



Ensuring Access to Essential Medicines in Least Developed Countries and Sub-Saharan Africa

American Pharmaceutical Group Position Paper, May 2006

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. One-third of the world's population, about two billion people, does not have access to essential healthcare services and medicine, simply because they live in poorer countries.

APG members are committed to enhancing access to medicines in Least Developed Countries (LDCs) and sub-Saharan 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 to companies based in LDCs.

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

The members of the APG already makes 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).



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 the existence of a politically stable and effective government.

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

- The proper collection and storage of medicines on arrival.
- The lack of official widespread corruption.
- Good transport distribution and regular re-supply.
- Health professionals to administer the medicines (for example, an HIV patient may need to take up to six medicines a day) and to monitor outcomes. In our experience, access to medicines is particularly curtailed by inadequate numbers of healthcare professionals. Many see this 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 LDCs in and sub-Saharan 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 developing 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.
- Encourage and facilitate the participation of previously uninvolved sectors of society in broad public private partnerships.

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Working with government: The APG welcomed participation in the development of the Department for International Development's *Increasing people's access to essential medicines in developing countries: a framework for good practice in the pharmaceutical industry*¹.

The APG will also be contributing to the Department's strategic paper for the next 5-10 years.

However, continued dialogue and partnership is needed to address outstanding issues regarding differential pricing, diversion, enhanced incentives for research and development related to diseases disproportionately affecting LDCs, the optimal geographic and disease area scope of differential pricing programmes, the continuing role of and need for donation schemes, and the participation of private sector companies outside the pharmaceutical industry.

Definition of geographic and disease area scope of differential pricing programmes:

In order to achieve the Millennium Development Health Goals, global efforts have to be concentrated where they are needed most – those countries that are poorest and / or carry disproportionate disease burdens. Differential pricing programmes therefore should be extended to LDCs and sub-Saharan Africa. Similarly, priority should be given to those diseases disproportionately affecting LDCs and sub-Saharan Africa. A focus on child mortality, improved maternal health and the priorities highlighted in the Millennium Development Goals – namely a reduction in, AIDS, tuberculosis and malaria – will ensure the most rapid progress.

Paediatric medicines: In 2005, around 700,000 children under 15 became infected with HIV, mainly through mother to child transmission (MTCT). About 90% of these MTCT infections occurred in Africa, where AIDS is beginning to reverse decades of steady progress in child survival.

¹ Department for International Development: *Increasing people's access to essential medicines in developing countries: a framework for good practice in the pharmaceutical industry*, 2005

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Mother to child transmission occurs when an HIV positive woman passes the virus to her baby. This can occur during pregnancy, labour and delivery, or breastfeeding. In the absence of any intervention, an estimated 15-30% of mothers with HIV infection will transmit the infection during pregnancy and delivery, and 10-20% through breast milk (source: WHO website, May 2006). Two of the most effective preventive measures are therefore safer delivery practices and the avoidance of breast-feeding where the mother is HIV positive.

Drugs for adults can also secure healthier children. ARV therapy for the mother can reduce the risk of transmission substantially. Where inadequate capacity precludes long-term ARV therapy, single-dose therapy for the mother, combined with short-term treatment for the infant can be highly beneficial.

A further major reduction could be achieved through paediatric medicines. However, just as there are problems with avoiding breast-feeding, due to cultural problems, so there are different challenges in treating children:

- The typical antibody diagnosis cannot be used for children under 18 months. A diagnosis for the virus itself is difficult and expensive.
- Paediatric antiretroviral therapy requires dosing by weight. Few healthcare workers in developing countries are trained to provide paediatric antiretroviral (ARV) therapy.
- Many paediatric formulations are in syrup form, which require refrigeration and tend to have a bitter taste.

The pharmaceutical industry, including APG members, is taking the following measures:

- Of the 21 innovator ARVs approved by the Department of Health and collection and Human Services/Food and the FDA for the treatment of HIV/AIDS in adults, 12 are approved for use in children, including seven for children under the age of two years. Four generic ARVs in paediatric formulations have been tentatively approved to date.
- All ARVs produced by APG member companies and on the WHO list are supplied in paediatric formulations at prices at least the same as for adult formulations.
- Research is being carried out into low dose tablet ARVs, which are clearly desirable.

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Drug prices: some 94% to 98% of medicines on WHO's list of essential medicines are off-patent (*source: a framework for good practice in the pharmaceutical industry, Department for International Development, March 2005*). For those very new essential medicines under patent, the TRIPS (Trade-Related Aspects of Intellectual Property Rights) agreement provides for least developed countries to manufacture them under licence (ie at manufacturing cost only) or to import them from other countries that manufacture them under licence.

Differential Pricing: differential pricing commonly refers to situations where company prices discriminate across markets to take account of social welfare and the ability to pay. APG members, acting individually, have contributed significantly to the process of enhancing access to medicines through voluntary differential pricing systems for key products. However, this should not be seen as a solution in itself – largely because it does not account for the challenges that remain in developing in-country healthcare capacity.

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. We welcome the Government's commitment in the "Framework"² to facilitate effective measures to combat this risk, as diversion within an LDC and between LDCs is a barrier to the development of sustainable medicines markets. It also jeopardises the sustainability of differential pricing itself. We therefore call on the Government to take stronger action – in the interest of citizens of both the developing and developed world.

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.

² Ibid



Research and development: The research-based pharmaceutical industry has made, and continues to make, a very significant contribution to the development of new medicines for diseases disproportionately affecting LDCs and sub-Saharan Africa.

However, it cannot accept responsibility for this need on its own. Increasing investment in R&D for diseases affecting these countries requires action by donors, international agencies, pharmaceutical companies and private and public research institutes.

The research-based pharmaceutical industry can only invest in drug development if there is a reasonable expectation that R&D investments will be recouped, and if the product of that investment – intellectual property – is protected.

Different sectors of the pharmaceutical research community have different funding and incentive requirements. A range of funding and incentives are needed. The APG therefore calls on the UK Government to urgently launch broad consultation on the full range of current and potential incentives for R&D into these disease areas, including:

- The effectiveness of R&D tax incentives. The APG welcomes these incentives, but the fact that medicine R&D takes place on a global, rather than national level, needs to be recognised. Current UK R&D incentives favour small and medium enterprises (SMEs). Yet it is the larger companies which invariably bear the heavy financial burden of global clinical programmes.
- Advanced Market Commitments (AMCs) under the IFF for Vaccines. The APG welcomes the proposed introduction of AMCs and calls for the rapid conclusion of this proposal. AMCs should not be considered for extension to medicines until the scheme for vaccines has been given a chance to prove itself.
- Exploring ways by which medicines approved by the Federal Drug Administration and European Medicines Evaluation Agency do not require further, additional time consuming and bureaucratic regulatory approval processes at a local national level.
- Innovative new proposals such as for extended intellectual property rights for medicines for diseases disproportionately affecting LDCs and sub-Saharan Africa.

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Broader Private Sector Participation: Private sector participation in enhancing access to healthcare has often focused narrowly on pharmaceutical industry efforts. The creation of environments that will support enhanced access to medicines now depend on public private partnership beyond the confines of the pharmaceutical industry. There is a strong argument to be made that Government should proactively promote the development of best-practice guidelines with other sectors of industry and society, as it has done in increasing people's access to essential medicines in developing countries: a framework for good practice in the pharmaceutical industry.

