



## **RESPONSE BY THE APG TO THE MEDICINES TRANSPARENCY ALLIANCE PHASE ONE PROPOSAL**

**THE AMERICAN PHARMACEUTICAL GROUP (APG), 30 NOVEMBER 2007**

The APG welcomes the detailed MeTA consultation paper from the Department for International Development (DFID), and the opportunity to put forward its comments.

The members of the Group appreciate the changes that have been made to DFID's proposals over the 18 months since the *Medicines Transparency Alliance (MeTA) - Draft Consultation Paper* (April 2006). The work has been considerable, many of the issues raised by the APG have been addressed, and the emphasis throughout on working with the pharmaceutical industry has been appreciated.

### **1. Overall Views**

The stated purpose of the MeTA proposal is to:

*pilot a new multi-stakeholder approach towards increasing transparency around the selection, regulation, procurement, sale and distribution of medicines in developing countries, thereby strengthening governance, improving efficiency, and encouraging innovative and responsible business practices. The goal of MeTA is to contribute to increased access to affordable essential medicines in developing countries, in co-operation with pharmaceutical companies (in line with Millennium Development Goal 8, Target 17) with the ultimate aim of improving health outcomes for poor people in developing countries.*

The Group agrees that transparency in the medicines supply chain is in theory an attractive aim. It has a number of potential advantages, including a possible reduction in both counterfeit medicines and the diversion of medicines to other countries. It would also provide an opportunity to highlight the impact of tariffs and taxes on the final cost to the patient – with the potential of forging international consensus on the need to reduce or even eliminate them.

However, we have concerns about the practicalities, as we have discussed with the Department. Some of these, set out in our Key Principles paper of 5 June 2007, attached here in Appendix 1, have been addressed, but others remain.

It is important not to expect too much from the MeTA proposal and to understand its limitations. For example, DFID rightly recognises that the approach depends on the

commitment and active support of national governments for pilot schemes, so whatever is proposed may be subject to changes to meet national circumstances.

In this regard, we welcome the proposal that each pilot country should have a multi-stakeholder working group or forum, and the APG will be suggesting forum members.

The APG welcomes the setting up of a formal MeTA Secretariat in 2008 (with interim arrangements in the meantime) as sensible and necessary. The Group will look forward to establishing contact with it.

Whatever the concerns, the willingness of DFID to discuss and work with all stakeholders, including pharmaceutical companies, is much appreciated. The Group looks forward to maintaining its good working relationship with DFID.

## **2. Specific Issues**

### **a) Disclosure of data**

The paper proposes the disclosure of data on medicine pricing (as well as on medicine quality, availability and use) and the proactive collection of such data.

DFID has argued that the price levels in Low Income Countries will come out anyway, and that it is better for it to be done by a responsible body. The current paper proposes that the move towards disclosure will be gradual and that there should be aggregated or confidential reports on procurement prices and mark-ups in the private sector.

The APG does not accept this argument. It believes that some Middle Income Countries will force down the prices they pay for medicines by deploying this information from Low Income Countries.

From the very start of discussions with DFID, the APG has argued that pricing information should be regarded as confidential. This disquiet remains and the Group regrets the Department's proposal that price information should be disclosed. The Group would like to explore further with DFID how confidentiality could be secured whilst still meeting the Department's objectives.

### **b) Focussing on big wins**

#### **The main diseases**

The APG has recommended that initially the medicines being tracked should be limited as far as practicable to big diseases highlighted in the Millennium Development Health Goals - HIV/AIDS, malaria and TB – rather than being over-ambitious. These are where the problems are greatest, and attention needs to be focussed on them rather than dissipated. This principal and the practicalities should be discussed and resolved in the pilot country fora.

### **Generic medicines**

We recommend that MeTA looks at the volume of transactions in medicines in the pilot countries, as this will show that transactions are heavily skewed towards generic medicines, rather than patented medicines. We believe that this point should be properly recognised in the MeTA Phase One Proposal paper and be taken into account in devising the programmes for each pilot country.

### **c) Evaluation**

We welcome the section entitled *Policy research and evaluation* (p24), but it is very short. Proper evaluation is crucial for the Department to show whether MeTA has achieved what the Department said it would achieve.

There is some time in hand for the Department to set this up, as the pilot schemes have very sensibly been extended to two years. We strongly recommend that, during 2008, the methods of evaluating the work in the pilot countries, and the way in which analyses and conclusions are to be reached and circulated, are further developed and set out publicly.

### **d) Policies, practice and data concerning the promotion of data**

We question the value of the emphasis on promotion, including that by the pharmaceutical industry, in the Phase One Proposal. Although this rightly refers to the codes of practice adopted by manufacturers, it deflects attention from the more serious issue of transparency by government.

We would like to see emphasis on:

- how procurement is carried out by governments in the pilot countries
- what financial resources are available for procurement
- what policies are in place to ensure that procurement is carried out in a transparent manner.

## Appendix 1

### The Medicines Transparency Alliance– key principles from the APG, June 2007

To assist the Department for International Development, the APG has set out below its ten key principles for any pilot schemes for the Medicines Transparency Alliance:

1. To set the pilot schemes in a healthcare context.
  - An adequate health infrastructure is the most important requisite for providing medicines; pilots should only be introduced where this exists
2. To focus on achievable big wins
  - Initially the medicines being tracked should be limited as far as practicable to big diseases highlighted in the Millennium Development Health Goals - HIV/AIDS, malaria and TB – rather than be over-ambitious
3. To concentrate on the poorest countries
  - Least-developed countries like Ghana and Uganda satisfy the criteria as they have the most acute problems and the poorest populations.
4. To avoid excessive focus on prices
  - To take into account regulatory issues, counterfeiting and healthcare governance
5. To maintain a multi-stakeholder approach
  - To keep all relevant stakeholders, including pharmaceutical companies, involved in the UK; and similarly to involve them in pilot country fora
6. To avoid unintended negative consequences
  - Unintended consequences could include reducing access to medicines in rural areas, cutting extra revenue received by hospitals and clinics from dispensing medicine fees, and driving pharmacists away by slashing their margins
7. To include the private and public sectors
  - Given the overlap between these two important sectors, any pilot scheme which looked only at the one but not the other would be deficient
8. To promote practical application
  - To help pilot country fora to devise practical and non-disruptive ways of tracking the determination of price at all stages along the entire supply chain
9. To work for the longer term
  - The aim must be to work for the long-term, avoiding short-termism
10. To set pilot evaluation schemes in place with clear criteria setting out what a successful outcome might look like, with time-limited targets.

## Appendix 2

### **About 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, because they live in poor 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).

### **Contact Details:**

APG Secretariat - Chris Mockler 020 739571275 – [mocklerc@fleishmaneuropa.com](mailto:mocklerc@fleishmaneuropa.com)  
- Kate Brightwell 020 7395 7166 – [brightwk@fleishmaneuropa.com](mailto:brightwk@fleishmaneuropa.com)  
40 Long Acre, London WC2E 9LG  
APG website [www.apg.uk.com](http://www.apg.uk.com)