



Ensuring Access to Essential Medicines in Developing Countries

American Pharmaceutical Group Position Paper, February 2010

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) particularly 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 make a real difference to the quality of healthcare and lives around the world through their individual initiatives and philanthropic programmes. Details of their policies and activities in the developing world can be found at www.apg.uk.com. The APG brochure is obtainable from the Secretariat, whose contact details are on the website.

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.

The APG has given its support to the UK Government to:

- Build and strengthen healthcare capacity and infrastructure in LICs. This includes sufficient human and other resources to ensure that treatments reach those in need
- Ensure appropriate incentives are put in place to encourage the development of new medicines for neglected diseases
- Protect intellectual property rights in middle income developing countries, as the private sector and public research institutions depend on such rights
- Reinforce efforts to combat illicit diversion and counterfeit drugs in both humanitarian and commercial markets.

3. Working with Government and IGFAM

The APG has welcomed its involvement in the development of Government policy, particularly, but not exclusively, with the Department for International Development (DFID).

This work has included discussions and submissions on a number of Government policies and publications. For example, in 2008 the APG was consulted by DFID in the Review it had commissioned of the UK Government's earlier *Framework for Good Practice in the Pharmaceutical Industry*. The Review was published in December 2008.

In early 2009, DFID proposed bringing together the industry group involved in the Review with DFID, the Department of Health and the Department for Business, Innovation and Skills. The resulting Industry-Government Forum on Access to Medicines (IGFAM) was launched in October 2009.

The modus operandi of IGFAM will be a series of dialogues structured around particular areas where industry and government can work together to improve access to medicines. NGOs, academics and other relevant institutions/people can also be involved.

Where appropriate, dialogues will be based on academic work commissioned by DFID to set out the evidence and to make proposals for policy ideas that might be worth pursuing, whether by industry or government.

Areas of interest include

- Differential pricing models for middle income and LICs, and extending them to a broader range of products, which will be the subject of the first IGFAM commissioned paper
- Exploring further licensing strategies as one route towards improving access in a commercially sustainable manner
- Developing new strategies to enhance access to products to treat non-communicable diseases in all markets
- Enhancing R&D in neglected areas such as paediatric medicines and diagnostics
- Harmonizing regulatory processes to support R&D and access strategies, particularly in sub-Saharan Africa.

4. Differential pricing programmes

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

For LICs this has meant that pharmaceutical companies have commonly provided such medicines for MDG diseases at cost; for middle income countries at levels substantially less than in the developed world.

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*).

The extension of differential prices to non-communicable diseases was called for in the DFID 2008 Review. This raises questions about whether the focus of the industry should be on the MDG diseases or widened to other disease areas.

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

Industry record

The pharmaceutical industry has a good record in providing new medicines and vaccines at differential prices. Even where diseases are largely or wholly to be found in the developing world, where returns on investment are low or nil, APG members have produced medicines for diseases such as those set out below:

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

These are only a few examples. *The IFPMA Health Partnerships: Developing World – 2009* lists over 200 programmes, capacity building activities, R&D into drugs and vaccines, and other health initiatives. It can be accessed at <http://www.ifpma.org/healthpartnerships/>

Patent Pools

One of the proposals being discussed by a number of organisations is the concept of sharing or pooling patents. Patent pools, as defined by the WHO Independent Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH):

An agreement between two or more patent owners to license one or more of their patents to one another or third parties

In line with this, the APG supports the mechanism in principle, dependant on the following provisos:

- They must concentrate on the needs of patients in Low Income Countries
- They must focus on areas of unmet medical need
- Involvement must always be voluntary
- They must be constructed in such a way as to avoid inappropriate exploitation by third parties
- They can be used as a complementary tool alongside other types of agreement such as public private partnerships, voluntary licenses and donations.

Co-operative Measures

New co-operative ways of developing new medicines are also being devised. Public private partnerships are a normal way through which the industry functions, and have been for some time. Others involve companies awarding voluntary licences to manufacture in the developing world; Advanced Market Commitments for vaccines; and Global Partnerships with leading charities such as the Clinton and Gates Foundations.

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), which was completed in 2005. To assist the poorest or Least Developed Countries, as defined by the WTO, it was 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. 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 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:

- Forms of “differential pricing” mechanisms within the pharmaceutical industry should help avoid the 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. 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. DFID has pilot schemes in seven countries, with the work due to be completed in 2010.

8. Counterfeit Medicines

The theft of IPR in developing countries has become extremely serious. Although robust data is needed, 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.

In 2009 the APG held a successful all-day Conference jointly with the Wellcome Trust on counterfeit medicines in the developed and developing world. Attendees were drawn from abroad as well from among UK experts and officials, and the Conference focussed on defining the issues, the impact of counterfeit medicines and the responses needed to tackle the issue.

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).

These are very serious accusations, but then 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
- Papers are often lost
- 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.

For some time, the APG has called for the UK Government to take the initiative to bolster registration in Africa by ensuring that medicines are approved through a faster, more harmonised system, that would not diminish the quality standard of medicines. The 2009 meeting in London for donors and other interested stakeholders arranged by DFID has been much welcomed. This is one of the subjects which IGFAM (see above) is likely to address.