

**Review of the UK Government's
2005 Framework for Good Practice
in the Pharmaceutical Industry**

**A review commissioned by the
UK Department for International Development**

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List of Acronyms

ABPI	Association of British Pharmaceutical Industries
ACT	Artemisinin-based Combination Therapy
AIDS	Acquired Immune Deficiency Syndrome
AMC	Advanced Market Commitment
AMFm	Affordable Medicines Facility for malaria
APG	American Pharmaceutical Group
API	Active Pharmaceutical Ingredient
APOC	African Programme for Onchocerciasis Control
ARV	Antiretroviral
BERR	(Department for) Business Enterprise & Regulatory Reform
CHAI	Clinton HIV/AIDS Initiative
DFID	Department for International Development
DNDi	Drugs for Neglected Diseases initiative
DOTS	Directly Observed Treatment Short course
DH	Department of Health
EDCTP	European & Developing Countries Clinical Trials Partnership
ESRC	Economic & Social Research Council
FDA	US Food & Drug Administration
GATB	Global Alliance for TB Drug Development
GPF	Good Practice Framework
GPRM	Global Price Reporting Mechanism
GRI	Global Reporting Initiative
GSK	GlaxoSmithKline
HIV	Human Immunodeficiency Virus
HMG	Her Majesty's Government
HMT	Her Majesty's Treasury
ICTSD	International Centre for Trade and Sustainable Development
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
IHP	International Health Partners
IP	Intellectual Property
IPO	UK Intellectual Property Office
LDC	Least Developed Country
LIC	Low-Income Country
MIC	Middle-Income Country
MMV	Medicines for Malaria Venture
MRC	Medical Research Council
MSF	Médecins Sans Frontières
MVI	Malaria Vaccine Initiative
NEPAD	New Partnership for Africa's Development
NGO	Non-Governmental Organisation
ODA	Official Development Assistance

List of Acronyms (cont.)

OPPI	Organisation of Pharmaceutical Producers of India
PEPFAR	President's Emergency Plan for AIDS Relief
PhRMA	Pharmaceutical Research & Manufacturers of America
PDP	Product Development PPP
PPP	Public-Private Partnership
PRM	Global Fund Price Reporting Mechanism
R&D	Research and Development
SSA	Sub-Saharan Africa
TB	Tuberculosis
TRIPS	Trade Related Aspects of Intellectual Property Rights
UKCDS	UK Collaborative on Development Sciences
UN	United Nations
UNCTAD	United Nations Conference on Trade Development
VRR	UK Vaccines Research Relief
WHO	World Health Organization
WTO	World Trade Organization

1. Executive Summary

In 2005, the UK Department for International Development (DFID), the UK Department of Health (DH) and the then UK Department of Trade and Industry,² published a policy paper that set out a framework for pharmaceutical companies on good practice in increasing access to medicines in developing countries.³ It also set out complementary UK government commitments. The framework covered four core areas: affordability, research and development, impact on developing countries, and reporting and verification.

The good practice framework (GPF) indicated that the UK would report on progress at a later date. Indeed, since 2005, there have been many developments in company and government policies and, more generally, in the global enabling environment for access. In order to assess these developments in some detail, DFID contracted a team to undertake this review, which is intended to provide:

- A review of the practices and policies outlined in the GPF;
- A review of the impact of the GPF itself;
- A brief review of the process for developing and implementing the GPF;
- An assessment of the performance of both government and companies against the GPF, noting in particular examples of industry good practice;
- Identification of key issues to be addressed by companies and government.

The review focuses on the research-based industry but the role of the generic industry has also been considered. It draws on desk-based research and key informant interviews with representatives of the UK Government, major pharmaceutical companies and associations, and other key stakeholder groups. The review will serve as a background paper to inform the UK Government's next steps in its work with the pharmaceutical industry and other stakeholders, such as investors, technical agencies and civil society organisations.

This review of the GPF suggests that the pharmaceutical industry is undergoing significant change and this includes an expansion into emerging markets. It is well-placed to engage in both middle-income country (MIC) and low-income country (LIC) markets, if companies continue their work to ensure poor people's access to their products. The best-placed companies are already integrating access issues into their core business model. There are promising signs of innovation and creativity in other companies. Overall, good progress has been made in relation to some areas of the GPF (such as industry engagement in R&D PDPs, and examples of innovative licensing) but there is a need for greater attention to other areas (such as affordability concerns in MICs, the disease

² Now the Department for Business Enterprise and Regulatory Reform (BERR)

³ *Increasing people's access to essential medicines in developing countries: a framework for good practice in the pharmaceutical industry*. March 2005
<http://www.dfid.gov.uk/Pubs/files/pharm-framework.pdf>

scope of differential pricing offers in LICs and LDCs, and reporting).

The UK Government departments that co-authored the GPF (DFID, DH and BERR) and others that were not original co-authors (IPO and HMT) remain closely engaged in the issues. Particularly good progress has been made in relation to meeting the financing commitments set out in the GPF. Her Majesty's Government (HMG) has made good on its promises to increase official development assistance (ODA) and to invest more in expanding HIV/AIDS treatment, enhancing R&D, and strengthening developing country health systems. In the process, the UK has been at the forefront of developing innovative new financing mechanisms. At the policy level, cross-departmental action to address health worker migration from developing countries to the UK has proved successful, and some support has been provided to developing countries on 'navigating' TRIPS, though more remains to be done in both areas. HMG has made less progress in supporting pharmaceutical companies to transparently report on their activities to increase access to medicines and to measure the impact they are having on the ground.

Taking into account the backdrop of change, and based on the findings of this review, we therefore conclude that:

- **Clear statements of government expectations regarding industry practice are valuable.** The need for companies to incorporate access issues into their core business model, coupled with broader economic uncertainty, means that clear signals from government may be particularly welcome at this time.
- **HMG should therefore consider issuing an updated policy statement** regarding industry responsibilities on access to medicines. This could take a number of possible forms, but should take account of the entire medicine supply chain and the role of the generics industry (particularly given the high volume of generic first-line ARVs supplied through the Global Fund and PEPFAR).
- If this policy statement takes the form of another GPF, **HMG should consider focusing in detail on three or four priority areas** in which it would like to see greatest progress. This would entail specifying the industry actions likely to have greatest impact and setting out what HMG will do specifically to facilitate and support these actions. Time-bound objectives would be useful in order to accelerate progress.
- Based on our assessment of progress made to date we would highlight the following priorities for consideration: **voluntary licensing and appropriate outsourcing/outlicensing; transparent differential pricing that is sustainable in MICs and for a broader product range in LICs/LDCs; access issues for non-communicable disease; enhancing R&D in specific, neglected areas** e.g. paediatric medicines and diagnostics; **regulatory harmonization** to support R&D and access strategies, particularly in Sub-Saharan Africa.
- HMG should continue – with increased regularity – **dialogue with industry**

- and other stakeholders** (particularly investors and key UK-based NGOs); for group discussions, every six months is probably realistic and sufficient;
- **Any future policy statement or framework should be monitored** through this process of dialogue; a 'light' monitoring and evaluation framework should be developed and maintained; outcome indicators are also needed.

2. Introduction

In 2005, the UK Department for International Development (DFID), the UK Department of Health (DH) and the then UK Department of Trade and Industry,⁴ published a policy paper that set out a framework for pharmaceutical companies on good practice in increasing access to medicines in developing countries.⁵ A summary of the good practice framework (GPF) can be found in *Annex One*. The paper also set out complementary UK government commitments.

Since that date, there have been many developments in company and government policies and, more generally, in the global enabling environment for access to medicines.

The UK Government's 2005 GPF indicated that the UK would report on progress at a later date in relation to:

- The impact of the GPF on both the UK Government and pharmaceutical companies;
- Its usefulness for companies and other stakeholders;
- Key outstanding issues;
- New areas of work;
- Ongoing developments in company approaches and policies towards access to medicines.

To this end, DFID contracted a review team in June 2008 to conduct research and collect data. *Annex Two* outlines the Terms of Reference for the review. This review is therefore intended to provide:

- A review of the practices and policies outlined in the GPF;
- A review of the impact of the GPF itself;
- A brief review of the process for developing and implementing the GPF and an assessment of this alongside those processes adopted for other similar documents;
- An assessment of the performance of both government and companies against the GPF, noting in particular examples of industry good practice;
- Identification of key issues that need to be addressed by companies and by government in future.

⁴ Now the Department for Business Enterprise and Regulatory Reform (BERR)

⁵ *Increasing people's access to essential medicines in developing countries: a framework for good practice in the pharmaceutical industry*. March 2005
<http://www.dfid.gov.uk/Pubs/files/pharm-framework.pdf>

The focus of the review has been on the research-based industry but the role of the generic industry has also been considered. The review will serve as a background paper to inform the UK Government's next steps in its work with the pharmaceutical industry and other stakeholders, such as investors, technical agencies and civil society organisations.

3. Methodology

Background research and consultation with industry, government stakeholders and other key informants for this review took place between July and September 2008. *Annex Three* provides details of the methodology. Desk-based research was carried out, covering websites and key documents in the public domain. In particular, examples of good practice were noted. A short briefing note was then shared with informants from the pharmaceutical industry (companies and associations), UK Government departments and other key stakeholders, and these informants were interviewed by telephone or face-to-face during September 2008. All key informants interviewed are listed in *Annex Four*.

Based on both the consultation process and material gathered in the public domain, key issues were identified that need to be addressed in future by the pharmaceutical industry and the UK Government (HMG), and these were outlined in a draft review report. Further consultation was conducted between HMG and industry representatives in mid-October 2008 to discuss the draft report and possible next steps. The report was then revised and this version finalised in December 2008.

4. Background to GPF 2005

The UK Government has been proactively engaged in global policy debates on access to medicines for much of the past decade. Since the early 2000s, DFID has maintained dedicated staffing to cover access to medicines issues at its London headquarters and has worked in close collaboration with other UK Government departments. This kind of capacity is, to the best of our knowledge, unique across bilateral donor agencies and puts the UK in an influential position on this agenda globally.

In 2001, the then UK Prime Minister established a high level Working Group on Increasing Access to Essential Medicines in the Developing World, which was chaired by then Secretary of State for International Development Clare Short MP. This Working Group, which had high-level pharmaceutical industry participation, reported in November 2002. Its recommendations focused on the need to support increased research and development (R&D) relevant to developing country health priorities and on the need for a global framework to facilitate

pharmaceutical company engagement in ‘voluntary, widespread, sustainable, and predictable differential pricing as the operational norm’.⁶

Alongside broader policy work culminating in seven UK Government (HMG) departments co-authoring a policy and planning document on access to medicines,⁷ DFID and other HMG departments deepened their dialogue with pharmaceutical companies subsequent to the Working Group’s report. Based on this dialogue, the government concluded that it would be valuable to produce a document clearly setting out HMG expectations regarding the role that pharmaceutical companies should play – alongside other stakeholders – in enhancing access to medicines for the poorest communities across the world. Through constructive dialogue and consultation spanning more than one year, it was agreed that the document should also highlight examples of good policy and practice across the industry and should set out what the UK would do (or continue to do) to facilitate actions by the industry and other stakeholders.

The resulting good practice framework (GPF) published in March 2005 therefore states the types of actions anticipated from the pharmaceutical industry across four areas: affordability, R&D, impact and reporting. For each of these areas, relevant HMG policies and plans are articulated. The document then sets out, in a subsequent ‘background’ section, more detail on the key issues affecting access to medicines in developing countries and it gives some examples of company practice. It also provides some analysis of the ethical and business case for action by pharmaceutical companies specifically. The GPF is summarized in more detail in *Annex One*.

In the next section of this review, we assess the progress that a cross-section of pharmaceutical companies has made against the GPF since 2005. This is followed by a similar assessment of progress made across the UK Government over this time period.

5. Progress by the Pharmaceutical Industry

This section presents a qualitative assessment of the progress the industry has made since 2005 against the four GPF elements. Findings are based on consultation with key informants and material available in the public domain for the specific companies that were part of the consultation. Company-specific examples are presented where appropriate, to illustrate progress, especially where innovative or unique strategies have been adopted to improve access to medicines in developing countries. The bibliography in *Annex Six* lists further

⁶ DFID (2002) ‘Report to the Prime Minister of the UK Working Group on Increasing Access to Essential Medicines in the Developing World: Policy Recommendations and Strategy.’ DFID November 2002. <http://www.dfid.gov.uk/pubs/files/accessmedicines-report281102.pdf>

⁷ DFID (2004) *Increasing access to essential medicines in the developing world: UK Government policy and plans* DFID, DTI, DH, FCO, HMT, Patent Office and the Inland Revenue

information sources relating to the different activities within individual company access programmes. A 'Global Health Progress' website, recently launched by the R&D industry, lists all partnerships (including those from academia, private and public sectors) with best practice examples, and enables useful searches by country/disease and other criteria.⁸

5.1 Affordability

5.1.1 Differential Pricing

The industry may practice differential pricing to reflect local market conditions and willingness to pay. In the most ambitious examples, differential pricing offers are not confined to specified institutions and are available to any buyer within both the public and private sectors.⁹ An example of this is GlaxoSmithKline's (GSK) strategy in India.¹⁰ Over a long period, GSK has built a very broad-based portfolio designed to meet the requirements of the Indian market, underpinned by premium brands with market-based pricing, and has supported this strategy by gradually localising production as sales volumes have increased. The benefits arising from greater efficiency and economies of scale are fundamental to GSK's market-based pricing policy in India.

Industry informants were unable to provide data on how differential prices are set in relation to production costs for low-income markets and related profit margins. The informants noted that the medicines supply chain was complex and that companies have manufacturing plants in several geographic locations, so the costs of manufacture were not uniform. The trend appears to be a move to differential pricing offers for middle-income countries (MICs) as a strategy to expand into those markets. Several companies are also starting to look at segmenting their differential price offers in the private sector to cater for high- and low-income patients within the same country. This is especially relevant in emerging markets such as India, China and Brazil where there is a large middle class.^{11,12,13}

A second form of differential pricing is when 'discounted' price offers are made by companies to specified institutions, predominantly in the public sector in low-income countries (LICs). These discounted prices may also include private sector

⁸ *Global Health Progress* <http://www.globalhealthprogress.org/index.php?parent=homepage>

⁹ *Merck's low-priced diabetes drug might change a few rules – Pharmaceuticals, Game Changer.* Businessworld Issue 17-23 June 2008 <http://www.businessworld.in/index.php/Pharma/Game-Changer.html>

¹⁰ GSK paper: *GSK in India: a model of flexibility- case study*

¹¹ Economist (15 May 2008). *Quagmire to Gold Mine.*

http://www.economist.com/business/displaystory.cfm?story_id=11376895&fsrc=RSS

¹² *Global Health Frontiers Project.* Center for Global Development http://www.cgdev.org/section/initiatives/_active/ghprn/otherinits/ghf

¹³ *Developing New Business Models.* PharmaFutures Report 3. <http://www.pharmafutures.org/aboutpf/researchstream1.asp?id=11>

and not-for-profit organisations running treatment programmes. Offers predominantly apply to antiretroviral (ARV) and anti-malarial medicines. Companies have been slow to extend differential pricing to medicines to treat other communicable diseases or indeed to chronic, non-communicable diseases.

Section 5.4 *Reporting and Verification* outlines some of the ways in which companies make their differential pricing offers accessible to stakeholders in developing countries. Companies such as Gilead, GSK and Roche publish their differential prices for ARVs on their company website. In general, companies quote discounted prices as ex-factory prices, which do not include shipping costs or customs duties and taxes, as these vary from country to country.

Most of the companies supplying differentially priced medicines through their access programmes say they worry about diversion and leakage to the private sector or to higher income countries. Company informants drew attention to the different strategies they use to combat diversion and leakage, such as differential packaging, coloured pills and/or branding. The experience from Novartis' Coartem®, an artemisinin-based combination therapy (ACT), suggests that diversion has not proved a significant problem. Perhaps this is because there is only a small private market for Coartem® in low-income settings, since even at the reduced price it is still several times more expensive than chloroquine and other (often less effective) medicines. In fact, to address this price gap, the Affordable Medicines Facility for malaria (AMFm) is being established, supported by the UK Government. The AMFm is an initiative to increase access to effective malaria treatment for people in endemic countries.¹⁴ By making ACTs available at a much lower price in both the public and private sectors (close to the prices of chloroquine and sulfadoxine-pyrimethamine) it is anticipated that ACTs will become more affordable, acceptable and widely used.

Antiretrovirals and Anti-malarials

Most of the R&D companies that produce ARVs provide information to Médecins sans Frontières (MSF), which publishes company discounted price offers for ARVs in its annually updated 'Untangling the Web of Antiretroviral Price Reductions'.¹⁵ Annex 1 of MSF's report summarizes prices in US dollars as quoted by companies for eligible institutions in selected developing countries. Annex 2 details the countries eligible under specific categories. In general, category 1 eligible countries are LDCs and Sub-Saharan African countries and category 2 are low- and lower-middle income countries as classified by the World Bank. Category 2 prices are frequently double those for category 1.

Abbott, Gilead, Merck and Roche offer category 1 and category 2 pricing across all their ARVs, regardless of whether these are generally considered first- or

¹⁴ Affordable Medicines Facility-Malaria

<http://www.rollbackmalaria.org/partnership/tf/globalsubsidy/080227AMFmBriefingDocument.pdf>

¹⁵ MSF "Untangling the Web of Antiretroviral Price Reductions"- 11th Edition July 2008
<http://www.msf.org/source/access/2008/untanglingtheweb2008english.pdf>

second-line therapies. Merck has different country eligibility criteria depending on the product and provides some of its ARVs free in Botswana.

GSK on the other hand has one set, discounted price for its ARVs for LDCs, Sub-Saharan African (SSA) countries, President's Emergency Plan for AIDS Relief (PEPFAR) and Global Fund recipients. For other low- and middle-income countries (LICs and MICs), public sector prices are negotiated on a case-by-case basis, either through the Accelerating Access Initiative (AAI) or bilaterally.

It is worth noting that generics do not have the restrictions relating to customer location that the branded products do (see MSF guide). An analysis by Boston University of 2006 prices of ARVs obtained from the World Health Organization (WHO) Global Price Reporting Mechanism (GPRM)¹⁶ and the Global Fund Price Reporting Mechanism (PRM)¹⁷ indicates that prices of the generic ARVs most often used for 1st line therapy were generally lower than their comparator originator brands. Interestingly, the Boston University study finds that this pattern is reversed for generic protease inhibitors (often needed to construct a viable 2nd line regimen), which were on average more expensive than the underlying branded originator during the period under review, though this situation may change over time.¹⁸ The Clinton HIV/AIDS Initiative (CHAI) has worked with generic manufacturers to reduce their ARV (and now ACT) prices through actual and projected production efficiencies and volume forecasts informed by CHAI programming, and a recent partnership with UNITAID.¹⁹

Seventeen pharmaceutical and diagnostic companies working on HIV and AIDS recently met with the UN Secretary General, Ban Ki-Moon, resulting in both the R&D and generics companies present making commitments to invest further funds and resources to increase access to HIV prevention and treatment.²⁰

Some anti-malarials, such as Novartis' Coartem®, are provided at not-for-profit prices through and in agreement with the WHO.²¹ Novartis has reduced its price twice since the WHO agreement was signed in 2001. GSK provides Malarone® at a single discounted price to the public sector in LDC and SSA countries for

¹⁶ Global Price Reporting Mechanism (GPRM) <http://www.who.int/hiv/amds/gprm/en/>

¹⁷ Global Fund Price Reporting Mechanism
http://www.theglobalfund.org/en/funds_raised/price_reporting/default.asp

¹⁸ Waning B. 'Public Procurement Databases Provide Insight into Strategies to Increase Access to Antiretroviral Medicines in Low Resource Settings.' IX World Conference on Clinical Pharmacology and Therapeutics. Quebec City, Canada. July 2008.

¹⁹ Magaziner, I and Soni, A 'Getting More for the Money - How Lower Prices Were Possible, Progress to Date, and the Challenges Ahead' Clinton Foundation news update, 1 November 2005
<http://www.clintonfoundation.org/news/news-media/110105-nr-cf-hs-ai-arv-usa-fe-getting-more-for-the-money>

²⁰ Secretary-General's statement following meeting with pharmaceutical and diagnostic companies working on HIV and AIDS – October 9th 2008.
<http://www.un.org/apps/sg/sgstats.asp?nid=3466>

²¹ Novartis-WHO Agreement for Coartem
http://www.who.int/malaria/cmc_upload/0/000/015/789/CoA_website5.pdf

treatment, but not for prophylaxis, in line with WHO guidelines.²² Sanofi-Aventis's fixed-dose combination anti-malarial As/Aq (Artesunate and Amodiaquine), which was pre-qualified by the WHO in October 2008, is offered at discounted prices in both the public and private sectors. In the private sector, discounted prices have been offered since 2004 to private retail pharmacies through an Antimalarial Drug Card Access Program (CAP). This scheme operates in five countries: Congo-Brazzaville, Gabon, Kenya, Madagascar and Mali.

Scope of Differential Pricing Offers

The review findings show that the pharmaceutical industry has been slow to extend its differential pricing offers beyond ARVs and anti-malarials. However, a few examples that predate the 2005 GPF exist. These include Roche's oseltamivir (Tamiflu), provided at deeply discounted prices to developing country governments for pandemic flu stockpiling, and Gilead provides AmBisome at a low-cost price for the treatment of leishmaniasis in developing countries in conjunction with the WHO and Non-Governmental Organisations (NGOs).

Sanofi-Aventis is one of the few companies that offers differential prices on a range of its communicable disease products including medicines for tuberculosis (TB), sleeping sickness and leishmaniasis, as well as epilepsy. However, these are geographically limited to a few countries. It is also piloting some differential pricing offers for diabetes.

New examples of differential pricing offers, which have been developed since the 2005 GPF, include Merck and GSK's cervical cancer vaccines Gardasil® and Cervarix® respectively, as well as their rotavirus vaccines in some LICs (often eligibility for discounted prices are based on GAVI country eligibility and United Nations Conference on Trade Development (UNCTAD) country criteria). It is worth noting that the retail price for the cervical cancer vaccines is still very high in emerging markets, such as Brazil, at about 360 US\$ per vaccinated girl. Many countries will need subsidies for some time, since for Latin America and the Caribbean, the estimated cost per vaccinated girl (including delivery and logistics costs) would have to be less than 25 US\$ for widespread vaccination to be cost-effective across all countries.²³

In terms of non-communicable disease, this review finds that very few medicines are provided at differential prices, despite the double burden of communicable and chronic non-communicable diseases in developing countries. Some exceptions highlighted during key informant interviews include Pfizer's limited differential prices on Sutent®, an anti-cancer medicine to treat kidney cancers. GSK has recently begun some pilot differential pricing offers in MICs that include medicines for diabetes, asthma and oncology. The review concludes that this issue is already a key area of debate in countries such as India and Thailand and

²² Key informant interview.

²³ International Union Against cancer (UICC)

http://www.uicc.org/index.php?option=com_content&task=view&id=16470&Itemid=537

will become more important as the double burden of disease faced by developing countries gains greater profile.

5.1.2. Compliance with UN Interagency Guidelines for Price Discounts for Single Source Medicines and with Guidelines on Drug Donations

Companies overall said they did not necessarily refer to the United Nations (UN) Interagency *Price Discounts for Single Source Medicines*,²⁴ but that their differential pricing offers were consistent with them. There were comments from some companies that, while they had been consulted by the WHO during the drafting of the 1999 Guidelines for Drug Donations,²⁵ this was not the case for the 2003 Guidelines for *Price Discounts for Single Source Medicines*. These guidelines are, however, a little out of date and need to be reviewed.

All companies with long-term donation programmes, or that made donations for humanitarian crisis situations through new initiatives such as International Health Partners (IHP),²⁶ stated compliance with the 1999 Guidelines for Drug Donations, which are currently being updated by WHO.

It has been recognised by the WHO and NGOs such as Oxfam, as well as by the UK Government, that medicine donations can be beneficial when they adhere to WHO's medicines donation guidelines and can be highly effective when focused on specific needs such as eradicable diseases or emergencies.^{27,28} Examples include the ivermectin programme (Merck's Mectizan® Donation Programme) for the elimination (as a public health problem) of river blindness (onchocerciasis) in West Africa, where a guaranteed supply of product has been promised to achieve elimination. Other examples include the International Trachoma Initiative with Pfizer's donation of azithromycin, as well as the albendazole donation by GSK for programmes to prevent and treat lymphatic filariasis²⁹ and the "Children without Worms" programme with mebendazole from J&J. Success has been in part due to the fact that management of these programmes has received strong technical support from WHO, others agencies and NGOs as part of a Public-

²⁴ WHO Guidelines for price discounts of single-source pharmaceuticals 2003
<http://www.who.int/medicinedocs/pdf/s4884e/s4884e.pdf>

²⁵ WHO Guidelines on Drug Donations 1999
<http://www.who.int/medicinedocs/pdf/whozip52e/whozip52e.pdf>

²⁶ International Health Partners <http://www.ihpuk.org/>

²⁷ Caines K, Lush L. *Impact of public-private partnerships addressing access to pharmaceuticals in selected low and middle income countries: a synthesis report from studies in Botswana, Sri Lanka, Uganda and Zambia. Initiative on Public-Private Partnerships for Health.* 2004.
<http://www.dfid.gov.uk/Pubs/files/ipp-ph-accesspharmaceuticals-synthesis.pdf>

²⁸ *Investing for life, Oxfam Briefing Paper.* November 2007. Accessed on 6 May 2008 at
http://www.oxfam.org/files/investing_for_life.pdf

²⁹ Ottesen EA, Hooper PJ, Bradley M, Biswas G (2008) 'The Global Programme to Eliminate Lymphatic Filariasis: Health Impact after 8 Years' *PLoS Neglected Tropical Diseases* 2(10): e317 doi:10.1371/journal.pntd.0000317

Private Partnership (PPP) arrangement, and because the medicine component contributes only a small part to the cost of the overall scheme.

For HIV/AIDS, Abbott donates the Determine® HIV-1/2 rapid diagnostic test kit in about 60 countries, for prevention of mother to child transmission (PMTCT). To date Abbott has donated 10 million kits and distributed a further 100 million tests at not-for-profit prices. In addition, Pfizer's Diflucan® Donation Program was launched in 2001 to provide treatment with fluconazole for oesophageal candidiasis and cryptococcal meningitis, both opportunistic infections (OIs) related to HIV/AIDS. Pfizer currently assists over 80 countries participating in the programme with training of health staff and pharmacists.

It is important to note, however, that UK Government policy does not support medicine donation programmes for long-term therapy³⁰ (chronic or prophylactic) such as the TB Directly Observed Treatment Short course (DOTS) or ARV treatment, as this would be unsustainable. In general, pharmaceutical companies have rather sought to sustain their contributions to tackling HIV/AIDS through differential pricing since corporations are unlikely to engage in long-term donation of expensive ARVs.^{31,32}

5.2 Research and Development (R&D)

Based on key informant interviews and research, this review finds that company reporting on R&D commitments for diseases that disproportionately affect developing countries (in terms of company policies, levels of investment, number of target molecules and number clinical trials) is more qualitative than quantitative. Companies indicate that this style of reporting reflects concerns around commercial confidentiality. In addition, specific reporting on R&D commitments for developing world disease treatments is rare and is usually integrated into a company's overall product portfolio. New initiatives such as G-Finder (see section 6.4) will hopefully provide a platform to improve systematic company reporting in this area.

Little information was available about whether and how companies are building affordability assessments into the product development process for developing country target markets. Companies such as GSK mention in their Corporate Responsibility Report that they build affordability into the Target Product Profile they work to, when developing products for diseases of the developing world.

³⁰ *Increasing people's access to essential medicines in developing countries: a framework for good practice in the pharmaceutical industry.* March 2005
<http://www.dfid.gov.uk/Pubs/files/pharm-framework.pdf>

³¹ Guilloux, A. and Moon, S. *Hidden Price Tags: Disease-Specific Drug Donations: Costs and Alternatives.* February 2001.
http://www.deolhonaspontes.org.br/media/file/Publicacoes/hidden_price_tags.pdf.

³² MSF "Untangling the Web of Antiretroviral Price Reductions"- 11th Edition July 2008
<http://www.msf.org/source/access/2008/untanglingtheweb2008english.pdf>

Companies negotiate prices for medicines with developing country governments on a bilateral basis and those involved in Product Development Public-Private Partnerships (PDPs) have made commitments to provide medicines for neglected diseases at not-for-profit prices, given that development costs for these medicines will largely be met by public funds.³³

5.2.1 Investment in R&D

The emergence of PPPs and PDPs over recent years has stimulated the industry to make increasing investments in R&D for neglected diseases. Companies conduct at least half of all new neglected-disease pharmaceutical development activity, which included 32 projects in 2005³⁴ and has increased steadily since then to about 67 drug and vaccine projects in 2008.³⁵ Companies either work through PDPs – e.g. the Drugs for Neglected Diseases initiative (DNDi), Malaria Vaccine Initiative (MVI) and WHO TDR as well as other WHO-led initiatives – or alone, usually with a view to subsequent partnership during the development phase.

Industry informants pointed out that, through the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and Pharmaceutical Research & Manufacturers of America (PhRMA), the industry has been exploring the idea of an R&D Consortium for treatments for diseases that disproportionately affect the developing world. The aim is to create a platform to encourage technology transfer, pool resources and share risk across the industry at the discovery phase. This proposed Consortium would then look to progress development of validated targets through PDPs. A meeting of industry R&D directors to discuss some proposed models took place in the USA in November 2008.

Investments in R&D have been made by companies such as GSK, whereby a dedicated group in their pharmaceuticals R&D organization has been created to focus on diseases of the developing world. This includes a drug discovery centre at their Tres Cantos R&D site in Spain where over 100 scientists focusing primarily on malaria and TB are based. A similar group exists in their vaccines arm based in Belgium. GSK receives grants from MMV, MVI and the Global Alliance for TB Drug Development (GATB) to expand the capacity of its research at these two sites. J&J's Tibotec company in Mechelen, Belgium is equally dedicated to this type of R&D.

³³ Moran M. (2005). *A Breakthrough in R&D for Neglected Diseases: New Ways to Get the Drugs We Need* PLoS Medicine Vol. 2, No. 9, e302 doi:10.1371/journal.pmed.0020302

http://medicine.plosjournals.org/archive/1549-1676/2/9/pdf/10.1371_journal.pmed.0020302-L.pdf

³⁴ Moran M. (2005). *A Breakthrough in R&D for Neglected Diseases: New Ways to Get the Drugs We Need* PLoS Medicine Vol. 2, No. 9, e302 doi:10.1371/journal.pmed.0020302

http://medicine.plosjournals.org/archive/1549-1676/2/9/pdf/10.1371_journal.pmed.0020302-L.pdf

³⁵ FPMA Status Report: Pharmaceutical Industry R&D for Diseases of the Developing World – 2008 http://www.ifpma.org/pdf/20081114Status_RnD_for_DDW_19Nov08.pdf

Another example of infrastructure and R&D investment is AstraZeneca's Bangalore Research Institute in India, which combines TB research and manufacturing capabilities. The Bangalore facility is dedicated to finding a new therapy for TB that will act on drug-resistant disease and reduce the complexity and/or the duration of treatment. Today, AstraZeneca is the only pharmaceutical company with a research programme in India totally dedicated to TB. In addition to a \$20 million initial investment in buildings and state-of-the-art equipment, AstraZeneca has committed a minimum of \$5 million per year to supporting the research programme.

Paediatric formulations

In 2007 the WHO issued its first Essential Medicines List for Children (EMLc) and identified huge gaps in the availability of much needed paediatric formulations. It and other stakeholders called on the industry to step up its investment into developing paediatric formulations. The WHO and MSF assert that companies are still not doing enough in this area. Of the 22 ARVs approved by the US Food and Drug Administration (FDA), eight are not approved for use in children and nine do not come in any kind of paediatric formulation.³⁶

This consultation did identify a few examples of new research into paediatric formulations, however. For example, Johnson & Johnson has two ARV medicines with paediatric formulations, one soon to be submitted to the FDA for approval and another in clinical trials. Gilead has Phase III trials for its HIV-1 infection medicine Viread® in both paediatric and adolescent populations. Abbott had a half-strength paediatric tablet for its second line ARV treatment combination lopinavir/ritonavir (Kaletra, Aluvia) approved in 2007 by the FDA, which is already available in Africa at half the price of the adult formulation. GSK has developed a number of ARV liquid paediatric formulations, all available at not-for-profit prices in LDCs and has recently developed scored versions of its leading ARV tablets. GSK is additionally supporting four paediatric clinical trials in LICs to determine the best methods to expand access to HIV/AIDS treatment. Merck has paediatric formulations of Stocrin™ (efavirenz), 50 mg and 200 mg tablets and an oral solution, which are used for children from ages 3 and older. (Bristol Myers Squibb is conducting a clinical trial to try to establish appropriate dosing of efavirenz in children from 6 months to 3 years.) Merck estimates that around 11% of people (more than 80,000) using Stocrin™ in developing countries and emerging markets are children. Merck is also currently conducting paediatric trials for Isentress™ (raltegravir).

Novartis is working with MMV on a paediatric formulation for Coartem® that dissolves in water and they hope to launch this product at the end of 2008. Sanofi-Aventis has developed a paediatric formulation for its anti-malarial As/Aq. Pfizer, on the other hand, is conducting trials for a combination therapy of Zithromax®-chloroquine as an anti-malarial that is safe for pregnant women to

³⁶ MSF "Untangling the Web of Antiretroviral Price Reductions"- 11th Edition July 2008
<http://www.msf.org/source/access/2008/untanglingtheweb2008english.pdf>

use.

In addition, the IFPMA has recently created a special Paediatric Task Force to enhance the contribution of industry expertise to improving the availability of medicines and vaccines for children. The IFPMA Paediatric Task Force will work with relevant intergovernmental organisations, non-governmental organisations and other key stakeholders to identify and address opportunities for the systematic expansion of medicine development for younger age groups.³⁷

5.2.2 Financial Incentives

Companies conducting R&D in the UK benefit from the R&D tax credit scheme and the Vaccines Research Relief (VRR). It is still too early to undertake a full evaluation of these tax credits; however, interim statistics suggest that 10 companies are claiming VRR each year at a cost of less than £5m.³⁸ The large multinational companies state that these two 'push' incentives are not sufficient to induce them to enter into new areas of research for neglected diseases, but may be more attractive to smaller bioscience companies who are in greater need of funding mechanisms that create regular cash flow.

'Pull' incentives to increase and accelerate the development and introduction of new pharmaceuticals (new vaccines in the first instance) include the Advanced Market Commitment (AMC) for the pneumococcal vaccine.^{39,40} This is a novel instrument, which the UK facilitated and helped to develop. In advance of the legal documents and official offer being finalised, the vaccine industry is adopting a 'wait and see' stance towards the AMC model and some companies have expressed scepticism that the amounts likely to be pledged by donors would be a sufficient incentive to enter into early-stage discovery of pharmaceutical targets. It is important to note that donors have not yet made pledges for any early-stage product AMC.⁴¹

Donors have committed \$1.5 billion as part of this AMC, in which GSK, Wyeth and a range of other companies including emerging market manufacturers are potential partners. Through the course of consultation for this review, Wyeth expressed concerns that it would not be able to meet GAVI's demands with its current manufacturing capacity. However, Wyeth indicated that the AMC could provide the encouragement needed for the company to invest in a new manufacturing plant.

³⁷ IFPMA Press Release on Pediatric Task Force

<http://www.ifpma.org/News/NewsReleaseDetail.aspx?nID=10485>

³⁸ Statistics are published and are available at:

http://www.hmrc.gov.uk/stats/corporate_tax/randdtcmenu.htm

³⁹ AMC for Pneumococcal Vaccine, Implementation Working Group Report, July 2008 http://www.vaccineamc.org/files/AMC_IWG10JULY08_2_.pdf

⁴⁰ http://www.who.int/immunization/sage/target_product_profile.pdf#

⁴¹ Key Informant Interviews

A major concern expressed by Wyeth and the industry as a whole, within the context of the AMC, is whether there will be demand from developing countries for the pneumococcal vaccine. The crafters of the AMC have recognized this demand-side risk – relating to uptake and disease burden awareness – and GAVI created a group tasked with raising awareness about disease burden. A small minimum volume guarantee over the first three years has been made by donors under the AMC in a bid to address this.

5.2.3 Product Development Public-Private Partnerships (PDPs)

Companies have continued their engagement with PDPs to develop medicines and vaccines for the developing world. The motivation for the R&D industry to engage in PDPs is to share the costs and risks involved in both the discovery and development stages, such that it becomes commercially viable and sustainable. This allows them to control costs and resources, which is in turn more acceptable to shareholders. The resulting pharmaceutical product leads can then be developed in conjunction with public partners.⁴²

Within these PDPs, IP ownership needs to be discussed upfront. Research shows that most companies still want a share of any IP, although some companies waive their IP rights and enter into non-exclusive voluntary licensing arrangements to be pursued at local level. Examples include Gilead granting rights to the International Partnership for Microbicides and CONRAD to develop, manufacture and (if proven efficacious) arrange for distribution in LICs of tenofovir as a microbicide to prevent HIV infection.

Sometimes companies contribute to PDPs through donation of a product rather than through co-development. An example of this is Gilead's support of HIV Pre-Exposure Prophylaxis (PrEP) clinical studies through a donation of Viread and Truvada. Partners include the Gates Foundation, the National Institutes of Health, US Centers for Disease Control (CDC), USAID and the Microbicides Trials Network (MTN).

To illustrate the range of disease PDPs the industry is engaged with, a cross-section of recent PDPs is presented in Table 1 overleaf. A more exhaustive list can be found on IFPMA's 'Health Partnerships: Developing World – 2008' website.⁴³

⁴² Moran M. (2005). *A Breakthrough in R&D for Neglected Diseases: New Ways to Get the Drugs We Need* PLoS Medicine Vol. 2, No. 9, e302 doi:10.1371/journal.pmed.0020302
http://medicine.plosjournals.org/archive/1549-1676/2/9/pdf/10.1371_journal.pmed.0020302-L.pdf

⁴³ IFPMA's Health Partnerships: Developing World – 2008 <http://www.ifpma.org/index.php?id=612>

Table 1. Cross-Section of Recent Industry R&D Partnerships

Company	Partner Organisation	Disease Area	Start date for arrangement
Pfizer	TDR	Chagas disease, leishmaniasis, malaria, onchocerciasis, schistosomiasis, sleeping sickness	2006
Merck	HIV Vaccine Trials Network & other partners	HIV	2003
Gilead, J&J, Merck, Pfizer	International Partnership for Microbicides	HIV Transmission	2004
Gilead	DNDi	Leishmaniasis (kala-azar)	2007 (This is not a formal partnership, but Gilead provides product donations to support DNDi clinical studies)
GSK	DNDi	Leishmaniasis, sleeping sickness, Chagas disease	2008
Sanofi	DNDi	Malaria	2005
GSK, Novartis, Sanofi	MMV	Malaria	Individual company programmes 2004, 2007, 2008 respectively
Novartis	TDR and others	Malaria	2006
Sanofi	DNDi	Malaria	2005
GSK	Malaria Vaccine Initiative (MVI)	Malaria Vaccine	1999 (but recent funding in September 2008 from Gates)
Wyeth	TDR	Onchocerciasis	1998
AstraZeneca	EU framework VI Consortium	TB	2003
GSK, Novartis, Sanofi	Global Alliance for TB Drug Development	TB	Individual company programmes 2003-2005
Wyeth	WHO, NIH, USAID & others	Vaccine for pneumococcal disease	2002
Novartis Vaccines Institute for Global Health (NVGH)	GAVI Alliance, WHO, UNICEF	Vaccine preventable diseases	2008

5.2.4 Clinical Trials in the Developing World

There are general concerns, expressed by NGOs and donors working in the access to medicines arena, that clinical trials carried out in some developing countries may not be conducted to the same standards as those in the US and Western Europe. Companies such as GSK, AstraZeneca and many others make a clear statement on clinical trials within their policy positions, stating their commitment to conducting trials ethically and to applying the same standards in both developing and developed countries. Transparency in this area has been enhanced since the R&D industry committed in 2005 to registering information about all new and ongoing clinical trials, other than exploratory trials, in a free,

publicly accessible clinical trials registry. This searchable web-based registry can be accessed via the IFPMA website.⁴⁴

All informants interviewed stated that their companies conduct clinical trials in developing countries according to the ICH Harmonized Tripartite Guideline and the Declaration of Helsinki. The WHO 'Guidelines on Good Clinical Practice' were used as a secondary reference. None of the companies interviewed had directly worked with the European and Developing Countries Clinical Trials Partnership (EDCTP), which this year celebrates its fifth anniversary. Many felt the process to engage with the EDCTP was currently too bureaucratic.

5.2.5 Access to Compound Libraries

A few companies have made compounds from their libraries available to researchers working on diseases affecting developing countries. Pfizer and Merck have given WHO TDR access to some of their libraries, and Tibotec (owned by J&J) made some of their libraries available to the International Partnership for Microbicides as part of their PDP agreements. Similar deals have been negotiated between DNDi and various companies.

Roche announced in April 2008 that it had entered into collaboration with the Institute for OneWorld Health (a not-for-profit pharmaceutical company). Under the agreement, OneWorld Health will screen compounds from the Roche library to identify a potential new drug for the treatment of diarrhoeal disease, which kills approximately 2 million children under the age of five in developing countries each year.

Overall, companies said that sharing parts of their compound libraries is not something they do easily, since they represent a cornerstone of a company's competitive success. However, though the industry favours other models for knowledge transfer, a proposed R&D Industry Consortium could provide a platform whereby compound libraries could be made available by companies for research projects specifically focused on 'diseases of the developing world'.

5.3 Impact on Developing Countries

5.3.1 Health System Capacity Building

Companies stressed that a primary consideration for any of their access programmes is that they should support national priorities and integrate into developing country health systems. Most of the companies consulted run education and community programmes and produce informational leaflets. Training health workers on the ground is often a component of their access programmes, to ensure projects become sustainable. Companies also work with global health partnerships, such as the GAVI Alliance and others, where a

⁴⁴ IFPMA Clinical Trials Portal http://clinicaltrials.ifpma.org/no_cache/en/myportal/index.htm

portion of any funding for procuring medicines is earmarked for health system and supply chain strengthening. Some of the most successful long-term company drug donation programmes have been integrated into the health systems of the countries concerned, such as Merck's ivermectin programme (see section 5.1.2) as part of the African Programme for Onchocerciasis Control (APOC).

Recently, Novartis has been running supply chain workshops to share best practice with various regional governments as part of their Coartem access programme, to help improve developing country governments' understanding of medicine supply chains and to improve their forecasting of medicine needs. It has also been running best practice workshops on malaria control and treatment and management of stockouts.

Since 2005, AstraZeneca has been running a pilot project in Ethiopia designed to build local capability in managing breast cancer, the second most common cancer among young Ethiopian women. The educational initiatives and development of standard treatment guidelines that form part of this programme, in addition to assistance provided in establishing future funding mechanisms for diagnosis and screening, will enhance project sustainability. AstraZeneca hopes the pilot will be successful enough to merit replicating the model in other countries.

In September 2008, Pfizer announced a novel partnership with Grameen Health to explore sustainable healthcare delivery models for the developing world. Initially, the partners will together evaluate strategies to improve Grameen Health's existing healthcare delivery systems and primary care clinics in rural Bangladesh. Appropriate business models that can be replicated in other LICs will then be identified at the end of the first year. As part of its commitment to the collaboration, Pfizer will dedicate key employees to provide technical and advisory support to the partnership.

In collaboration with Oxford University, Johnson and Johnson and Tibotec have provided scholarships to students from the developing world to study for a Master of Science degree in Global Health Sciences.

5.3.2 Intellectual Property

Many companies stressed the importance of Intellectual Property (IP) protection and data exclusivity as a means to reward R&D but state that they do respect the legitimate use of Trade Related Aspects of Intellectual Property Rights (TRIPS) flexibilities. Many provide their public policy positions on IP on their access websites. Companies say they generally reserve the right to lobby for stronger IP protection in developing countries. In the case of data exclusivity, they generally consider that this is what the TRIPS Agreement implies. For example, GSK

supports a ten-year period of data exclusivity plus additional protection for new indications and formulations in both developing and developed countries.⁴⁵

Since 2005, several countries have utilised the compulsory licensing flexibilities allowed under TRIPS, including Brazil and Thailand.⁴⁶ In the case of Thailand – which in 2006 and 2007 issued several compulsory licenses, including for ARVs and heart disease medicines from Abbott, Merck and Sanofi-Aventis – the industry argued that its use of compulsory licences went beyond TRIPS, by amounting to a systematic use of compulsory licensing to reduce the cost of public sector drug purchase. Companies lobbied governments and the European Commission to persuade Thailand to change its policies. In 2006, Abbott confirmed that it would not seek registration for seven new products in Thailand, in response to the Thai government's decision to issue a compulsory license for the HIV protease inhibitor Kaletra (lopinavir/ritonavir).⁴⁷ The seven products included a new heat-stable version of Kaletra, called Aluvia, which is highly desirable in Asian climates. Abbott stated that its medicines that were already registered and available on the Thai market (such as the non-heat stable Kaletra) would not be withdrawn

In India, Novartis challenged the rejection of its patent application for Glivec in the Chennai High Court and also asked the court to declare section 3(d) of the Indian Patents Act unconstitutional and in breach of India's obligation under the TRIPS Agreement. The Court rejected both the latter claims, and the validity of the patent is still to be considered under an administrative appeal process. Novartis argued that the court ruling would discourage the investments in innovation needed to bring better medicines to patients and that inadequacies in Indian patent law would have negative consequences for patients and public health in India and abroad.⁴⁸

On the other hand, in 2003, Roche donated the rights and the technology to manufacture its medicine benzonidazole to the Brazilian government. Benzonidazole is the most effective drug used to treat the tropical disease Chagas. As a result of this donation of IP rights, and a new partnership between Lafepe (a Brazilian company) and DNDi, the first paediatric formulation of benzonidazole will be made available to patients by the end of 2009.⁴⁹ The drug will be sold at cost, with no profit to the institutions involved in its development, and will be available for distribution worldwide.

Licensing

Several companies have issued voluntary licences, predominantly for 1st line

⁴⁵ <http://www.gsk.com/policies/GSK-on-regulatory-data-protection.pdf>

⁴⁶ Cohen J. *AIDS DRUGS: Brazil, Thailand Override Big Pharma Patents* (11 May 2007). *Science* **316** (5826), 816.

⁴⁷ <http://www.msf.org.hk/public/contents/news?ha=&wc=0&hb=&hc=&revision%5fid=28148&item%5fid=27034>

⁴⁸ <http://www.novartis.com/newsroom/media-releases/en/2007/1144199.shtml>

⁴⁹ Chagas Disease: Agreement between Lafepe and DNDi on Safe, Easy-to-Use Treatment for Children. http://www.dndi.org/newsletters/17/9_2.htm

ARVs. An example is GSK, which has issued 8 licences for its ARVs (2 in Kenya and 6 in South Africa). Some of these are for manufacture, while others permit importation of generic versions from India. Tibotec (owned by Johnson & Johnson) also provides darunavir (Prezista™) to LDC and SSA countries at discounted prices through a royalty free licensing and partnership agreement with Aspen Pharmacare of South Africa. But it is generally used as a 3rd line therapy and requires boosting with Abbott's ritonavir (Norvir), which is a temperature-sensitive product, and thus use of Prezista™ may be limited in the developing world. However, Abbot has now completed the development of a new heat-stable tablet formulation of Norvir, which they say they will register broadly around the world. This will remove the need for its refrigeration.⁵⁰ Tibotec Pharmaceuticals has recently announced that it has signed a royalty-free, non-exclusive license agreement with Emcure Pharmaceuticals Limited of India to distribute the protease inhibitor *darunavir* (DRV) in India.

Companies state that the relative lack of voluntary licences issued overall is due in part to the current lack of GMP-compliant manufacturing capability in developing countries. Very few licences for non-HIV medicines have been issued. Some industry informants questioned the transferability of lessons arising from the licensing of ARVs, highlighting the importance of relative disease burden and the availability of financing and resources. In addition, companies such as Abbott believe that generics companies will not invest in manufacturing plants unless market volumes are guaranteed. The company has decided not to adopt a voluntary licensing strategy. Instead Abbott has invested in increasing its manufacturing and supply capacity for its ARV medicines and has adopted a policy of broad registration and differential pricing of their ARV medicines.

Meanwhile, Roche has pledged not to file patents on any new ARVs in SSA and does not file or enforce patents on any Roche medicines in LDCs. Roche will provide generic manufacturers interested in producing versions of its ARV medicines for LDCs and SSA with letters granting immunity from suit, upon request. This policy enables local manufacturers to produce generic ARV medicines for supply to LDCs and SSA without the need for a formal licence. In addition, Roche launched a new initiative in 2006, the AIDS Technology Transfer Initiative⁵¹, to provide local manufacturers with the technical expertise to produce their own generic version of Saquinavir. This aims to help strengthen manufacturing capability and capacity within these countries. As of January 2008, the initiative included eight African manufacturers and one Asian manufacturer based in Bangladesh. In addition, Roche has received expressions of interest from 39 manufacturers in 17 eligible countries, including Ghana and Nigeria.

⁵⁰ Horn T. *Norvir Tablets Similar to Capsules, Expected in 2009* (August 2008).

http://www.aidsmeds.com/articles/hiv_norvir_tablet_2211_15142.shtml

⁵¹ Roche AIDS technology Transfer Initiative http://www.roche.com/sus_acc_tti.pdf

Another novel approach is Gilead's partnership with 10 Indian companies, where it provides full technology transfer to enable partners to produce and distribute quality-assured, low-cost generic versions of Gilead's HIV medicines in 95 developing countries. The licences are non-exclusive, so this collaboration has the potential to lower costs by ensuring competitive pricing and using generic partner companies' extensive expertise in achieving efficiencies and knowledge of developing country supply chains. Gilead receives a five percent royalty on sales, while the generic company partners have the freedom to set prices for their products. Gilead also allows unrestricted API supply among all Indian licensees and Gilead's own API supplier. Overall, this is a novel and encouraging access approach by Gilead.

Some NGOs such as MSF have however criticized the details of the voluntary licences by Gilead and other companies, which limit the countries to which the generic manufacturing partners can export. The voluntary licences often exclude countries such as Brazil and China, who therefore will not benefit from the lower priced generic medicines and the related improved access.

Merck has also issued non-exclusive, royalty-free licences to four South African manufacturers – Adcock Ingram, Aspen Pharmacare, Aurobindo and Cipla Medpro – to enable them to produce and supply generic versions of efavirenz for South Africa and certain other markets within the Southern African Development Community.

To further illustrate the industry's move to unlock the potential of emerging markets, GSK recently announced a licensing collaboration with South African pharmaceutical company Aspen, and its joint venture partner Strides Arcolab Ltd (Strides). This signals a significant new strategy from GSK to accelerate sales growth in emerging markets. Emerging markets are forecast to grow by 13% – three times that of Western markets – and will account for 40% of growth in the worldwide pharmaceutical market by 2020.⁵²

5.3.3 Ethical Promotion of Medicines

All the R&D companies consulted have their own codes of ethics for marketing and promotion of their medicines, which are often more stringent than those of the trade associations that represent them such as the IFPMA,⁵³ the EFPIA⁵⁴ in Europe and the ABPI⁵⁵ in the UK. The companies often extend these codes of

⁵² Economist (15 May 2008). *Quagmire to Gold Mine*.

http://www.economist.com/business/displaystory.cfm?story_id=11376895&fsrc=RSS

⁵³ IFPMA Code Of Pharmaceutical Marketing Practices May 2006

<http://www.ifpma.org/pdf/IFPMA-TheCode-FinalVersion-30May2006-EN.pdf>

⁵⁴ EFPIA Code On The Promotion Of Prescription-Only Medicines To, And Interactions With, Healthcare Professionals

<http://www.efpia.eu/Content/Default.asp?PageID=559&DocID=3483>

⁵⁵ General industry code of practice 2008

<http://www.abpi.org.uk/%2Fpublications%2Fpdfs%2Fpmpca%5Fcode2008%2Epdf>

ethics to their agents and distributors as part of their contracts in developing countries.

Recorded contraventions of the IFPMA and ABPI codes appear to be infrequent, although recently the ABPI suspended Roche from its membership for six months, in relation to the inappropriate supply of a prescription-only medicine.⁵⁶ Most of the national associations have only a domestic remit, so do not monitor activities in developing countries for example, and the international associations such as IFPMA realistically do not have enough capacity to monitor the companies' activities in this area and rely on informants either from within industry itself or by third parties such as NGO watchdogs.

One issue to note is that local generics manufacturers around the globe do not have a unified code of ethics for promotion of medicines, although some of the larger Indian generics manufacturers belong to the Organisation of Pharmaceutical Producers of India (OPPI), an affiliate of the IFPMA. International companies feel they are sometimes at a disadvantage because they operate under much stricter codes of practice than many local manufacturers are obliged to do. This is potentially an area that DFID could explore with developing country governments: to encourage their national drug regulatory agencies (NDRAs) to develop codes of ethics and apply them appropriately, to both local manufacturers and multinational companies, in the interests of patients.

Companies' codes of ethics and those of the associations to which they belong abide by the OECD anti-bribery convention⁵⁷ and other anti-corruption measures. There is little transparency, however, regarding any payments made to or received from developing country governments where bilateral price negotiations take place (i.e. between a company and a specific developing country government). Exceptions are where public procurement tendering processes and documents are put into the public domain by the developing country governments concerned. The Medicines Transparency Alliance (MeTA) could be a vehicle for making improvements in this area, at least in its pilot countries.

Most informants admitted that they were not very familiar with the OECD Guidelines for Multinational Enterprises.⁵⁸ Many assumed that their legal departments ensured that their access and social corporate responsibility programmes are consistent with the OECD guidelines.

⁵⁶ ABPI press release 14 July 2008. Company Suspended From ABPI Membership Over Breaches Of Code Of Practice. http://www.abpi.org.uk/press/press_releases_08/140708.asp

⁵⁷ OECD Anti-bribery Convention
[http://www.oecd.org/document/21/0,3343,en_2649_34859_2017813_1_1_1_1,00.html - Text of the Convention](http://www.oecd.org/document/21/0,3343,en_2649_34859_2017813_1_1_1_1,00.html-Text_of_the_Convention)

⁵⁸ OECD Guidelines for Multinational Enterprises
http://www.oecd.org/document/28/0,3343,en_2649_34889_2397532_1_1_1_1,00.html

5.4 Reporting and Verification

All the companies consulted report to varying degrees on their access to medicines programmes for developing countries, either as stand alone 'corporate responsibility' or 'access' reports, or as part of their annual reports. Many also have websites dedicated to access to medicines in the developing world (see *Annex Six* for bibliography and web links for individual companies). Notable are GSK, Roche and Novartis' access websites – not only for details of their access programmes, which the majority of companies consulted have, but for the breadth of their public policy position papers relating to issues such as differential pricing offers and IP. GSK's has the most breadth and is frequently updated.⁵⁹

In terms of making access to medicines reports available to a wide range of stakeholders in developing countries, most companies rely on hard copy annual reports and information on their company websites at the global (corporate) level, but regional offices will often have additional materials printed and distributed locally. Companies also collaborate with NGOs such as MSF to publicize their differential pricing offers for ARVs to a wider developing country community and to input into both the WHO GPRM⁶⁰ and the Global Fund PRM.⁶¹

New initiatives in reporting include the G-FINDER survey⁶² that was launched online on 15 July 2008. The survey will track and report on global investment into research and development (R&D) for new medicines and vaccines for neglected diseases and is funded by the Bill and Melinda Gates Foundation. The following companies are part of the stakeholder network: AstraZeneca, GSK Bio, Merck & Co., Novartis, Pfizer, Sanofi-Aventis and Wyeth-Ayerst Lederle.

Some companies, as a reaction to the ATM Index (see section 7), are trying to develop pharmaceutical sector indicators for their access programmes. Currently, it is difficult to compare access to medicines and corporate responsibility activities across companies using existing reporting systems. The differences in company strategies, expertise in various research and therapeutic areas, geographic reach and portfolios all drive business focus and are reflected in how companies report on performance. In addition, research highlights that company cultures, not to mention the various definitions and outcome measures they use in their reporting, can differ greatly. A simple example to illustrate this is the use of 'corporate responsibility', 'corporate citizenship' and 'sustainability' by various companies to mean essentially the same thing. So rendering access reports comparable continues to be a major challenge.

⁵⁹ GSK Reports and publications - Public policies

<http://www.gsk.com/reportsandpublications-policies.htm>

⁶⁰ Global Price Reporting Mechanism (GPRM) <http://www.who.int/hiv/amds/gprm/en/>

⁶¹ Global Fund Price Reporting Mechanism

http://www.theglobalfund.org/en/funds_raised/price_reporting/default.asp

⁶² G-FINDER: Global Funding of Innovation for Neglected Diseases

<http://www.thegeorgeinstitute.org/iih/research/health-policy/current-projects/g-find-global-funding-of-innovation-for-neglected-diseases.cfm>

The use of third-party verifiers to measure and report on the impact of corporate responsibility, including access to medicines programmes, could make comparability easier. Merck, Novartis and Roche used the Global Reporting Initiative (GRI), an independent organization that establishes voluntary global guidelines for reporting on corporate responsibility, to verify their 2007 reports. Others like Abbott, AstraZeneca, GSK and Sanofi-Aventis used the GRI framework as a reference. AstraZeneca also had its corporate responsibility report certified by Bureau Veritas, as did GSK for its “Access” web pages as well as the access pages in its corporate responsibility report. Many companies use consultation with stakeholders and advocates working in the access to medicines arena – such as Oxfam, MSF and others – as a means to measure impact and to review their annual reports. In addition, the IFPMA has had a third-party institution conduct a critical assessment of its members’ global health partnerships.⁶³

6. Progress by HMG

This section presents a qualitative assessment of the progress the UK Government has made since 2005 against the four GPF elements. It is based on consultation with key HMG informants and material available in the public domain.

6.1 Affordability

It is worth noting that the notion of ‘affordability’ within an access to medicines framework has two sides: pricing on the one hand, and availability of financing on the other.

6.1.1 Financial Commitments

In terms of financial commitments made since the 2005 policy paper, the UK has pledged £6 billion over seven years to strengthen health systems and services in developing countries. In addition to this, the UK has committed £1 billion to the Global Fund for 2008-2015 (subject to performance). This long-term pledge signals the level of the Government’s commitment to health, including contributing to international efforts to provide comprehensive HIV prevention, treatment, care and support and to improving access to essential medicines.⁶⁴ Total UK development assistance in 2007/08 was estimated at £5.3 billion. The UK has also committed to more than doubling its overall aid budget between

⁶³ http://www.ifpma.org/pdf/ifpma_health_partnerships_survey_2007.pdf Critical Review of the IFPMA Health Partnerships

⁶⁴ Douglas Alexander speech: “Achieving Universal Access” – the UK’s strategy to tackle AIDS in developing countries, 2 June 2008
<http://www.dfid.gov.uk/news/files/Speeches/DAlexander-aids-full-speech.asp>

2008 and 2013. Total development assistance will reach £9.1 billion in 2010/11, representing 0.56% of GNI. By 2013 it will increase to 0.7% of GNI in line with UN targets.

The Government's efforts in increasing development assistance have included initiatives such as the new International Finance Facility for Immunisation (IFFIm). The IFFIm is currently supported by the governments of France, Italy, Norway, South Africa, Spain, Sweden and the United Kingdom. President Lula of Brazil has also announced that his country intends to make a 20-year commitment to IFFIm. IFFIm funds the GAVI Alliance. The World Bank is the Treasury Manager for IFFIm. The UK has committed £1.38 billion to the IFFIm over twenty years. An anticipated total IFFIm investment of US\$4 billion is expected to protect more than 500 million children through immunisation campaigns against measles, tetanus and yellow fever. To date, \$1.2 billion has been raised through two bond issues.⁶⁵

Another area in which the UK Government has been heavily engaged is bilateral and multilateral debt relief. Thirty-three countries are receiving debt relief under one or both of these initiatives and eight other countries are potentially eligible. This debt relief is worth around US\$100 billion in 2007 net present value (NPV) terms if all creditors participate.⁶⁶ In 2006/2007 DFID provided debt relief totalling £144.8m, representing 3% of DFID's development assistance programme.⁶⁷

DFID has also made long-term commitments to the Global Fund (see above) and to UNITAID (£790 million over 20 years, subject to performance). DFID is also considering support to the CHAI, which *inter alia* aims to speed the introduction of ACTs and ARVs into African countries.

A further £50 million commitment was recently made by DFID to tackle parasitic and bacterial tropical diseases like onchocerciasis (river blindness), lymphatic filariasis (elephantiasis), blinding trachoma and schistosomiasis (bilharzia).⁶⁸

6.1.2 Health Worker Migration

International migration accounts for some of the loss of health workers from developing country public health systems. A recent study has shown that the number of foreign-trained doctors has tripled in several OECD countries over the past three decades.⁶⁹ The number of foreign-trained doctors from countries with chronic shortages of health workers is relatively small (less than 10% of the workforce) in developed countries. However, for some African countries, the

⁶⁵ <http://www.iff-immunisation.org/>

⁶⁶ Debt Relief-Ten Years on. <http://www.dfid.gov.uk/mdq/debtrelief-10yearson.asp>

⁶⁷ Reporting Debt of Relief. <http://www.dfid.gov.uk/Pubs/files/sid2007/section2.asp>

⁶⁸ <http://www.dfid.gov.uk/news/files//pressreleases/tropical-diseases.asp>

⁶⁹ Connell J, Zurn P, Stilwell B, Awases M, Braichet J-M, Sub-Saharan Africa: Beyond the health worker migration crisis, *Social Science & Medicine* 64 (May 2007) 1876-1891.

migration of a few dozen doctors can mean losing more than 30% of their workforce, even as basic health needs remain unmet locally. The UK Government says that many health workers on the other hand simply move into the private sector or out of healthcare altogether due to poor working conditions. However, the UK Government has worked – including through the EU and WHO – to support coordinated action to prevent active recruitment by the NHS of health workers from low-income countries. A 2001 NHS Code of Practice (revised in 2004) restricts active recruitment of health workers.⁷⁰ The UK has expanded its domestic doctor training places by 50% to reduce demand for overseas recruits. An evaluation of the NHS code of conduct has shown that fewer international health workers are now working in the UK than in 2000-2005. Case studies from Kenya and Ghana suggest that numbers of nurses leaving for the UK and other countries have declined significantly since peaking in 2000-2003. However, it is not possible to assess accurately the role that the Code has played since amendments to immigration rules and UK training policies are also thought to have influenced change. A further evaluation is planned.

The UK also supports two new initiatives under development: the drafting of an EU Code of Practice on International Recruitment; and a global code of conduct, on which the Global Health Workforce Alliance (GHWA) is leading.⁷¹

6.1.3 Monitoring Prices, Diversion and Counterfeiting of Medicines

The UK Government continues to support the WHO and Health Action International (HAI) to develop and ensure use of their survey tool to improve market information about medicine prices. In addition, in May 2008, DFID launched the Medicines Transparency Alliance (MeTA)⁷² in collaboration with the WHO and the World Bank, which builds on the WHO/HAI methodology and experience and other relevant initiatives. MeTA takes a multi-stakeholder approach to build greater transparency and accountability in the medicines supply chain, using data to inform policy development and improve consumer awareness and advocacy.

On the other hand, this review finds that the UK Government has not yet worked sufficiently with pharmaceutical companies and other stakeholders to support and enhance company reporting on affordability e.g. on differential prices of medicines for LICs and MICs. MeTA may go some way to facilitating this in future.

The UK Government could collaborate more closely with G8 governments, the EU, industry and others to monitor and develop strategies to stem diversion of medicines away from the low-income markets and buyers to whom differential

⁷⁰ Code of Practice for Recruitment of Foreign Health workers into the NHS
<http://www.nhsemployers.org/primary/workforce-551.cfm>

⁷¹ <http://www.ghwa.org/>

⁷² <http://www.medicinestransparency.org>

prices are offered. The UK Government says it has not been very engaged in this particular area possibly due to the absence of good data available to either governments or industry as to the scope of this potential problem. Once again, MeTA may potentially help with future data collection and analysis in this area, but only within its pilot countries.

Working with the WHO, pharmaceutical companies and others, the UK Government continues to support the production of quality-assured drugs, and to tackle counterfeit and substandard medicines. The UK Healthcare products Regulatory Agency (MHRA) has a 2007-2010 Anti-counterfeiting Strategy and collaborates with other regulatory agencies globally to address this issue.⁷³ The UK is also a signatory to a number of anti-counterfeit treaties and initiatives, and is currently involved in negotiating the Anti-Counterfeiting Trade Agreement (ACTA). It is keen to ensure this treaty does not create barriers to accessing medicines or to the entry of legitimate quality-assured generics into developing country markets.

Through coordinated donor action, and alongside the WHO and others, the UK Government is working to improve and harmonise drug registration/regulation in Sub-Saharan Africa. An initiative being developed by DFID in conjunction with the Southern African Development Community will have a component to improve drug regulation.

6.2 Research and Development

6.2.1 Financial Incentives

The UK finances both 'push' and 'pull' incentives, in recognition of the need to address market failures in R&D for neglected diseases in developing countries. 'Push' incentives include the UK's R&D tax credits⁷⁴ and specifically the Vaccines Research Relief (VRR),⁷⁵ introduced for all expenditure from April 2003 onwards. It is still too early to undertake a full evaluation of these tax credits; however, interim statistics suggest that 10 companies are claiming VRR each year at a cost of less than £5m.⁷⁶

'Pull' incentives to increase and accelerate the development and introduction of new pharmaceuticals (new vaccines in the first instance) include the Advanced Market Commitment (AMC). This is a novel instrument, which the UK facilitated and helped to develop (see above, section 5.2.2).

⁷³ MHRA 2007- 2010 Anti-counterfeiting Strategy
<http://www.mhra.gov.uk/home/groups/ei/documents/websitesresources/con2033156.pdf>

⁷⁴ UK R& D tax relief for large companies
<http://www.hmrc.gov.uk/manuals/cirdmanual/CIRD85000.htm>

⁷⁵ UK Vaccines Tax Relief <http://www.hmrc.gov.uk/manuals/cirdmanual/CIRD75000.htm>

⁷⁶ Statistics are published and are available at:
http://www.hmrc.gov.uk/stats/corporate_tax/randdcmenu.htm

6.2.2 DFID Investments in Product Development Partnerships (PDPs)

The UK has invested in PDPs since 1998, when it was the first government to provide funding for the International AIDS Vaccine Initiative (IAVI). The UK is one of the largest government donors to PDPs, giving around £25 million in 2007/8 (£70 million between 2005-8). Current investments in PDPs amount to approximately 50% of DFID's total health research budget. Table 2 overleaf outlines DFID's current levels of investment in PDPs.

In the context of the near doubling of the overall research budget to £220 million by 2011, DFID says it will:

- Increase funding by up to 100% for the PDPs that DFID it already supports;
- Expand DFID's PDP portfolio to meet priority health needs;
- Improve research and coordination to accelerate the roll-out of new drugs, diagnostics, vaccines and microbicides.

Table 2. DFID's Current Investments in PDPs

Disease	Technology	PDP	Pledge	Timescale
Malaria	Drugs	Medicines for Malaria Venture (MMV)	£10m	2005-10
TB	Drugs	Global Alliance for TB Drug Development (GATB)	£6.5m	2005-8
HIV	Vaccines	International AIDS Vaccine Alliance (IAVI)	£20m	2005-8
	Microbicides	International Partnership for Microbicides (IPM)	£7.5m	2005-8
		Microbicide Development Programme	£23.8m	2006-9
Neglected diseases	Drugs	Drugs for Neglected Diseases initiative (DNDi)	£6.5m	2005-8

6.2.3 New Initiatives to Stimulate and Support R&D

In February 2007, donors announced US\$1.5 billion in financing for a pilot AMC for pneumococcal vaccines (see section 5.2.2 for more on industry engagement). The UK contribution is US\$485m. The lead donor is Italy (US\$635m) and the other donors are Canada (US\$200m), Russia (US\$80m), Norway (US\$50m) and the Gates Foundation (US\$50m). GAVI is the implementing agency, working with the World Bank as Treasury Manager and UNICEF as procurement agent. Developing countries and vaccine companies have been engaged through structured consultations.

DFID has also supported the work of the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH), which considered ways to increase R&D for products relevant to the health needs of developing countries. DFID is also considering support to the Expert Working Group being established by WHO as part of the Strategy and Plan of Action agreed by the Intergovernmental Working Group (IGWG) set up following the CIPIH report.

6.2.4 Identifying Research Needs in Developing Countries

DFID works through the Medical Research Council (MRC), which represents the UK on the European and Developing Countries Clinical Trials Partnership (EDCTP).⁷⁷ The MRC is involved in the discussions about research needs, but is influenced by its relationship with DFID. For other global health partnerships, DFID has a variety of collaborations with each, but without a formal mechanism for influencing research needs.

6.2.5 Support for Research in Low- and Middle-Income Countries

The UK supports research in developing countries, as well as uptake of new medicines within their health systems, mainly through support to PDPs, GAVI, the pilot AMC, and prospectively to the Affordable Medicines Facility for Malaria (AMFm). The activities of the MRC and the Wellcome Trust are also relevant. Current DFID funding to MMV is matched by Wellcome. DFID says it is also working with Wellcome to build research capacity in several African countries. DFID has given £4 million per year for the last 5 years to the MRC, but is working to develop a new Concordat, which will shift the focus towards funding clinical trials (which DFID does separately at the moment) and will match funding for the EDCTP. The funding profile is yet to be decided but is likely to be in the order of £10 million per year for the next 5 years. Last year DFID gave £7.5m to EDCTP through the MRC as matched funding, following an acceleration of progress by the EDCTP.

6.2.6 Support for the Research Funders Forum on Health in Developing Countries

The UK Research Funders Forum for Health includes DFID, MRC, Wellcome Trust, Economic and Social Science Research Council (ESRC) and the Department of Health. It aims to facilitate discussion regarding current developments in each of the organisations and to identify areas in which they can collaborate. Joined-up UK approaches to different initiatives are discussed, including for instance the ministerial summit on health research in Bamako in 2008. The Forum also explores complementarity of activities to support the development of research capacity in developing countries. In 2006, the UK Collaborative on Development Sciences (UKCDS) was formed.⁷⁸ The UKCDS

⁷⁷ <http://www.edctp.org>

⁷⁸ <http://www.ukcnds.org.uk/>

brings together the key UK funders and stakeholders who provide support for the development sciences research base. It aims to provide a framework for a more coordinated approach to development sciences research, in order to increase its relevance and impact on national and international policies and activities, aimed at improving the lives of the world's poorest people.

DFID is also the current chair of the PDP Funders Forum, which brings together the major funders of PDPs globally, to share information and undertake joint tasks, such as evaluations of MMV and IPM.

6.3 Impact in Developing Countries

6.3.1 Millennium Development Goals and Access to Medicines

The UK Government, through DFID, continues to work throughout the developing world on a wide range of development issues and programmes, with the aim of fulfilling the Millennium Development Goals (MDGs).

In a continuing commitment to reaching MDG 6 (combat HIV and AIDS, malaria and other diseases), the UK launched its updated AIDS strategy *Achieving Universal Access - the UK's strategy for halting and reversing the spread of HIV in the developing world* in June 2008.⁷⁹ At the UN MDG meeting held at the end of September 2008, \$3 billion worth of new global commitments were made to the fight against malaria.⁸⁰ Within these commitments, the UK pledged £40 million to support the AMFm, which the UK has encouraged the Global Fund to host. Additionally, a UK commitment was made to increase malaria R&D funding to at least £5 million per year by 2010.

In addition, also at the UN MDG meeting, International Development Secretary Douglas Alexander and Kemal Dervis, United Nations Development Programme (UNDP) Administrator, launched the Global Business Call to Action (BCTA) partnership. The BCTA aims to get private sector companies involved in spreading growth and prosperity throughout the developing world. Merck & Co and Pfizer are part of this partnership.

6.3.2 Health System Strengthening

At the same recent UN MDG meeting in New York, a UK-led initiative was launched that will see Prime Minister Gordon Brown and World Bank president Robert Zoellick chairing a new High Level Task Force on Innovative International Financing for Health Systems, which will develop recommendations on the innovative finance mechanisms that are needed to strengthen healthcare systems and pay for healthcare workers. The focus of this initiative will be MDGs

⁷⁹ *Achieving Universal Access –the UK's strategy for halting and reversing the spread of HIV in the developing world.* <http://www.dfid.gov.uk/Pubs/files/achieving-universal-access.pdf>

⁸⁰ <http://www.un.org/millenniumgoals/2008highlevel/>

4 and 5 (improving maternal and child health).

The UK Government launched the International Health Partnership (IHP) in September 2007.⁸¹ The IHP and related initiatives (now referred to as IHP+) aim to harmonize the efforts of donors and other international partners in health behind developing countries' own plans for health sector reform and delivery. The UK has pledged £450 million over the next three years to support the IHP in eight of the poorest countries. In addition, DFID is currently involved in preliminary discussions with WHO, the Gates and Clinton Foundations and the New Partnership for Africa's Development (NEPAD) about the development of a project to improve regulatory processes through improved collaboration between regulatory authorities and regional economic communities in sub-Saharan Africa.

6.3.3 TRIPS Flexibilities

Lastly, the UK Government says it supports developing countries in understanding and making appropriate use of the flexibilities within World Trade Organisation rules governing intellectual property. This is achieved through support to UNCTAD and the International Centre for Trade and Sustainable Development (ICTSD), and has included in-country training in Botswana and Kenya. In the next year, the UK-IPO plans to improve its bilateral relations with countries so as to improve the flow of information on IPR policies and issues.

6.4 Reporting and Verification

The Government made some general commitments through the GPF to support companies in improving reporting on their access to medicines programmes, including their differential pricing offers as well as R&D investments. However, little progress appears to have been made in this respect by the UK Government since 2005.

7. Impact of UK 2005 GPF

The global environment affecting access to medicines has changed fairly significantly since the GPF was published in 2005. First, the pharmaceutical industry is undergoing a structural shift towards greater engagement in emerging markets – particularly in the rapidly growing economies of Asia, South America and the Middle East. These economies are seen as potential growth markets for research-based and generics companies alike. This reorientation and other factors have prompted the restructuring of several major pharmaceutical companies and a change in the shape of the industry as a whole. As biotechnology companies have become more critical to pharmaceutical R&D, generics companies – particularly those in India – have become more critical to

⁸¹ <http://www.who.int/healthsystems/ihp/en/>

pharmaceutical manufacturing and supply. This is true not just in relation to emerging markets but to the established pharmaceutical markets as well.

Secondly, the world has seen a growth in the level of donor financing available to support the development and supply of pharmaceutical products. For example, since the GPF was published, several major new initiatives have come on stream, which are aimed at meeting the needs of LICs in particular. Many examples are outlined in the above sections of this report and include the IFFIm, the AMC, UNITAID and the US President's Malaria Initiative (PMI). PEPFAR has also been reauthorised by the US Congress to the tune of \$39 billion.⁸² Alongside this, several developing country governments have taken steps to ensure more sustainable domestic financing for the health sector and for medicines specifically. For example, Ghana, Nigeria and Kenya are among the countries that have launched or are in the process of launching ambitious national health insurance schemes. The pharmaceutical market in both LICs and MICs thus looks more sustainable now than it did even three years ago.

In addition, during recent years, the industry – with a particular focus on the larger research-based companies – has attracted greater attention from those seeking to encourage and/or assess company progress on access to medicines and related issues with societal value. Examples of relevant initiatives (some of which have received modest DFID support) include:

- PharmaFutures, which brings pharmaceutical companies and long-run investors together to discuss societal issues that affect the industry's long-term value. It was launched prior to the 2005 GPF, but is currently in its third phase focusing in more detail on the issues faced by the pharmaceutical industry as it expands across emerging markets.
- The Pharmaceutical Shareowners Forum, which serves as a convening forum for European pension funds and other long-run investors in the pharmaceutical sector. The forum evolved subsequent to the success of the Pharmaceutical Shareowners Group (PSG), which released an "investors' statement" covering access to medicines issues in 2003 and a fuller report on the pharmaceutical sector in 2004 (and which is now dormant).
- The Interfaith Center on Corporate Responsibility (ICCR), which released a report entitled 'Benchmarking AIDS' in 2006 that assessed the pharmaceutical industry's response to HIV/AIDS and other public health crises in emerging markets.⁸³ The ICCR has also co-ordinated its US members in responding to decisions made by individual companies

⁸² See <http://www.pepfar.gov/press/107735.htm>

⁸³ ICCR (2006) 'Benchmarking AIDS: Evaluating pharmaceutical company responses to the public health crisis in emerging markets' Interfaith Center on Corporate Responsibility, The Corporate Examiner, Vo 34, No 6-7, August 1st 2006
http://www.iccr.org/news/press_releases/pdf%20files/CEvol34no6-7AIDSexecsum.pdf (Executive Summary)

regarding access to their medicines, such as Abbott's decisions regarding drug registration in Thailand.⁸⁴

- The ATM Index, which is the first attempt to comprehensively assess and compare the performance of pharmaceutical companies across a range of indicators of corporate commitment to access to medicines. (This follows the limited, one-off Core Ratings index released in 2004, but is not directly related to it.) The first ATM Index report was issued in 2008 and has attracted a good deal of attention, including in the financial and industry press.⁸⁵ Indeed, in a Time magazine essay in August, Bill Gates cited the ATM Index as something worthy of replication, not just in the pharmaceutical sector but in other sectors too.⁸⁶
- Oxfam's access to medicines programme. This includes its 2007 report 'Investing for Life', which attempted to assess the business case for pharmaceutical companies to act more decisively and creatively to address access to medicines.⁸⁷ This in turn built on Oxfam's earlier work with VSO and Save the Children to publish 'Beyond Philanthropy', a 2002 assessment of the pharmaceutical industry's social responsibilities.
- The remit of the UN Special Rapporteur on the Right to Health, which over recent years has included work on access to medicines. Though most of the Special Rapporteur's work focused on the role of states, he also looked at the role of the private sector and this culminated in the publication of guidelines for the pharmaceutical industry, in draft in November 2007 and in final form in August 2008.⁸⁸

Against this backdrop it is difficult to attribute any progress made by the pharmaceutical industry on access to medicines specifically to the UK's 2005 GPF. Indeed, evidence from key informants working on the above initiatives suggests that it takes at least five years for such efforts to effect meaningful change. The GPF has certainly contributed to the thinking of the major pharmaceutical companies working in the area of access to medicines and it has been referenced by them in other consultation responses and discussions in the past couple of years. Clearly, it is one of many tools or activities that have helped to move the debate forward. Through consultation for this review, we have solicited the judgements of a wide range of stakeholders on the influence that the 2005 GPF – and HMG's work on access to medicines more generally – has had and is continuing to have. We have also examined the process by which the GPF

⁸⁴ ICCR (2007) 'Christian Brothers Investment Services, ICCR Shareholders Urge Abbott to Reverse Decision, Keep HIV/AIDS Drug on Shelf in Thailand' ICCR press release, March 2007 http://www.iccr.org/news/press_releases/2007/pr_abbott032207.htm

⁸⁵ <http://www.atmindex.org/>

⁸⁶ Bill Gates 'Making Capitalism More Creative' in TIME Magazine (print edition 11th August 2008, Vol. 172, No. 6) <http://www.time.com/time/business/article/0,8599,1828069-1,00.html>

⁸⁷ Oxfam (2007) 'Investing for Life' http://www.oxfamamerica.org/newsandpublications/publications/briefing_papers/investing-for-life/OxfamInternational_InvestingforLife.pdf

⁸⁸ http://www2.essex.ac.uk/human_rights_centre/rth/docs/GA%202008.pdf

was developed, launched and implemented alongside the processes adopted for the other relevant frameworks and indices outlined above.

As outlined previously, the GPF emerged from a longer-term process of dialogue and collaboration – across HMG, with the pharmaceutical industry and with other stakeholders. Since 2001, DFID had been building relationships with the two major UK pharmaceutical companies, GSK and AstraZeneca, and then began meeting at regular intervals with the American Pharmaceutical Group (APG), a group of US-based companies with representation in the UK. These discussions focused on what more the industry could do to improve access to their products and on related HMG policy developments – in short, precisely the topics covered in the GPF. When the process of researching and drafting the GPF was underway, this dialogue intensified and the draft GPF document went through several rounds of consultation with the industry and other stakeholders. Companies were also able to contribute examples of their own activities that represented ‘good practice’, through consultation with DFID. Therefore, when the document was published in March 2005, it contained no ‘surprises’ from an industry point of view. The accompanying DFID press release was framed in terms of an intensified ‘government-industry partnership’.⁸⁹

By contrast, some of the other initiatives outlined above took a more hands-off approach to the industry, developing a framework first and then consulting industry on it. Indeed, from the perspective of some stakeholders (both those reacting to the GPF in 2005 and those interviewed for this review), the GPF was less ambitious than it could have been in ‘stretching’ the industry’s commitment to and action on the issues, in part because companies were so closely engaged in the process – though the same stakeholders also recognise the benefits of this closer co-operation. Not surprisingly, pharmaceutical companies have expressed a preference for continued close engagement with HMG. Further, some companies have been openly critical of the hands-off approach taken by other initiatives, such as the ATM Index and particularly the UN Special Rapporteur’s Guidelines. In any case, given the numerous approaches outlined above, all of which seek to develop industry guidelines and/or shape industry performance, DFID should consider further how best to link with and complement others’ efforts. In the past, DFID has engaged in advisory groups allied to some of these other initiatives and this is likely to be valuable in the future too.

Our own assessment has concluded that each of these initiatives – with their respective positioning in relationship to the industry – offers distinct value. The ATM Index is unique as a ranking system, whereas the other initiatives each represent the ‘voice’ and legitimate interests of a specific stakeholder group (institutional investors or civil society, for example). Among these, the GPF uniquely represents the voice of government and therefore adds value in

⁸⁹ DFID (2005b) ‘Renewed commitment to government – industry partnership to improve access to medicines’ DFID press release, March 2005
<http://www.dfid.gov.uk/news/files/improve-access-medicines.pdf>

outlining the expectations of the State, both as an industry regulator (and sponsor) and as a bilateral donor.

Given the UK Government's well-developed policy framework on access to medicines (unusual across bilateral donors), the high level of relevant expertise exhibited by its departmental officials and the significant financial investment it is making in addressing the issues, there is certainly scope for HMG to be more ambitious in its dealings with the pharmaceutical industry.

The GPF had greater impact than it might have had, because it complemented and to differing degrees informed other similar initiatives, but also because it complemented other HMG activities on access to medicines. The HMG 'policy and plans' document published in 2004 set out broad priorities;⁹⁰ the GPF echoed these but with greater detail on their relevance to the industry. Both documents had been read, digested and in some cases referred back to by the non-industry informants to this review. Many of them felt the GPF had put down important markers on 'difficult' issues, such as medicines donations and TRIPS. Industry informants involved found the process and dialogue during the development of the GPF useful, perhaps more so than the document itself. They did, however, acknowledge that it was a seminal document and they suggested that amongst similar initiatives and frameworks the GPF was viewed as the most valuable.

However, the momentum developed through HMG consultation and publication of the GPF was not sustained. Two follow-up roundtables between industry and HMG were held, one on R&D hosted by AstraZeneca and another on pricing hosted by DFID. However, informants to this review suggested that DFID/HMG dialogue with the industry and others had decreased in regularity following the GPF's launch. In addition, there was little focus in the GPF on outcome measures and no monitoring and evaluation framework was developed, so progress against the framework was not systematically captured over time. Finally, the HMG review of the GPF was not undertaken as planned in 2006 (though this report forms part of the delayed review process). HMG therefore lost some of the traction it appeared to have in 2004-05 with respect to industry responsibilities specifically – and perhaps in terms of influencing the broader policy agenda on access to medicines globally, in which pharmaceutical companies and industry associations now engage more proactively, e.g. through IMPACT and IGWG.

⁹⁰ DFID (2004) *'Increasing access to essential medicines in the developing world: UK Government policy and plans.'* DFID, DH, DTI, PO, IR, HMT and FCO, June 2004
<http://www.dfid.gov.uk/pubs/files/accessmedicines.pdf>

8. Discussion and Conclusions

As outlined previously, the global pharmaceutical industry is changing shape. As many larger research-based and generics companies expand into emerging markets, the issue of access to medicines in MICs and LICs is likely to grow in importance, not diminish – not least given the number of initiatives now focused on assessing industry performance in this area. However, even the most progressive companies will most likely continue to navigate the territory delicately, given the pressure they face in established markets and especially in the US, where escalating healthcare costs are contributing to the case for comprehensive health sector reform. The ongoing credit crisis and the resulting volatility in global capital markets bring additional pressures to bear on this key industrial sector.

This review of the UK Government's 2005 good practice framework (GPF) for the pharmaceutical sector suggests that the industry is well-placed to expand its engagement in both MIC and LIC markets, if companies continue their work to ensure poor people's access to their products. The best-placed companies are already integrating access issues into their core business model. There are promising signs of innovation and creativity in other companies. Overall, as set out in section 5 of this report, good progress has been made in relation to some areas of the GPF (such as industry engagement in R&D PDPs, and examples of innovative licensing) but there is a need for greater attention to other areas (such as affordability concerns in MICs, the disease scope of differential pricing offers in LICs and LDCs, and reporting).

The UK Government departments that co-authored the GPF (DFID, DH and BERR) and others that were not original co-authors (IPO and HMT) remain closely engaged in the issues. Particularly good progress has been made in relation to meeting the financing commitments set out in the 2005 GPF. HMG has made good on its promises to increase ODA in line with plans to meet the UN target of 0.7% of GNI and to invest more in expanding HIV/AIDS treatment, enhancing R&D, and strengthening developing country health systems. In the process, the UK has been at the forefront of developing innovative new financing mechanisms. At the policy level, cross-departmental action to address the 'brain drain' of health workers from developing countries has proved successful, and some support has been provided to developing countries on 'navigating' TRIPS, though more remains to be done in both areas. HMG has made less progress in supporting pharmaceutical companies to transparently report on their activities to increase access to medicines and the impact they are having on the ground.

Taking into account the backdrop of change, and based on the findings of this review, we therefore conclude that:

- **Clear statements of government expectations regarding industry practice are valuable.** The need for companies to incorporate access issues

into their core business model, coupled with broader economic uncertainty, means that clear signals from government may be particularly welcome at this time.

- **HMG should therefore consider issuing an updated policy statement** regarding industry responsibilities on access to medicines. This could take a number of possible forms, but should take account of the entire medicine supply chain and the role of the generics industry (particularly given the high volume of generic medicines being procured with support from initiatives such as the Global Fund).
- If this policy statement takes the form of another GPF, **HMG should consider focusing in detail on three or four priority areas** in which it would like to see greatest progress. This would entail specifying industry actions that are likely to have greatest impact and setting out what HMG will do specifically to facilitate and support these actions. Time bound objectives would be useful in order to accelerate action.
- Based on the assessment of progress made to date (in sections 5 and 6 of this review) we would highlight the following priorities for consideration:
 - Exploring innovative and creative **voluntary licensing and other appropriate outsourcing/outlicensing strategies** as one route towards improving access in a commercially sustainable manner;
 - Developing appropriate and sustainable **differential pricing models for MICs**, as one component of a broader strategy to facilitate access in emerging markets;
 - Expanding differential pricing to a **broader product range in LICs and LDCs**;
 - Developing new strategies to enhance access to products to treat **non-communicable diseases**, in all markets;
 - **Enhancing R&D in specific, neglected areas** such as paediatric medicines and diagnostics.
 - **Harmonizing regulatory processes** to support R&D and access strategies, particularly in Sub-Saharan Africa. This is an area in which the UK is already working with WHO and others, such as regional bodies, but efforts might be enhanced further and the opportunities harmonization offers to expand access could be discussed in more detail with the pharmaceutical industry.
- **HMG should recommence regular dialogue with industry and other stakeholders** (particularly investors and key UK-based NGOs); for group meetings, every six months is probably realistic and sufficient. HMG should also explore how best to engage a broader cross-section of the industry (e.g. including generic manufacturers and perhaps UK bioscience companies);
- **Any future policy statement or framework should be monitored** through this process of dialogue; a 'light' monitoring and evaluation framework should be developed and maintained; outcome indicators are also needed.

Finally, this review has underscored very firmly the high regard in which the UK Government, and DFID specifically, is held by the pharmaceutical industry and

others working to increase access to medicines in developing countries. HMG consistently underestimates its influence on this issue. This modesty is no doubt one of the contributors to others' respect for UK Government departments and their officials. But there is a strong sense that the UK could use this influence more strategically to effect change across the pharmaceutical sector, including through dialogue between UK politicians, industry CEOs and other senior figures in global health and development. Indeed, as new CEOs seek to make their mark and as key players such as Bill Gates state their interest in industry performance on access issues, an important window of opportunity is now opening. The UK Government, and others seeking to improve health outcomes for the world's poorest people, must seize this opportunity.

Annexes

Annex One Summary of GPF 2005

The GPF addressed the four key elements outlined below. More detail is outlined in the original 2005 policy paper.

1. Affordability

The GPF highlighted affordability of essential medicines as a key factor affecting access. The UK Government therefore encouraged industry to develop, maintain and expand differential pricing offers for developing countries (close to the cost of manufacture for least developed countries) – especially where the only available product is single-source (patented). The GPF suggested that these differential pricing offers should be in line with developing country disease priorities and should not place an undue burden on health system capacity. The industry is encouraged to minimise diversion and leakage and make differential pricing offers accessible, publicly promote them and ensure clarity on what mark ups (e.g. shipping costs, duties and taxes) these prices include. Finally, the industry is urged to publicly commit to and report on compliance with UN interagency guidelines on drug donations and ‘price discounts for single-source medicines’.

The Government in turn is supporting health system strengthening in developing countries. More broadly it committed to increase overall levels of development assistance. Additional financial commitments highlighted in the GPF include £1.5 billion up to 2008 for AIDS related work, including £259 million to the Global Fund to Fight AIDS, Tuberculosis and Malaria. The GPF also emphasizes international efforts to increase global development financing through instruments such as the International Financing Facility (IFF) for vaccination with GAVI or cancellation of multilateral debt. The Government also pledged to continue to support PPPs and WHO, address medicines quality assurance, fight counterfeiting, tackle diversion of differentially priced medicines and the recruitment of skilled health workers from developing countries into the National Health Service (NHS).

2. Research & Development

The UK Government encouraged companies to increase their investment in R&D for medicines and vaccines for diseases affecting the developing world, as well as develop paediatric formulations for new and existing medicines and to report on these commitments. Other suggestions included new approaches to intellectual property (IP) management to allow knowledge transfer and to maximize the benefits of R&D, as well as to work with and through relevant PPPs and make use of the various UK R&D tax credits. Lastly the UK Government

encourages companies to conduct clinical trials in developing countries according to various international guidelines (Helsinki Declaration, WHO and ICH Harmonized Tripartite guidelines) and, where relevant, through the European and Developing Countries Clinical Trials Partnership (EDCTP).

To support these activities by companies, the Government said it would work with different stakeholders to increase levels of R&D for diseases of the developing world. This included work with the EU and the WHO Commission on Intellectual Property Rights Innovation and Public Health to create additional incentives for this R&D, and work to monitor uptake of the UK's existing R&D tax credits and vaccines research relief and to honour commitments it made in 2004 to work with other governments and the industry to develop models for Advance Purchase Commitments that would stimulate faster R&D for HIV and malaria vaccines. It also pledged to continue to work with partners to identify research needs and to support product development partnerships (PDPs), especially partnerships working on vaccines for HIV and malaria, as well as supporting developing countries in planning at an early stage for the uptake of new medicines/vaccines across their health system.

3. Impact on Developing Countries

Pharmaceutical companies were encouraged to work with other stakeholders and PPPs to ensure any access to medicines programmes did not create parallel systems, but were integrated with national disease priorities and systems. Companies were urged to commit to respect legitimate use of flexibilities in the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement and the Doha Declaration and to explore opportunities for local production or issuing voluntary licences, if this led to increased sustainability of access. Finally, companies were encouraged to commit to international good practice guidelines for the promotion of medicines (WHO and IFPMA) as well as implement corporate responsibility policies in line with the OECD Guidelines for Multinational Enterprises.

When the GPF was published, DFID worked in 150 countries worldwide and had increased its overseas development assistance from 0.34% of Gross National Income (GNI) in 1997 to 0.47% in 2008 with a goal of reaching the UN target of 0.7% of GNI by 2013. In terms of impact on access to medicines specifically, DFID stated that its work focuses on health system strengthening, increasing human resources and enhancing the capacity of national medicines supply chains, and that HMG also lends support to developing countries in understanding and making appropriate use of the flexibilities within the TRIPS agreement.

4. Reporting and Verification

The UK Government was keen for the industry to increase both the scope and quality of reporting of their access to medicines policies and programmes. It encouraged regular, transparent and accessible reporting (to developing country stakeholders) by companies of their access to medicines programmes. In addition, it urged companies to implement measures to render company reports more comparable, as well as to work with third party verifiers, to assess impact, where relevant, and report on it.

Annex Two Terms of Reference/Briefing Note

RESEARCH FOR A BACKGROUND PAPER ON GOOD PRACTICE IN THE PHARMACEUTICAL INDUSTRY AND UK GOVERNMENT POLICIES ON ACCESS TO MEDICINES

Background

In 2005, the UK Department for International Development (DFID), the UK Department of Health (DH) and the then UK Department of Trade and Industry,⁹¹ published a policy paper that set out a framework to provide guidance to pharmaceutical companies on best practices in increasing access to medicines in developing countries.⁹² The paper also set out complementary UK government commitments.

Since that date, there have been many developments in company and government policies and, more generally, in the global environment for access. The UK and other donor governments have substantially increased their commitments to organisations such as the Global Fund to Fight AIDS, TB and Malaria,⁹³ and access to key medicines – in particular to ARVs – has expanded significantly. Initiatives have also been taken to stimulate innovation such as the Advanced Market Commitment⁹⁴ for pneumococcal vaccines. Governments and companies have worked together through public-private partnerships to develop new drugs and vaccines needed in developing countries. Many companies have maintained or developed their differential pricing offers for developing countries and some have licensed their technologies more freely to developing country producers. But there is still much more that both governments and companies need to do to help improve access to medicines.

Research and Consultation Objectives

The UK Government's 2005 framework suggested that the UK should report on progress at a later date including in relation to:

- The impact of the framework on both the UK Government and pharmaceutical companies;
- Its usefulness for companies and other stakeholders;
- Key outstanding issues;

⁹¹ Now the Department for Business Enterprise and Regulatory Reform (BERR)

⁹² *Increasing people's access to essential medicines in developing countries: a framework for good practice in the pharmaceutical industry*. March 2005
<http://www.dfid.gov.uk/Pubs/files/pharm-framework.pdf>

⁹³ Pledges and Contributions to the Global Fund
http://www.theglobalfund.org/en/funds_raised/pledges/

⁹⁴ Advance market commitments for vaccines <http://www.vaccineamc.org/>

- New areas of work.

To this end, DFID has contracted two consultants, Emma Back and Samia Saad, to conduct research and collect data to include:

- A thorough review of the practices and policies outlined in the 2005 framework relating to affordability, research and development, impact in developing countries, and reporting and verification;
- A review of the impact of the 2005 framework itself on UK Government and industry policy and actions;
- A review of the process for developing and implementing the 2005 framework and an assessment of this alongside those processes adopted for other similar documents (for example those developed by industry investors, Oxfam, the Access to Medicines Index and the UN Special Rapporteur on the Right to Health):
- Gathering material relating to the performance of both government and companies against these policies, noting in particular examples of good practice;
- A consultation where necessary on future policies and plans with industry representatives through an already established Industry Working Group supported by the Association of British Pharmaceutical Industries (ABPI);
- Identification of key issues that need to be addressed by companies and government in the light of current circumstances to promote better access to medicines, including through interviews with key informants in companies, government and other stakeholders including civil society.

The focus of the research will be on the research-based industry but it will also consider the role of the generic industry and how good practice principles might apply to its activities. The consultation will also include technical agencies such as the World Health Organization (WHO) and third party providers and facilitators of access to medicines programmes where relevant.

The purpose of the research is to produce a background paper documenting developments since 2005 and assessing progress. The paper will form the basis for a subsequent revision of the UK's 2005 Good Practice Framework.

Timelines

1. Desk based research will be conducted in July and August 2008;
2. Consultation where necessary with industry, UK Government departments and other relevant stakeholders will be conducted between 1-19 September 2008;
3. A draft research report will be circulated to industry and others in early October 2008;

4. Further consultation to discuss the draft research report will be conducted in mid-October 2008.

Outputs

Based on the reviews and consultations outlined above, a background report will be produced to inform the subsequent edition of the UK's Good Practice Framework, the development of which will be managed by DFID, in collaboration with BERR, DH and the Intellectual Property Office (IPO).

The consultants' background report will set out the developments in industry and government since 2005 in relation to the aspirations and commitments made in the 2005 UK Government paper and will contain:

1. Factual material on the policies pursued by industry and government in relation to research, pricing, patenting, licensing and other areas covered in the 2005 framework;
2. A qualitative assessment of progress made since 2005, by industry and government, in implementing policies on access to medicines, identifying key areas where good progress has been made, and areas in which there is room for improvement;
3. An assessment of the impact of the 2005 framework paper specifically (and of the process employed to develop it and to track its implementation) in stimulating such progress.

Please address any comments or queries about this research to:

- Emma Back: emma.back1@hotmail.com
- Samia Saad: samiasaad@gmail.com

Annex Three Methodology

Background research and consultation for this review took place between July and September 2008. It began with detailed desk-based research, covering websites and key documents in the public domain, including company reports and assessments by others of industry performance in the areas covered by the GPF. Some internal documents from DFID's files were also reviewed. In particular, examples of good practice were noted.

A short briefing note was shared with industry and government stakeholders for the review and with other potential informants. It was also emailed to the *e-drug* and Intellectual Property Rights and Healthcare (*IP-Health*) listservs, with a request for comments to the consultants. However, apart from two responses, these postings did not yield any feedback from the global access to medicines community that subscribes to these lists.

Consultation with industry (companies and associations), UK Government departments and other key stakeholders was conducted through telephone or face-to-face interviews during September 2008. To facilitate interaction with industry representatives, an industry panel was established, supported by the Association of British Pharmaceutical Industries (ABPI).

To ensure systematic consultation, two separate survey questionnaires – one for industry and another for the UK Government – were developed by the consultants in conjunction with DFID. The questionnaires were based on the four core elements of the 2005 GPF. They also explored future plans, alongside an assessment of the impact of the 2005 GPF itself. A copy of both questionnaires is contained in *Annex Three*. The questionnaire was sent by email by Samia Saad to industry informants on 20th August, with a brief explanation of the research project and a request for interview between 9th and 19th September 2008. Similarly the Government Questionnaire was sent out to relevant key informants in September 2008. For other stakeholders, a set of common questions was developed. In all cases, informants were encouraged to share additional information and opinions beyond the questions asked, if they so wished.

A total of 17 industry informants, representing 10 Research and Development (R&D) pharmaceutical companies and four trade associations, were interviewed using the survey questionnaire to guide discussions. Eight key informants from five relevant UK Government departments (BERR, DFID, DH, HM Treasury and IPO) were also consulted. In addition, recognizing that the access to medicines agenda extends well beyond the R&D industry, further key informants were selected from the World Health Organisation (WHO), the generics industry, Médecins Sans Frontières (MSF), the Bill and Melinda Gates Foundation, Oxfam,

the ATM Index, PharmaFutures and Henderson Global Investors. The former UN Special Rapporteur for the Right to Health was also interviewed. All key informants interviewed are listed in *Annex Two*.

Based on both the consultation process and material gathered in the public domain, key issues were identified that need to be addressed in future by the pharmaceutical industry and the UK Government. These are reflected in this draft review report. Further consultation to discuss this draft report and possible next steps will be conducted in mid-October 2008.

Annex Four Key informants

HM Government

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Will Niblett	Global Health Team Leader	DH	Will.niblett@dh.gsi.gov.uk
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Industry

Contact	Role	Company	Email
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Civil society, investors and technical agencies

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Annex Five Survey Questionnaires

Annex 5.1 Industry Survey Questionnaire

Assessment of the Impact of the UK Government's 2005 Framework for Good Practice for the Pharmaceutical Industry

Name:

Organisation name:

Country:

Section 1. Record of Good Practice

Please outline below any policies and practices pursued by your organization in relation to the UK Government's 2005 Good Practice Framework for the Pharmaceutical industry, giving recent examples or referencing case studies of good practice where relevant.

1. Research & Development

a. Since 2005, has your organization increased levels of investment in research and development for medicines and vaccines for diseases disproportionately affecting developing countries, and/or developed appropriate formulations for particular needs groups, such as children? Please give specific examples.

b. Have you utilised
 i. the UK R&D tax credit?
 ii. the Vaccines Research Relief?

Please give details.

c. Has your organization built assessments of affordability and acceptability in target markets into the product development process, so as to contribute to the development of sustainable markets in developing countries and ensure access?

d. Have you made agreements with PDPs or others relating to intellectual property to facilitate research and development on diseases mainly affecting developing countries? Please give examples

- e. Have you made available compounds from your libraries to researchers working on diseases affecting developing countries, and on what terms? Give examples.
- f. Do you work in partnership with others including through public private partnerships (PPPs)?
- i. Have you to this end worked with relevant PPPs to align their efforts behind national needs in developing countries, to regularly and publicly report on progress, and to adopt inclusive governance structures?
- g. Do you report on your commitments to R&D for treatments for diseases that disproportionately affect developing countries in terms of:
- i. policies
 - ii. levels of investment (including through PPPs)
 - iii. number of target molecules
 - iv. the number of clinical trials under way (Phase I, II, III)
- h. Which guidelines do you follow when conducting trials in developing countries e.g. WHO's *Guidelines on good clinical practice*, the *Guideline for good clinical practice: ICH Harmonised Tripartite Guideline*, and the *Declaration of Helsinki* ?
- i. Have you worked through the European and Developing Countries Clinical Trials Partnership (EDCTP)?

2. Affordability

- a. Please give details, or provide reference, to the differential pricing offers for developing countries made by your company? Differentiate between offers made to LDCS, SSA, low and middle income developing countries?
- b. Have you extended the disease scope of your differential pricing offers since 2005? Have you taken account of any burdens your differential pricing offers have placed on developing countries where you operate?
- c. On what basis do you set differential prices in relation to production costs for LDCS, sub-Saharan Africa and other low and middle income developing countries? Please give specific examples with profit margins if possible
- d. Apart from any special offers to public, non-profit and similar organizations, give examples of cases where prices on the open market are tailored to the purchasing power of the population? Do you seek to price medicines differentially on the open market to cater for high and low income

consumers?

- f. Has your organization taken steps to minimise *risks of diversion* and leakage by
- i. using differential packaging where appropriate, by working with recipient countries
 - ii. using differential branding where appropriate, by working with recipient countries
 - iii. using instruments such as the EU Regulation on Diversion?
- g. Using appropriate media, including websites, has your organization publicly promoted and reported on differential pricing offers to:
- i. potential recipient governments and other local stakeholders
 - ii. national, regional and international pricing surveys
 - iii. home country authorities and stakeholders
- h. Does your organization ensure reporting on price is clear on whether prices include 'ex-factory' added costs such as freight, insurance, import duties or taxes?
- i. Does your organisation publicly commit to and report on compliance with, the WHO, UNAIDS, UNICEF and UNFPA *Guidelines for price discounts of single-source Pharmaceuticals*?
- j. Does your organization publicly commit to, and report on compliance with, the WHO's 1999 *Interagency guidelines for drug donations*?

3. Impact In Developing Countries

- a. Do you work with stakeholders in countries of operation to ensure access to medicines initiatives are integrated with national systems and priorities, and to avoid 'vertical' and 'parallel' systems?
- b. Has your organization made a commitment to respect the legitimate use of Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement flexibilities, including those set out in the WTO General Council's 30 August 2003 Decision on TRIPS and Public Health?
- c. Do you lobby publicly or privately for governments to introduce measures that go beyond TRIPS requirements? For example, in relation to data exclusivity.
- d. Since 2005, give details of voluntary licences granted to local manufacturers in developing countries. In what ways will these increase sustainable access to essential medicines?

- e. What guidelines do you follow in relation to the promotion of medicines in developing countries?
- f. Do you support sustainable financing in developing countries through:
 - i. prompt payment of local taxes
 - ii. transparency in payments to, and received from, governments
 - iii. compliance with all appropriate instruments to counter corruption (including the OECD anti-bribery convention)
- g. Have you developed and implemented corporate responsibility policies consistent with the OECD Guidelines for Multinational Enterprises that support national development strategies (including by maximising the positive social and environmental impacts of company operations, and through support for good governance and pro-poor policy environments)?

4. Reporting and Verification

- a. Do you report regularly on access to essential medicines activities?
- b. Have you taken steps to make reports accessible to a wide range of stakeholders, including key stakeholders in developing countries?
- c. Have you taken steps to enhance comparability between your reports and those of other companies?
- d. Do you work with third party verifiers where appropriate, to measure, and report on, impact?

Section 2. Impact of the UK Government 2005 Good Practice Framework Paper

- 1. In your view, how useful has the 2005 Good Practice Framework paper been to key stakeholders working to increase access to medicines?
- 2. What degree of impact has the 2005 Good Practice Framework paper had on your organisation specifically? Please give specific examples where possible.

Section 3. Future Policies and Plans

- 1. What new developments are planned in your organisation's policies and

approaches to increase access to essential medicines in developing countries?

Section 4. Key Outstanding Issues

1. What key issues still need to be addressed in the light of current circumstances to promote better access to medicines by
 - a. Companies
 - b. Governments – donor and recipient
2. Do you have any further comments or advice you wish to share with DFID as they review their 2005 Good Practice Framework?

Thank you for your time and input into this review on behalf of DFID

Annex 5.2 UK Government Survey Questionnaire

Assessment of the UK Government's Commitments in Relation to its 2005 Framework for Good Practice in the Pharmaceutical Industry

Name:

UK Department:

Section 1. Record of UK Government Commitments

Please outline below any policies and initiatives implemented by your Department in relation to the commitments made in the UK Government's 2005 Good Practice Framework for the Pharmaceutical industry. Please also indicate levels of funding allocated for all programmes and initiatives, where relevant.

1. Research and Development

a. What policies and initiatives has your department implemented – working with developing countries, other donors, multilateral agencies, research, bioscience and generic industry and other stakeholders – to increase levels of R&D for diseases that disproportionately affect the poor in developing countries?

Specifically:

- i. What measures to promote and monitor R&D tax credits in the UK, and specifically the Vaccines Research Relief, have been put in place?
- ii. What additional incentives for such R&D have been created, in conjunction with the EU, the WHO and other stakeholders?

b. How has the UK government contributed to existing product development Public Private Partnerships (PPPs), including the International AIDS Vaccine Initiative, the Medicines for Malaria Venture and the Global HIV Vaccine Enterprise? How have these PPPs been promoted and measured?

c. What new PPP initiatives, such as the Advanced Market Commitment for pneumococcal vaccines, have been developed with UK input or support, to stimulate innovation to develop new drugs and vaccines needed in developing countries?

d. Please give examples of how the UK Government has worked with global health partnerships and the European & Developing Countries Clinical Trials

Partnership (EDCTP) to identify research needs?

e. How as the UK Government supported low- and middle-income countries to (a) undertake research, and (b) plan and coordinate from an early stage for the introduction of new products into existing health policy, procurement and delivery systems?

f. What level of funding and other support has your Department contributed to the Medical Research Council and the Wellcome Trust as part of the Research Funders Forum on Health in Developing Countries? Please give examples of some of the research outcomes of this initiative.

g. How has your Department worked with pharmaceutical companies (and other stakeholders) to support and enhance their company reporting with respect to their R&D commitments for diseases disproportionately affecting the poor?

2. Affordability

a. What financial commitments has the UK Government honoured between 2004 and 2008, and made for the future, to support efforts to strengthen health systems and increase the purchasing power of developing country governments?

Specifically in terms of:

- i. Level and increases of UK development assistance, especially for areas such as for developing country health system strengthening?
- ii. Increasing level of international development assistance through initiatives such as the international Finance Facility (IFF) e.g. to organizations such as the Global Alliance for Vaccination and Immunisation?
- iii. Cancellation of developing countries' bilateral debt and working with other government donors to cancel multilateral debt.
- iv. Commitments to AIDS-related work such as pledges to the Global Fund to Fight AIDS, TB and Malaria

b. How has the UK Government continued to provide support to PPPs designed to increase access to existing medicines e.g. the Global Fund, the Global Alliance to Eliminate Lymphatic Filariasis and the African Programme for Onchocerciasis?

c. How has the UK Government provided support to the WHO and to other bodies that contribute to strengthening developing countries' in the areas of

- i. medicines procurement
 - ii. storage and distribution systems
 - iii. national treatment guidelines
 - iv. essential medicines lists
 - v. improvements in prescription, drug use and drug monitoring
- d. How has the UK Government worked, including through the EU and WHO, to support coordinated action to prevent active recruitment by the NHS of healthcare workers from overseas countries?
- e. How has the UK Government supported WHO and Health Action International to develop and ensure use of their survey tool to improve market information about medicines prices?
- f. How has the UK Government worked with EU partners to support efforts to address diversion of medicines to non-EU markets?
- g. What initiatives has the UK Government been working on with WHO, pharmaceutical companies and others to support the production of quality assured drugs, and to tackle counterfeit and substandard medicines?
- h. How has the UK Government worked with G8 colleagues to gain commitments to increasing access to essential medicines, including in relation to differential pricing, addressing leakage and diversion, and price referencing by G8 governments against prices offered to developing countries?
- i. How has the UK Government worked with pharmaceutical companies (and other stakeholders) to support and enhance company reporting on affordability e.g. on differential prices of medicines for low- and middle-income countries?

3. Impact in Developing Countries

- a. How has the UK Government continued to contribute to the United Nations' eight 'Millennium Development Goals' (MDGs)?

Specifically give examples of both initiatives and financial commitments in relation to the following areas of work with a direct impact on access to medicines in developing countries:

- i. health systems strengthening
- ii. increasing human resources in health systems
- iii. enhancing the capacity of national medicines procurement, storage and distribution systems
- iv. support to developing countries in understanding and making appropriate

use of the flexibilities within WTO rules governing intellectual property

4. Reporting and Verification

a. What policies and initiatives has the UK Government developed to facilitate an increase in the quality and scope of reporting on company policies and activities affecting access to medicines? How has the visibility of / access to such reporting been facilitated?

Specifically in relation to:

- i. pharmaceutical companies regular reporting on access to essential medicines activities
- ii. enhancing comparability between company reports
- iii. working with third party verifiers where appropriate, to measure, and report on impact

Section 2. Impact of the UK Government 2005 Good Practice Framework Paper

1. In your view, how useful has the 2005 Good Practice Framework paper been to key stakeholders, including Government Departments, working to increase access to medicines?
2. What degree of impact has the 2005 Good Practice Framework paper had on your Department specifically? Please give specific examples where possible.

Section 3. Future Policies and Plans

1. What new developments are planned in your Department's policies and approaches to increase access to essential medicines in developing countries?

Section 4. Key Outstanding Issues

1. What key issues still need to be addressed in the light of current circumstances to promote better access to medicines by
 - a. Governments – donor and recipient
 - b. Companies
2. Do you have any further comments or advice you wish to share with DFID as they review the UK Government's 2005 Good Practice Framework?

Thank you for your time and input into this review on behalf of DFID

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<http://www.malariavaccine.org/>

WHO Special Programme for Research and Training in Tropical Diseases (TDR)

<http://www.who.int/tdr/about/mission.htm>

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