

# Increasing access to essential medicines in the developing world: UK Government policy and plans



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Cover photo: Charles, 9, receives medication at an orphanage in Nairobi, Kenya (Radhika Chalasani/Corbis).

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# Foreword

The World Health Organisation estimates that one-third of the world's population are without the access to medicines they need. Increasing access to essential medicines is a critical part of the global effort to improve health in the developing world and to tackle key diseases such as HIV/AIDS, tuberculosis and malaria.

Of late, the focus of international debate – particularly for HIV/AIDS – has been on drug prices and their affordability in the developing world. This is an important issue we must continue to address. However, cheaper drugs and other medicines cannot reach the poor without the health services to deliver them – to ensure the right medicines are used at the right time. And in many cases, new medicines are needed to cope with emerging drug resistance, to support prevention efforts, or to provide treatment options where these are currently limited.

The UK Government is very committed to tackling these issues. We recognise that this requires a coherent, collaborative effort across different government departments. This paper is issued with that in mind. It sets out what needs to be done and outlines what the UK Government will do in response, concentrating on the issues we are best placed to address.

The paper necessarily focuses, therefore, on what's needed internationally, from a UK policy perspective. But what happens within developing countries will be crucial. Progress will depend on all stakeholders – public and private sector, civil society and communities – working together, under the determined leadership of developing country governments, to tackle all the barriers that limit access to medicines by the poorest. It is only by committing ourselves to partnership in this way that we will make a real difference.



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# Executive summary

- 1.1 The lack of access to essential medicines in developing countries is one of the most pressing global health issues. Tackling this could save millions of lives every year. Yet major inequities remain, with a limited supply of affordable medicines and inadequate health systems to deliver them in many developing countries, and a continuing shortage of new products to meet developing country health needs.
- 1.2 The UK Government accords high priority to addressing this issue. It is an important part of our work – internationally and with our partners in developing countries – to tackle key diseases, strengthen health systems and improve health outcomes, particularly amongst the poorest and most vulnerable populations. That is why the Prime Minister established the high level UK Working Group on Increasing Access to Essential Medicines in the Developing World in 2001. It is also why we have strengthened policy and action across the UK Government to address this important issue.
- 1.3 This paper sets out the UK Government’s assessment of the key challenges that must be addressed if we are to increase access to medicines in the developing world. It aims to communicate clearly both this assessment, and our own plans, to interested parties. It will also serve to co-ordinate activity across relevant government departments.
- 1.4 Section 2 of the paper sets out the scale of the problem. It sets out the relationship between poverty and health, and the role of essential medicines in addressing ill health in the developing world, with reference to relevant international goals and targets. It also summarises the roles of key UK Government departments that have joined together to tackle the agenda. Section 3 then outlines in more detail the issues that developing countries and their partners must address in order to increase access to essential medicines, drawing on the WHO Access Framework. It also addresses the current imbalances in the global pharmaceutical market.
- 1.5 In Section 4, we outline recent progress – in the UK, internationally, and by developing countries. The focus is on health policy and systems, but important progress has also been made in trade negotiations and by the private sector. Here, and in Annex 2 of the paper, the recommendations of the UK Working Group are outlined and progress reported against them. This demonstrates that there has been good progress – in the UK, EU, G8, World Trade Organisation and elsewhere – but that there remains much to do.
- 1.6 With this in mind, Section 5 of the paper outlines the UK Government’s key objectives and plans for the coming months and years. Our proposed activities cover four areas:

- Support to developing countries through the UK development assistance programme, where we are strengthening our efforts to address the access to medicines agenda, including through our work to increase poor people's access to health services.
- Trade policy, where the top priority is to support developing countries in understanding and making use of the flexibilities within World Trade Organisation rules governing intellectual property.
- Our engagement with the business community, where we plan to work with the pharmaceutical industry to ensure the longer term supply of affordable medicines to developing countries and to stimulate 'best practice' by companies as they engage in developing country markets.
- Our 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, where we plan a broad programme of activity.

1.7 This paper aims to send a clear message to developing country governments, international agencies and donors, civil society, the pharmaceutical industry, the broader private sector and the research community that the UK Government is committed to working in partnership to address the lack of access to essential medicines in the developing world. The paper also sets out an ambitious programme of action for the UK Government and others. Related areas of UK Government policy and action are covered elsewhere; this paper should therefore be read alongside these documents, such as the forthcoming UK Government strategy on HIV and AIDS and the associated policy on treatment and care.

# Introduction

- 2.1 Tackling ill health is vital to tackling poverty in the developing world. Better health can contribute directly to diminishing poverty by improving quality of life, expanding opportunities, and safeguarding livelihoods and productivity. Conversely, the poor are most vulnerable to ill health and have the least means to address it<sup>1</sup>. Tackling poverty is therefore vital to improving health. This close relationship between health and poverty is universally recognised. The internationally agreed Millennium Development Goals (MDGs) have a strong focus on health outcomes, including the need to significantly improve maternal and child health outcomes and to tackle the burden of HIV/AIDS and other major diseases. The MDGs are set out in full in Annex 1 of this paper.
- 2.2 Yet the high burden of ill health in developing countries persists, particularly amongst the poorest populations. This places developing country health budgets and services under extreme pressure. Even where relevant technologies and interventions exist and are known to be effective, many people will not get access to them. High levels of disease, suffering and death prevail<sup>2</sup>:
- Globally more than 10 million children die every year. All but around 1% of these deaths occur in developing countries and more than half are caused by malnutrition, pneumonia, diarrhoea, measles, malaria and HIV/AIDS. Effective, low-cost interventions are available that could prevent at least two-thirds of these deaths.
  - More than half a million women die each year of pregnancy-related complications, 99% of them in developing countries. Increasing the coverage of cost-effective interventions could reduce maternal mortality rates by as much as 74%.
  - The global HIV/AIDS pandemic continues to worsen. Around 40 million people are now living with HIV/AIDS, over 5 million infections occur each year, and 70% of all infections occur in Sub-Saharan Africa. It is estimated that 6 million people are in need of anti-retroviral therapy but that most (around 93%) currently lack access to it.
- 2.3 Improving access to essential medicines, and to health services more broadly, is therefore key to tackling ill health and reducing mortality rates in the developing world. Essential medicines save lives and improve health when they are available, affordable, of assured quality and properly used. However, lack of access to medicines remains one of the most serious global health problems. Although considerable progress has been made in the last 25 years – since the World Health Organisation

<sup>1</sup> DFID, Better Health for Poor People (November 2000).

<sup>2</sup> Data sourced from: WHO, World Health Report 2003; World Bank, The MDGs for Health: Rising to the Challenge (forthcoming).

(WHO) introduced the essential medicines concept – the benefits have been unequally distributed across the global population. Nearly two thirds of the world’s people are estimated to have access to full and effective treatments with the medicines they need – this leaves one-third without regular access, mostly in Asia and Africa. The problem may be worsening as resistance develops to key medicines, such as those for malaria, TB and pneumonia – and where new medicines are developed to replace those no longer effective, they are frequently more expensive and may also require more stringent supervision to ensure they are properly used.

- 2.4 Progress must be made. It is estimated that by improving access to existing medicines and vaccines, approximately 10 million lives could be saved every year: 4 million in Africa and South-East Asia alone. With the arrival of new medicines and vaccines, even more might be achieved. The international community has long recognised this: developing countries and donor governments alike have committed themselves to action, including through setting appropriate goals and targets, in particular the internationally agreed MDGs. Some of the most relevant targets are set out in Box 1 below. If we are to come close to meeting these very ambitious targets, we need concerted action in line with WHO’s Access Framework covering sustainable financing, affordable prices, reliable health and supply systems, and the rational selection and use of essential medicines<sup>3</sup>, coupled with increased efforts to develop needed vaccines, drugs and other health technologies. This framework is set out in more detail in Section 3 of this paper.

### Box 1: Key international targets for access to medicines

The Millennium Development Goals:

- Goal 8, Target 17 – In co-operation with pharmaceutical companies, provide access to affordable, essential drugs in developing countries;
- Indicator 46 – Proportion of population with access to affordable essential drugs on a sustainable basis

WHO and UNAIDS ‘3 by 5’ target for HIV/AIDS treatment:

- Three million people – two million in Africa – receiving treatment by the end of 2005

The Abuja targets for malaria in Africa:

- Ensure that by 2005 at least 60% of those suffering from malaria have prompt access to, and are able to correctly use, affordable and appropriate treatment within 24 hours of the onset of symptoms

The Amsterdam targets for TB:

- By 2005, 70% of people with infectious TB will be diagnosed, and 85% cured

<sup>3</sup> WHO Policy Perspectives on Medicines – Equitable access to essential medicines: a framework for collective action (March 2004).

- 2.5 The framework for access to medicines demands collective action, by developing country governments and healthcare providers, donors, international agencies, non-governmental organisations, pharmaceutical<sup>4</sup> and biotechnology companies and the broader private sector. Yet more players must be engaged if we are to research and develop new products to tackle diseases prevalent in the developing world, including relevant public-private partnerships, biotechnology 'start-ups', research institutes and academia. These many stakeholders must work together, with shared goals and collective determination, if we are to see progress.
- 2.6 The UK Government accords high priority to the drive to increase access to medicines in the developing world. It is an important part of our work, through the UK development assistance programme and elsewhere, to tackle HIV/AIDS, TB, malaria and other priority diseases and to improve access to health services in the developing world. Progress on access to medicines will be necessary if we are to make progress in maternal and child health outcomes in line with the MDGs, particularly in Africa. This is why the Prime Minister established, in July 2001, the high level UK Working Group on Increasing Access to Essential Medicines in the Developing World<sup>5</sup>; and it is why we have strengthened policy and action across the UK Government in order to implement the Working Group's recommendations.
- 2.7 There are many UK Government departments engaged in the effort to increase access to medicines in the developing world. The relevant departments and their responsibilities include:
- The Department for International Development (DFID) which is responsible for promoting sustainable development and reducing poverty, including through the administration of UK development and humanitarian assistance;
  - The Department of Health (DH) which has responsibility on behalf of Government for sponsorship of the UK-based pharmaceutical and healthcare industries and an interest in international health issues;
  - The Department of Trade and Industry (DTI), which leads on trade policy, including trade-related intellectual property, in collaboration with the Patent Office, holds the sponsorship role for the UK biotechnology industry and leads on business relations with the research-based bioscience industry more generally. Within the DTI, the Office of Science and Technology (OST) has responsibility for the Research Councils and an interest in science and technology capacity building in developing countries;

<sup>4</sup> There has been much recent focus on the role of the international research-based pharmaceutical industry, particularly in relation to the development and supply of ARVs for HIV/AIDS. In this paper, we use the term 'pharmaceutical industry' broadly to include both research-based and (particularly the larger) generics companies, unless otherwise specified.

<sup>5</sup> The Working Group was chaired by Clare Short, the then Secretary of State for International Development, and reported to the Prime Minister in November 2002. The report is available at [www.dfid.gov.uk](http://www.dfid.gov.uk) – progress against the report's recommendations is outlined in Annex 2 of this paper.

- The Patent Office (PO) which administers the intellectual property rights for the UK and is responsible for UK policy on both domestic and international intellectual property issues;
- Her Majesty's Treasury (HMT) which is responsible for promoting UK economic prospects by pursuing international financial stability and increased global prosperity, including especially protecting the most vulnerable;
- The Inland Revenue (IR) which operates the research and development (R&D) tax credit and Vaccines Research Relief;
- The Foreign and Commonwealth Office (FCO) which co-ordinates across Whitehall on the G8 and EU Presidencies which we will hold during 2005.

The Prime Minister's office is also engaged in cross-government policy dialogue on access to medicines, in light of the PM's personal commitment to Africa, and to tackling HIV/AIDS in particular.

2.8 We believe it is important to clearly set out UK Government (HMG) policy on access to medicines, which cuts across many areas of international and UK activity. We are issuing this paper now in order to:

- Follow up on commitments that we have made internationally. These include the MDGs, the G8 commitment at Okinawa to "implement an ambitious plan on infectious diseases, notably HIV/AIDS, malaria and tuberculosis" and the G8 Evian Health Action Plan;
- Report on progress against the recommendations of the high level UK Working Group, which were outlined in its report to the Prime Minister in November 2002;
- Articulate publicly for the first time the effort across HMG to address access to medicines and, where possible, set out our future plans. This includes looking ahead to global-level events next year and beyond – such as the UK Presidencies of the European Union (EU) and G8, the Commission for Africa and the UN 'Stocktake' of progress against the MDGs – and stating our expectations of the international community as we move forwards.

# What do we mean by access to medicines?

- 3.1 People lack access to medicines where they cannot obtain the products they need to prevent or treat a medical condition. This might be because a product is unavailable or is not offered, or because it is unaffordable. So prices, and ability to pay, matter – particularly to poor people and to the governments of the poorest countries. Often, poor people in the developing world pay for medicines out of their own pocket, which can account for 60-90% of their total household spend on healthcare. That some three million people in Vietnam fall into poverty each year because of healthcare related expenditures demonstrates the burden this represents<sup>6</sup>. As a consequence, there has been much focus in recent years on the price of medicines, particularly for newer treatments such as those for HIV/AIDS.
- 3.2 However, price is by no means the only barrier to access. Inadequate financing for health, poor priority setting, inappropriate drug selection and prescription, and weak health and supply systems – often with limited access for the poorest and most marginalised – also play a significant part in preventing people from getting the care they need<sup>7</sup>. Individuals may themselves be unaware of their health needs, or of the health services and products that might be available, or of strategies they can take to protect their own health. The WHO Access Framework sets out the key actions required by developing country governments and others to address access to medicines, and is summarised as follows<sup>8</sup>:

## Rational selection and use of essential medicines

- Develop national treatment guidelines based on the best available evidence concerning efficacy, safety, quality, and cost-effectiveness;
- Develop a national list of essential medicines based on national treatment guidelines;
- Use a national list of essential medicines for procurement, reimbursement, training, donations and supervision;
- Improve prescription and drug use practices.

<sup>6</sup> Wagstaff, cited in Bhushan, I et al: Human capital of the poor in Viet Nam, Asian Development Bank (2001).

<sup>7</sup> WHO Medicines Strategy 2000-2003; also, WHO/IFPMA Action Paper: Improving access to essential drugs through innovative partnerships (2000).

<sup>8</sup> We recognise that the WHO framework is a menu of policy options. Its application will necessarily vary from country to country, with different aspects of the framework prioritised according to context.

### Affordable prices

- Use available and impartial information on prices;
- Allow price competition in the local market;
- Promote bulk procurement;
- Implement generics policies;
- Negotiate equitable pricing for newer essential medicines for priority diseases;
- Undertake price negotiation for newly registered essential medicines;
- Eliminate duties, tariffs and taxes on essential medicines;
- Reduce mark-ups through more efficient distribution and dispensing systems;
- Encourage local production of essential medicines of assured quality when appropriate and feasible;
- Include WTO/TRIPS<sup>9</sup> compatible safeguards in national legislation and apply them as appropriate.

### Sustainable financing

- Increase public funding for health, including for essential medicines;
- Reduce out-of-pocket spending, especially by the poor;
- Expand health insurance through national, local, and employer schemes;
- Target external funding at specific diseases with high public health impact;
- Explore other financing mechanisms, such as debt-relief and solidarity funds.

### Reliable health and supply systems

- Integrate medicines into health sector development;
- Create efficient public-private-NGO mix approaches in service delivery<sup>10</sup>;
- Assure quality of medicines through regulatory control;
- Explore various purchasing schemes such as procurement co-operatives;
- Include traditional medicines in healthcare provision (with associated quality assurance).

<sup>9</sup> World Trade Organisation (WTO) / Trade Related Aspects of Intellectual Property Rights (TRIPS).

<sup>10</sup> Developing country healthcare often involves a broad range of service providers, including the public health service, private clinics, workplace clinics, military hospitals, mission and NGO services, herbalists and other traditional healers, and a wide range of 'informal' drug outlets (sometimes called 'chemical sellers'). Data from many countries suggests that the poorest populations seek care most regularly from traditional healers and the private sector (often 'chemical sellers').

- 3.3 The WHO Access Framework primarily focuses on access to existing medicines. But, for many diseases the array of drugs, vaccines, diagnostics and other technologies is limited. **Research and development for new products** is necessary<sup>11</sup>. The needs vary and much of the science is difficult. Co-ordinated investments are needed across the research process, from basic research, through translational research, into product development and introduction. In some cases existing drugs that no longer have an impact need to be replaced, as for malaria. For TB, whilst the combination of drugs has an impact in simple cases, treatment typically takes 6 to 8 months – a new drug that drastically reduced this time would be a huge help in improving the lives of people with TB. Indeed, in many therapeutic areas, there is a need for drugs that are more easily administered, particularly for children. For many diseases (including HIV, TB and malaria) a preventative vaccine would have a massive impact on the disease burden and the cost-effectiveness of care programmes. To produce a microbicide active against HIV, we need to develop a whole new class of products. These are just examples, but whatever the endeavour it is critical from an early stage to consider the access implications – to develop technology that can be brought to market and delivery modes that are acceptable to target populations, and to manage intellectual property such that products become available and prices affordable. This will require an understanding of, and engagement with, target populations (particularly with respect to the poorest and most vulnerable).
- 3.4 Clearly there is a high degree of interrelationship between all the above factors. They can be mutually reinforcing. For example, lower drug prices can assist in releasing health sector funds to build health systems capacity or to contribute towards country-level research; the availability of affordable medicines gives an incentive for treatment and improves the morale of health workers, and can also improve prescription practices; and sustainable financing by developing country governments and donors can help generate a more stable market for healthcare products, which can encourage needed (and targeted) R&D and facilitate sustainable price reductions. This latter point is particularly important when we consider the mismatch between public health needs in developing countries and the current nature of the global pharmaceutical market:
- WHO estimates that 15% of the world's population consumes 91% of the world's production of pharmaceuticals, by value<sup>12</sup>;
  - Developing country markets constitute 88% of vaccine sector volumes, but only 18% of global revenues from vaccine sales<sup>13</sup>;
  - Africa constitutes just 1.1% of the global pharmaceutical market, by value;<sup>14</sup>

<sup>11</sup> UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (2004) identified target product profiles for Kinetoplastids (Visceral and Cutaneous Leishmaniasis, African Trypanosomiasis, Chagas Disease), Helminths (Schistosomiasis, Onchocerciasis, Lymphatic Filariasis) Tuberculosis and Malaria.

<sup>12</sup> World Health Report 2003.

<sup>13</sup> Mercer Consulting 'Lessons Learned: New Procurement Strategies for Vaccines' (July 2002) at [www.vaccinealliance.org](http://www.vaccinealliance.org).

<sup>14</sup> This statistic is based on global sales data from IMS.

- Every year more than US \$70 billion is spent on health research and development by the public and private sectors. An estimated 10% of this is used for research into 90% of the world's health problems. This is known as "the 10/90 gap"<sup>15</sup>;
- Between 1975 and 1999, of 1,393 new drugs developed only 13 (1% of the total) were to treat tropical diseases, which together account for over 9% of the global disease burden<sup>16</sup>.

This imbalance arises because, whilst public health demand is high, purchasing power is weak – economic demand is therefore too low to stimulate R&D or to encourage a broad range of suppliers to enter the developing world market. Public policy actions that send appropriate signals to the pharmaceutical market must be identified if we are to correct the imbalance and make progress on all the factors outlined above.

3.5 Addressing the barriers to access to medicines therefore requires action to strengthen health systems, and action at policy level – not just in health but in other areas. For example, successfully tackling theft, diversion<sup>17</sup> and the smuggling of counterfeit drugs will require the engagement of customs services and many others, alongside the health sector response; reducing taxes and tariffs on medicines must involve finance ministries and revenue services; and addressing the inaccessibility of health facilities will require the engagement of many stakeholders, including those involved in transport, public works, infrastructural development and local government services. The relationship between access to medicines and trade policy is the subject of significant contemporary debate, internationally and within developing countries, as moves towards harmonisation in areas such as intellectual property protection can present real challenges for developing countries (though, ultimately, this can present opportunities as well). In summary, tackling access to medicines requires action across a range of sectors, involving many players, and against the backdrop of an international environment that is both complex and challenging – it is easy to see why progress is so difficult to achieve.

<sup>15</sup> Global Forum for Health Research website: [www.globalforumhealth.org](http://www.globalforumhealth.org)

<sup>16</sup> See 'Fatal Imbalance' (2001) and other information at Médecins Sans Frontières website: [www.msf.org](http://www.msf.org); it is important to note that there were nevertheless new medicines developed over this period with high relevance to developing country needs, which also have a market in richer countries – ARVs for HIV/AIDS are one example. Other medicines, such as new anti-malarials, have been developed post-1999.

<sup>17</sup> 'Diversion' refers to the rerouting of cheaper medicines, away from the developing world and back to richer countries; 'leakage' is also used to describe the diversion of medicines away from intended recipients, e.g. from the public sector into the private sector, onto the black market, or across regional borders.

## Box 2: Why access to medicines matters – the impact on individuals

### The importance of commodity security for maternal and child health

A lack of affordable medicines and other health commodities has a direct impact on the health of mothers and children. For example, the UN Population Fund (UNFPA) estimate that each \$1 million shortfall in support for contraceptives means an estimated: 360,000 more unwanted pregnancies; 150,000 additional induced abortions; 800 maternal deaths; 11,000 infant deaths; and 14,000 additional deaths of children under 5.<sup>18</sup>

### From UNICEF: Geeta's story

"Geeta (name changed), a 23-year-old woman in Chennai, India, had no reason to suspect that she was HIV-positive. She had been married for only two months when she became pregnant.

When a hospital counsellor at the antenatal clinic asked her if she would like to be tested, she said yes as a precautionary measure. When she got the results, she was devastated. She tested positive. She feared not only that she would pass the virus to her child, but that she would succumb to the disease in a few years, leaving her child orphaned. "When the counsellor told me that I was HIV-positive, I screamed and screamed and then I just wept. I knew what it meant," Geeta said.

A pilot project sponsored by the Indian Government and UNICEF offered her some hope. In January 2000, the National AIDS Control Organization and UNICEF launched the Prevention of Parent-to-Child-Transmission project at 11 medical institutions in India. Three were in Chennai, capital of the southern state of Tamil Nadu, which has one of highest HIV prevalence rates in the country. An estimated 1.5 per cent of the population is affected by HIV/AIDS.

Like some 16,500 pregnant women who have benefited from the project, Geeta first went to the Rajah Ramawamy Mudaliar Maternity Hospital for antenatal care. At monthly sessions with specially trained counsellors, women receive information about pregnancy, diet, exercise, breastfeeding and HIV/AIDS. They are also offered free HIV tests. If they test positive, they are offered free AZT treatment as well as iron and folic acid supplements. Geeta was one of the lucky ones. She received treatment and her baby has tested negative for the disease.

Almost 4 million people live with HIV/AIDS in India, and some 30,000 babies are born HIV-positive each year. Although treatment is available at many clinics, many women fail to make use of it because of the stigma attached to HIV/AIDS. Even Geeta has yet to tell her family that she is HIV-positive. In October 2001, Cipla, an Indian pharmaceutical company, began providing UNICEF with free Nevirapine for HIV-positive mothers and babies. Nevirapine is cheaper and administered more discreetly than AZT. More women are now seeking treatment."<sup>19</sup>

<sup>18</sup> UNFPA website: [www.unfpa.org/supplies/essentials/1a.htm](http://www.unfpa.org/supplies/essentials/1a.htm)

<sup>19</sup> UN Children's Fund (UNICEF) Real Lives, website: [www.unicef.org/infobycountry/india\\_2044.html](http://www.unicef.org/infobycountry/india_2044.html)

- 3.6 What can developed country governments, donor agencies and other key stakeholders do to support developing countries in their efforts to increase access to medicines? Clearly, as the MDGs set out, we share common aims – to reduce child and maternal mortality, and to tackle HIV/AIDS and other major diseases. However, as all stakeholders are under pressure to deliver rapid results, there can be a drive towards ‘vertical’ (disease or issue-specific) programming, which may undermine longer-term efforts to develop appropriate policies and to build health systems capacity. A balance is required, with donor governments stepping in to support policies and programmes that are owned and led by developing countries, to finance and facilitate the development and supply of new health technologies, and to ensure that any issues presented by the broader trade and health policy environment are appropriately addressed.

# What progress have we made?

## 4.1 Action by the UK Government

4.1.1 In recent years the international community has focused attention on the urgent need to increase support for controlling HIV/AIDS and other communicable diseases in the developing world. Significant emphasis has been rightly placed on public and private sector responsibilities at the international level for action to increase poor people's access to essential medicines. Within the UK, much analysis has been undertaken to map out these responsibilities, one example being the 2001 Cabinet Office Performance and Innovation Unit report 'Tackling the diseases of poverty' which outlined a range of options for global financing of R&D and commodity purchase.

4.1.2 Following the G8 Summit in Genoa in 2001, and at the request of the Prime Minister, the UK Secretary of State for International Development established and chaired a Working Group on Increasing Access to Essential Medicines in the Developing World. The Working Group was asked specifically to consider:

- ways of improving access to medicines through measures such as facilitating differential pricing arrangements and encouraging appropriate donations; and
- feasible public policies for adoption by the UK Government to increase R&D into diseases affecting poor people.

4.1.3 The Working Group brought together senior representatives from the UK research-based pharmaceutical industry, the UN, European Commission, Foundations, the Ugandan government, and UK Government Ministers from Health, Trade and Industry, and the Treasury. The Working Group was supported by a series of expert background papers, as well as consultations with UK-based NGOs and international generic pharmaceutical companies. The Working Group's report to the Prime Minister, published in November 2002, supported specific UK actions on the R&D agenda, and outlined steps towards a global framework to facilitate voluntary, widespread, sustainable, and predictable differential pricing<sup>20</sup>.

4.1.4 Today, 20 months after the Working Group made its recommendations, it is clear that some important progress has been made. For instance, the EU Regulation on diversion of differentially priced medicines has taken effect; the G8 has made specific commitments on access to medicines and R&D through the Evian Health Action Plan; individual pharmaceutical companies have made further pricing offers to developing countries and some have strengthened their related R&D. The EU has created the valuable European and Developing Country Clinical Trials Partnership which

<sup>20</sup> DFID, Report to the Prime Minister of the UK Working Group on Increasing Access to Essential Medicines in the Developing World: Policy Recommendations and Strategy (November 2002).

will make available at least Euro 400 million for clinical trials and capacity building in Africa. In the UK, immediate actions included the introduction of the Vaccines Research Relief in April 2002, which took effect in April 2003<sup>21</sup>. The progress to date is set out in more detail, alongside the original Working Group recommendations, in the table at Annex 2 of this paper.

- 4.1.5 Following on from the Working Group, the UK Government has worked to increase policy coherence across the full range of issues affecting access to medicines in the developing world, from TRIPS and Public Health through to R&D incentives and investment. Nine different UK Government departments are now engaged in this effort, co-ordinated by DFID (see 2.7 above for a list of the relevant departments). Within DFID, an Access to Medicines team was established in April 2003 to take forward immediate policy work in this area, complementing DFID work at country level, in international fora and on related policy issues such as HIV/AIDS and research.
- 4.1.6 In addition, the UK Government recently funded a Commission on Intellectual Property Rights to examine how intellectual property rights (IPRs) could be made to work better for developing countries and poor people – in health and other areas. The Commission was set up in May 2001 and given complete independence to reach its own conclusions. It was chaired by an American Law Professor and included five other international experts on IPRs. The Commission reported in September 2002, which was followed by the UK Government's response in May 2003. The response did not endorse the entirety of the Commission's report or its recommendations, but broadly considered that the report had raised important issues that the international community should continue to debate. It also endorsed a number of recommendations from the report, a number of which are being followed up through DFID's IPR strategy. As hitherto, the lead on IPRs lies with DTI and the Patent Office, but the strategy highlights a specific role for DFID particularly in the areas of technical assistance and research specific to developing countries. Within this work, health aspects have been given priority.

## 4.2 Action by others in the UK

- 4.2.1 **Civil Society** has played a key role in building momentum around the drive to increase access to medicines in developing countries. In the UK (and beyond) VSO, Oxfam, Christian Aid, The Essential Drugs Project, ActionAid, Save the Children Fund and many others have been working on access to medicines and related issues for several years. The Essential Drugs Project in particular acts as a catalyst and information resource for many NGOs and others, and has received financial support from them. Other important work in the NGO sector includes that on corporate social responsibility in the pharmaceutical industry<sup>22</sup>; campaigns to provide treatment to people living with HIV/AIDS, and related work on the use of fixed-dose combination

<sup>21</sup> Also in April 2002, provision was made to remove a tax disincentive which could have applied to gifts of medical supplies or equipment for humanitarian purposes.

<sup>22</sup> Oxfam, VSO and SCF produced a landmark report entitled 'Beyond Philanthropy' (2002) calling for companies to mainstream access to medicines within business strategies.

ARVs; and campaigns linked to TRIPS and Public Health, in the context of broader work on global trade rules. NGOs can play a particularly important role in highlighting equity concerns and ensuring that the needs of marginalised communities are considered in global policy debates. For example, international civil society organisations such as Médecins Sans Frontières (MSF) and Health Action International (HAI) play a critical role in bringing evidence from countries, including findings from operational research, to the table in international fora.

4.2.2 **Research institutions** in the UK have a long history of engagement in international public health. In basic and clinical research the Medical Research Council has partnered DFID both via a Concordat arrangement and specific contracts to develop new products, of late most notably microbicides. The Wellcome Trust have recently established a new theme concentrating on 'public health and populations' and have a strong portfolio of malaria research in particular that they are keen to see picked up and translated into products. Many individual universities have excellent capacity, for example the University of Oxford is engaged in developing both malaria and HIV vaccines, whilst the International AIDS Vaccine Initiative's core Immunology Laboratory is based at Imperial College London. The London School of Hygiene and Tropical Medicine and the Liverpool School of Tropical Medicine engage both in developing technology and in evaluating its effectiveness in implementation, advising policy makers and managers on how to maximise impact and use.

4.2.3 **International pharmaceutical companies** are also engaging in the drive to improve access to medicines in a number of different ways. Traditionally this is in terms of the delivery of new medicines and health technologies that are responsible for saving lives and improving quality of life on a global scale. However, increasingly the pharmaceutical industry also engages through:

- Addressing the affordability of medicines in poor countries, including through differential pricing offers;
- Increasing research and development into diseases prevalent in developing countries, involving issues related to levels of investment, the management of intellectual property, and conduct of clinical trials;
- Engaging with developing countries in manufacture and supply, including through out-licensing and the transfer of technology.

International pharmaceutical and biotechnology companies have increased their engagement in the above areas in recent years and are strengthening their collaboration with other companies, research institutes and other stakeholders. Some UK examples are given in Boxes 3 and 4 below.

### Box 3: Access to medicines: the role of UK companies

#### Case study: GlaxoSmithKline

GSK's Chief Executive Officer, JP Garnier recently stated that "when I took over as CEO of GSK, I said that I did not want to be head of a company that caters only to the rich. I stand by that"<sup>23</sup>. GSK stands out particularly in terms of the transparency of its pricing offers, regular updates on progress, the scope of its R&D for diseases disproportionately affecting developing countries, and commitments to the regular review of pricing offers.

In terms of affordability, GSK has committed to making its anti-retroviral and anti-malarial medicines available at not-for-profit prices. It has produced clear documentation outlining eligible countries (Sub-Saharan Africa, all Least Developed Countries and all projects fully financed by the GFATM – making a total of 100 countries currently) and eligible organisations (governments and other not-for-profit providers, and private companies providing treatment to uninsured employees in Sub-Saharan Africa). Prices for the relevant products are published, and are CIP (Carriage and Insurance Paid to destination). The company is also involved in pilot projects in five African countries to assess the feasibility of offering a wider range of products at preferential prices. GSK was instrumental in the development of the EU Anti-Diversion Regulation and has registered seven products under it. It has sought to explain the merits of the Regulation to other companies. It has also developed differentiated packaging and tablets for its leading ARVs in an attempt to stop diversion. Finally, GSK has developed R&D, voluntary license and technology transfer agreements with companies in South Africa, India and with the Brazilian Government's Fiocruz.

GSK believes that it is the only company undertaking R&D into both prevention and treatment of the WHO's three priority diseases – AIDS, TB and malaria. It regularly reports on the number of R&D projects of relevance to the developing world (16) and on those aimed at producing medicines and vaccines for diseases disproportionately affecting developing countries (7). The company reported 27 ARV clinical trials in developing countries in 2004. GSK's R&D for other diseases affecting developing countries revolves around a dedicated group based in the UK and Spain, for which drug development projects are prioritised primarily on their socio-economic and public health benefits rather than potential commercial returns. New work in 2003 included a new meningitis vaccine produced in collaboration with WHO, extended investment in the Medicines for Malaria Venture, and the launch of Lapdap for the treatment of malaria.

The company also works with community groups in over 100 countries on health and education programmes, with a major focus on HIV/AIDS, lymphatic filariasis and malaria. This includes the Positive Action Programme which partners with 28 community-based organisations to promote HIV treatment literacy and care for people living with HIV/AIDS in 34 countries.

Finally, GSK seeks to extend its influence to encourage international donors and multilateral institutions to provide further support to increase access to medicines, as well as engaging in debate at the national level to encourage developing country governments to strengthen health systems and address stigma, particularly against HIV/AIDS.

<sup>23</sup> GSK, Facing the Challenge: Two Years On (January 2004).

- 4.2.4 Companies are working sometimes individually or, as is increasingly the case, in joint initiatives with partners from the public or the private sector. 'Public-Private Partnerships' (PPPs) have become increasingly common, seeking as they do to bring together stakeholders to combine their expertise and capacities. Examples include Merck's Mectizan (ivermectin) donation programme as part of the partnerships to eradicate onchocerciasis in Africa, the International Trachoma Initiative (a partnership between Pfizer and the Edna McConnell Clark Foundation to eliminate blinding trachoma) and the partnership between WHO, DFID, GSK, the Liverpool School of Tropical Medicine and other researchers to develop the low-cost anti-malarial drug Lapdap. Many argue that PPPs offer a way of closing the gap that can exist between the needs of the private sector, and the objectives – in terms of public health and global public goods – of the public sector and civil society. Issues of sustainability cut across all industry activities, with great importance placed on the predictability and durability of different approaches.
- 4.2.5 **UK investors** have also been proactive, encouraging pharmaceutical companies to explore their roles in improving access to medicines in developing countries, stressing the importance of integrating access issues into business strategy, and initiating efforts by pan-European investors to engage more systematically in the access to medicines agenda. The Pharmaceutical Shareowners Group issued an investor statement on pharmaceutical companies and the public health crisis in emerging markets in March 2003, which set out a framework of best practice for the sector. This demonstrated that investors were legitimately concerned about the potential impact of access to medicines on the long-term sustainability of the sector and emphasised the importance of companies responding proactively, to protect their license to operate and to secure long-term shareholder value.

## Box 4: Developing new medicines: the role of UK companies and research organisations

### Case study: AstraZeneca

In 2001 AstraZeneca made a \$10 million capital investment in new laboratories at its R&D facility in Bangalore, India, which was completed and opened in June 2003. Work at the Bangalore Research Institute is focused on finding a new treatment for tuberculosis, an infectious disease that is newly diagnosed in some two million people every year in India and in over eight million people worldwide. It is the single largest cause of adult death from infectious disease in the world. AstraZeneca is the only pharmaceutical company with a research programme in India totally dedicated to TB. The company is also spending another \$10 million on state-of-the-art equipment and has committed a minimum of \$5 million a year from 2001 to 2005 to support the research programme. More than 80 scientists recruited from leading research institutions around the world currently work at the facility, and the company plans to recruit more international experts over the coming years.

Backed by advanced technologies such as microbial genomics, AstraZeneca's scientists in Bangalore are focused on developing improved diagnostic tests and discovering new therapies that are more effective against persistent organisms and resistant bacteria that are increasing in incidence. The Bangalore scientists also work closely with AstraZeneca's infection research centre in Boston, US, and with external academic leaders in the field.

### Case study: UK Research Institutions

*The Wellcome Trust* funds science and technology research and capacity building in developing countries via investment in research centres, alliances and fellowships. As examples, in Kenya the Wellcome Trust-KEMRI Research Programme in Nairobi targets the pharmacology and therapeutics of antimalarial drugs, as well as malaria epidemiology, control and health policy. The South East Asia Major programme is based in Bangkok (Thailand) and Ho Chi Min City (Vietnam). Amongst other diseases, it is investigating avian influenza, typhoid, diphtheria, dengue, tuberculosis and malaria.

*The Medical Research Council* (MRC) has funded, and participated in, a number of clinical trials aimed at optimising or evaluating drug interventions for HIV in adults and children. MRC's Clinical Trials Unit Division of HIV Research focuses on preventing infection (vaccines, microbicides) and optimising the long-term use of effective therapies for those who are infected. Paediatric trials are co-ordinated through the Paediatric European Network for the Treatment of AIDS (PENTA). Many of the trials involve unlicensed drugs or new uses for licensed drugs and may be used as supporting evidence for licensing applications in the UK and Europe. Over the last 5 years the Unit has been involved in 16 trials addressing HIV therapy and management in adults and 6 in children; one 'phase I' trial of candidate vaccine product in HIV negative people and three 'phase II' trials of the potential microbicide dextrin sulphate. MRC has an intellectual interest in dextrin sulphate, as it is MRC funded research that first demonstrated the antiviral properties of the compound.

### 4.3 Broader international progress

- 4.3.1 Beyond the UK, there has been good progress made on key **European Union** activities. Key to this was the agreement reached in May 2003 on a new EU Regulation (953/2003) to tackle the diversion of differentially priced medicines away from developing countries, in the hope that this will encourage companies to offer a greater range of products at significantly reduced prices. Several pharmaceutical companies are now taking steps to register products with the European Commission under the terms of this Regulation. The European Commission is also undertaking important work to strengthen the EU framework for research on poverty-related diseases. This includes the establishment of a European and Developing Countries Clinical Trials Partnership (EDCTP) and analytical work to assess whether additional incentives might be offered by the EU to encourage greater private sector investment in R&D.
- 4.3.2 The **G8** Health Action Plan launched at the Evian Summit in June 2003 emphasised the need to take an integrated approach and to work in partnership with a broad range of stakeholders, including industry. The integrated approach included actions on pricing and affordability, but also tackled product diversion and systems leakage, and an agreement by G8 countries not to benchmark prices in their own markets against those for partner countries. The G8 Health Action Plan is in line with the UK's overall approach and provides a good basis for collaborative action by G8 and other donors and the broader international community. Building on these past commitments, the G8 announced in Sea Island this year its support for a global HIV vaccine enterprise, to co-ordinate and accelerate R&D in this field.
- 4.3.3 The **WHO** is responsible for setting global norms and standards in health and remains a major stakeholder on access to medicines issues. In addition to ongoing work on health systems, essential drugs and medicines policy and standards, and communicable and non-communicable disease control, WHO has recently launched several major initiatives intended to increase access to medicines and other healthcare products. These include new commodity facilities for HIV/AIDS (the AIDS Medicines and Diagnostics Service) and malaria (the Malaria Medicines and Supplies Service) alongside that for TB (the Global TB Drug Facility established under the Stop TB partnership banner). In addition, on World AIDS Day 2003 UNAIDS and WHO launched the '3 by 5' initiative to provide access to antiretroviral therapy to 3 million people in developing countries by the end of 2005. The UK Government moved swiftly to contribute £3m (\$5m) to this initiative. This is in addition to the £12.5m that DFID already provides annually to WHO to finance its overall work programme, and the UK's assessed contribution to WHO met by the Department of Health (\$23.4m per annum, and set to rise in line with changes in UN assessments). One important WHO-led initiative is the United Nations pre-qualification project (Procurement, Quality and Sourcing Project: Access to HIV/AIDS, tuberculosis and malaria products of acceptable quality) in which products and manufacturers are assessed to ensure quality, safety and efficacy (or bio-equivalence) standards are met. It ensures that developing countries and global health initiatives can feel secure in their procurement and use of

key products. Another important initiative is the recently established WHO Commission on Intellectual Property Rights, Innovation and Public Health.

- 4.3.4 The UK is an active member of a number of **global health initiatives and partnerships**. These have the potential to contribute to increasing access to essential medicines through providing supra-national support to health programmes. Partnerships differ in their objectives and main modes of operation, and include those that provide financing, co-ordination of stakeholders, technical assistance, or advocacy. Partnerships have most potential where they develop complementary and effective working relationships with other players – including multilateral agencies such as the WHO – and clearly demonstrate their added value.
- 4.3.5 Partnerships which provide *sustainable financing* – such as the Global Fund to Fight AIDS, TB and Malaria (GFATM) and the Global Alliance on Vaccines and Immunisation (GAVI) – can act as a channel for increased aid flows to countries, and leverage additional private sector funds. Larger financing partnerships are able to make use of their size and longer-term commitment to secure products in the market. The GAVI Vaccine Fund has aimed to bring forward production and marketing of vaccines close to market availability, to ensure a secure supply and therefore reduce the risk for vaccine manufacturers as they scale up production. This in turn will impact on prices, as increased supplies are available on world markets. In the case of the Hepatitis B vaccine, the price per dose is expected to fall rapidly (from \$2 per dose in 1993 to less than 50c by 2004/5). Security in the market has also encouraged the emergence of new manufacturers in India and China.
- 4.3.6 *Co-ordination functions* are wide-ranging. One example is the Global TB Drug Facility which – in addition to its technical assistance, quality assurance and capacity-building roles – combines centralized, pooled procurement with a grant-making facility. It is therefore able to guarantee a minimum demand to negotiate prices with manufacturers. Drug prices have fallen – by approximately 30% compared with previous international tenders – to less than US\$10 for a 6-8 month course of treatment. Many developing countries had been paying far higher prices due to inefficient procurement mechanisms.
- 4.3.7 Partnerships providing *technical assistance* support national governments and agencies on technical strategies or policies, quality assurance and procurement procedures for medicines. They also support countries in their relations with other players, including financing partnerships. For example, the Stop TB and Roll Back Malaria partnerships both have a key role in supporting countries to develop effective proposals for the GFATM, and in fostering networks to share knowledge and experience.

- 4.3.8 Global initiatives can also engage effectively in *advocacy and brokerage*. For example, the Clinton Foundation has engaged in brokering price reductions for HIV/AIDS drugs and diagnostics, in part through assistance to manufacturers to examine (and address) efficiencies in production. Effective working relations between the Clinton Foundation and other partnerships offer the potential to extend these benefits. An agreement between the Clinton Foundation, the GFATM, World Bank and UNICEF should allow countries supported by these agencies to gain access to the drug and diagnostic prices brokered by the Clinton Foundation.
- 4.3.9 Finally, there are a growing number of international partnerships (often referred to as product development Public-Private Partnerships – PD PPPs) designed to *co-ordinate and enhance R&D* within a particular field of health research. These include the Medicines for Malaria Venture (MMV), the International AIDS Vaccine Initiative (IAVI) and the International Partnership for Microbicides (IPM) – all of which the UK supports – as well as a range of other PD PPPs covering TB, neglected tropical diseases and diagnostics. Key advantages of the partnerships are their abilities to:
- generate efficiencies by allowing researchers to share information and collaborate more effectively along the spectrum from basic research into product development;
  - expand the volume of R&D on diseases that disproportionately affect the poor through pooling investments in R&D from across the public, private and philanthropic sectors, leveraging scientific interest and product development skills;
  - accelerate the R&D process through higher levels of funding, interest and market demand;
  - seek improved efficacy by prioritising the most likely candidates for investment (through what is sometimes called a ‘portfolio’ approach to product development);
  - seek affordability by selecting the most appropriate science and managing intellectual property in the interests of the poor.

Collectively, these factors should increase the chances of success, which may in turn increase levels of investment in R&D for the developing world by donors, the private sector and other potential financiers.

- 4.3.10 Another key issue within the access to medicines agenda relates to the broader trade and economic environment. **The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights** (the TRIPS Agreement) lays down minimum standards for intellectual property protection in WTO Member States. A major concern in developing countries relates to the implications of the extension of intellectual property protection in developing countries for poor people’s access to medicines – most notably, the impact that the introduction of the TRIPS Agreement either has had or will have (when fully implemented) on the price of patented medicines.

- 4.3.11 In recognition of the gravity of the public health problems afflicting many developing and Least Developed Countries (LDCs), especially those resulting from HIV/AIDS, TB, malaria and other epidemics, the WTO produced a Ministerial Declaration on TRIPS and Public Health (Doha, November 2001)<sup>24</sup>. This reaffirmed the flexibilities within the TRIPS Agreement, stating that the Agreement does not, and should not, prevent countries from taking measures to protect public health. In effect it confirmed the status quo, whereby each WTO member has the right to utilise TRIPS-compliant measures, including the issuing of a compulsory license (CL)<sup>25</sup>, in the face of a public health need. The Declaration also extended to 2016 the date by which LDCs need to implement their obligations in the pharmaceutical sector under the TRIPS Agreement.
- 4.3.12 Paragraph 6 of the Declaration recognised that, since any medicines produced under a CL had to be predominantly used in the domestic market, countries with no, or insufficient, capacity in the pharmaceutical sector were unable to benefit from CLs. Prior to 2005 this is not a problem since some of the countries producing copies of patented medicines are developing countries that have not fully implemented TRIPS (such as India). After 2005, these countries are obliged to implement TRIPS, and while continuing to make copies of existing patented medicines for export to other countries would have been permitted, the copying of newly patented medicines would not. The Declaration mandated the TRIPS Council – the WTO body which administers the TRIPS Agreement – to find a solution to enable countries with insufficient or no manufacturing capacities in the pharmaceutical sector to make effective use of the compulsory licensing provisions already present in the TRIPS Agreement. It is on this issue – the outstanding mandate from Doha – that agreement was reached in Geneva, immediately before the WTO Ministerial in Cancun in September 2003.
- 4.3.13 The TRIPS and Public Health Decision (General Council, 30 August 2003) lays the legal groundwork to allow poor countries with no, or insufficient, manufacturing capacity in their pharmaceutical sector to import copies of patented medicines. These can be imported from countries such as India, following the issuing of a compulsory license in both the importing and exporting country.

<sup>24</sup> The Doha Declaration on the TRIPS Agreement and Public Health (reference WT/MIN(01)/DEC/W/2, date 14th November 2001) re-affirmed the right of WTO Members to use, to the full, the provisions of the TRIPS Agreement which provide flexibility for this purpose. These flexibilities include:

- In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
- Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.
- Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
- The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

<sup>25</sup> A compulsory license is where an appropriate government body (the Patent Office in the UK) licenses the manufacture sale and distribution of an invention to an authorised third party without the consent of the patent holder.

4.3.14 The Decision is a significant step. It should help increase supply and availability through market competition, and should also help to reduce the price in poor countries of patented medicines that come onto the market after 2005. The option to use compulsory licensing provides countries with a useful bargaining tool for negotiating prices with suppliers of patented medicines and should encourage the latter to reduce prices. Discussions continue in Geneva, with a view to turning the 30 August Decision into an amendment to the TRIPS Agreement. The UK Government would prefer to see a swift conclusion to these discussions and an amendment which faithfully reflects the agreement reached on 30 August. However, it is worth noting that delays in concluding on the textual amendment to the TRIPS Agreement will not affect countries' ability to use the Decision, which is already a part of the WTO statute book.

## 4.4 Progress by developing countries

4.4.1 Of course, much recent progress has been made within developing countries, by governments and other stakeholders. There are many examples of good practice – we draw out just two in Box 5 below. Examples of general trends across many countries include:

- Improvements in health service performance and utilisation are being reported by a number of countries in Sub-Saharan Africa (SSA), where increasingly donors are providing support through government budgets. In Ghana, immunisation rates have increased and more nurses have been deployed. In Uganda, outpatient attendances have almost doubled, user fees have been removed for primary health services, the drug budget has doubled, immunisation rates have increased by 20%, and health worker numbers have increased substantially. In Tanzania immunisation rates have increased, Vitamin A and malaria bed-net distribution has increased and there is improved malaria treatment; and in both Uganda and Tanzania planning and management of services at the district levels has improved significantly. In due course, all of these improvements can be expected to lead to better child and maternal health outcomes.
- Greater attention is being given to the need for enhanced and more effective domestic financing for health, supported in part by the evidence collated by the 2001 Commission on Macroeconomics and Health (CMH) – in addition to taking such work forward through national planning departments and committees, several developing countries have established temporary national CMHs to undertake further analysis at country level. A key health financing strategy being considered in many countries is national health insurance, to include reimbursement of drug and other healthcare costs for the poorest. Whether such strategies can be successfully implemented will be a key factor in determining the extent to which the poorest populations can secure access to essential medicines.
- Many developing countries are making needed drug policy changes – for example, to Artemisinin-based Combination Therapy (ACT) for malaria – based on technical advice and support from WHO and other competent authorities, and are taking steps to incorporate ARVs for HIV/AIDS into their Essential Medicines Lists.

- Beyond the health sector, developing countries are considering the implications of TRIPS compliance and some are already incorporating TRIPS-compatible safeguards into their national patent legislation; and many countries are pressing ahead with the reduction of taxes and tariffs on key medicines and other healthcare products such as bed-nets.

## Box 5: Recent progress by developing countries

### Case study: Ghana

The Government of Ghana has made important strides in strengthening health systems and improving essential medicines access, supply and logistics. Recent national drug policy revision and intellectual property legislation have provided a sound basis for the protection of public health and the development of a supportive rights and trade environment. Standardised pricing, quality assurance and strengthened procurement and supply management are contributing to greater access for the poor and greater confidence in the public sector.

With support from DFID, a cross-government advisory group under the Ghana National Drugs Programme, with private sector and development partner participation, has embarked on concrete actions to further strengthen the enabling environment and enhance Ghana's programme to sustainably increase access to essential medicines. In partnership with WHO and other agencies, Ghana will evaluate its position on local manufacturing and the importation of high priority drugs for AIDS, TB and malaria, and examine barriers to and opportunities for greater regional trade. Harmonisation of patent laws is underway and guidelines for the use of TRIPS safeguards will assist in making flexibilities work for better pricing as the country scales up its response to priority diseases. This will be complemented by actions to strengthen pharmacovigilance and improve consumer education and demand.

### Case study: the Caribbean

The Eastern Caribbean region has taken progressive steps over recent decades to increase access to medicines, for example through regional bulk procurement and harmonisation of essential medicines lists and regulatory systems. Against this backdrop, the Clinton Foundation has recently negotiated advantageous ARV procurement deals with a number of generic manufacturers in India and South Africa that will enable initial purchase by the OECS (Organisation of Eastern Caribbean States) at US\$239 per patient per year. This represents a saving of more than 60% on prices currently paid by OECS countries. Work is ongoing to reduce freight charges, which are particularly high in the Caribbean, so that the OECS Pharmaceutical Procurement Service will soon access these medicines at ever lower cost.

DFID Caribbean are working with the OECS countries to "quick start" and further support the coordinated HIV/AIDS treatment programme in the sub-region. Among other things the funds will provide immediate access to ARVs for some 300 people who are currently not in treatment programmes.

# Future strategy and plans

## 5.1 Strategic priorities for the UK

5.1.1 Increasing access to essential medicines in the developing world will remain a priority for the UK internationally and for cross-government collaboration. As we plan our future activities in this area, we will pay particular attention to the opportunities presented in 2005 by the UK Presidencies of the G8 and EU – during which Africa and HIV/AIDS will be particular priorities – the work of the Commission for Africa, the UN ‘Stocktake’ of progress against the MDGs and discussions on the International Finance Facility (IFF). HMG activities will contribute to three strategic objectives:

- **Strengthening the UK contribution** to efforts to increase access to existing medicines in developing countries and to expand and accelerate R&D into new drugs, vaccines, diagnostics and other healthcare products for the developing world;
- **Stimulating greater commitment and action from other stakeholders**, and encouraging stronger collaboration and harmonisation between them, with a particular focus on partnerships between the public and private sectors;
- **Building a stronger enabling environment** for action at international and country level, with particular attention to the impact on access to medicines of policies beyond the health sector (e.g. economics, trade and regional integration).

With these objectives in mind, we plan a range of activities across HMG. These are outlined below.

## 5.2 Priorities for the UK development assistance programme

5.2.1 In many developing countries, DFID is moving increasingly towards support to government budgets (Poverty Reduction Budget Support) and unearmarked sector-wide funding, in order to better support national priorities and minimise transaction costs. However, in health as well as other areas, DFID also aims to support countries through technical assistance and earmarked programming where appropriate – again this would be in support of national priorities and plans, such as those for tackling key diseases, reducing child and maternal mortality or building health systems capacity. Such support might include:

- Programmes to strengthen health infrastructure and management and improve access to health services (the priorities for work in this area are set out in more detail in Box 6 below);
- Assistance in developing appropriate national drug policies, particularly where a major change in policy is envisaged e.g. for malaria;

- Disease-specific programming where appropriate and supportive of broader health strategies – current examples include funding for malaria, e.g. in Tanzania; for polio, e.g. in India, where steps are being taken to integrate polio into routine immunisation; for HIV/AIDS in many countries, including South Africa, Nigeria, Uganda, Cambodia and Russia; for TB, e.g. in India and China;
- Programmes to improve reproductive and maternal health services and access to them;
- Government-wide support relevant to medicines, e.g. strengthening government procurement, improving customs services and vigilance, developing appropriate trade policies;
- Building the capacity of developing countries to engage in global trade, innovation, and R&D;
- Responding swiftly and appropriately to emergency situations, e.g. DFID recently provided funds for the use of a new vaccine to tackle the emerging meningitis epidemic in West Africa.

DFID policy and action in these areas is not covered in detail in this document. It is set out elsewhere, for example in the 2000 DFID publication 'Better health for poor people,' and in forthcoming documents – such as the HMG Strategy on HIV and AIDS and associated policy on treatment and care, and papers on reproductive health and maternal mortality.

5.2.2 DFID is in the process of developing internal guidance on how best to pursue strategies to increase access to medicines through the above modes of support. Where appropriate, research is being commissioned to inform the development of guidance notes and policy approaches. We will also draw on some of the more innovative approaches taken at country level, such as the multi-stakeholder approach being pursued by the Government of Ghana (see Box 5 above) and the work of Management Sciences for Health (MSH) and others on the accreditation of informal chemical sellers.

#### **Box 6: Strengthening health systems to deliver medicines to the poor**

Many of the poorest and most vulnerable people in the developing world do not have access to the health services they need. Health systems are often ill equipped to deal with present demands, let alone emerging public health priorities. The financing burden falls disproportionately on the poorest. DFID believes that no-one should be denied access to basic health services on the basis of their inability to pay.

UK development assistance for health emphasises the importance of strengthening health systems as a means for *increasing access to health services*. This includes ensuring access to commodities such as drugs, vaccines, diagnostics and contraceptives. Accordingly DFID has committed over £1.5 billion to strengthening health systems since 1997. Wherever possible, this work is in support of country-led poverty reduction and health sector strategies.

## Improving provision and access

Greater access to health services is essential if the health-related MDG targets are to be met. Services should be appropriate to local needs, acceptable, affordable, physically accessible and of high quality. Making services work for poor people in this way involves both changing service delivery arrangements and reforming public institutions. It requires governments to be accountable to their citizens by putting poor people at the centre of service provision. Governments have responsibility for leadership, policy direction, regulation and finance, and ensuring adequate and high quality delivery of health services through the public, private, or not-for-profit sectors. Regulation, better information and monitoring systems can help *improve accountability* of providers to citizens and governments. Building effective demand for services is also required. This entails a commitment to increasing poor people's voice in policy-making and improving their ability to hold providers accountable for the delivery and quality of services. *Strengthening the voice of poor people* to demand health services might occur through consultation on health sector or poverty reduction strategies, through institutions that articulate rights or entitlements, or through political processes. Creating the conditions for citizens to participate in the monitoring or oversight of providers can help improve accountability and quality of service (e.g. helping to deal with high absenteeism amongst healthworkers).

On the supply side the UK is working with partners at country-level to *increase the supply of services*, addressing key constraints including infrastructure, management, trained staff, commodity security, and mechanisms to ensure evidence-based practice.

## Key constraints

*Increased financing* (both domestic and international) for health is needed. In 14 SSA countries annual public spending on health is less than \$5 per capita each year, but in some SSA countries this is increasing (e.g. Mozambique) as a result of increased political commitment. But increased financing alone is not enough. Recent evidence indicates that public financing for health services disproportionately benefits the better off. Improving accountability and oversight can help make financing progressive and ensure it reaches front line service providers and patients in an equitable manner.

The critical shortage of *service providers and other human resources for health* is a major challenge for many countries. This will require short and longer-term responses to problems such as low pay and poor incentives, migration, deployment and retention as part of wider service delivery systems.

The UK Government is undertaking work on improving access to services in difficult environments including those that are in, at risk of, or emerging from conflict. In these contexts improving the accountability of state to citizens may be impossible. Working through the UN system to build accountability and deliver services, and strengthening the role of private providers are some ways to improve access. These states contain 14% of the world's population – without addressing access concerns in these contexts we will not meet the MDG targets.

continued overleaf

### International action

Internationally, the UK (DFID and HMT) is working with a group of senior policy makers from developed and developing countries through *The High Level Forum on the Health-Related MDGs* to take stock, review progress and identify opportunities for accelerating action on the health-related MDGs, particularly action to increase access to health services. The central themes of the first meeting and resulting Recommendations for Action<sup>26</sup> were: resources, effectiveness and harmonisation, human resources as a critical constraint to scaling up, and monitoring progress.

The UK Government will continue to support *WHO's role in technical co-operation at country level* with governments and other stakeholders to develop appropriate drug policies, define essential medicines lists, manage procurement and distribution systems, and facilitate rational use of medicines. We will also encourage WHO to strengthen its internal collaboration and coherence, across related workstreams such as essential drugs and medicines policy, health systems, tropical disease research and work on major diseases e.g. HIV/AIDS, TB and malaria.

- 5.2.3 DFID will also continue to lend its support to **global health funds and partnerships** which are poverty focused, which are effective aid instruments, which clearly add value and are complementary to other players. Whilst we recognise that different kinds of partnerships will be needed for different diseases, we will support implementation, lesson learning and knowledge transfer between countries and between the different partnerships that provide similar services. We are keen to see that the newer WHO mechanisms for support to countries on drugs and other commodities for malaria and HIV/AIDS learn from the successes of the Global TB Drug Facility, and are able to assist in the development of country capacity to effectively access sources of finance including the GFATM.
- 5.2.4 We will support developing country representation in the governance of partnerships, and will also seek to empower and support the WHO to play a proper role at country and regional level to stimulate effective use of partnerships by country governments. Where appropriate we will fund regional fora for knowledge transfer and lesson learning – as we have done in the past for Roll Back Malaria.
- 5.2.5 We recognise that funds and partnerships involved in commodity purchase can have a profound impact on the nature of the pharmaceutical market in developing countries. We will endeavour to take full account of this in determining our own financial contributions to such funds and partnerships. We will support the GFATM, and other partnerships, to monitor the prices of relevant commodities and to make this information freely available, including to organisations compiling drug price

<sup>26</sup> World Bank and WHO. High-Level Forum on the Health MDGs. Geneva, 8–9 January 2004. Summary of discussions and agreed action points.

information sources (such as WHO, MSH and MSF). We also recognise the need to accelerate the price reductions that accompany market maturity, through arrangements such as advance purchase contracts for specific types of product. For example, the core strategy of the Global Alliance for Vaccines and Immunisation (GAVI) is to encourage earlier production of vaccines and accelerate market maturity and falling prices, through commitments to purchase specific vaccines.

- 5.2.6 The UK has proposed the formation of an International Finance Facility (IFF), which would front-load aid resources and ensure a longer term and predictable flow of funds to countries. GAVI have approached DFID and HMT to explore whether IFF frontloading principles can be applied to their own financing structure. We are currently supporting technical work with GAVI to better understand the scope of this opportunity. Such an initiative would potentially strengthen the organisation's ability both to send signals to manufacturers of vaccines to increase production and encourage new investments, as well as providing greater predictability and security of funds to countrywide immunisation systems. Using long-term donor commitments, GAVI would issue bonds in capital markets, thereby bringing forward development resources for use in the short-term when they can make the greatest difference. Because donor commitments would be made on a 10 to 15 year basis, this form of financing would provide a stable, predictable flow of resources enabling market supply obstacles to be overcome, lowering the price and increasing the supply of current and near to market vaccines.
- 5.2.7 DFID's programmatic work is complemented by UK Government **engagement in international fora**. This includes our engagement in the World Health Assembly and WHO Executive Board, with UNAIDS, UNFPA and UNICEF, with the World Bank, and in the United Nations General Assembly and its Special Sessions. We will continue to pursue UK Government policy objectives for health and development through such fora. More recently, the WTO has become more important, due to the reasons set out in Section 4 above. Our plans in this area are set out in the next section.

### 5.3 TRIPS and Public Health

- 5.3.1 The UK Government is fully committed to the Doha Declaration on TRIPS and Public Health and to **facilitating the implementation of the TRIPS and Public Health Decision** reached at the WTO on 30 August 2003 (see Section 4.3 above for details). Three strands of work are planned:
- Working with other WTO Member States via the EU to amend the TRIPS Agreement;
  - Amending UK patent legislation in the context of a coherent EU approach;
  - Funding research and capacity building to facilitate implementation of the Decision at country level.

- 5.3.2 The Decision required the TRIPS Council to initiate work on **amending the TRIPS Agreement** to reflect the Decision by the end of 2003, with a view to such an amendment being adopted within six months. The UK Government is working closely with the European Commission to ensure that the amendment clearly reflects the 30 August Decision. It is essential that discussions on substantive issues are not reopened. One of the UK's key objectives is to ensure that the relative weights of the two texts that constitute the Decision (i.e. the Decision itself and the clarifying statement from the Chairman of the TRIPS Council) are maintained and that the totality of the package is preserved.
- 5.3.3 The UK Government will be **amending national patent legislation** to allow for the granting of compulsory licenses for export of copies of patented medicines in accordance with conditions set out in the Decision. The amendment will probably require a statutory instrument and will be based on legislation to be introduced by the EU. The European Commission has already initiated discussions on this. The Commission plans to get a Community-wide Regulation passed in the lifetime of the current Council, which will be the end of October this year. The UK will act promptly to implement the Regulation, hopefully by the end of 2004. The Patent Office is also looking at compulsory licensing procedures to see if they can be further streamlined.
- 5.3.4 As set out in Section 4.3 above, the 30 August Decision enables the use of important public policy tools that might help ensure the longer-term supply of affordable medicines to LDCs and others with limited pharmaceutical manufacturing capacity. However, there are a number of possible economic, administrative and legal challenges that poor countries may face in making use of the Decision and other flexibilities within TRIPS. The UK Government will continue to fund **research and capacity building** to overcome such challenges. Several important initiatives are already underway including the recent launch of a major resource book on different IP strategies for countries at different levels of development, which is being rolled out in key institutions. It also includes regular regional dialogues bringing together stakeholders from developing countries (government, policy makers, NGOs, private sector, academia) to strengthen capacity to formulate appropriate IP legislation and regulations to meet development objectives. A central theme in all this work has been the TRIPS flexibilities and their operational implications in country for access to medicines. In order to help partners in developing countries to implement this work on the ground, the UK Government is pushing for a multi-stakeholder dialogue on improving the quality of technical assistance on IPRs.

## 5.4 Engagement with the business community

- 5.4.1 The UK Government is committed to working with the business community to increase access to medicines for poor communities in developing countries. This includes companies in the pharmaceutical sector, and non-pharmaceutical companies, including those acting as employers and investors in developing countries.

## The pharmaceutical industry

5.4.2 We will work with the pharmaceutical industry – both research-based and generic – to facilitate and encourage a commercially viable response to developing country needs with respect to access to medicines, to include:

- More widespread differential pricing of existing medicines to increase affordability in developing countries;
- Enhanced corporate impact on access to medicines in developing countries, including through corporate social responsibility;
- Greater investment in the research and development of medicines to treat diseases disproportionately affecting the developing world.

The first two of these areas are covered in this section; work on research and development is outlined in Section 5.5 below.

5.4.3 The UK will continue to engage with the industry on issues of affordability, seeking to encourage widespread commitment to differential pricing as the operational norm in line with the recommendations of the UK Working Group on Increasing Access to Essential Medicines in the Developing World. This will include:

- **Support for the EU Regulation on diversion.** With our EU colleagues, we will monitor the EU Regulation to assess its impact, and to ensure its successful use. This includes ensuring that protection against diversion into the EU is robust and credible. This protection should include actions to strengthen customs vigilance in developing countries and at EU borders, and continued efforts by pharmaceutical manufacturers to differentially package or otherwise identify their differentially priced products.
- **Contributing to the evidence base on affordability,** to develop understanding around the success of different approaches, including public-private partnerships and individual corporate initiatives. We are currently providing financial support to the Initiative on Public-Private Partnerships for Health to this end.
- Work with individual companies and trade associations, and with other stakeholders, to bring **greater transparency and durability** to differential pricing offers. We will press for an expanded scope for pricing offers, to replicate the significant price reductions of ARVs in other priority areas of public health in the developing world.
- **Encouraging active dialogue between industry and developing country governments** to explore how best to work together to increase access to medicines, including through the use of TRIPS compliant licensing models in developing countries. Where appropriate, we will encourage further use of voluntary licensing and the transfer of technology to developing countries, in order to facilitate access to medicines.

5.4.4 We will also contribute to **building the evidence base that underpins business decisions** with respect to emerging and poor markets, as a first step to identifying measures to address market 'failure'. This includes providing support to Pharma Futures, a scenario planning exercise designed to permit industry and its investors to assess and successfully act on the long-term challenges facing the pharmaceutical industry, while responding positively and in an economically viable way to the demand for health as a global public good.

### Best practice in the pharmaceutical industry

5.4.5 The UK Government is engaged with the pharmaceutical industry to encourage best practice with respect to access to medicines issues. This work includes:

- Publishing a framework to encourage best practice. This framework will contain best practice principles, and is being developed in close co-operation with the pharmaceutical industry and other key stakeholders.
- Gathering case studies of corporate activity that will be used to illustrate best practice with regard to access to medicines.
- Work to increase the volume, quality and scope of company reporting on access to medicines issues. Building on the UK Operating and Financial Review, and consulting other reporting guidelines (e.g. the Association of British Insurers disclosure guidelines) companies will be encouraged to benchmark performance against industry best practice and existing relevant codes, including the appropriate WHO Guidelines (for example those for Drug Donations, Price Discounts of Single-Source Pharmaceuticals, and Good Clinical Practice for trials on pharmaceutical products) the OECD Guidelines for Multinational Enterprises and the United Nations Global Compact.

### Corporate social responsibility

5.4.6 Corporate social responsibility (CSR) provides an important tool that can help to expand access to medicines in developing countries. Pharmaceutical and non-pharmaceutical companies can significantly contribute to the enabling environment that makes medicines more accessible, including in terms of contributing to, and advocating for, sustainable financing, helping to strengthen health systems, and through direct provision of healthcare, including medicines, to their employees. In addition, the Chancellor has called for a move to 'Third Generation' CSR where companies' contributions to development are recognised to include their support for good governance and pro-poor policy environments, alongside other impacts on the ground.

5.4.7 Companies, particularly multinational corporations, are increasingly providing healthcare to employees, their partners and dependents, and in some cases, to wider communities. This is most developed in relation to HIV/AIDS where prevention and care programmes have been operating for some years, and where more recently, some companies are providing ARV treatment to employees and others. However, provision

of health services that increase access to medicines is not confined to HIV/AIDS. Increasingly companies are involved in programmes to address other diseases and are making available broader health insurance.

- 5.4.8 In addition, companies can contribute to the development of health services by working with governments to share expertise and skills. For example, company expertise can contribute to the strengthening of medicine procurement, storage, distribution and supply systems by applying logistics, stock control, forecasting and supply experience. Companies can work with business associations to share good practice within the business community, including through the development of business models for healthcare provision.
- 5.4.9 Sustainable financing of health services can be supported directly through corporate payments to public authorities, including through taxes, tariffs and any other appropriate fiscal flows. Support for actions to tackle corruption and bribery can contribute to greater financial transparency. This can provide greater stability to government finances, including in relation to health expenditures. To this end the OECD Convention on bribery of foreign officials should be complied with. Finally, companies with specific interests in access to medicines in developing countries can use their influence to encourage and support domestic and donor governments in efforts to strengthen health systems.
- 5.4.10 Furthermore, corporate activities supportive of pro-poor development can contribute indirectly to efforts to improve health. Foreign investors in developing countries can contribute to economic growth through access to capital, technology transfer, access to specialised skills, the sourcing of raw, semi-finished or finished products, and through their location of manufacturing and/or research investments. Where businesses are committed to socially responsible practices, they can have considerable impact. They can reinforce the poverty reduction strategies of the countries in which they operate, contribute to environmental sustainability and promote core labour standards and human rights.
- 5.4.11 HMG will continue to engage with companies and other stakeholders to maximise the pro-poor development impacts of corporate activity through:
- Developing case studies of pro-poor Third Generation CSR and how it impacts on access to medicines.
  - Support for industry activities particularly regarding policies extending access to poor communities in developing countries, in relation to pharmaceutical companies, employers providing benefits to staff, dependents and local communities, and through CSR initiatives.
  - Support for general private sector, and sector-specific initiatives (e.g. Pharma Futures and Business Partners for Development), and work to develop the evidence base on pro-poor Foreign Direct Investment.

- And, through work on best practice principles, reporting and transparency in the pharmaceutical industry, as set out in 5.4.5 above.

## 5.5 Strengthening research and development

5.5.1 The UK Government is strongly committed to scaling up research and development (R&D) for diseases that disproportionately affect the poor. The following section outlines how we will evaluate our existing tax credits and enhance our cross-departmental strategy, aligning the approaches and investments of the OST, DTI, DH, IR, HMT and DFID.

### Monitoring and evaluating the fiscal incentives for R&D

5.5.2 R&D tax credits for small and medium sized companies were introduced in 2000 and for large companies in 2002. These tax credits are available for all companies undertaking innovative R&D and represent a 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 (BERD) indicates that around 25% of R&D spending is in the pharmaceutical sector and therefore a significant element of this Government support will encourage R&D in that sector.

5.5.3 In addition, there is a targeted relief specifically aimed at research into vaccines and other medicines for TB, malaria and HIV/AIDS. Vaccines Research Relief took effect for expenditure from April 2003.

5.5.4 Monitoring data on claims for Vaccines Research Relief will be extracted from tax returns on a regular basis. Confidentiality restrictions may be a real issue in publicising monitoring data given that less than 50 companies are expected to take up this targeted relief – however subject to that, it is proposed this monitoring data will provide the core information on the take-up and impact of the Vaccines Research Relief.

5.5.5 However, it is currently too early to start to reach any conclusions on the impact of the Vaccines Research Relief. Company tax returns are retrospective in nature and so the first claims for the relief are not expected until later in 2004. The evaluation of the relief will build on this monitoring data but will need to reflect the fact that research decisions, and research outcomes, are long-term and so we would expect any impacts to appear in the medium to long-term.

5.5.6 Evaluation of the mainstream UK R&D tax credit available for all R&D will, over time, provide information on the effect of the credit, its design and whether any further changes are needed. Once data begins to be received on the Vaccines Research Relief a similar programme of evaluation can be implemented.

5.5.7 One issue, which has already arisen, is whether the targeted relief is in line with the current state of medical research in the area of HIV/AIDS. This, and any other emerging issues, will be kept under review.

## Further stimulating R&D investment

5.5.8 Our overall objective in this area is to provide strategic financial and analytical support for the development of new tools and technologies to meet the health needs of poor people in developing countries. We strongly support the involvement of end-users and researchers from developing countries in the global R&D process. We encourage developing countries to take responsibility for determining the research needs of their populations and for co-ordinating the contributions from domestic and international partners. We will support countries to strengthen their skills and engagement in the research process. Building capacity and leadership in cross-cutting areas like ethical review, clinical trial design and implementation, regulatory agency strengthening and post-introduction monitoring and evaluation is important. Developing countries also have the ability to produce innovative research ideas responding directly to the needs of their populations, which we will seek to harness although we see an integral role for enhanced action by donor governments, companies and researchers from developed countries. All countries will need to be assured via appropriate governance mechanisms that any new products are suitable for target populations, affordable and safe. To these ends, we plan a comprehensive programme of HMG activity, set out below.

5.5.9 We will participate in global processes to demonstrate how new products and technologies could contribute to the achievement of the MDGs; **prioritise relative needs for new products and technologies**; and build a strong development and investment case for R&D on diseases that affect the poor, by:

- Strengthening the global health partnerships and European and Developing Countries Clinical Trials Partnership (EDCTP)<sup>27</sup> to identify research needs, support countries to undertake research, and plan and co-ordinate from an early stage for the introduction of new products into existing health service policy, procurement and delivery systems;
- Acting to build international collaboration between the funders of product development, in order to agree best practice approaches including monitoring and evaluation frameworks, particularly for public-private partnerships.

5.5.10 We will also explore, evaluate and utilise different **mechanisms for investing** in the development of new products by:

- Supporting the MRC to represent HMG on the EDCTP (Assembly and Partnership Board)<sup>28</sup>;

<sup>27</sup> EDCTP is a European Union Joint Programme, comprising programmes from participating European states, the institutional and/or national programmes in Developing Countries and co-funded activities in partnerships with other initiatives and/or industry. Its mission is to accelerate the development of new clinical interventions to fight HIV/AIDS, malaria and tuberculosis in developing countries, particularly Sub-Saharan Africa, and to improve generally the quality of research in relation to these diseases.

<sup>28</sup> Particular issues of interest will be: EDCTP operational policies, fundraising methods, co-ordination of European and global science, integration of EDCTP and other collaborative research processes, especially PPPs.

- Prioritising programmes for international public health, product development, adaptation and adoption in the new DFID Research Strategy, with a focus on PPPs, capacity building and communications strategies;
- Exploring the use of new financing mechanisms to invest in scaling up manufacturing capacity for near to market tools and technologies and to buy products, in order to build a sustainable market and stimulate private sector investment in R&D;
- Encouraging applications to government funding schemes designed to foster private sector involvement in development-related business opportunities.<sup>29</sup>

5.5.11 We will develop and implement strategies to enhance **global knowledge sharing and access to information** to facilitate increased levels of R&D involving UK and international researchers, by:

- Working with the MRC, Wellcome Trust and across UK Government departments (e.g. DFID, DTI, DH) to establish a **Research Funders Forum on Health in Developing Countries**. The draft terms of reference are:
  - To exchange information on strategy, policy and current research activities
  - To identify any international initiatives requiring a coordinated UK response
  - To consider new opportunities for joint working or joint funding
  - To promote opportunities for Getting Research into Policy and Practice.
- The Funders Forum could address points of particular weakness in the R&D chain, for example:
  - strengthening the role of overseas technology promoters to broker R&D partnerships between UK and developing country scientists, public-private partnerships and manufacturers;
  - the 'translation' of possible candidates from discovery to development;
  - clinical trial site identification, development and maintenance of capacity;
  - a non-disease specific review of the enabling tools and technologies needed to support pre-clinical work;
  - encouraging UK contributions to solving outstanding scientific challenges.

5.5.12 We will also seek to improve the UK and global **enabling environment** for R&D relevant to developing country health needs, by:

- Mainstreaming product development for diseases of the developing world in HMG strategies to promote innovation and knowledge transfer in science and technology, particularly in the bioscience and pharmaceutical industries;

<sup>29</sup> For example, the DFID Business Linkages Challenge Fund.

- Encouraging the prioritisation of product development for local disease priorities in developing country R&D strategies;
- Consideration of approaches to enhance the level of appropriate commercialisation of academic research and pull-through from the Science, Engineering and Technology base, via increased awareness of alternative routes to market (for example the Product Development PPPs, as above);
- Supporting developed and developing countries to develop skills in intellectual property management that enhance their engagement in global R&D processes and enable public health benefits<sup>30</sup>.

5.5.13 We will collaborate with domestic, European and global partners to assess the impacts of existing and potential **incentive structures** and introduce further incentives if possible, by:

- Strongly supporting the work of the WHO Commission on Intellectual Property Rights, Innovation and Public Health, using their interim findings to inform our strategies and priorities for the UK Presidencies of the G8 and EU in 2005;
- Participating in the European Commission's ongoing review of further European actions that could be taken to stimulate increased industry involvement, from large research-based pharmaceutical companies, biotechnology companies and academic institutions;
- Monitoring, evaluating and if appropriate extending the existing UK targeted tax relief (as set out above).

5.5.14 We will further collaborate with domestic, European and global partners to clarify outstanding issues related to the **licensing and regulation** of products designed for use in developing countries for public health benefit. Specifically, we will:

- Support the UK Medicines and Healthcare products Regulatory Agency (MHRA) and the European Medicines Agency (EMA), in their discussions with WHO and other national and regional regulatory authorities, to clarify the scope and roles of international and national bodies in the licensing and regulation of new drugs for first use in developing countries where internationally validated regulatory competence may be limited;
- Contribute to the evidence base on the emerging issues in the efficient approval of clinical trials, regulatory pathways, capacity for the evaluation, approval and registration of new technologies in developing countries. A study to inform discussion of these issues has already been commissioned.

<sup>30</sup> For example, in our work with, and support to, The Centre for the Management of Intellectual Property in Health Research and Development (MIHR).

5.5.15 Finally, we will collaborate with domestic and global partners to **strengthen capacity in developing countries** to set priorities, undertake health research and contribute to product development, by:

- Encouraging discussion of how HMG can enhance the enabling environment for science, technology and innovation in developing countries;
- Investing in capacity building as a core outcome of DFID-funded research programmes, including via the EDCTP and programmes at country-level;
- Investing in science and technology capacity building through partnerships with UK Government and academic organisations, for example via the Higher Education Links programme and UK research institutions;
- Strengthening the capacity of public sector institutions, via DFID country programmes, in order that they can demand and use scientific knowledge.

## 5.6 Ways of working

5.6.1 It will be important to continue our close collaboration across the UK Government and with key external stakeholders as we move to implement this strategy. Across government, the existing HMG officials group on access to medicines will be one mechanism through which we can communicate effectively and maintain policy coherence. But different HMG departments will need to work together more directly in several areas: for example, DFID, DH, DTI, OST, HMT and the Inland Revenue will work closely together to stimulate increased R&D. DFID will continue to play a co-ordinating role on access to medicines issues, with capacity dedicated to this function.

5.6.2 We will of course continue to consult and work collaboratively with a range of stakeholders beyond government. In addition to regular dialogue with key organisations and groups on the access to medicines agenda, we will engage in targeted consultation on specific areas of activity. For example, DFID will lead a consultation over the coming months with pharmaceutical companies and key stakeholders in the sector, to develop the best practice framework referred to in Section 5.4.5 of this paper. We will also facilitate the sharing of new knowledge and evidence, including through the proactive dissemination of research and guidance that we have funded. We aim to review the use and impact of this research and guidance, and to review progress against the objectives outlined in this paper, towards the end of 2005, engaging external stakeholders as appropriate.

# Consultation

- 6.1 This policy paper has been developed through a lengthy period of analysis and dialogue with key external stakeholders. The policy has evolved over the last year through regular and ad hoc meetings between UK Government departments and other governments and international agencies, pharmaceutical companies and their investors, industry associations, non-governmental organisations and research institutions. Dialogue with developing country governments and other country-level partners, including through our bilateral relationships and in international fora, continues to be vital to the development of our policy.
- 6.2 In addition to this ongoing dialogue, an earlier draft of this paper was circulated to a broad range of external contacts for comment. In response, we received valuable comments from 21 individual organisations and four associations or representational groups. Many of these comments were detailed and thoughtful, some with referenced material. They have been fully considered and incorporated where appropriate, and the detail retained on internal DFID records for future reference, in order to inform our work as we move forward. The nature of the response we have received thus far confirms the high level of interest and commitment of all those involved towards doing their part to increase access to essential medicines in the developing world.

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For further information about the UK Government's policy and activities in the areas outlined in this paper, please consult the following:

- The PIU study 'Tackling the diseases of poverty' can be found at <http://www.number-10.gov.uk/su/health/default.htm>
- The DFID website <http://www.dfid.gov.uk> includes a range of information and resources on access to medicines issues, health and HIV/AIDS. The report of the high level UK Working Group on Increasing Access to Essential Medicines in the Developing World can be found on the DFID website
- The DH website <http://www.doh.gov.uk> holds information on pharmaceuticals and on research and development investments
- The Patent Office website gives more information on TRIPS and public health: <http://www.patent.gov.uk/about/ippd/issues/trips.htm>
- Further information on the R&D tax credits and Vaccines Research Relief can be found at [www.inlandrevenue.gov.uk/randd](http://www.inlandrevenue.gov.uk/randd)
- Further information on the International Finance Facility can be found at [www.hm-treasury.gov.uk/IFF](http://www.hm-treasury.gov.uk/IFF)

We would also welcome comments on this paper and views on the various issues raised in it – please send these to [atm@dfid.gov.uk](mailto:atm@dfid.gov.uk)

# Annex 1

Millennium Development Goals	
Goals and targets (from the Millennium Declaration)	Indicators for monitoring progress
<b>Goal 1: Eradicate extreme poverty and hunger</b>	
<b>Target 1:</b> Halve, between 1990 and 2015, the proportion of people whose income is less than one dollar a day	<ol style="list-style-type: none"> <li>1. Proportion of population below \$1 (PPP) per day<sup>31</sup></li> <li>2. Poverty gap ratio [incidence x depth of poverty]</li> <li>3. Share of poorest quintile in national consumption</li> </ol>
<b>Target 2:</b> Halve, between 1990 and 2015, the proportion of people who suffer from hunger	<ol style="list-style-type: none"> <li>4. Prevalence of underweight children under-five years of age</li> <li>5. Proportion of population below minimum level of dietary energy consumption</li> </ol>
<b>Goal 2: Achieve universal primary education</b>	
<b>Target 3:</b> Ensure that, by 2015, children everywhere, boys and girls alike, will be able to complete a full course of primary schooling	<ol style="list-style-type: none"> <li>6. Net enrolment ratio in primary education</li> <li>7. Proportion of pupils starting grade 1 who reach grade 5</li> <li>8. Literacy rate of 15-24 year-olds</li> </ol>
<b>Goal 3: Promote gender equality and empower women</b>	
<b>Target 4:</b> Eliminate gender disparity in primary and secondary education preferably by 2005 and to all levels of education no later than 2015	<ol style="list-style-type: none"> <li>9. Ratios of girls to boys in primary, secondary and tertiary education</li> <li>10. Ratio of literate females to males of 15-24 year-olds</li> <li>11. Share of women in wage employment in the non-agricultural sector</li> <li>12. Proportion of seats held by women in national parliament</li> </ol>
<b>Goal 4: Reduce child mortality</b>	
<b>Target 5:</b> Reduce by two-thirds, between 1990 and 2015, the under-five mortality rate	<ol style="list-style-type: none"> <li>13. Under-five mortality rate</li> <li>14. Infant mortality rate</li> <li>15. Proportion of 1 year-old children immunised against measles</li> </ol>
<b>Goal 5: Improve maternal health</b>	
<b>Target 6:</b> Reduce by three-quarters, between 1990 and 2015, the maternal mortality ratio	<ol style="list-style-type: none"> <li>16. Maternal mortality ratio</li> <li>17. Proportion of births attended by skilled health personnel</li> </ol>

<sup>31</sup> For monitoring country poverty trends, indicators based on national poverty lines should be used, where available.

<b>Goal 6: Combat HIV/AIDS, malaria and other diseases</b>	
<b>Target 7:</b> Have halted by 2015 and begun to reverse the spread of HIV/AIDS	<p><b>18.</b> HIV prevalence among 15-24 year old pregnant women</p> <p><b>19.</b> Condom use rate or the contraceptive prevalence rate<sup>32</sup></p> <p><b>20.</b> Number of children orphaned by HIV/AIDS<sup>33</sup></p>
<b>Target 8:</b> Have halted by 2015 and begun to reverse the incidence of malaria and other major diseases	<p><b>21.</b> Prevalence and death rates associated with malaria</p> <p><b>22.</b> Proportion of population in malaria risk areas using effective malaria prevention and treatment measures<sup>34</sup></p> <p><b>23.</b> Prevalence and death rates associated with tuberculosis</p> <p><b>24.</b> Proportion of tuberculosis cases detected and cured under directly observed treatment short course (DOTS)</p>
<b>Goal 7: Ensure environmental sustainability</b>	
<b>Target 9:</b> Integrate the principles of sustainable development into country policies and programmes and reverse the loss of environmental resources	<p><b>25.</b> Proportion of land area covered by forest</p> <p><b>26.</b> Ratio of area protected to maintain biological diversity to surface area</p> <p><b>27.</b> Energy use (kg oil equivalent) per \$1 GDP (PPP)</p> <p><b>28.</b> Carbon dioxide emissions (per capita) and consumption of ozone-depleting CFCs (ODP tons)</p> <p><b>29.</b> Proportion of population using solid fuels</p>
<b>Target 10:</b> Halve, by 2015, the proportion of people without sustainable access to safe drinking water	<b>30.</b> Proportion of population with sustainable access to an improved water source, urban and rural
<b>Target 11:</b> By 2020, to have achieved a significant improvement in the lives of at least 100 million slum dwellers	<p><b>31.</b> Proportion of urban population with access to improved sanitation</p> <p><b>32.</b> Proportion of households with access to secure tenure (owned or rented)</p>

continued overleaf

<sup>32</sup> Amongst contraceptive methods, only condoms are effective in preventing HIV transmission. The contraceptive prevalence rate is also useful in tracking progress in other health, gender and poverty goals. Because the condom use rate is only measured amongst women in union, it will be supplemented by an indicator on condom use in high risk situations. These indicators will be augmented with an indicator of knowledge and misconceptions regarding HIV/AIDS by 15-24 year-olds (UNICEF – WHO).

<sup>33</sup> To be measured by the ratio of proportion of orphans to non-orphans aged 10-14 who are attending school.

<sup>34</sup> Prevention to be measured by the % of under 5s sleeping under insecticide treated bednets; treatment to be measured by % of under 5s who are appropriately treated.

Goals and targets (from the Millennium Declaration)	Indicators for monitoring progress
<b>Goal 8: Develop a global partnership for development</b>	
<p><b>Target 12:</b> Develop further an open, rule-based, predictable, non-discriminatory trading and financial system</p> <p>Includes a commitment to good governance, development, and poverty reduction – both nationally and internationally</p> <p><b>Target 13:</b> Address the special needs of the least developed countries</p> <p>Includes: tariff and quota free access for least developed countries' exports; enhanced programme of debt relief for HIPC and cancellation of official bilateral debt; and more generous ODA for countries committed to poverty reduction</p> <p><b>Target 14:</b> Address the special needs of landlocked countries and small island developing States</p> <p>(through the Programme of Action for the Sustainable Development of Small Island Developing States and the outcome of the twenty-second special session of the General Assembly)</p> <p><b>Target 15:</b> Deal comprehensively with the debt problems of developing countries through national and international measures in order to make debt sustainable in the long term</p>	<p><i>Some of the indicators listed below are monitored separately for the least developed countries (LDCs), Africa, landlocked countries and small island developing States.</i></p> <p><b>Official development assistance</b></p> <p><b>33.</b> Net ODA, total and to LDCs, as percentage of OECD/DAC donors' gross national income</p> <p><b>34.</b> Proportion of total bilateral, sector-allocable ODA of OECD/DAC donors to basic social services (basic education, primary health care, nutrition, safe water and sanitation)</p> <p><b>35.</b> Proportion of bilateral ODA of OECD/DAC donors that is untied</p> <p><b>36.</b> ODA received in landlocked countries as proportion of their GNIs</p> <p><b>37.</b> ODA received in small island developing States as proportion of their GNIs</p> <p><b>Market access</b></p> <p><b>38.</b> Proportion of total developed country imports (by value and excluding arms) from developing countries and LDCs, admitted free of duties</p> <p><b>39.</b> Average tariffs imposed by developed countries on agricultural products and textiles and clothing from developing countries</p> <p><b>40.</b> Agricultural support estimate for OECD countries as percentage of their GDP</p> <p><b>41.</b> Proportion of ODA provided to help build trade capacity<sup>35</sup></p> <p><b>Debt sustainability</b></p> <p><b>42.</b> Total number of countries that have reached their HIPC decision points and number that have reached their HIPC completion points (cumulative)</p> <p><b>43.</b> Debt relief committed under HIPC initiative, US\$</p> <p><b>44.</b> Debt service as a percentage of exports of goods and services</p>

<sup>35</sup> OECD and WTO are collecting data that will be available from 2001 onwards.

<b>Target 16:</b> In co-operation with developing countries, develop and implement strategies for decent and productive work for youth	<b>45.</b> Unemployment rate of 15-24 year-olds, each sex and total <sup>36</sup>
<b>Target 17:</b> In co-operation with pharmaceutical companies, provide access to affordable, essential drugs in developing countries	<b>46.</b> Proportion of population with access to affordable essential drugs on a sustainable basis
<b>Target 18:</b> In co-operation with the private sector, make available the benefits of new technologies, especially information and communications	<b>47.</b> Telephone lines and cellular subscribers per 100 population <b>48.</b> Personal computers in use per 100 population and Internet users per 100 population

The Millennium Development Goals and targets come from the Millennium Declaration signed by 189 countries, including 147 Heads of State, in September 2000 [www.un.org/documents/ga/res/55/a55r002.pdf](http://www.un.org/documents/ga/res/55/a55r002.pdf) – A/RES/55/2).

The goals and targets are inter-related and should be seen as a whole. They represent a partnership between the developed countries and the developing countries determined, as the Declaration states, “to create an environment – at the national and global levels alike – which is conducive to development and the elimination of poverty.”

<sup>36</sup> An improved measure of the target is under development by ILO for future years.

## Annex 2: Progress against recommended actions following the high level UK Working Group

Differential pricing – recommended actions		Progress since 2002
<p><b>Goal:</b> Build international commitment for a widespread, voluntary system of differential pricing of essential medicines for the developing world as the operational norm. Key target for G8 Summit in France 2003</p>		
G8	<ul style="list-style-type: none"> <li>Government process to be determined</li> </ul>	<ul style="list-style-type: none"> <li>Evian Health Action plan agreed 2003</li> <li>HIV vaccine enterprise commitment 2004</li> </ul>
Other high income markets	<ul style="list-style-type: none"> <li>Switzerland, Australia, New Zealand (Consider commonwealth secretariat)</li> <li>International pharmaceutical manufacturers associations</li> </ul>	<ul style="list-style-type: none"> <li>Dialogue continuing with relevant industry associations</li> </ul>
EU	<ul style="list-style-type: none"> <li>Continued support for Tiered pricing within EU Programme for Accelerated Action on HIV/AIDS, Malaria and TB in the context of poverty reduction</li> <li>EU Legislation through trade council 2002</li> <li>Gain support from European Pharmaceutical Federation</li> </ul>	<ul style="list-style-type: none"> <li>EU Regulation on diversion agreed May 2003; now in use</li> <li>EFPIA support secured</li> </ul>
Developing Countries	<ul style="list-style-type: none"> <li>Broad commitment through NEPAD and the G8 Action Plan for Africa</li> <li>Proposed consultation with key developing countries</li> </ul>	<ul style="list-style-type: none"> <li>Commitments outlined in G8 Action Plan for Africa, following G8 Africa Personal Representatives discussions</li> <li>Dialogue continues with developing countries; specific UK support to Government of Ghana; GSK pilots elsewhere</li> </ul>
UN	<ul style="list-style-type: none"> <li>WHA resolution 13.8 passed May 2002</li> <li>Consider technical briefing WHA 2003</li> <li>WHO propose monitoring framework</li> </ul>	<ul style="list-style-type: none"> <li>WHA 2003 passed several relevant resolutions; establishment of WHO Commission on Intellectual Property Rights, Innovation and Public Health.</li> </ul>

Pharmaceutical Industry	<ul style="list-style-type: none"> <li>– Continued public commitment from UK based pharmaceutical industry</li> <li>– Discussions with major companies outside the UK</li> <li>– Discussion with industry trade associations EFPIA, PhRMA and IFPMA.</li> <li>– Consider discussions with IFPMA – WHO annual roundtable</li> <li>– Facilitated by UK industry and DH where appropriate</li> </ul>	<ul style="list-style-type: none"> <li>– UK based industry have made further price reductions and have issued several voluntary licenses</li> <li>– Engagement and dialogue increased with others, e.g. the American Pharmaceuticals Group; continued dialogue with relevant associations</li> </ul>
Other Trade issues	<ul style="list-style-type: none"> <li>– Multilateral and bilateral negotiations where appropriate to eliminate tariffs on differentially priced products (Consider Economic Partnership Agreements)</li> </ul>	<ul style="list-style-type: none"> <li>– Developing countries taking action to tackle taxes, tariffs and mark-ups; Health Action International project strengthening evidence base and tools (with support from UK and others)</li> </ul>
Other Related Issues	<ul style="list-style-type: none"> <li>– Further work with stakeholders on definition and parameters for independent audit.</li> <li>– Increase appropriate donations from UK sources in line with voluntary WHO/Interagency Guidelines on Drug Donations. Tax measure introduced in 2002 Finance Act.</li> </ul>	<ul style="list-style-type: none"> <li>– European Commission handling audit issues in context of EU Regulation</li> <li>– Use of UK tax measure on donations of healthcare products being monitored</li> </ul>
Other International	<ul style="list-style-type: none"> <li>– Build on international experience to strengthen nature of agreements and develop capacity for bulk purchasing</li> </ul>	<ul style="list-style-type: none"> <li>– WHO facilities developed for HIV and malaria; GDF for TB evaluated (with DFID support); several regional bulk procurement mechanisms under consideration</li> </ul>

continued overleaf

Research and development – recommended actions		Progress since 2002
<p><b>Goal: Policies that will increase level of UK R&amp;D into essential medicines for poor people in the developing world</b></p>		
UK Govt	<ul style="list-style-type: none"> <li>– 2002 Finance Act passed. Commitment to monitor overall R&amp;D expenditure</li> <li>– 2003 further examine policy potential of supportive EU Orphaned Drug Legislation or changes in regulatory framework to reduce delays</li> <li>– Continue to work as appropriate with NGOs and Foundations</li> </ul>	<ul style="list-style-type: none"> <li>– Vaccines Research Relief now active; monitoring of R&amp;D tax credit underway and arrangements for monitoring of VRR being developed</li> <li>– EU work on additional incentives continuing</li> <li>– UK a founding member of the European and Developing Countries Clinical Trials Partnership (EDCTP)</li> <li>– Regular HMG dialogue and engagement with civil society and Foundations; IPPPH meeting on PD PPPs April 2004 (with support from UK and others)</li> <li>– Established dialogue with partners such as the Drugs for Neglected Diseases Initiative (DNDi) who are developing products for diseases with the smallest commercial markets</li> </ul>

## Department for International Development

The Department for International Development (DFID) is the UK Government department responsible for promoting sustainable development and reducing poverty. The central focus of the Government's policy, based on the 1997 and 2000 White Papers on International Development, is a commitment to the internationally agreed Millennium Development Goals, to be achieved by 2015. These seek to:

- Eradicate extreme poverty and hunger
- Achieve universal primary education
- Promote gender equality and empower women
- Reduce child mortality
- Improve maternal health
- Combat HIV/AIDS, malaria and other diseases
- Ensure environmental sustainability
- Develop a global partnership for development

DFID's assistance is concentrated in the poorest countries of sub-Saharan Africa and Asia, but also contributes to poverty reduction and sustainable development in middle-income countries, including those in Latin America and Eastern Europe.

DFID works in partnership with governments committed to the Millennium Development Goals, with civil society, the private sector and the research community. It also works with multilateral institutions, including the World Bank, United Nations agencies, and the European Commission.

DFID has headquarters in London and East Kilbride, offices in many developing countries, and staff based in British embassies and high commissions around the world.

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