



The APG Submission of 3 June 2004 to the Department for International Development's Consultation Paper: *Increasing Access to Essential Medicines in the Developing World: UK Government Policy and Plans.*

The American Pharmaceutical Group (APG) commends the Department for International Development (DFID) for the publication of the draft consultation paper, *Increasing Access to Essential Medicines in the Developing World: UK Government Policy and Plans.*

The APG believes this paper will encourage both increased commitment to enhancing access to medicines in the developing world, and improved understanding of the issues affecting that commitment.



1. Background on the American Pharmaceutical Group

The American Pharmaceutical Group (APG) was set up in 1985 to improve understanding of the industry, and the health care contribution of the American companies in particular, among Government, Parliament and interested stakeholders. The APG works closely with the industry's trade body, the Association of the British Pharmaceutical Industry, but with the US being the most competitive market for medicines in the world and accounting for over half of the developed world's R&D, the APG is able to add a special perspective.

2. A shared concern

The APG shares DFID's concern over the many millions of people who die every year of preventable and/or treatable diseases. It remains committed to contribute to global efforts to lower those unacceptable figures.

Individual members of the APG have been among the leading companies in providing HIV medicines at significant discounts. Members of the APG are also founding members of the Accelerating Access Initiative, which involves UN organisations in increasing access to HIV and AIDS care in the developing world. By the end of 2003, the AAI had provided treatments to more than 150,000 patients in Africa – double the number treated six months earlier. Prices of ARV medicines in particular have come down significantly in the past four years – since the AAI began in May 2000. And with the influx of new funds for HIV/AIDS, TB and malaria – through the Global Fund, PEPFAR, and bilateral programs like DFID's – it is now possible to look more comprehensively at the factors of



human resource capacity and healthcare infrastructure that continue to limit the more rapid expansion of access to medicines in the developing world.

The very fact that effective, low cost interventions could prevent two-thirds of the world's 10-million child deaths every year, underpins the APG's contention that broad public healthcare capacity, more than the cost and availability of drugs alone, determine access to essential medicines for the majority of people in the developing world. Even low-cost drugs require healthcare workers to prescribe and provide them. And the demands that diseases such as HIV, AIDS and tuberculosis make on healthcare capacity are very extensive.

3. Healthcare Capacity, the Key to Drug Access

Existing therapies for high-prevalence diseases such as HIV, AIDS and tuberculosis, simply cannot be provided safely to patients in the absence of comprehensive care programmes that can support the monitoring of disease progression, ensure high levels of patient concordance with prescribed therapies, guard against the potential development of drug resistance, and effectively treat opportunistic infections.

HIV, AIDS and tuberculosis did not create the shortfall in healthcare capacity in the developing world. However, due to their long latency and broad pathological manifestations, HIV, AIDS and tuberculosis have dramatically highlighted and exacerbated the systemic inadequacies, many of which existed long before the dramatic rise in the prevalence of these diseases. Capacity is largely the sum of commitments past and no amount of money can instantly rectify heritages of underdevelopment.



Similarly, access to medicines depends on a broad set of factors – from the funding of the development of those drugs in the first place to the political will to commit the resources to provide essential medicines – being in place. Continued over-emphasis of pricing alone as a factor will at best detract from breaking down other, more challenging, barriers to broad access to essential medicines. At worst, it could lead to drugs becoming available in healthcare environments that could not provide them without compromising patient safety.

4. Global Commitment

Creating a global healthcare environment that can facilitate universal access to essential medicines will require a global effort from a broad scope of stakeholders. The APG remains committed to helping to maximise global healthcare capacity through the development of new medicines, as well as more easily administered new formulations of existing drugs. Members of the APG believe this to be their primary role in global efforts to enhance access to essential drugs.

Members of the APG will also continue to contribute to a large number of corporate social responsibility programmes, aimed at making sure more people receive the medicine they need.

Developing and providing essential medicines that will improve the lives of people wherever they are, is the *raison de être* of the members of the APG. Creating universal



access to those medicines is a global challenge requiring significant efforts from stakeholders outside the pharmaceutical industry.

The UK Government, through DFID and other organs of state, can and should play an essential role in channelling those efforts, as well as in creating and maintaining a political and economic environment that is conducive to broad commitment. That is the essence of public-private partnership. And partnership will remain the key to enhanced access to essential medicines.

5. Specific Comment

The APG requests DFID to consider the following specific comments to the paper.

5.1 Resistance (Paper 2.3)

The APG is particularly concerned about the development of resistance to existing drugs for high-prevalence diseases, such as malaria and tuberculosis, as well as in particular, HIV and AIDS. Patient concordance (adherence) with prescribed therapies remains the most effective barrier to the development of drug resistance. This underlines the need for broad healthcare capacity to monitor and evaluate both adherence and resistance development – capacity that is often lacking in those societies in most desperate need of essential medicines. Comprehensive patient information, education and communication campaigns will be vital to ensuring broad patient concordance.



In this light, the APG suggests that the following sentence should be added to the end of the paper's paragraph 2.3:

The resistance risk underlines the need for broad healthcare capacity to monitor and evaluate both adherence and resistance development – capacity that is often lacking in those societies in most desperate need of essential medicines. Comprehensive patient information, education and communication campaigns will be vital to ensuring broad patient concordance. Similarly, ensuring universally high quality of ARVs must be a global concern, as low quality medicine too could cause the development of resistance.

5.2 New Products (Paper 2.4 & 3.3)

The APG commends DFID for its recognition of the need to include new medicines on essential drugs lists. Given this need, it is essential to also create a framework for the funding of research and development programmes aimed at developing essential new medicines. That framework needs to extend beyond the pharmaceutical industry, as the commercial viability of drugs specifically essential for the developing world cannot always be ensured.

The APG suggests the following sentences should be added to the paper's paragraph 3.3:

“While the pharmaceutical industry has a commercial interest in the research and development of new drugs, the responsibility for that research rests with society as a whole. This duty is particularly relevant for the research of medicines specifically aimed at circumstances in developing countries, as the commercial viability of such drugs



cannot be guaranteed. It is therefore essential for governments to create an economic and policy environment that encourages proactive commitment to expanded access from the pharmaceutical industry.”

5.3 Knowledge of need (Paper 3.1 & 3.2)

The long latency and broad pathological manifestations of diseases such as HIV, AIDS and tuberculosis places a specific need on broad information, education and communication campaigns. People also lack access to medicines, if they do not **know** that they need it in the first place.

The reference to medicines in the first sentence in 3.1 is too narrow and the APG therefore recommends that it should read (changes underlined) as follows:

People lack access to medicines when they cannot obtain the products and supporting services that are needed for the appropriate use of medicines. All these are needed to prevent, diagnose, treat or manage a medical condition.

The APG also suggests the following addition (underlined) to the paper’s paragraph 3.2:

However, price is no longer the main the only barrier to access. Inadequate financing for health, poor priority setting, inadequate drug selection and prescription, and weak health and supply systems ~~also~~ play a more significant part in preventing people from getting the care they need. What is more, people will not seek access to drugs, if they are not aware of their need for it. This is particularly the case with HIV, AIDS and TB. Broad information, education and communication campaigns are therefore essential for



enhancing access to medicines in the developing world. Simple, accurate and convenient tests for HIV and TB, supported by confidential counselling, is an unavoidable gateway to access to medicine and must be universally available. The WHO framework...

5.4 The 10/90 Gap (Paper 3.4)

The need for research and development of new medicines that can narrow the 10/90 gap is undeniable. However, this must be complemented by non-biomedical research into the socio-cultural, socio-economic, political and systemic causes that contribute to this unacceptable divide. (Please refer in this regard to the Global Forum for Health Research). It will be of particular importance that this research must be underpinned by European, if not global, cooperation.

5.5 Building Health System Capacity (Paper 3.6)

The APG believes enhancing healthcare capacity remains the key to broad access to essential medicines. Vertical programming, with inadequate development of supporting programmes, specifically jeopardises programme sustainability and patient concordance – which in turn has serious implications for the development of drug resistance.

The APG therefore suggest that the last sentence above (underlined) should be included in the paper's paragraph 3.6.



5.6 International Pharmaceutical Companies (Paper 4.2.3)

The increase in commitment is not limited to UK pharmaceutical and biotechnology companies. The APG suggests the first sentence after the bullet list under 4.2.3 should read:

“Pharmaceutical and biotechnology companies based in the United Kingdom have increased their engagement...”

In addition, the APG would appreciate inclusion of additional case studies (such as in Box 3) that recognises the contribution of non-UK companies, which have been based in the UK for many years. DFID rightly recognises that access to medicines is a global challenge that requires a global response. So the exclusion of companies long based in the UK, which have contributed extensively to the developing world, simply because their parent companies are non-UK, contradicts this global approach.

5.7 Engagement with the pharmaceutical industry (Paper 5.4)

The APG was surprised to find the close focus on pricing at the outset of this section. It is our view that pricing should be considered as part of a range of factors which should, together, create an environment conducive to public private partnership in efforts to expand access to essential medicines.

The APG would appreciate it if this policy document could spell out government’s commitment to facilitating an economic and regulatory environment that would protect the commercial viability of the pharmaceutical industry, while encouraging private participation in the expansion of access to essential medicines.



We suggest the following should be added below the paper’s headline 5.4 and above paragraph 5.4.1:

“Expansion of access to essential drugs in the developing world depends on close cooperation between the public and private sector. Such a partnership will depend on the establishment of a global economical and political environment that encourages the industry to contribute to this expansion, while protecting their commercial viability. The UK government is committed to the establishment and maintenance of such an environment.”

5.8 Further engagement (Paper 5.4.1)

The APG appreciates the UK government’s commitment to further engagement with the pharmaceutical industry. We believe this engagement should focus on the creation of an environment that would be conducive to the achievement of the three bulleted objectives outlined in this section. The APG considers the development of such an environment the government’s most important contribution in a broad public-private partnership aimed at expanding access to drugs.

5.9 Affordability (Paper 5.4.2)

Affordability is not purely a function of price. It depends in the first place on the budget of the buyer. Any discussion with the pharmaceutical industry on issues of affordability, must therefore form part of a larger debate of all factors influencing both the cost of



drugs, and the money developing countries will have available to buy those drugs. Focusing on pricing in isolation, forces a skewed view of the pharmaceutical industry's responsibility in making medicines more affordable.

This point could be spelled out in the paper's paragraph 5.4.2:

“Affordability is not purely a function of price. It also depends on the budget of the buyer. The UK Government should conduct any discussion with the pharmaceutical industry on issues of affordability as part of a larger debate of all factors influencing both the cost of drugs, and the money developing countries will have available to buy those drugs.”

Bullet 2: The APG, through its individual members, has a significant contribution to make to the evidence base on affordability. We would welcome any opportunity to make this contribution.

Bullet 3: In pressing for replication of the significant price reductions of ARVs in other priority areas, governments must carefully weigh up the impact such pressure would have on the commercial viability of further research into those priority diseases.

The APG therefore suggests the following addition to bullet 3:

...to differential price offerings, while recognising the need to protect the commercial viability of the pharmaceutical industry.



Bullet 4: According to the World Health Organisation, 95% of drugs included in the WHO Essential Medicine List are already produced under licence, or without licences with impunity. Yet this key fact is not evident in the current draft.

6. Appreciation

The APG appreciates the opportunity to make this submission and would welcome additional discussion in this regard.