

**Stakeholder dialogue session  
London, 16 October 2007**

# Access to medicines in middle-income countries

Context facilitated a workshop in October 2007 to seek stakeholder views on GSK's approach to access to medicines in middle-income countries. This was the third in a series of stakeholder workshops. Previous sessions looked at access to HIV/AIDS medicines in developing countries and R&D into diseases of the developing world.

These dialogue sessions enable stakeholders to raise their views in an open and frank way. It is useful for GSK to hear different perspectives when developing policies, even if the company does not always agree with them. Participants attend the meeting on the understanding that they should not expect GSK to incorporate all the divergent views in its policies.

## Attendees

### **Guests:**

Robert Barrington, F&C Asset Management  
Olive Boles, International Business Leaders Forum  
Michelle Childs, Consumer Project on Technology  
Cheri Grace, HLSP Institute  
Kate Ives, CARE International  
Andrew Jack, Financial Times  
Ken Shadlen, London School of Economics  
Helena Vines-Fiestas, Oxfam

### **From GlaxoSmithKline:**

Julia King, Vice President Corporate Responsibility,  
Robert Court, Vice President Government Affairs International

### **From Context:**

Beckie Herbert, Director (facilitator)  
Jamie Rusby, Consultant

## Agenda

Stakeholders were asked to give their views in three areas:

1. Is GSK's approach to access to medicines in middle-income countries appropriate?
2. What more could GSK reasonably be expected to do?
3. What role should GSK play in addressing other factors that prevent patients in middle-income countries receiving treatments (eg taxes and tariffs, lack of healthcare infrastructure)?

## Findings

### What is a middle-income country?

Participants emphasised the importance of increasing access in MICs. It was pointed out that many MICs have large numbers of very poor people. Companies should not treat MICs like high-income countries.

*"I have trouble with the concept of middle-income. These are poor countries. If you look at GDP per capita they are in the middle, but they are full of poor people with overburdened health systems."*

*"Companies should not have the same expectations as they do of developed country markets. There are still a lot of poor people in MICs."*

*"It would be useful for the report to illustrate the range of income levels in middle income countries. There are many very poor people in MICs, we are not just talking about the middle class."*

### Strategy and communications

Participants felt that GSK does not have a clear strategy on access in middle-income countries (MICs). They would like GSK to be clearer on its approach and objectives and to avoid spin in its communications. In particular they would like to know if GSK regards MICs as significant commercial markets.

*"GSK does not really articulate a strategic approach to these markets. Are they important in terms of future business opportunities?"*

*"Access in MICS is now of more interest than the LDC question. This is the issue that pharma needs to crack. There is a commercial opportunity here but none of the pharma companies are very well equipped yet to make money in these markets. Novo Nordisk is perhaps best placed, partly due to its products, and GSK is probably next. But the company doesn't appear to have a clear strategy for how they are going to do this."*

*"Their CR report is commendable in its coverage of MICs until you get to the bit on IP laws in India. This is spin. They don't mention that new ARVs will be covered by IP laws or that pricing is a key part of the equation. This is just glossed over."*

### Chronic diseases

Many participants pointed out that chronic diseases are a growing problem in MICs. It was suggested that GSK take a broad approach to access that encompasses all its medicines, not just those for HIV/AIDS, malaria and TB.

*"There needs to be more recognition of diseases outside the big three. The increase in chronic diseases (eg diabetes), will place a big burden on MICs."*

*"Non-communicable diseases are an area of great need."*

*"Access should be about all products. It's about your core business, not just a few drugs."*

*"There is too much focus on pricing for infectious diseases. You should be talking about drugs for diseases like diabetes."*

### **Companies as healthcare partners?**

There was a discussion on the broader role of pharmaceutical companies in MICs. It was suggested that companies should seek to be a healthcare partner to governments.

*"There is a natural dividing line in developed countries between the role of the state and companies. This dissolves in MICs. Companies need to work out how to be healthcare partners."*

*"I'd like to know how GSK is working with the rest of the industry and the UK government on pricing and transparency."*

*"Private programmes to serve the base of the pyramid need to be done in conjunction with government. When done separately they can be disruptive. Companies should support the creation of public health systems and embed private programmes in these."*

### **Increasing access**

There was recognition for the work GSK is doing on access to medicines but participants expected the company to go further. There was a discussion on different ways to increase access. Options suggested including tiered pricing and lower-cost manufacturing.

*"The pharma industry's reputation is unjustly negative. 25 years of research into HIV treatment is a fantastic commitment."*

*"Oxfam are in talks with GSK on innovative approaches to increase access, including differential pricing."*

*"GSK could pay more attention to lowering costs in manufacturing. This has not been a focus in the past as the profits have been too high and*

*manufacturing has been a small cost in comparison. They could use third party or generic manufacturers to lower costs. There could be more work done to create differentiated pricing within and between countries."*

*"Preferential pricing should be used. Wealthy people go private they don't use the state system. You would still have a market even if you gave drugs away to the poor people. MICs are contributing to innovation through the private sector."*

### **Obstacles to preferential pricing**

There was a discussion on product diversion as a potential obstacle to preferential pricing for MICs and to differential pricing within countries. Some participants felt that concerns on this issue have been over-played by the industry.

*"There is a fear of jeopardising prices in developed countries through flow back of products and buyers benchmarking prices with developing countries. However physical product diversion has been limited. Buyers already know the structure of the healthcare market so benchmarking would not be a major issue."*

*"I wonder if the issue of diversion has been overstated. Are the mechanisms being used to stop diversion also marketing tools against generics?"*

### **Transparency on pricing**

It was felt that companies should be clearer on the preferential prices they negotiate with MICs. This would help to increase access, for example by making it more difficult for intermediaries to add mark-ups. Some participants advocated that GSK adopt a tiered pricing approach rather than negotiating prices on a case-by-case basis. This would improve consistency, and make price negotiations straightforward and less time-consuming for MICs.

Transparency would also benefit the companies by increasing trust and making it less likely that MICs will use mechanisms such as compulsory licences.

Greater transparency on lobbying would also help to build trust.

*"There isn't enough transparency on pricing. Companies say they are selling the drug at the lowest price possible, and then they lower it three months later."*

*"It is a mistake to have a case by case approach. There will be a requirement for more transparency on your approach to pricing in the future."*

*"Compulsory licences could be avoided with lower prices and more transparent pricing structures."*

*"I can see why drug companies want to rebalance the playing field with generics companies through trade agreements. But lobbying is regarded with suspicion. Companies need to find honest intermediaries to conduct these campaigns."*

### **Intellectual property**

Intellectual property laws and the pharmaceutical companies' approach to IP were cited as two of the biggest obstacles to access.

Many participants felt that pharmaceutical companies use IP laws to place unnecessary obstacles in the way of generic companies. Companies were also criticised for their attitude to governments who implement the flexibilities of TRIPS, such as compulsory licensing.

*"Voluntary licences shouldn't be limited geographically or confined to ARVs. Where is the incentive if you can only sell to African markets? Pharma companies should not hinder the role of generics. The more companies that compete the lower the prices. You need to look at the long-term interests of society, not just short-term profits."*

*"When a patent is near to expiring pharma companies play the system trying to get every last hour out of it. This means no one knows when the patent will expire so there is no incentive for generics companies to prepare for production."*

*"Pharma companies still have an aggressive attitude to IP. They push for strong IP inappropriately, stifling the generics industry. There is abuse of trade agreements - extending patents, suing generics companies, and lobbying governments not to pass laws (eg in the Philippines). They are interfering with developing countries' right to implement flexible measures."*

*"Companies say they support Dohar and compulsory licensing. But data exclusivity kills compulsory licensing."*

There was concern about new patent laws in India and how these would be used by companies. Companies, such as GSK, who make second line ARVs are likely to come under more pressure on this issue. Unlike first line ARVs, these drugs will be covered by the new patent laws.

Participants would like to know whether and how GSK intends to apply its patents in India.

*“Patents for second line HIV drugs will be a big issue because these are still on patent in MICs. How does GSK intend to respond to this issue?”*

*“IP protection in India is a serious concern and probably the most important issue in access. India is the pharmacy of the world. It’s a major supplier to the least developed countries. Is GSK engaging on this issue?”*

### **Can the IP model be replaced?**

There was a discussion on whether new business models could be adopted to resolve problems relating to IP protection in MICs. Several participants mentioned the possibility of finding new ways to motivate and reward research, rather than relying on IP protection. For example, government funding for R&D in return for unrestricted use of the resulting products.

*“Pharma companies are locked into a framework of IP laws that are not helpful for cracking MIC markets. Do pharma companies need to reinvent their business model?”*

*“The question is how can we promote innovation and access? Drug companies should give unrestricted use of drugs in return for support for R&D. Of course the terms need to be worked through - what percentage of healthcare budgets will pharma companies expect to take in return for waiving IP protection for their drugs?”*

*“NGO rhetoric excludes a discussion on how to fund innovation. The middle-class in countries like China should be paying for innovation. This is morally right.”*

### **The responsibility of others**

There was a discussion on the role of other stakeholders in increasing access to medicines. It was suggested that governments and generic companies could do more to remove obstacles.

*“Development is multi-faceted – its about economics, education and government. These things tend to get forgotten in discussions on access.”*

*“Pharma companies have legitimate questions about the royalty rates they receive from generic companies and compulsory licences. Generic companies should make a financial contribution and support clinical trials.”*

### **Addressing other obstacles to access**

It was felt that the industry does have a role to play in addressing barriers beyond pricing such as healthcare infrastructure and mark-ups. Companies should not use these problems as an excuse for inactivity.

*"Lack of healthcare infrastructure is used as an excuse to do less on pricing."*

*"Lack of healthcare infrastructure is not an excuse for not doing anything on pricing. If the prices are high there is very little incentive to invest in healthcare infrastructure as you would have no drugs for treatments."*

*"More transparency from the industry on pricing would reveal mark-ups and extra costs like taxes."*

*"Companies should look at partnerships (eg with other sectors) to increase healthcare infrastructure. Other sectors including water and waste management companies and education, all have a role to play in tackling the root causes of ill-health."*

*"Reaching patients at the bottom of the pyramid requires collective action, but companies have a strong facilitating role to play."*