

Increasing people's access to essential medicines in developing countries: a framework for good practice in the pharmaceutical industry

A UK Government policy paper

March 2005

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Executive summary

The United Kingdom has been at the forefront of efforts to increase the availability of medicines for poor people in developing countries. Working as part of the international community, Government, non-governmental organisations, business enterprises – particularly pharmaceutical companies operating in the UK – and institutional investors have worked individually and together to achieve a great deal.

There has been considerable success – increased levels of financing, generic competition and offers by research-based pharmaceutical companies mean the price of first line antiretrovirals (ARVs) have dropped by as much as 98 per cent over the last four years. At the end of 2004 720,000 people in developing countries were receiving antiretroviral therapy (ART), an increase of approximately 75 per cent from a year earlier.

However, one third of the world's population still lacks access to the medicines they need. Poverty is both a reason people lack access to medicines, and is in turn caused by lack of access. The UK Government is committed to reducing poverty. Increasing access to essential medicines for poor people in developing countries is a vital part of this.

In 2001 the Prime Minister established a high level UK *Working Group on Increasing Access to Essential Medicines in the Developing World*. This reported in November 2002, recommending more support for research and development for diseases disproportionately affecting developing countries, and a global framework to facilitate voluntary, widespread, sustainable and predictable, differential pricing by pharmaceutical companies. This was followed in June 2004 by *Increasing access to essential medicines in the developing world: UK Government policy and plans*, which detailed how the UK Government is working in partnership with developing country governments, donors, international agencies, NGOs and the private sector to increase access to medicines.

Responsibility for increasing access to essential medicines rests with the whole international community. Progress depends on everyone working in partnership to build health systems in developing countries, increase financing, make medicines more affordable, and increase the amount of new medicines developed for diseases affecting developing countries.

In this context there is a particular role for pharmaceutical companies. As the producers of existing, and developers of new, medicines they can – and do – make a difference within their sphere of influence. This is the ethical case for action.

There are also strategic reasons for companies to act. There is a risk of reputational damage, undermined intellectual property regimes, and loss of market share if companies are not seen to be contributing to efforts to increase access to essential medicines in developing countries.

Most large pharmaceutical companies are already engaged in efforts to increase access to essential medicines in developing countries, including through reduced pricing offers for selected products, research and development activities, donations and through support for health systems strengthening in developing countries. Approaches vary, and many are exclusively concerned with HIV and AIDS. Some companies undertake research, and provide drugs, for specific diseases including malaria, tuberculosis, onchocerciasis, lymphatic filariasis and trachoma.

This framework builds on the good work being done by many pharmaceutical companies. Its purpose is to encourage pharmaceutical companies to redouble their efforts – to go further – and to continue to work in partnership with other stakeholders to help move poor people in developing countries from being on – or beyond – the periphery of the global pharmaceutical market, to being firmly within it. The UK Government believes that sustainable solutions must ultimately involve the development of sustainable markets for pharmaceutical products in developing countries. This will only be achieved through concerted action to build the capacity of health systems and to ensure resources are available to fund them. Making medicines more affordable is one important component in achieving sustainability.

For this reason the UK Government favours approaches by pharmaceutical companies based on differential pricing rather than donations. Disease eradication programmes can be well supported with donated products, and donations can sometimes be useful in emergency situations. All donations must be carried out in accordance with relevant WHO guidelines. However, donations will not provide a solution to the general, long-term needs for essential medicines in developing countries. They are especially unsuited to chronic conditions where consistency of supply is vital. It is not sustainable for companies to give away their products indefinitely and in significant quantities. At worst, donations can impose hidden costs on recipients, distort national healthcare priorities, involve unwanted or unsuitable products, and can undermine the development of local markets by locking out competition.

The UK Working Group on Increasing Access to Essential Medicines in the Developing World found that differential pricing was economically and commercially viable. Focusing on all least developed countries, and sub-Saharan Africa, it set an objective that differential pricing would result in prices close to the cost of manufacture. However, it is important to note that differential pricing can also lead to

problems if terms and conditions prove directly or indirectly costly, and if potential competitors are excluded.

This framework seeks to provide guidance to pharmaceutical companies. It builds on the good work of many of the companies in the industry, and encourages pharmaceutical companies to go further by:

- Engaging in widespread differential pricing of essential medicines in developing countries, especially the world's poorest, to support the development of viable markets. Particular attention should be paid to medicines produced by one manufacturer, where competition is often limited (single-source medicines).
- Increasing research and development investment for diseases affecting developing countries, including through engagement in public-private partnerships.
- Working to support broader health and development goals in developing countries, including by considering voluntary licences.
- Reporting on activities designed to increase access to essential medicines.

Achieving improved access to medicines in developing countries is not solely the responsibility of pharmaceutical companies. Differential pricing raises the risk of diversion, with lower priced products diverted from legitimate purchasers back to richer markets. This is of particular concern for single-source products that command high prices in developed country markets. This threatens the sustainability of differential pricing. Companies can take steps to minimise this, through the use of different packaging and formulation. The G8 committed at Evian in 2003 to work to tackle diversion, and the EU has subsequently introduced a regulation to combat diversion. Developed and developing countries need to continue to work together and with pharmaceutical companies to minimise the risks of diversion.

In addition, health systems need to be strengthened, financing needs to be increased from national and international agencies for the purchase of medicines, and more support needs to be given to research and development for diseases disproportionately affecting developing countries.

The UK is committed to actively playing its part. DFID works with a range of groups in partnership as part of its work to increase access to medicines. Plans and approaches are contained in a variety of framework documents, strategies and papers guiding our work with developing country governments, donors, multilateral institutions, NGOs and the private sector. This Framework is part of the UK's general approach to working in partnership.

DFID spent £1.5 billion since 1997 to improve the services that deliver essential medicines to people in developing countries. We are increasing our overseas aid budget to £6.5 billion a year by 2007–08. The UK Government is also working on innovative ways of increasing development financing, through the International Financing Facility which will double international development assistance, and through debt relief. In 2004 the UK committed to spend £1.5 billion on AIDS-related activities over the next three years, including treatment, and we have doubled our funding to the Global Fund to Fight AIDS, TB and Malaria.

The UK Government also supports R&D investments, through direct financial support for initiatives such as the Medicines for Malaria Venture, the International Partnership for Microbicides and the International AIDS Vaccine Initiative. Innovative incentives in the form of research tax credits have been implemented and the UK is working with the European Union and supporting the World Health Organisation in developing new research incentives.

Finally, the UK Government is taking action with political leadership during 2005 with Africa a priority and AIDS a centrepiece of the UK's EU and G8 Presidencies.

By working together, people in affected communities, the pharmaceutical industry, developing country governments, donors, international agencies and NGOs can make essential medicines more affordable, available and accessible.

Section one: Introduction

This document forms part of the UK Government's work on increasing access to essential medicines for poor people in developing countries.

In November 2002 the high level *Working Group on Increasing Access to Essential Medicines in the Developing World*, which was established by the Prime Minister, gave its recommendations. The group – which comprised members of the UK Government, the pharmaceutical industry, the European Commission, charitable foundations and academic institutes, developing countries, the World Health Organisation (WHO) and the World Trade Organisation (WTO) – recommended specific UK steps that could be taken to support increased research and development for diseases affecting developing countries, and outlined steps towards a global framework to facilitate voluntary, widespread, sustainable and predictable, differential pricing by pharmaceutical companies. The group found that differential pricing was economically and commercially viable.¹ Focusing on all least developed countries and sub-Saharan Africa, it set an objective that differential pricing would result in prices close to the cost of manufacture.²

In June 2004 the Government published *Increasing access to essential medicines in the developing world: UK Government policy and plans*³ which outlines the UK's work with developing country governments, donors, multilateral agencies, NGOs and the private sector to address the barriers to effective access to medicines in developing countries, including through:

- Support to developing countries through the UK development assistance programme, including through significantly increased financing, and strengthening of efforts to address the access to medicines agenda, including by increasing poor people's access to health services.
- Trade policy, where a priority is support to developing countries in understanding and making appropriate use of the flexibilities within World Trade Organisation rules governing intellectual property.
- UK efforts – and those of the broader international community – to stimulate increased research and development into new medicines and other healthcare products relevant to developing country health needs.

1 *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>)

2 In effect this seeks prices that would be reached in a competitive market, and allows for sale of medicines to be profitable. A vital condition for differential pricing to work would be commitments from wealthier markets not to reference their own prices against those charged in the poorest countries.

3 *Increasing access to essential medicines in the developing world: UK Government policy and plans*, DFID, June 2004 (<http://www.dfid.gov.uk/pubs/files/accessmedicines.pdf>)

In addition, the UK Government committed to work in partnership with the business community, including the pharmaceutical industry, to ensure the longer-term supply of affordable essential medicines to developing countries and to build on 'best practice' by companies as they engage in developing country markets.

This document sets out a framework that seeks to achieve this. It is based on existing best practice in the pharmaceutical industry, and has emerged from consultations with a wide variety of groups,⁴ including the pharmaceutical industry. The framework's development was influenced by a request from some companies for a clearer articulation of what the UK Government would like to see companies do in this area.

Most major pharmaceutical companies are already working to increase access to essential medicines through a variety of approaches regarding affordability, research and development, and programmes in developing countries to strengthen health systems infrastructure. There are examples of this throughout the framework. The issues limiting poor people's access to medicines are many and varied, and pharmaceutical companies – research based and generic – can only do so much through their own efforts. Without effective health systems, or the money to buy medicines, many patients in poor countries will be denied access to even the cheapest medicines.

Box 1: How DFID works in partnership

DFID supports long-term programmes to help tackle the underlying causes of poverty. DFID also responds to emergencies, both natural and man-made.

DFID's work with the pharmaceutical industry is just part of the way in which DFID works with other groups. DFID works in partnership with governments, civil society, the private sector and others. It also works with multilateral institutions, including the World Bank, United Nations agencies, and the European Commission.

Plans and objectives related to increasing access to essential medicines are contained in a variety of strategy papers, frameworks and plans.

Country Assistance Plans (CAPs) are developed for countries in which DFID works. Institutional Strategy Papers (ISPs) provide a framework for joint action for DFID and institutions such as WHO. In addition, many non-governmental organisations have Partnership Programme Agreements (PPAs) with DFID. Further information on any of these can be found at <http://www.dfid.gov.uk>.

⁴ See Annex 1

This framework seeks to provide guidance to pharmaceutical companies by building on the best work being done by the industry,⁵ and to do so in the context of work that has been done by institutional investors,⁶ NGOs,⁷ industry associations,⁸ international agencies⁹ and many others. It seeks to outline practices that have, in the past, brought the greatest benefits to developing countries. It also encourages transparency, disclosure and the measurement of impact. The framework identifies UK and other policies that support and encourage good practice.

The detail of the framework is contained in section two of this paper. Section three provides the analytical background.

The framework covers a wide range of issues, many of which are directly relevant to the activities undertaken by many research-based pharmaceutical companies. It is also relevant for generic firms (for instance in relation to differential pricing and price transparency), and for bioscience companies (for instance in relation to product development public-private partnerships). In addition, third party providers and facilitators of access to medicines programmes, such as NGOs and private healthcare companies, will find it applies to some of their own operations.

5 See examples throughout this framework. For further information see company websites and the Association of the British Pharmaceutical Industry (<http://www.abpi.org.uk>), the European Federation of Pharmaceutical Industries and Associations (<http://www.efpia.org>), or the International Federation of Pharmaceutical Manufacturers Associations (<http://www.ifpma.org>).

6 See *Fulfilling its Potential: Sustainability, Responsibility and Ethics in the Pharmaceutical Industry*, Henderson Global Investors, September 2003; See also the work of the Pharmaceutical Shareowners Group (PSG), which represents 14 institutional investors with over £900 billion of assets under management. In March 2003 the group launched the *Investor statement and framework on pharmaceutical companies and the public health crisis in emerging markets*. In September 2004 PSG published *The public health crisis in emerging markets: an institutional investor perspective on the implications for the pharmaceutical industry*.

7 See VSO, Oxfam and Save the Children, *Beyond Philanthropy: the pharmaceutical industry, corporate social responsibility and the developing world*, July 2002; See also Medecins Sans Frontieres' work on access to medicines and pricing for ARVs and other medicines <http://www.msf.org>.

8 For example, The International Federation of Pharmaceutical Manufacturers Associations (IFPMA) *Code of Pharmaceutical Practices and Research and Development for Neglected Diseases: Lessons Learnt and Remaining Challenges*, October 2004.

9 For example, WHO's work on drug donations and medicinal promotion, as well as the *WHO Medicines Strategy 2004 – 2007* and the *World Medicines Situation, WHO 2004*. See also The Partnership for Quality Medical Donations <http://www.pqmd.org>, and the Global Health Initiative of the World Economic Forum <http://www.weforum.org/globalhealth>.

Section two: Good practice framework

This framework is divided into four sections: the affordability of essential medicines, investment in R&D, pharmaceutical company impacts on the ground in developing countries, and the importance of reporting. Each section outlines the activities the UK Government encourages companies to build on, and the relevant policies and plans of the Government.

Affordability

The UK Government recognises the contribution many companies are making to improving access to essential medicines, and encourages companies to match these standards, and to:

- Develop, or maintain, differential pricing offers for developing countries.¹⁰
- Pay particular attention to single source¹¹ pharmaceuticals where offers by individual companies can increase access to newer medicines.
- Work with developing countries to assess offers against priority communicable and non-communicable disease needs in countries of operation, with a view to progressively, and sustainably, extending the disease scope of differential pricing offers.¹²
- Assess conditions¹³ attached to offers against health systems capacity in recipient countries, and ensure conditions do not cause undue burden.
- Make differential prices for the least developed countries (LDCs) and sub-Saharan Africa close to the cost of manufacture.¹⁴

10 The UK high level Working Group recommended an initial focus that covered all least developed countries (LDCs) globally, and all countries in sub-Saharan Africa. It noted that in time international agreement would make way globally for more widespread agreements. See annex 2 for a full list of least developed and sub-Saharan African countries.

11 Single-source pharmaceuticals are typically products with patent protection or marketing exclusivity.

12 The UK high level working group argued that gaining international commitment for the vision of differential pricing as the operational norm would be greatly facilitated by limiting it in the first instance to the disease conditions of HIV and AIDS (including opportunistic diseases), TB and malaria, and then extending as needed to products for other disease conditions – bringing more companies and products on board.

13 For example, conditions related to handling, distribution and reporting on the use of medicines.

14 The UK high level working group did not agree a single formulaic approach to calculating prices. It found that calculating price and costs was complex, but that by definition prices should exclude research and development, marketing, sales and corporate administration costs. However, prices do not have to be not-for-profit.

- Within LDCs provide differentially priced medicines through all locally appropriate procurement and delivery channels.¹⁵
- Within middle income countries (MICs)¹⁶ make differentially priced medicines available to public and not-for-profit entities.¹⁷
- Minimise risks of diversion and leakage by using differential packaging and/or branding where appropriate, by working with recipient countries, and by using instruments such as the EU Regulation on Diversion.¹⁸
- Using appropriate media, including websites, publicly promote and report on differential pricing offers to: potential recipient governments and other stakeholders; national, regional and international pricing surveys; home country authorities and stakeholders.
- Monitor and publicly disclose (as above) on the basis of product scope, price, population coverage, countries, pro-poor nature, product leakage, health systems strengthening and the overall commitment of stakeholders.¹⁹
- Ensure reporting on price is clear on whether prices include 'ex-factory' added costs such as freight, insurance, import duties or taxes.²⁰

15 The UK high level working group argued that reaching the poor through the private sector can be achieved through a number of strategies. Poor people in LDCs access upwards of two-thirds of their medicines through the private sector. Limiting differential pricing to the public sector in LDCs results in a continued lack of access for poor people. The viable market in LDCs is limited, yet the cost to government of segmenting the market and preventing internal leakage could be considerable.

16 See Annex 3 for a full list of MICs.

17 It is appropriate to preserve viable private markets in middle income countries to support differential pricing.

18 Council Regulation (EC) No 953/2003 of 26 May 2003 to avoid trade diversion into the European Union of certain key medicines. Both patented and generic products can be registered. Medicines have to be made available either with a price cut of 75 per cent off the average 'ex factory' price in OECD countries, or at the cost of production plus 15 per cent. Further information can be found at <http://trade-info.cec.eu.int/cgi-bin/antitradediversion/index.pl>

19 These were the parameters identified by the members of the UK high level working group, who agreed that it was necessary to monitor efforts. The group found that systematic monitoring would need to take place, requiring a) overall global monitoring on these parameters and b) monitoring of changes to country access.

20 Manufacturers use a set of terms (Incoterms) to describe the degree to which various costs are included in the price. For example:

- CIF (cost, insurance, and freight): includes insurance and transport charges up to the port of destination;
- CFR (cost and freight): includes transport charges up to the port of destination (sea shipments only);
- CPT (carriage paid to): includes transport charges up to the place of destination;
- DDU (delivered duty unpaid): includes delivery, but not import duties or unloading costs;
- EXW (ex works): does not include loading, insurance, or freight; and
- FOB (free on board): the price of goods at the point of shipment, but does not include the cost of insurance and freight (transportation)

Source: International Drug Price Indicator Guide, MSH, 2003.

- Publicly commit to, and report on compliance with, the WHO, UNAIDS, UNICEF and UNFPA *Guidelines for price discounts of single-source pharmaceuticals*.²¹
- Publicly commit to, and report on compliance with, the *Interagency guidelines for drug donations*.²²

To support and make these responses effective, the UK Government is supporting efforts to strengthen health systems and increase the purchasing power of developing country governments. The [UK Government](#):

- Has increased development assistance each year since 1997, and has committed that UK development assistance will reach £6.5 billion a year in 2007–08. This is a real-terms increase of 140 per cent since 1997, and represents 0.47 per cent of gross national income.²³
- Is working internationally on innovative ways of increasing total global development financing. This includes work on the International Finance Facility (IFF) which, by front-loading development assistance, aims to double the amount of aid from developed to developing countries.²⁴ In addition the UK has been at the forefront of efforts to address unsustainable debt in developing countries, including through work to cancel multilateral debt.²⁵
- Is working with the Global Alliance for Vaccination and Immunisation on an IFF for immunisation to raise \$4–\$8 billion to support health systems development, and procurement and the introduction of new and underused vaccines into national immunisation programmes.
- Has committed £1.5 billion since 1997 to strengthen developing country health systems.
- Has also committed to spend at least £1.5 billion over the next three years on AIDS-related work, including antiretroviral therapy (ART) and treatment of opportunistic infections. The UK fully supports the WHO and UNAIDS ‘3 by 5’ target to get 3 million people on treatment for HIV and AIDS by the end of 2005.

21 See <http://www.who.int/medicines/library/par/who-edm-par-2003-3/who-edm-par-2003-3.doc>

22 These have been developed by WHO in cooperation with the major international agencies active in humanitarian relief. See <http://www.who.int/medicines/library/par/who-edm-par-1999-4/who-edm-par-99-4.pdf>; See also the Guidelines of the Partnership for Quality Medical Donations (http://www.pqmd.org/guide_fm.html) for practical advice on managing drug and medical product donations in a manner consistent with the *Interagency guidelines on drug donations*.

23 See http://www.hm-treasury.gov.uk/spending_review/spend_sr04/press/spend_sr04_press09.cfm

24 http://www.hm-treasury.gov.uk/documents/international_issues/international_development/development_iff.cfm

25 <http://www.dfid.gov.uk/mdg/debt-ukmultidebtinitiative.asp>

- Has doubled its funding to the Global Fund to Fight AIDS, TB and Malaria (the Global Fund) over the next three years, having pledged £259 million through to 2007–08.
- Provides support to public-private partnerships designed to increase access to existing medicines, including The Global Fund (above), The Global Alliance to Eliminate Lymphatic Filariasis and the African Programme for Onchocerciasis.
- Provides significant support to the World Health Organisation (WHO) and to other bodies that contribute to strengthening developing countries' medicines procurement, storage and distribution systems, national treatment guidelines, essential medicines lists and improvements in prescription, drug use and drug monitoring.
- Introduced a code of practice in 2001 preventing active recruitment by the NHS of healthcare workers from overseas countries. The code was reviewed in 2004 to strengthen its impact, and to build independent sector commitment to the same principles. The UK is working internationally, including through the EU and WHO, to support coordinated action.
- Is supporting WHO and Health Action International to develop and ensure use of a survey tool to improve market information about medicines prices.
- Will continue to support efforts to address diversion of medicines, including by working to ensure instruments designed to address diversion, such as the EU Regulation on Diversion, are effective and useful, and by working with European Union partners to consider ways of minimising the risk of diversion to non-EU markets.
- Will continue to work with WHO, pharmaceutical companies and others to support the production of quality drugs, and to tackle counterfeit and other substandard medicines.
- Worked with our colleagues at the G8 in Evian in 2003 to gain a series of commitments to increasing access to essential medicines, including in relation to differential pricing, and commitments to address leakage and diversion, and to ensure G8 governments do not reference their own prices against those offered to developing countries.
- Will work with pharmaceutical companies and other stakeholders as appropriate to support and enhance company reporting.

Research and development

The UK recognises that some companies are embracing the good practices below, and encourages all *companies* to:

- Increase levels of investment in research and development for medicines and vaccines for diseases disproportionately affecting developing countries, and to develop appropriate formulations for particular needs groups, such as children.
- Utilise the UK R&D tax credit²⁶ and Vaccines Research Relief.²⁷
- Build assessments of affordability and acceptability in target markets into the development process so as to contribute to the development of sustainable markets in developing countries and ensure access.
- Develop approaches to intellectual property management that optimise the benefits of R&D, including through sharing knowledge.²⁸
- Where appropriate, assess existing and new medicines against indications relevant to diseases disproportionately affecting developing countries, and make these treatments available.
- Work in partnership with others where appropriate, including through public-private partnerships (PPPs).
- Encourage PPPs to align efforts behind national needs in developing countries, to regularly and publicly report on progress, and to adopt inclusive governance structures that include key stakeholders.
- Report on commitments to R&D for treatments for diseases disproportionately affecting developing countries. Reporting could address policies, levels of investment (including through PPPs), number of target molecules, and the number of clinical trials under way (Phase I, II, III).

26 R&D tax credits for small and medium sized companies were introduced in 2000, and for large companies in 2002. They represent UK Government investment in R&D of around £700 million per annum. The Office of National Statistics 2002 survey of business expenditure on R&D indicates that around 25 per cent of R&D spending in the UK is in the pharmaceutical sector.

27 The Vaccines Research Relief is intended to help pharmaceutical and other companies undertaking research into:

- vaccines and medicines for the prevention and treatment of TB and malaria;
- vaccines for the prevention of HIV infection;
- vaccines and medicines for the prevention of the onset of AIDS or the treatment of AIDS resulting from infection by HIV in certain prescribed clades (sub-types) which occur mostly in countries in the developing world.

For further information see <http://www.inlandrevenue.gov.uk/budget2002/revbn14.htm>

28 For example, working through public-private partnerships, companies could adopt innovative approaches to intellectual property and technology transfer, such as, where appropriate, the provision of anti-HIV compounds for microbicide products.

- Undertake clinical trials in developing countries where appropriate and in line with the WHO's *Guidelines on good clinical practice*, the *Guideline for good clinical practice: ICH Harmonised Tripartite Guideline*, and the *Declaration of Helsinki*.
- Where appropriate, work through the European and Developing Countries Clinical Trials Partnership (EDCTP).²⁹

To support and make these responses effective, the *UK Government*:

- Will work 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.³⁰
- Will monitor and promote the R&D tax credits in the UK, including the Vaccines Research Relief.
- Will work with the EU, the WHO Commission on Intellectual Property Rights Innovation and Public Health and other stakeholders to develop appropriate additional incentives for R&D for disease disproportionately affecting developing countries.
- Announced in December 2004 the Government's intention to work with government and industry partners to develop proposals for Advance Purchase Commitments as a means to stimulate greater and accelerated research and development for HIV and malaria vaccines for use in developing countries.
- Will continue to work with global health partnerships and the EDCTP to identify research needs.
- Will support countries to undertake research and plan and coordinate from an early stage for the introduction of new products into existing health policy, procurement and delivery systems.
- Will continue to support a number of product development PPPs, including the International AIDS Vaccine Initiative, the Medicines for Malaria Venture and the International Partnership for Microbicides. The UK has also signed up to the Global HIV Vaccine Enterprise announced at the 2004 G8 summit at Sea Island in the United States.

²⁹ The mission of the EDCTP is to accelerate the development of new clinical interventions to fight HIV and AIDS, malaria and tuberculosis in developing countries, particularly sub-Saharan Africa, and to improve generally the quality of research in relation to these diseases. See <http://www.edctp.org>

³⁰ For further information please see *Increasing access to essential medicines in the developing world: UK Government policy and plans*, DFID, June 2004.

- Will work to promote and measure success in PPPs.
- Is working with the Medical Research Council and the Wellcome Trust to establish a Research Funders Forum on Health in Developing Countries so as to coordinate research efforts and address particular points of weakness in the R&D chain.
- Will work with pharmaceutical companies and other stakeholders as appropriate to support and enhance company reporting.

Impact in developing countries

Whilst the activities encouraged in relation to affordability and research and development are intended to maximise the benefit of company operations in developing countries, there are a number of additional issues affecting the success or otherwise of companies' access to medicines initiatives.

*The UK Government encourages **companies** to build on existing good practices to:*

- 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.
- Commit 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.³¹
- Explore opportunities for production in developing countries, including through wholly owned subsidiaries and the use of voluntary licences, where these measures would increase sustainable access to essential medicines.
- Commit to follow WHO and IFPMA guidelines on promotion of medicines.³²
- Support sustainable financing in developing countries through: prompt payment of local taxes; transparency in payments to, and received from, governments; and compliance with all appropriate instruments to counter corruption (including the OECD anti-bribery convention).³³

³¹ See the Doha Declaration on the TRIPS agreement and public health (http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm) and the related Decision of the General Council of 30 August 2003 (http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm)

³² <http://www.ifpma.org> and <http://www.who.int>

³³ *OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions*, OECD, 1999.

- Develop and implement corporate responsibility policies consistent with the OECD Guidelines for Multinational Enterprises³⁴ that support national development, including by maximising the positive social and environmental impacts of their operations, and through support for good governance and pro-poor policy environments.³⁵

The *UK Government* works throughout the developing world on a wide variety of programmes. DFID works directly in over 150 countries worldwide. Total UK overseas development assistance (oda) as a proportion of Gross National Income (GNI) will rise from 0.34 per cent today to 0.47 per cent in 2007-08, representing a real terms increase in UK oda of 140 per cent since 1997. The Government wishes to continue to raise UK oda at the rate of growth achieved in 2007-08, which would mean that total oda would reach the UN target of 0.7 per cent of GNI by 2013. If the UK's proposal for the International Finance Facility is agreed, the equivalent of an 0.7 per cent oda/GNI ratio could be achieved by 2008-09.

DFID's work forms part of a global promise to:

- halve the number of people living in extreme poverty and hunger
- ensure that all children receive primary education
- promote sexual equality and give women a stronger voice
- reduce child death rates
- improve the health of mothers
- combat HIV & AIDS, malaria and other diseases
- make sure the environment is protected
- build a global partnership for those working in development.

Together, these form the United Nations' eight 'Millennium Development Goals', with a 2015 deadline. Each of these Goals has its own, measurable, targets.

Areas of work with a direct impact on access to medicines in developing countries and supported by DFID include: health systems strengthening; increasing human resources in health systems; enhancing the capacity of national medicines procurement, storage and distribution systems; and, support to developing countries in understanding and making appropriate use of the flexibilities within WTO rules governing intellectual property.³⁶

34 *The OECD Guidelines for Multinational Enterprises*, Revision 2000, OECD 2000.

35 For further information see: <http://www.csr.gov.uk>

36 For further information see <http://www.dfid.gov.uk>

Reporting and verification

Whilst there are some good examples, the UK is keen to see an increase in the quality and scope of reporting on company access to medicines policies and activities. It would be useful for stakeholders in the UK and in developing countries to be able to access detailed information on company activities.

The UK Government encourages companies to:

- Report regularly on access to essential medicines activities.
- Take steps to make reports accessible to a wide range of stakeholders, including key stakeholders in developing countries.
- Take steps to enhance comparability between company reports.
- Work with third party verifiers where appropriate, to measure, and report on, impact.

Next steps

At the core of this framework, and the Government's work more generally on increasing access to essential medicines, is the need to develop sustainable solutions. This includes the need to bring developing countries into the global pharmaceutical market.

Achieving this is not the sole responsibility of pharmaceutical companies. The development of viable markets for existing and new pharmaceutical products in developing countries requires a partnership between many actors. But it is a partnership within which the primary producers and investors in medicines and medicines development – pharmaceutical companies – have a significant role to play. The Government is committed to work with companies to increase access to essential medicines, including through existing and new policies and frameworks, at the UK, European and international levels.

Working with the pharmaceutical industry, the UK will report on this framework in 2006, including in terms of the impact of the framework, the usefulness of the framework for companies and other stakeholders, key outstanding issues on which government and industry have continued to work together, new areas of work to address barriers to access, and developments in company policies and approaches to increasing access to essential medicines.

Section three: Background

Access to essential medicines

In 2002 there were almost 6 million deaths from HIV and AIDS, TB and malaria.³⁷ The World Health Organisation (WHO) estimates that by 2015 over 10.5 million lives could be saved every year by expanding access to existing health interventions to prevent or treat infectious diseases, maternal and perinatal conditions, childhood diseases, and non-communicable diseases. Most of these interventions depend on essential medicines.³⁸

Whilst the global percentage of people without access to essential medicines has dropped from 50 per cent in 1975 to about one-third today, the absolute numbers of people haven't changed and remain at about 1.7 billion.³⁹ In low-income countries, the share of pharmaceuticals consumed fell from 3.9 per cent of the world total in 1985 to 2.9 per cent in 1999.⁴⁰ In some of the poorest countries in Africa and Asia more than half the population still have no regular access.⁴¹ In India an estimated 50–65 percent of the population, and in Africa almost half the total population, lack access.⁴²

Box 2: Six barriers to access:

- **Unreliable medicines supply:** one of the main reasons for lack of access. Failures in supply systems and inefficient procurement cause shortages and wastes scarce resources.
- **Irrational use of medicines:**⁴³ a major problem worldwide, it is estimated that half of all medicines are inappropriately prescribed, dispensed or sold, and that half of all patients fail to take their medicine properly.
- **Unfair health financing mechanisms:** leaving households responsible for the cost of essential medicines.
- **Unaffordable medicines prices:** especially for newer medicines.
- **Poor quality medicines:** Counterfeit and substandard medicines remain a global problem.
- **Lack of new medicines:** most medicine research and development is focused on the medical conditions of developed countries.

Source: WHO Medicines Strategy 2004 – 2007

37 WHO Medicines Strategy: Countries at the Core 2004 – 2007, WHO, 2004.

38 Ibid.

39 Between 1.3 and 2.1 billion people. *The World Medicines Situation*, WHO, 2004 p 61.

40 Ibid P61.

41 Opcit WHO Medicines Strategy.

42 Opcit *The World Medicines Situation*.

43 WHO defines rational use as being when 'Patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community' WHO 1985, in *Promoting rational use of medicines: core components*, WHO, September 2002.

Responsibility for increasing access to essential medicines rests with the whole international community. Progress requires donors, international agencies, NGOs and the private sector to work with, and listen to, developing country governments. Particularly, national and international action is required to:

- Build health systems in developing countries, including by increasing the numbers of healthcare professionals, building capacity for procurement, storage and distribution of medicines, and improving rational use of drugs through training to ensure the right people get the right medicines with the right care and oversight.
- Increase financing for health care, including for the purchase of medicines.
- Make essential medicines more affordable, including in terms of prices charged by pharmaceutical companies (both research-based and generic), and by addressing costs added to these prices.
- Increase the number of new medicines developed for diseases disproportionately affecting developing countries, including through innovative public-private partnerships and approaches to intellectual property.⁴⁴

Of the six factors listed by WHO in Box 2, two can be significantly affected by the activities of research-based and generic pharmaceutical companies:

- Unaffordable medicines prices
- Lack of new products⁴⁵

Medicines prices

Medicines are often too expensive for poor communities in developing countries. Up to 90 per cent of people in developing countries have to pay for medicines directly.⁴⁶ In the absence of effective public healthcare systems, medicines account for between 50 and 90 per cent of out of pocket expenditure on health for households in low-income countries.⁴⁷

⁴⁴ For further information on UK Government activities, see *Increasing access to essential medicines in the developing world: UK Government policy and plans*, DFID, June 2004.

⁴⁵ Including new formulations, such as for children.

⁴⁶ *Report of the Workshop on Differential Pricing and Financing of Essential Medicines*, WHO and WTO Secretariats, Norwegian Foreign Affairs Ministry, Global Health Council, April 2001.

⁴⁷ *Opcit WHO Medicines Strategy*.

Box 3: Medicines prices

Final consumer prices are generally made up of a combination of the price charged by the manufacturer, import tariffs, port charges, clearance and freight costs, pre-shipment inspection fees, a pharmacy board fee, importer's margins, VAT, central government taxes, state government taxes, local town duty, and a wholesaler's retail mark up. Typically the largest mark ups are the importer's, wholesaler's and retailer's margins, which can add 50 – 80 per cent to the 'factory gate price'. WHO recommends that medicines on a country's essential medicines list (EML) should not be subject to tariffs. Many countries comply with this.

Source: *The World Medicines Situation*

Box 4: Patents and generics

WHO defines 'original brands' as innovative pharmaceutical products with patent protection. These usually come from one company and are often called 'single-source' medicines. 'Generics' are pharmaceutical products intended to be interchangeable with the originator product, marketed after expiry of the patent or other exclusivity rights and usually manufactured without a licence from the innovator company. Within 'generics' there are branded generics, each manufactured by a single company – 'other brands' – and 'commodity generics', sold under the generic name and manufactured and marketed by many companies.

Patented and generic drugs are manufactured by research-based pharmaceutical companies and/or generic companies. Research-based companies do produce generic medicines, often where production continues once a patent has lapsed. The largest generic company in the world is Novartis of Switzerland, which is a major innovator company. Some generic companies based in the developing world, including India, China, Brazil and South Africa, produce high quality medicines for the international market, as well as for local consumption. China is the second largest producer of pharmaceutical ingredients in the world.

Sources: *The World Medicines Situation*; Grace C, 2004 *The effect of changing intellectual property on pharmaceutical industry prospects in India and China: considerations for access to medicines*, DFID HSRC.

Patented medicines are generally – though not always – more expensive than generic medicines. This reflects the significant research and development costs involved in bringing new medicines to market. Patents provide a time-limited period of marketing exclusivity enabling companies to recoup these costs and to make a profit. If there were no patents it is unlikely that companies would take the risk of investing in the development of new medicines.

A study on the difference in price between 30 essential generic and original brand medicines found that in Ghana, brand medicines were more expensive than generic medicines by a factor of 18 in public facilities, 11 in private facilities, 10 in pharmacies, and only 1.5 times in NGOs and religious missions.⁴⁸ Other studies have found similar differences.⁴⁹

Single-source medicines

Single-source medicines are available from only one company and are generally patent protected. They usually sell at higher prices, and cannot be copied by other manufacturers until the patent lapses.

Research suggests that between 94 and 98 per cent of medicines on WHO's Model List⁵⁰ are off-patent.⁵¹ Multiple producers and competitive markets should keep prices for these drugs low. This is not always the case for a number of reasons (see below).

Since patented products usually sell for higher prices, access to such drugs can be limited in poorer countries. Even though few medicines on the Model List are on patent, those that are tend to be important, newer drugs. In addition, there are a number of reasons to think that the proportion will increase in the future.

For instance, certain types of medicines are more highly patented than others. Antiretrovirals (ARVs) are a good example, and the potential impact of patenting in this class is high. In addition, a patent on one of a combination of drugs can reduce access to a co-formulated drug even if the other drugs in the combination are not patented. Furthermore, patents in only one or two key countries can have a significant impact on other countries where patents might not have been taken out. For example,

48 'Strategies for enhancing access to medicines', Management Sciences for Health, Boston (<http://www.msh.org/seam/3.1.3.htm>) in WHO *The World Medicines Situation*, WHO, 2004 p 69.

49 see Health Action International <http://www.haiweb.org/medicineprices>

50 WHO's Model List is a list of essential medicines needed in developing countries that has been developed since 1977. It serves as a reference for countries for the establishment of their own national Essential Medicines Lists. It currently has 316 active substances.

51 See Attaran A *How do patents and economic policies affect access to essential medicines in developing countries?* Health Affairs, Volume 23, No. 3 May/June 2004; Attaran A, Gillespie-White L, *Do patents for antiretroviral drugs constrain access to AIDS treatment in Africa?* JAMA 2000; 286: 1886-1892; Goemaere *et al.* 4 Journal of the American Medical Association 287 no 7 (2002): 841; Boulet, Garrison & t'Hoën *Drug patents under the spotlight* May 2003, MSF.

patents do not exist on the majority of ARVs in many African countries. However, 95 per cent of ARVs are patented in South Africa,⁵² which has manufacturing potential for domestic use and regional export. It is important to note that some research based companies have granted voluntary licences or indicated that they will not enforce their patents, and that most companies producing these drugs have developed pricing offers for the treatment of AIDS in the poorest countries (see below).

It is likely that the number of patented medicines on the Model List will increase. Until the 13th Edition in April 2003, many patented products were excluded because of cost. With cost having been a factor during most of the Model List's life it is inevitably weighted towards off-patent medicines. As cost considerations change, and new medicines are developed, the proportion of patented drugs on the Model List will increase.

However, lower prices for single-source medicines will be of little benefit if there is limited finance to buy medicines, poor quality health systems, and inefficient drug procurement, storage and distribution systems.

Multiple-source medicines

Multiple-source medicines are usually generic and generally off-patent. Multiple producers and purchasers, minimally differentiated products, and low barriers to entry mean competitive markets should keep prices low. As previously noted, well over 90 per cent of medicines on WHO's Model List are off-patent.

However, generics prices do vary, and are not always lower than original brand medicines or branded generics. In addition, cheap generic essential medicines are not always available. For instance, data from the 2001 Kenya medicine prices survey found that of the outlets surveyed, half had the original brand of ceftriaxone,⁵³ less than 20 per cent had the leading generic version, and 35 per cent had some form of generic version.⁵⁴

Ultimately, lack of access to cheap generics is due to poor quality health systems, including in terms of procurement and distribution, and lack of financing to purchase medicines. The UK Government is addressing these areas in its work generally on increasing access to essential medicines in developing countries.⁵⁵

52 Goemaere et al. *Do patents prevent access to drugs for HIV in developing countries?* Journal of the American Medical Association 287 no 7 (2002).

53 Ceftriaxone is a long acting injectable cephalosporin antibiotic that can be used in a range of indications, including: chancroid, gonorrhoea, lyme disease, meningitis, osteomyelitis, pelvic inflammatory disease, pneumonia, septic arthritis, septicaemia and certain upper respiratory tract infections (WHO Essential Medicines Library, accessed 16/11/04, http://mednet3.who.int/eml/medicines_link.asp?drugId=57)

54 Essential Drugs Monitor No 33 2003 p 15.

55 See *Increasing access to essential medicines in the developing world: UK Government policy and plans*, DFID, June 2004.

Company responses

Companies have developed a range of approaches to increasing access to their medicines in developing countries. Differential pricing, generic competition and increased financing have brought the price of first line ARVs down by as much as 98 per cent over the last four years.⁵⁶ Most companies⁵⁷ producing ARVs have developed differential pricing schemes for developing countries, and in some cases these prices are comparable to the price of generics.

Box 5: Pharmaceutical company differential pricing offers

Novartis has established a framework with WHO whereby public sector purchasers in developing countries receive a reduced price for its artemisinin based antimalarial Coartem.

GSK sells its AIDS medicines and antimalarials at not-for-profit prices to public sector customers and not-for-profit organisations in 64 countries – all LDCs and all of sub-Saharan Africa (SSA). In addition, all private employers in SSA who provide care and treatment to their uninsured staff can purchase its ARVs at not-for-profit preferential prices. All projects fully funded by the Global Fund to Fight AIDS TB and Malaria are also eligible, which means that its not-for-profit prices are now available in over 100 countries.

Merck's pricing policy for Crixivan™ (indinavir sulfate) and Stocrin™ (efavirenz) means that in LDCs and those hardest hit by AIDS, Merck makes no profit on the sale of these medicines. Significant discounts are offered to other countries meeting set criteria relating to level of development and adult HIV prevalence; more than 110 countries are eligible for discounted ARVs.

Roche makes its HIV protease inhibitor medicines available at no profit prices to the world's Least Developed Countries and sub-Saharan Africa. The company also offers reduced pricing for these medicines in low income and lower middle income countries. Together the no profit and reduced prices are applicable to 85% of all people living with HIV/AIDS in the world.

⁵⁶ See <http://www.accessmed-msf.org/prod/publications.asp>

⁵⁷ For example, Abbott, Boehringer Ingelheim (BI), Bristol-Myers Squibb, Gilead, GlaxoSmithKline (GSK), Merck and Roche have all made ARVs available at differential prices. These companies also operate through the Accelerating Access Initiative, which recently reported that as of September 2004 over 330,000 people with HIV in developing countries were being treated with medicines supplied by AAI companies. This represents approximately 50 per cent of all treatment in developing countries (see http://www.unaids.org/acc_access/index.html; see also Sturchio, *J Partnership for action: the experience of the accelerating access initiative, 2000 – 2004, and lessons learned* in Attaran, A & Granville, B ed *Developing essential medicines: the way forward*, London, RIIA, 2004).

The majority of pharmaceutical companies have developed some form of differential pricing for some of their product range. Many are also involved in donations of drugs for disease control and/or eradication programmes.

Research for DFID looking at 14 research-based pharmaceutical companies found that they were all engaged in efforts to increase access to medicines.⁵⁸ Twelve of the 14 companies offered differential pricing on at least one drug, whilst nine offered donations schemes. All company policies had been developed for specific diseases, primarily HIV and AIDS, malaria, cancer, sleeping sickness, vaccines, and diseases of the developing world, with many approaches exclusively concerned with HIV and AIDS. Of the 14 companies examined, eight make HIV and AIDS drugs available, two distribute sleeping sickness drugs, two make cancer treatment available and two make vaccines available. Treatments for leprosy, diabetes, lymphatic filariasis, trachoma and chagas disease are each made available by one company.

There is a need for greater transparency of policies and pricing by both research-based and generic companies. Some companies provide information about their policies on their websites and through other channels. But many companies do not make such information transparent or accessible. Generics companies have limited information available, and research-based companies for the most part do not publish prices for middle-income countries. It is also difficult to compare access to medicines reporting.

Differential pricing approaches also vary in terms of price, qualifying countries, and eligible sectors (private, public and non-governmental). Some companies use the United Nations Conference on Trade and Development's (UNCTAD) definition of least developed countries, others the United Nations Development Programme's (UNDP) Human Development Index and others the World Bank's income categorisation as criteria for country eligibility. Most offers are not available in the private sector even in LDCs, despite the majority of people accessing health care through the private sector in developing countries.

⁵⁸ Research was commissioned for DFID and is unpublished. It was based on the policies of pharmaceutical companies as of August 2004.

Box 6: Prices and eligibility of three products from three different companies

Merck Stocrin © (efavirenz)
600mg

Prices and eligibility (countries):

– US\$346.75/year for Low Human Development Index (HDI) countries plus medium HDI countries with adult HIV prevalence of 1 per cent or greater.

– US\$767/year for medium HDI countries with adult prevalence less than 1 per cent.

Delivery of goods: CIF

Eligibility (bodies):

Governments, international organisations, NGOs, private sector organisations (e.g. employers, hospitals and insurers). Merck & Co. does not rule out supplying ARVs to patients through retail pharmacies.

Ranbaxy Triviro LNS ©
(d4T/3TC/NVP)
40mg+150mg+200mg

Prices and eligibility

(countries): US\$292/year. Prices apply to orders for a minimum of 1.5 million units. Different prices are offered for smaller quantities (500,000 or 1 million units).

All countries are eligible.

Delivery of goods: FOB
Delhi/Mumbai (India).

Eligibility (bodies): NGOs and governments or programmes supported by them.

Roche Viracept © (nelfinavir)
250 mg

Prices and eligibility (countries):

– CHF 1194/year = US\$942/year for all countries in sub-Saharan Africa and all UN defined least developed countries.

– CHF 4055/year = US\$3201/year in low income countries and lower middle income countries – as classified by the World Bank.

Delivery of goods: Terms and conditions: effective date 1 March 2003. FCA Basel (CH), CAD (cash against documents) 30 days at sight. Minimum order and delivery amount per shipment is CHF 10,000 (US\$7891).

Eligibility (bodies):

Governments, non-profit institutional providers of HIV care, NGOs.

Reproduced from *Untangling the web of price reductions: a pricing guide for the purchase of ARVs for developing countries*. 6th Edition, MSF, 19 April 2004.

Lack of new products

The Global Forum for Health Research estimates that US \$70 billion is spent each year on health research and development by the public and private sectors worldwide. An estimated 10 per cent of this is used for research into 90 per cent of the world's health problems.⁵⁹ There is an urgent need for stepped-up investments in new and improved technologies to address diseases affecting poor people in developing countries,⁶⁰ as well as a need to streamline the development of new drugs in order to reduce the overall cost of R&D for neglected diseases.⁶¹

Only one per cent of the medicines developed over the past 25 years were for tropical diseases and tuberculosis, which account for 11 per cent of the global disease burden.⁶² Research and development for new products for childhood diseases, especially for vaccines for acute respiratory illness, diarrhoea and common tropical

59 The Global Forum for Health Research, <http://www.globalforumhealth.org>

60 *Research and Development for Neglected Diseases: Lessons Learned and Remaining Challenges* International Federation of Pharmaceutical Manufacturers Associations October 2004.

61 Opcit IFPMA.

62 Opcit WHO Medicines Strategy WHO 2004.

diseases is critically short.⁶³ In addition, more work is needed to develop paediatric formulations of existing medicines, including for ARVs.

Increasing investment in research and development for diseases affecting developing countries requires action by donors, international agencies, pharmaceutical companies and private and public research institutes, as well as other groups. Creative public investment policies and public-private partnerships can, and do, help to increase investment and incentivise additional research by pharmaceutical companies. Product development public-private partnerships (PD-PPPs) such as the Medicines for Malaria Venture (MMV), the International Partnership for Microbicides (IPM) and the International AIDS Vaccine Initiative (IAVI) are making significant progress.

In some cases, such as malaria, resistance to existing drugs means that some no longer have an impact and need to be replaced. In other cases existing medicines have serious shortcomings. For instance, treatments for African trypanosomiasis, chagas disease, leishmaniasis and dengue fever are generally regarded as having major problems related to safety, (partial) efficacy, and inappropriate dosage forms. Of these, only dengue fever actually has no effective drug available.⁶⁴ For TB, whilst the combination of drugs has an impact in simple cases, treatment typically takes six to eight months – a new drug that drastically reduced this time would be a breakthrough, reducing risk of resistance and improving the lives of people with TB. For many diseases the urgent need is for preventive vaccines and other technologies. A microbicide active against HIV would bring enormous benefits, particularly to women and girls who are more physically and socially vulnerable to HIV.

Company responses

Research-based companies, and increasingly generic companies, are engaged in numerous initiatives to increase research and development investment into diseases affecting developing countries. Individual company efforts, PD-PPPs, innovative approaches to intellectual property management, and other collaborative efforts have led to new products and formulations.

⁶³ Opcit IFPMA.

⁶⁴ Opcit *Research and development for neglected diseases*, IFPMA.

Box 7: Pharmaceutical company R&D work

AstraZeneca: In 2001 AstraZeneca made a US\$10 million capital investment in new laboratories, and has since committed another \$30 million for laboratory equipment and operations costs at its research and development centre in Bangalore in India. The facility is focused on finding a new therapy for TB that will act in drug-resistant disease and reduce the complexity and/or the duration of treatment. The research programme, which also involves collaborations with academia, is utilising the latest technologies in drug discovery and development to find new candidate drugs that are better than existing treatments, active with shorter duration of therapy, and active against latent disease and resistance organisms.

Johnson & Johnson: Tibotec, part of the Johnson & Johnson family of companies, and the International Partnership for Microbicides (IPM) completed an agreement in March 2004 to develop a safe and effective microbicide to help protect women against HIV infection. IPM has a royalty-free licence to develop, manufacture and deliver TMC 120, a non-nucleoside reverse transcriptase inhibitor, as a microbicide for the prevention of HIV, in resource-poor countries.

GSK: In addition to its work on HIV and AIDS, GSK has a dedicated group, based in the UK, US and Spain, within its pharmaceutical research and development organisation to ensure a focus on diseases disproportionately affecting developing countries. For this group, drug development projects are prioritised primarily on their socio-economic and public health benefits rather than their commercial returns. A similar group exists in its vaccines organisation based in Belgium.

Support for health systems and broader development

The policies and practices of pharmaceutical companies – both research-based and generic – can also have a direct and indirect bearing on other factors affecting access to essential medicines. The way companies promote and market their products can affect rational use of medicines. The ways in which companies work with national medicines procurement, storage and distribution systems in developing countries can affect these systems' long-term viability. The way companies work with regulatory agencies and local producers in developing countries can have an impact on the quality of those medicines that are available. For instance, where appropriate, voluntary licences can support increased access to quality medicines. Finally, companies can contribute indirectly to health systems development – and broader development – by being good corporate citizens, including with respect to any payments (such as taxes and other fiscal transfers) to local and national authorities.

Box 8: Health systems strengthening and increasing access to medicines

Merck: In 2000 Merck, the Government of Botswana, The Merck Company Foundation and the Bill & Melinda Gates Foundation, established the African Comprehensive HIV/AIDS Partnerships (ACHAP). Its goal is to support and enhance Botswana's response to the HIV/AIDS epidemic through a comprehensive approach to prevention, care, treatment and support. The Merck Company Foundation and the Gates Foundation each contribute \$50 million to the initiative. In addition, Merck is donating antiretroviral (ARV) medicines to Botswana's national ARV therapy programme for the partnership's duration.

Lilly: Each year, roughly 300,000 new cases of multi drug resistant TB (MDR-TB) occurs in more than 100 countries, largely in the developing world. The Lilly MDR-TB Partnership was announced in June 2003 by Lilly and WHO, along with key partners such as the Centers for Disease Control and Prevention (CDC). Components of the partnership include technology transfer to manufacture two Lilly antibiotics necessary in nations where MDR-TB is most prevalent, including South Africa, training in good manufacturing practices for each new facility, and provision of Lilly antibiotics at a fraction of their cost to WHO-approved 'DOTS-Plus' treatment programmes.

Pfizer: The Infectious Diseases Institute (IDI) at Makerere University in Kampala, Uganda is a new medical facility providing state of the art training and treatment of HIV and AIDS and other infectious diseases. Pfizer Inc and the Pfizer Foundation have contributed more than US\$15 million to support the new medical Institute. The Institute provides care for approximately 300 patients each day and is intended to be a major centre for training medical professionals in advanced HIV and AIDS management techniques.

GSK: GSK has granted voluntary licences to six African generics companies for its leading ARVs. To facilitate distribution of reduced price product in sub-Saharan Africa, **Shire Pharmaceuticals plc**, which has a Master Licence agreement with GSK, has agreed to waive or reduce its rights to any royalty payments from GSK.

Roche: The company has pledged to neither file patents for new HIV drugs nor to enforce any patents the company holds for its antiretroviral medications in LDCs or sub-Saharan Africa. This means generic versions of such medicines can be produced in these countries without need for a voluntary or compulsory licence.

Pharmaceutical industry stakeholders

The role of pharmaceutical companies in increasing access to medicines has attracted a great deal of attention in recent years from a variety of groups, including governments, multilateral agencies, the media, institutional investors and NGOs. Ethical arguments about what should be done have developed into arguments about the business case for action. The business case will vary according to company product mix and geographical exposure, but it rests on perceived threats to business interests and long-term profitability if companies cannot demonstrate that, within their spheres of influence, they are seeking to address the lack of access to essential medicines in developing countries in a sustainable manner. Threats include:

- **Reputational risk** from activist campaigns and negative media coverage, which can undermine staff morale, reduce the ability to recruit and retain the best employees, and damage relationships with key stakeholders such as governments and public and private sector procurement agents.
- **Intellectual property (IP) risk**, as failure to actively market affordable drugs in developing countries can lead to criticisms and campaigns which undermine IP systems in these markets, threatens the international IP system more generally, and increases the risk of loss of IP rights. Calls for radical overhaul of national and international IP regimes are often fuelled by accusations that existing approaches are making essential medicines too expensive in developing countries.
- **Market risk**, as competitors – whether generic or research-based – move into, and establish themselves in, developing country markets. This is influenced by – and in turn influences – IP risk, as competitors might be better able to enter markets if countries utilise the flexibilities contained in the WTO TRIPS agreement.

Conversely, pharmaceutical companies that do address access to essential medicines issues can enhance their reputation, protect the credibility of the IP system, and are better able to maintain and build market share in developing countries.

These threats and opportunities concern a number of stakeholders. In 2002 a joint report from Oxfam, Save the Children and VSO challenged the pharmaceutical industry to 'improve its efforts to tackle the health crisis affecting children and adults in developing countries'.⁶⁵ The Pharmaceutical Shareowners Group (PSG) issued a statement in 2003 on company responses to the lack of access to medicines in developing countries, stating, 'whether from a reputation, market development or corporate citizenship perspective, investors see a business case for pharmaceutical companies to make a proactive response to the crisis'.⁶⁶ PSG subsequently published

⁶⁵ Opcit Oxfam, SCF, VSO 2002.

⁶⁶ Opcit PSG 2003.

a report in 2004 which recognised that real progress had been made by some companies, notably GSK and Merck, but encouraged all companies to 'understand the business impact of the crisis and ... to adopt best practice where this can protect long-term shareholder value'.⁶⁷ In May 2003 Core Ratings⁶⁸ argued that 'there is concern among leading institutional investors that if pharmaceutical companies do not voluntarily help with LDC health problems, they will suffer "unfriendly" regulatory change, reputational damage and find courts less sympathetic when it comes to defending the patent life and pricing of drugs'.⁶⁹

There are clear ethical arguments for pharmaceutical companies, governments, donors, international agencies and NGOs to do all they can to increase access to essential medicines. There are also business arguments to say that action is in the interests of pharmaceutical companies.

Sustainable solutions

At the core of the UK Government's work to increase access to essential medicines in developing countries is the desire to effect sustainable solutions. The sustainable response must lead to the development of viable markets for pharmaceutical products in developing countries. Only in this way will pharmaceutical companies include developing country markets within their business development strategies, including in relation to investment in research and development for treatments for diseases disproportionately affecting developing countries.

For this reason the UK Government favours approaches based on differential pricing rather than donations. Donations can work well in disease eradication programmes, and, when undertaken responsibly, can have a role in emergencies. However, for the majority of long-term, general, essential medicines needs of developing countries, donations are not suitable. At the very least it is not sustainable for companies to give away their products indefinitely and in significant quantities. At worst donations can impose hidden costs on recipients, distort national healthcare priorities, involve unwanted or unsuitable products, and can undermine the development of local markets by locking out competition.

Donations

Donations in emergencies have had a mixed track record. However, in some emergency situations, where the relevant national authorities have requested specific

⁶⁷ Opcit PSG 2004.

⁶⁸ CoreRatings is a rating agency providing independent investment analysis of corporate responsibility risks
<http://www.coreratings.com>

⁶⁹ *Philanthropy or good business: emerging market issues for the global pharmaceutical industry*, CoreRatings, May 2003.

products and where activities are carried out in accordance with relevant WHO guidelines, they have been valuable.

Disease eradication programmes can be well suited to donations, where companies work with national authorities and international agencies as part of a comprehensive programme, and commit to provide the necessary medicine(s) until the programme is complete. For instance, research by IPPPH⁷⁰ found that donations schemes for a number of tropical disease⁷¹ drug access public-private partnerships (PPPs) in Sri Lanka, Uganda and Zambia 'provided considerable benefit with negligible negative side-effects'.⁷² The programmes involved donations by Novartis, GSK, Merck, Aventis, Bayer and Bristol-Myers Squibb. The research concluded that diseases that can be 'eliminated' as major public health problems are well suited to this approach because of their time limited nature, thus 'minimising the risk of dependency relationship[s] and unsustainable programmes'.⁷³ Other factors contributing to the programmes' success included: the companies' pledges to contribute for the life of the programme; the low value of, and lack of market in rich countries for, the medicines involved (which meant fewer concerns regarding diversion and leakage); and, the fact that the programmes were well integrated with national health systems and undertaken in the context of wider global or regional programmes.⁷⁴

However, donations are not a sustainable solution to the majority of the health needs of developing countries, particularly for chronic diseases. At the very least it is not sustainable for pharmaceutical companies to give away their products in significant quantities. This is increasingly accepted in the pharmaceutical industry. As the CEO of Merck put it, 'Giving our medicines away in general is an unsustainable and unrealistic answer because, at the end of the day, we must earn an adequate return on our investment in order to fund future research'.⁷⁵

At worst, donations can impose burdens on developing country health systems, involve unwanted and inappropriate medicines, and can hinder the development of viable markets.⁷⁶ Problems with inappropriate and unwanted medicines should be resolved if companies follow the WHO guidelines on donations, as the majority of large pharmaceutical companies do. However, even donations that fully comply with

70 Initiative on Public Private Partnerships for Health. <http://www.ippph.org>

71 Leprosy, lymphatic filariasis, malaria, onchocerciasis and sleeping sickness.

72 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, October 2004, p 9.

73 Ibid.

74 Ibid.

75 Gilmartin, R *Innovation, Ethics and Core Values* Vital Speeches of the Day 1998 <http://www.votd.com>

76 Guilloux, A & Moon, S Hidden Price Tags: disease specific drug donations: costs and alternatives *Medecins Sans Frontieres (MSF)* October 2000.

the WHO guidelines can ultimately suppress competition. Pharmaceutical companies – whether research-based or generic – cannot profitably engage with a market at the same time as the medicines against which they would be competing are being given away free of charge. This is more of a problem if acceptance of a donation appears to rule out use of competitor medicines.

IPPPH's research found that whilst differential pricing and donations did bring significant benefits to the ultimate recipients for drug access programmes for HIV and AIDS, donation programmes' 'long-term indirect effects can rule out local competition, particularly if the public sector partner perceives an obligation to use a sole source'.⁷⁷ In addition, reporting, storage and distribution conditions and requirements can make donations more expensive than anticipated, and run the risk of overwhelming the limited capacity of health services by diverting staff, and duplicating financial, monitoring and evaluation systems.⁷⁸

Differential pricing

Increasingly companies are adopting differential pricing as the most sustainable solution to the problem of access to affordable medicines.⁷⁹ Differential pricing can help support viable markets, and competition can lead to lower prices.

Box 9: ARVs

ARVs offer a good lesson in the way markets can be developed. Lower prices for ARVs helped bring about the decision to make the drugs available in developing countries. This has led donors to significantly increase financing available for antiretroviral therapy, and this has in turn brought about volume growth in the market for the pharmaceutical industry. With WHO and others recognising that donor funds must be made available for some previously out-of-reach disease areas in the poorest developing countries, it seems possible that other treatments such as for cancer, diabetes⁸⁰ and heart disease might also follow.

The UK Working Group on Increasing Access to Essential Medicines in the Developing World found that differential pricing was economically and commercially viable. Other research has come to similar conclusions. One study suggested that differential pricing was economically viable because the variable costs comprise about 15 per cent of the total costs of producing pharmaceuticals.⁸¹ Companies can decide

77 Opcit Caines, K & Lush, L p 10.

78 Opcit Guilloux, A & Moon, S; Opcit Caines and Lush.

79 Opcit PSG 2004. PSG worked with Astra Zeneca, Bristol-Myers Squibb, GlaxoSmithKline, Merck & Co, Novartis, Pfizer and Roche.

80 Currently only a limited selection of drugs and insulins are included on the Model List.

81 Grace, C. *Equitable Pricing of Newer Essential Medicines for Developing Countries: evidence for the potential of different mechanisms* WHO 2003.

flexibly on the market in which they recover non-variable costs (such as fixed production costs, R&D, marketing and administration expenditure). With pricing close to the cost of manufacture, companies can still earn a profit. Differential pricing should be desirable for pharmaceutical companies. Developing countries currently contribute very little to overall profits, and differential pricing offers a rational way for global companies to maximise profits on products sold in both low and high-income countries. However, market segmentation to avoid leakage and diversion is vital if differential pricing is going to work.

Whilst differential pricing can support competitive markets, it does not do so automatically. Research from 2003 found a number of problems that can occur, including lack of transparency (particularly where agreements were negotiated in, and kept, secret), problems arising when offers were limited to specific sectors (such as excluding the private sector), and market distortions which can undermine competitive markets (not least if the outcome is the exclusion from the market of generic competitors).⁸² WHO notes that under differential pricing schemes 'countries have little control ... in terms of which medicines are available, over what period, through which channels and in what volume'.⁸³

IPPPH's research echoed these concerns, finding that the discounts they looked at continued to be fragmented and uncoordinated. It reported 'widely held' perceptions that discounts 'precluded the use of generics'.⁸⁴ It noted that offers were largely restricted to the public sector, which created three main problems: the majority of people accessed treatment in sub-Saharan Africa through the private sector; risk of leakage and diversion puts additional pressure on the public sector's drug supply and management system; local pharmaceutical markets are distorted, making it difficult for the private sector to obtain ARVs at competitive prices.⁸⁵

Competitive markets and R&D

The UK Government would like to see a situation where pricing is affordable for the recipient country, and economically viable for the producing company.⁸⁶ Differential pricing is likely to be most effective where offers are transparent, and free of market distorting conditions, especially those limiting the feasibility of alternative offers from competitors. With due regard to patents, other companies should be able to enter the market such that healthy competition can sustain low prices and a good range of products.

82 Ibid.

83 Opcit *WHO The World Medicines Situation*.

84 Opcit Caines and Lush p 10.

85 Ibid.

86 See also *Report of the Workshop on Differential Pricing and Financing of Essential Medicines*, WHO and WTO Secretariats, Norwegian Foreign Affairs Ministry, Global Health Council, April 2001, which defines differential pricing as where prices charged by the seller are adapted to the purchasing power of governments and households in different countries.

One of the additional benefits of differential pricing is that it supports research and development. Increased investment in research and development for medicines and vaccines for diseases that disproportionately affect developing countries is needed. There are many ways of achieving this and many companies are already engaging in innovative research efforts. However, one of the key ways will be to develop sustainable markets in developing countries, so that companies have an incentive not only to enter markets with existing products, but also to invest in new products for these markets.

Increasing investment in R&D for diseases affecting developing countries requires concerted action by the whole international community, including donors, developing countries, pharmaceutical companies and private and public research institutes.

Other ways in which pharmaceutical companies can stimulate the development of competitive markets can include technology transfer and voluntary licences, support for local production of medicines in developing countries and support for appropriate use of TRIPS flexibilities.

There can be significant challenges involved in the local production of medicines in developing countries, including the difficulties involved in achieving international quality standards, achieving a meaningful market share in a larger regional market, and dependence on imported active pharmaceutical ingredients (APIs), the cost of which may fluctuate. Where resources are scarce it might be the case that priority be given to building health systems, and strengthening medicines procurement, storage and distribution systems. However, local production can play a valuable role in building overall local capacity and enabling developing countries to increase access to essential medicines.⁸⁷

Provision of voluntary licences and technology transfer can support local production. This approach is being used by a number of companies to increase productive capacity for drugs for developing countries.⁸⁸

Companies can also contribute to efforts to increase access to essential medicines by supporting the provisions and flexibilities of the TRIPS agreement. TRIPS provides important protection for intellectual property rights, and contains a number of flexibilities that can be used to source medicines, including through compulsory

⁸⁷ See Guimier, J-C. Lee, E. & Grupper, M. *Processes and Issues for Improving Access to Medicines: the evidence base for domestic production and greater access to medicines*, DFID Health Systems Resource Centre September 2004; and Grace, C. *Leveraging the Private Sector for Public Health Objectives*, DFID Health Systems Resource Centre, September 2004.

⁸⁸ For an interesting discussion on the pros and cons of some of these approaches, including voluntary licences, see Grace, C. *Equitable Pricing of New Essential Medicines for Developing Countries: evidence for the potential of different mechanisms*, WHO, 2003.

licences and government use clauses.⁸⁹ The November 2001 WTO Ministerial meeting at Doha issued a declaration on TRIPS and Public Health stating that TRIPS does not, and should not, prevent countries from taking measures to protect public health. Recognising that countries with no, or insufficient, industry of their own could not make use of some flexibilities, the WTO reached a decision on 30 August 2003 allowing countries with no, or insufficient, capacity in their pharmaceutical industry to import copies of on-patent drugs.⁹⁰

It is important that all actors able to influence the development and implementation of TRIPS and other intellectual property regimes respect the TRIPS agreement and subsequent interpretations and decisions. The UK fully supports the TRIPS agreement, and the right of developing countries to make use of the flexibilities provided therein. Whilst the Government supports the right of developing countries to adopt standards beyond TRIPS if they consider it is in their interests to do so, we also believe that bilateral and other agreements should not, as a matter of course, oblige countries to adopt intellectual property standards or timetables that go beyond TRIPS. For our part, we will seek to ensure that EU agreements with developing countries avoid imposing obligations beyond TRIPS⁹¹ and encourage others that can influence the development of intellectual property regimes to adopt a similar position.

89 See Baker, B. *Processes and Issues for Improving Access to Medicines: willingness and ability to utilise TRIPS flexibilities in non-producing countries*, DFID Health Systems Resource Centre, September 2004.

90 This was done by waiving (under specific conditions) the TRIPS clause that required that the larger share of any pharmaceuticals produced under compulsory licence were used domestically. This opens the way for countries to issue a compulsory licence expressly so as to export to a country (that must also issue a compulsory licence) that had no, or insufficient, pharmaceutical industry of its own.

91 See *The UK Government Response to the Report of the Commission on Intellectual Property Rights 'Integrating Intellectual Property Rights and Development Policy'*, DFID and DTI, 2002
http://www.iprcommission.org/graphic/uk_government_response.htm

Section four: Conclusion

Increasing access to essential medicines in developing countries requires concerted action by the whole international community.

Pharmaceutical companies are making significant progress in increasing access to their medicines. As ever, more can be done. Developing countries, donors and others are also making significant progress, and again, much more can be done.

2005 offers an opportunity for the international community to work together to reduce poverty, including by increasing access to medicines in developing countries.

The UK Government looks forward to continuing to work with the pharmaceutical industry and other stakeholders to improve the lives of people – and support sustainable development – worldwide.

Annex 1: Organisations consulted during the development of this framework include:

AstraZeneca

GlaxoSmithKline

Abbott

Lilly

Merck & Co., Inc.

Wyeth

Johnson & Johnson

Pfizer

Bristol-Myers Squibb

Bayer Healthcare

Boehringer Ingelheim

Novartis

Novo Nordisk

Sanofi Aventis

F.Hoffmann-La Roche

Schering

International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)

European Federation of Pharmaceutical Industries and Associations (EFPIA)

The Association of the British Pharmaceutical Industry (ABPI)

The American Pharmaceutical Group (APG)

VSO

Christian Aid

Oxfam

Save The Children UK

International HIV/AIDS Alliance

Action Aid

Medecins Sans Frontieres

The Essential Drugs Project

WHO

CoreRatings

Accountability

Health Systems Resource Centre

World Economic Forum Global Health Initiative

The Pharmaceutical Shareowners Group

Pharmafutures

Annex 2: Least developed and sub-Saharan countries

Least developed countries (50)

| | | |
|----------------------------|--------------------------------|-----------------------|
| Afghanistan | Rwanda | Gabon |
| Angola | Samoa | Gambia |
| Bangladesh | Sao Tome and Principe | Ghana |
| Benin | Senegal | Guinea |
| Bhutan | Sierra Leone | Guinea-Bissau |
| Burkina Faso | Solomon Island | Kenya |
| Burma | Somalia | Lesotho |
| Burundi | Sudan | Liberia |
| Cambodia | Timor-Leste | Madagascar |
| Cape Verde | Togo | Malawi |
| Central African Republic | Tuvalu | Mali |
| Chad | Uganda | Mauritania |
| Comoros | Tanzania | Mauritius |
| Congo, Dem. Rep. | Vanuatu | Mayotte |
| Djibouti | Yemen | Mozambique |
| Equatorial Guinea | Zambia | Namibia |
| Eritrea | Sub-Saharan Africa (48) | Niger |
| Ethiopia | Angola | Nigeria |
| Gambia | Benin | Rwanda |
| Guinea | Botswana | Sao Tome and Principe |
| Guinea-Bissau | Burkina Faso | Senegal |
| Haiti | Burundi | Seychelles |
| Kiribati | Cameroon | Sierra Leone |
| Lao People's Dem. Republic | Cape Verde | Somalia |
| Lesotho | Central African Republic | South Africa |
| Liberia | Chad | Sudan |
| Madagascar | Comoros | Swaziland |
| Malawi | Congo, Dem. Rep. | Tanzania |
| Maldives | Congo, Rep | Togo |
| Mali | Cote d'Ivoire | Uganda |
| Mauritania | Equatorial Guinea | Zambia |
| Mozambique | Eritrea | Zimbabwe |
| Nepal | Ethiopia | |
| Niger | | |

Source: UNCTAD and World Bank

Annex 3: Middle-income countries (MICs)

Lower-middle-income economies (56)

| | | |
|------------------------|---|--------------------------------|
| Albania | Marshall Islands | Botswana |
| Algeria | Micronesia, Fed. Sts. | Chile |
| Armenia | Morocco | Costa Rica |
| Azerbaijan | Namibia | Croatia |
| Belarus | Paraguay | Czech Republic |
| Bolivia | Peru | Dominica |
| Bosnia and Herzegovina | Philippines | Estonia |
| Brazil | Romania | Gabon |
| Bulgaria | Russian Federation | Grenada |
| Cape Verde | Samoa | Hungary |
| China | Serbia and Montenegro | Latvia |
| Colombia | South Africa | Lebanon |
| Cuba | Sri Lanka | Libya |
| Djibouti | Suriname | Lithuania |
| Dominican Republic | Swaziland | Malaysia |
| Ecuador | Syrian Arab Republic | Mauritius |
| Egypt, Arab Rep. | Thailand | Mayotte |
| El Salvador | Tonga | Mexico |
| Fiji | Tunisia | Northern Mariana Islands |
| Georgia | Turkey | Oman |
| Guatemala | Turkmenistan | Palau |
| Guyana | Ukraine | Panama |
| Honduras | Vanuatu | Poland |
| Indonesia | West Bank and Gaza | Saudi Arabia |
| Iran, Islamic Rep. | Upper-middle-income economies (37) | Seychelles |
| Iraq | American Samoa | Slovak Republic |
| Jamaica | Antigua and Barbuda | St. Kitts and Nevis |
| Jordan | Argentina | St. Lucia |
| Kazakhstan | Barbados | St. Vincent and the Grenadines |
| Kiribati | Belize | Trinidad and Tobago |
| Macedonia, FYR | | Uruguay |
| Maldives | | Venezuela, RB |

Source: World Bank

Department for International Development

DFID, the Department for International Development: leading the British government's fight against world poverty.

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- promote sexual equality and give women a stronger voice
- reduce child death rates
- improve the health of mothers
- combat HIV & AIDS, malaria and other diseases
- make sure the environment is protected
- build a global partnership for those working in development.

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Published by the Department for International Development. Printed in the UK, 2005, on recycled material containing 80% post-consumer waste and 20% totally chlorine free virgin pulp.

Product reference: PD 031

ISBN: 1 86192 708 8