



Ensuring Access to Essential Medicines in Developing Countries in Africa

American Pharmaceutical Group Position Paper, July 2008

1. The American Pharmaceutical Group (APG)

The APG represents all the major American pharmaceutical companies which are also based in the UK.

The Group believes that basic healthcare should be independent of where people live. About two billion people, one-third of the world's population, do not have access to essential healthcare services and medicine; many of them live in low income countries.

APG member companies are committed to enhancing access to medicines in Low Income Countries (LICs) in Africa through a variety of measures, including:

- Research and development of new medicines for diseases disproportionately affecting developing countries
- Humanitarian programmes, product donations and product access programmes that provide medicines at significant discounts, or at no profit levels
- Capacity building programmes, ranging from local health care professional skills development, to technology transfers going to companies based in LICs.

Together, these individual programmes improve and extend the lives of millions of the world's most disadvantaged people.

The members of the APG already make a real difference to the quality of healthcare and lives around the world through a variety of individual initiatives and philanthropic programmes. These are set out in the APG brochure "Access to Medicines" (see www.apg.uk.com).

2. The Importance of Infrastructure

The research-based pharmaceutical industry's ability to contribute to enhanced access to medicines in poorer countries depends entirely on the environments in which it operates.

Self-evidently, the pharmaceutical industry can best (and sometimes only) operate in the absence of civil war and in the presence of politically stable and effective governments.

However the need for a proper infrastructure goes deeper. The role of the pharmaceutical industry in the provision of medicines depends upon:

- Quality-assured manufacturing
 - The proper collection and storage of medicines on arrival
 - The reliability of governments, and the absence of any corruption
 - Good transport distribution and regular re-supply
 - Healthcare professionals to administer the medicines and to monitor outcomes.
- Access to medicines is particularly curtailed by inadequate numbers of healthcare professionals, which many see as the single most important obstacle to treatment.

To maximise the industry's current contribution to improving access to medicines, the APG has given its support to the UK Government in its commitments to:

- Build and strengthen healthcare capacity and infrastructure in LICs in Africa. This effort should include human resources and technology to ensure available medicines reach those people who need it
- Ensure appropriate incentives are put in place to encourage the development of new medicines for neglected diseases
- Promote patient health by establishing reliable intellectual property infrastructures in developing countries (the private sector and public research institutions depend on such rights), including adequate trademark and customs enforcement
- Reinforce efforts to combat illicit diversion and counterfeit drugs in both humanitarian and commercial markets.

3. Working with Government

The APG has welcomed its involvement in the development of Government policy, particularly (but not only) with the Department for International Development (DFID). This work has included discussions and submissions on Government publications:

- *Advanced Market Commitments* for new vaccines in developing countries (2006)
- Submission to the DFID consultation document *Health Strategy* (2006)
- *Global Health Partnerships* by Lord Crisp (2007)
- The Department of Health – the CMO’s *Health is Global* consultation (2007)
- Response to DFID’s *Medicine Transparency Alliance (MeTA) Phase One Proposal* (2007)
- Submission to DFID’s *Updating Taking Action – the UK’s strategy for tackling AIDS in the developing world* (2007).

The Group is working in 2008 with DFID in updating the latter’s paper on good practice in the pharmaceutical industry.

The APG has sent papers to the Government, for example on differential pricing and harmonizing the registration of medicines in Africa, and has discussed paediatric medicines, prevention of mother-to-child transmission and intellectual property rights.

4. Differential pricing programmes

In order to achieve the Millennium Development Goals, global efforts have to be concentrated where they are needed most – those countries that are poorest and / or carry disproportionate disease burdens.

As the Department for International Development has said: “*the majority of pharmaceutical companies have developed some form of ‘differential pricing’ for some of their product range*”¹. For LICs this is commonly at cost; for middle income countries at levels substantially less than in the developed world.

¹ Increasing people’s access to essential medicines in developing countries: a framework for good practice in the pharmaceutical industry. A UK Government policy paper, DFID, March 2005.

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For both LICs and middle income countries, it is worth noting that some 95% of medicines on WHO's list of essential medicines are off-patent (*source: A framework for good practice in the pharmaceutical industry, DFID, March 2005*).

In addition, LICs are exempt from patent protection on medicines and, if they do not manufacturing capacity, can import them from other countries under compulsory licences (see Section 6 on Intellectual Property Rights below).

5. The Medicines Transparency Alliance (MeTA)

At the launch of MeTA on 15 May 2008, the DFID Secretary of State said that:

“The problems of price, quality and availability can be tackled by improving transparency and access to information. MeTA will provide citizens, health care workers and others with information to challenge corruption, excessive pricing and waste.”

MeTA is new scheme for increasing transparency around the selection, regulation, procurement, sale and distribution of medicines in developing countries from port to patient. The focus is on strengthening developing country capacity to collect, analyse, disseminate and use data on medicine quality, availability, pricing and use.

The APG engaged closely with DFID for some 18 months, welcomed its constructive approach and was pleased that many of the Group's recommendations were accepted. The theory of MeTA is attractive, but a number of practical concerns have been raised such as the range of medicines to be included, the avoidance of unintended consequences (for example, cutting revenue for hospitals and clinics from dispensing fees) and having clear evaluation schemes in place. DFID has proposed pilot schemes in seven countries, the first starting in late 2007, with the work being spread over some two years.



6. Intellectual Property Rights

The main pillar in tackling disease through medicines and vaccines has been the protection of Intellectual Property Rights (IPRs) with additional market protection through data exclusivity where appropriate. Both provide protection for new medicines for a reasonable period. They are essential for sustained investment in the research and development (R&D) of new and improved medicines.

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is a comprehensive international agreement on intellectual property administered by the World Trade Organisation (WTO). To assist the poorest or Least Developed Countries, as defined by the WTO, it was later agreed that patent protection would not be extended to them until 2016. It may be extended beyond that. An additional article in 2005 to the TRIPS agreement allowed members to produce and export pharmaceutical products under compulsory licences.

Compulsory Licences and Middle Income Countries

The TRIPS Agreement allows a member state to make use of a patent without the authorisation of the company holding the patent. This compulsory licence can be issued without consultation in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use, with the country itself being able to determine what constitutes a national emergency.

In 2006 the Thai military Government overrode a patent for an anti-retroviral drug, and the following year patents for a heart disease drug and a drug to treat HIV/AIDS were also overridden. In 2008, the Thai Public Health Minister announced that the imposition of compulsory licences on three cancer drugs was being considered.

The real issue is not Thailand itself, but the example set for other middle income countries, the most important of which are Brazil, Russia, India and China. It was disquieting that in 2007 the Brazilian Government also issued a compulsory licence for an HIV drug. If these and other middle-income countries were to follow these precedents, the whole structure of global patent protection could be undermined. This could mean that

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research-based companies, presumably unable to recover the lost revenue from the developed world, would be forced to cut their R&D substantially.

The APG believes that:

- It is useful that some form of “differential pricing” mechanism exists within the pharmaceutical industry, and that this alone should help avoid any need for compulsory licences
- There must be proper consultation with right holders, within a reasonable period, before compulsory licences are adopted
- Compulsory licences should be a matter of last resort, not the first. The WTO should be encouraged to set up an institutional framework where the justification for compulsory licences can be properly considered in the light of the intended application of TRIPS
- The UK Government should adopt a more pro-active role. It has long supported IPR as a way of rewarding costs and encouraging innovation and, as a leading member of the European Union, helped to negotiate the TRIPS agreement.

7. New medicines: industry record, patent pools and co-operative measures

New medicines

The pharmaceutical industry has a good record in the developing world in terms of providing new medicines and vaccines, at differential prices, and in supporting health infrastructures on the ground. The work and achievements of APG member companies are set out in its booklet. Even where diseases are largely or wholly to be found in the developing world, where returns on investment are low or nil, the industry has produced medicines for diseases such as Chagas, Dengue Fever, Sleeping Sickness, river blindness and leprosy. The vaccine for hepatitis B is being widely adopted.

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Table 1: Examples of developing world specific diseases and the medicines produced by APG members for their treatment.

Disease	Medicine/Product	Company
Diarrhoeal diseases – cholera, dysentery, etc	Questran (<i>Colestyramine</i>)	BMS
Leprosy	Mycobutin (<i>Rifabutin</i>)	Pfizer
Lymphatic filiarisis	Mectizan (<i>Ivermectin</i>) combined with Albenza (<i>albendazole</i>)	Merck & Co (GSK)
Malaria	Vibramycin (<i>Doxycycline</i>)	Pfizer
Onchocerciasis (River blindness)	Mectizan (<i>Ivermectin</i>) (Moxidectin – Phase II)	Merck & Co Wyeth
Pneumococcal disease (pneumonia, meningitis, osteomyelitis etc)	Prevenar (<i>Pneumococcal saccharide</i>)	Wyeth
Schistosmiasis (Bilharzia)	Vansil (<i>Oxamniquine</i>)	Pfizer
Tuberculosis/Multi-Drug Resistant TB	Capastat (<i>Capreomycin</i>) Seromycin (<i>Cycloserine</i>)	Lilly

Patent pools

One of the proposals being discussed by a number of organisations is the concept of sharing or pooling patents. In particular, the WHO and UNITAID have focussed on a patent pool for Anti-Retrovirals (ARVs) which they believe could facilitate the development of fixed dose combinations and reduce prices by increasing competition through more non-exclusive licensing.

There have been instances of pharmaceutical companies working together. For example, Atripla, a fixed dose combination drug for treating HIV, combines two medicines from Gilead Sciences with one from Bristol-Myers Squibb, with marketing and distribution in much of the developing world being handled by Merck and Co.

However there is no precedent for the involvement of national governments or international bodies in pharmaceutical patent pools, so this would be new territory. The



APG welcomes the decision by the World Health Organisation to proceed by way of a voluntary rather than a compulsory approach

Co-operation

New co-operative ways of developing new medicines are also being devised. Pharmaceutical companies are working with Governments on Advanced Market Commitments for vaccines; in Public-Private Partnerships; and in Global Partnerships with leading charities such as the Clinton and Gates Foundations. In addition, some companies have awarded voluntary licences to manufacture in the developing world.

8. Counterfeit Medicines

The theft of IPR in developing countries has become extremely serious. It is estimated that 10% to 15% of the world's drug supply is counterfeit, with the situation being exceptionally serious in Southeast Asia. (*Far Eastern Review, February 2008*)

This was confirmed by *The Lancet* which stated that:

“In developing countries, where drug regulatory systems can be weak or non-existent, around 10% - 30% of medicines might be counterfeit. Antimalarials have been a particular target for counterfeiters, and fakes have flooded the market in many Asian countries.” (10 May 2008)

In such instances, the danger to public health comes not only from the consequences of not treating illnesses, but from the risk of increasing drug resistance.

Governments with support, where appropriate, from the pharmaceutical industry, can:

- Strengthen their ability to regulate the drug supply (see Section 9) below
- Warn doctors, pharmacists and nurses about counterfeiting
- Educate medical staff and the public
- Monitor the flow of company products, such as through new track-and-trace technologies
- introduce criminal penalties in countries where counterfeiting medicines are not considered a crime and increase the penalties in other countries where necessary.

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9. Harmonizing the Registration of Medicines in Africa

The World Health Organisation has estimated that “*one-third of WHO Member States have no medicines regulatory authority, or at best very limited capacity for regulation of the pharmaceutical market. Regulatory gaps are common, with the informal sector for medicines supply often neglected.*” (WHO Medicines Strategy 2004-07).

The consequences are very serious for patients and for the efficient supply of safe medicines:

- Regulators themselves are often poorly qualified and may only duplicate work being carried out by their neighbours
- There is a greater use of substandard or counterfeit medicines which may cause damage to health, treatment failure or death
- Treatment with ineffective medicines leads to the emergence of anti-microbial resistance
- Understaffed systems inevitably mean delays in developing countries licensing a new medicine. This is done following the issuing of a Certificate of Pharmaceutical Product from the source country.

One solution is the harmonization of drug registration by internationally regarded authorities, much like the system which has developed in the Western world. This would:

- Improve the implementation of regulatory requirements and standards by manufacturers and distributors
- Enable manufacturers to supply effective drugs more rapidly.

The APG strongly supports any initiative which would help to bolster registration in Africa to ensure medicines are adequately approved through a faster, more harmonised system that would not in any way diminish the quality standard of medicines being approved.

10. Other Issues

Paediatric medicines: in 2007 an estimated 420,000 children were newly infected with HIV, the vast majority of them through mother to child transmission (MTCT). (*source: WHO website, May 2008*).

MTCT is almost entirely preventable, where services are available, however the coverage levels are remarkably low in most resource-limited countries.

Safer delivery practices and the avoidance of breast-feeding where the mother is HIV positive are vital. Drugs for adults can also secure healthier children, as ARV therapy for the mother can substantially reduce the risk of transmission.

Diversion: the diversion of medicines that are donated or provided at low price is a betrayal of the people whom the medicines are intended, and an unwarranted threat to the industry. The APG welcomes the Government's commitment in *Increasing people's access to essential medicines in developing countries: a framework for good practice in the pharmaceutical industry* (2005) to facilitate effective measures to combat this risk, as diversion within an LIC and between LICs and other countries is a barrier to the development of sustainable medicines markets. It also jeopardises the sustainability of differential pricing itself.

Donation schemes: pharmaceutical companies, often in partnership with experienced private voluntary organisations, have provided professional and appropriate donations. These have been provided on a purely philanthropic basis, in line with WHO guidelines, and have included disaster relief, disease eradication programmes and treatment of acute opportunistic infections. Such efforts complement, or are key components in, programmes to facilitate sustainable access as well. Appropriate donations programmes, when aligned with infrastructure development, can provide sustainable solutions to improving access.