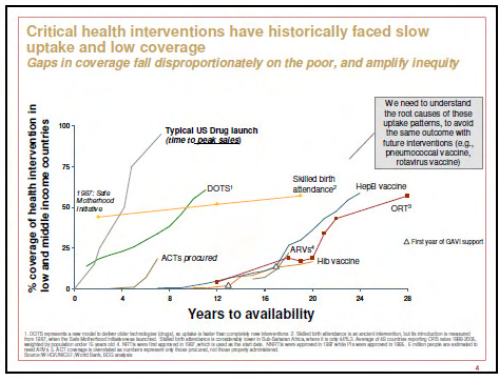


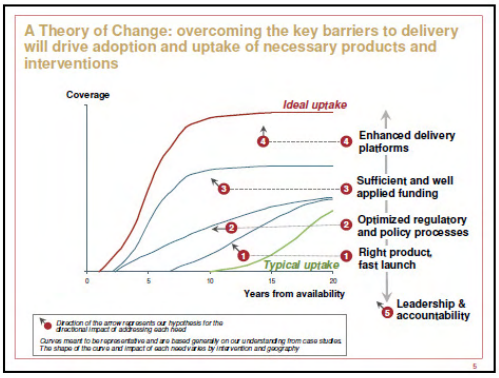


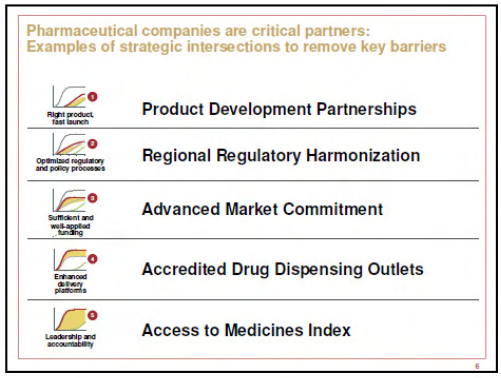


Annex 5: IGFAM- Gates Foundation Presentation

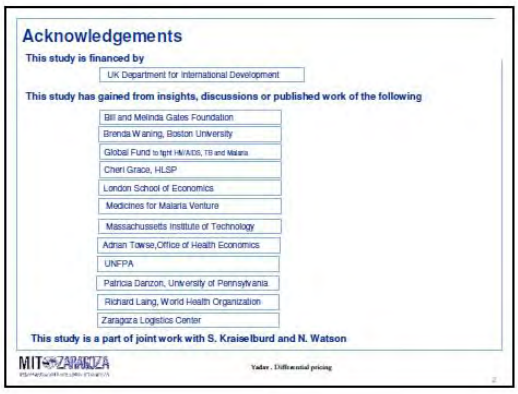


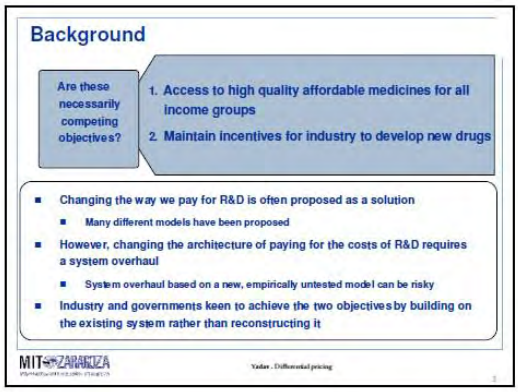


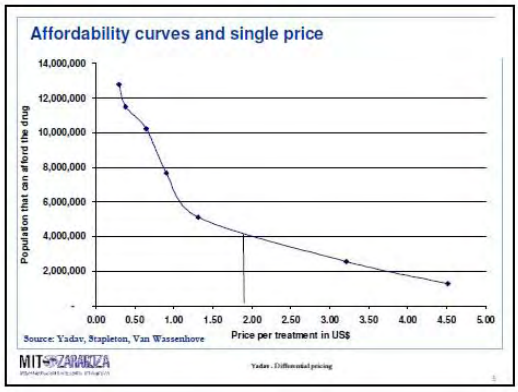




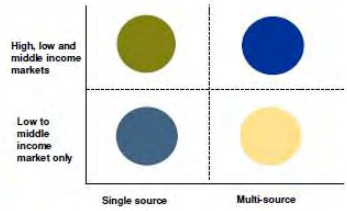
Annex 6: Differential Pricing Presentation - DFID







One dimensional (single vs. multiple source) market dynamics do not capture the realities



Each has different degrees of applicability of differential pricing and hence requires different caveats

Existing examples of differential pricing

Contraceptives	◆ Price of contraceptives in low income countries is lower by a factor of 10-100 ◆ Careful product versioning and differential branding ◆ Social marketing and social franchising often used as the sales channel

Differential pricing in Reproductive Health Commodities

	UNFPA	Market price in the US
Condom (piece)	0.025	0.50
IUD (Unit)	0.430	350.00
Injectable (dose)	0.675	65.00
OCs (cycle)	0.175	30.00
Spermicides (tablet)	0.060	1.20
Implants (set)	23.000	393.00

Source : UNFPA data 2005

Existing examples of differential pricing

Contraceptives	◆ Price of contraceptives in low income countries is lower by a factor of 10-100 ◆ Careful product versioning and differential branding ◆ Social marketing and social franchising often used as the sales channel
Vaccines	◆ Price of vaccines is much lower in developing countries ◆ Vaccines are purchased by UNICEF and vaccination programs are run by state and NGO actors ◆ Higher opportunities for differentiation due to multi-valency ◆ Little risk of leakage and good supply chain traceability
HIV/AIDS Drugs	◆ Multiple examples of tiered-pricing ◆ Political pressures from LMICs to reduce prices ◆ High risk of informational arbitrage to erode margins in high income markets ◆ With new entrants, supply market dynamics also working in favor of using price differentials

Existing examples of differential pricing (2)

Malaria Drugs	◆ Intra country price differential between public and private sector ◆ Plans to further differentiate the prices within the private sector channel to better reflect ability-to-pay of each segment

Coartem® and channel based market segmentation and pricing

Public Sector	Non-Premium Private Sector	Private Sector
		
100-160 million patients	**100-200 million patients**	**20-25 million patients**
Coartem® $ 0.36 – 1.30 Risk of leakage into private channel also presents itself as reputational risk to the financing agency (GF, WB, USPMI)	Currently, Coartem® $8-12 Various initiatives underway to provide preferential price to this sector Small controlled pilots show little leakage into the premium private sector	Coartem® $8-12 Riamet® (Europe) $50-60

Source: Novartis

Existing examples of differential pricing (2)

Malaria Drugs	◆ Intra country price differential between public and private sector ◆ Plans to further differentiate the prices within the private sector channel to better reflect ability-to-pay of each segment
OI drugs	◆ Dual markets ◆ Multi-sourced ◆ No clear examples of positive differential pricing at the manufacturer level ◆ No significant volume effects
Essential medicines	◆ No clear examples of positive differential pricing at the manufacturer level ◆ Evidence of prices paid by patients being negatively correlated to their ability to pay ◆ No significant volume or income effects in prices ◆ Drug donation programs with $p = 0$ in a few instances

MIT ZARAMZA Yadav . Differential pricing

What factors govern the manufacturer's price setting problem in markets with large institutional purchasers ?

- Volume of purchase
- Ability-to-Pay
- Security of financing (in the case of public sector buyer)
- Transaction Cost

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Current Challenges to Differential Pricing

- Differential pricing requires separable markets. Market separability falls apart very quickly due to informational arbitrage
- Low price in one country spreads across boundaries due to the negotiating power of large buyers
- Under a three tiered pricing structure (e.g. many ARVs), populations in LMICs with wide income distributions obtain treatments at prices higher than the relatively more affluent segments in the LDC or LICs
  - ◆ This creates political pressure to bring down prices
- Reference pricing done by some LMICs further limits the ability to engage in differential pricing

- Is country the right level of geography for differential pricing?
- Treaty of Westphalia is not binding to differential pricing
- We need to think of more appropriate segmentation

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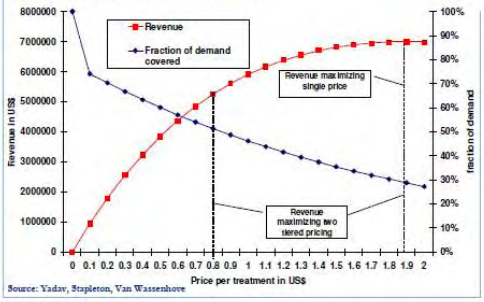
Intra country differential pricing



Source: Yadav, Stapleton, Van Wassenhove

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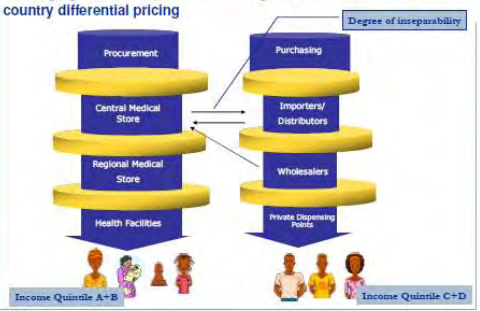
Leveraging channel separation and target reach to achieve intra country differential pricing



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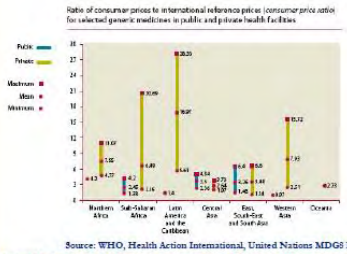
Differences of price between public and private sector for select medicines



Source: WHO, Health Action International, United Nations MDG8 Report

The risk of physical arbitrage between two different price segments is not as huge as some have conjectured in the past

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