

Key Issues

There are a number of issues that affect global access to medicines in which the APG plays an active role.

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.

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
- Integrity of the supply chain to prevent counterfeit medicines
- Good transport distribution and regular re-supply
- Healthcare professionals administer the medicines and monitor the outcomes. Access to medicines is particularly curtailed by inadequate numbers of healthcare professionals.

Differential pricing

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.

The majority of pharmaceutical companies have developed some form of “*differential pricing*” for some of their product range. For low income countries, as defined by the Department for International Development in 2005¹, this is commonly at or around cost; for middle income countries prices are at levels substantially less than in the developed world.

For both low and middle income countries, it is worth noting that about 95 per cent of medicines on the World Health Organisation's (WHO) list of essential medicines are off-patent².

Registration of medicines in Africa

In some parts of the world there are overarching regulatory authorities responsible for the registration of medicines within that area, such as the Food and Drug Administration (FDA) in the United States and the European Medicines Agency (EMA) in Europe. There is no overarching body for medicine registration in Africa, therefore individual countries have their own licensing arrangements.

The need for some form of harmonised procedures for the registration of medicines in Africa, is widely recognised. The WHO 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 APG would strongly support the UK Government in setting up a conference of stakeholders 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.



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.
2. IFPMA Issues: Intellectual Property Rights. Available at: <http://www.ifpma.org/Issues/index.php?id=418>

Intellectual Property Rights (IPRs)

IPRs provide patent protection for new medicines for a reasonable period. It is an essential pre-condition for sustained investment in new medicines.

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), established in 1995 by the World Trade Organisation (WTO), introduced a comprehensive international agreement on intellectual property for medicines.

The poorest, i.e. low income countries, were helped by them not being required to adopt patents until 2016. This date may be extended.

TRIPS also allow a member state, in special circumstances, to make use of a patent without the authorisation of the company holding the patent. This power should only be used judiciously. However, in 2006 and 2007 one middle income country overrode three patents and subsequently announced that it was considering the imposition of compulsory licences on three cancer drugs. The real issue is the precedent set for other middle income countries. The biggest developing markets are Brazil, Russia, India and China. If such countries were to follow the example above, the whole structure of global patent protection could be undermined. Research-based companies, if unable to recover the lost revenue from the developing world, could be forced to cut their research and development substantially.

The APG believes that:

- The provision of medicines at “*differential prices*” and in some cases the provision of voluntary licences, 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
- Governments should adopt a more pro-active role. Many governments have long supported IPR as a way of rewarding risk investments and encouraging innovation and, as members of the European Union, many also helped to negotiate the TRIPS agreement.

“The **problems** of **price, quality** and **availability** can be **tackled** by **improving transparency** and **access to information...**”

Transparency

Medicines Transparency Alliance (MeTA)

The focus of MeTA, a scheme put forward by the UK Government, is on strengthening a developing country’s capacity to collect, analyse, disseminate and use data on medicine price, quality, availability and use.

At the launch of MeTA in May 2008, Douglas Alexander, Secretary of State for International Development, said that “*Too many people die needlessly because they can’t get the medicines they need. There are currently 2 billion people around the world who do not have access to affordable medical services. A lot of medicines are not affordable, they are of poor quality, or they are simply not available. The problems of price, quality and availability can be tackled by improving transparency and access to information. MeTA will provide citizens, healthcare workers and others with information to challenge corruption, excessive pricing and waste. We now have a common approach and by working together millions of lives could be saved.*”³

The APG has engaged closely with the Government and was pleased that many of the Group’s suggestions were accepted. The theory of MeTA is attractive, but a number of practical concerns remain and these should be addressed in the pilot schemes proposed in seven countries, the first having started in late 2007, with the work being spread over some two years.