REPORT TO THE PRIME MINISTER

UK WORKING GROUP ON INCREASING ACCESS TO ESSENTIAL MEDICINES IN THE DEVELOPING WORLD

--

POLICY RECOMMENDATIONS AND STRATEGY

--

CLARE SHORT,
SECRETARY OF STATE FOR INTERNATIONAL DEVELOPMENT

28 NOVEMBER 2002
INTRODUCTION

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. The G8 Summit in Okinawa 2000 had the fight against these diseases as a priority. Much of that agenda was focused on increasing poor peoples’ access to essential medicines.

2. Since Okinawa, international commitment – and pressure – has been maintained in this area. High-level commitment and increased financing has been announced at important development fora, and one important milestone has been the establishment of the Global Fund to Fight AIDS, TB and Malaria.

3. But this alone will not be enough. At the G8 Summit in Genoa in 2001, the UK Prime Minister announced his intention to establish a high-level working group on increasing access to essential medicines in the developing world (Annex 3). The Working Group was not asked to tackle every aspect of this agenda, but specifically to consider:

- Ways of improving access to medicines through measures such as facilitating differential pricing arrangements and encouraging appropriate donations
- What policies could be pursued by the UK Government that would increase research and development (R&D) into diseases of poor people?

4. The Working Group brought together senior representatives from the UK pharmaceutical industry, the UN, EC, Foundations and UK Ministers from Health, Trade, and Treasury (Annex 2). UK based NGOs and international generics companies were also consulted during the process.

5. This report outlines the discussions and conclusions of the Working Group. It supports specific action on the R&D agenda, and outlines an ambitious international agenda to facilitate a framework for voluntary, widespread, sustainable, and predictable differential pricing as the operational norm. It proposes, as a short-term goal, to have significant international commitment to an overarching framework for differential pricing in place in time for the 2003 G8 Summit in France.

---

1. DP is sometimes referred to a “tiered pricing”, “equity pricing” or “preferential pricing”. They all refer to the same principle of adapting prices to purchasing power of the world’s poorest countries.
6. The developing world suffers a massive and avoidable burden of disease as a result of HIV/AIDS, TB, Malaria, childhood illnesses and other conditions. Yet in the simplest terms, poor people in the developing world do not have access to the essential medicines. The result is human suffering and significant economic consequences that make, and keep, people poor.

7. Increasing access to essential medicines in the developing world is a complex policy area. Access to essential drugs requires sustainable financing, reliable health care and delivery systems, rational drug policies around prescribing and use, and prices that are affordable. The Working Group recognised the need for action in all of these areas. Discussions were placed in the context of this broader access agenda but quickly focused on specific policy areas.

8. The price of medicines is one of the key obstacles keeping people from the drugs they need. Drugs are the major item of health expenditure for the poor, typically accounting for 60-90% of household health expenditure. The Working Group considered key issues around the price of essential medicines. Action has already taken place to lower the price of essential medicines through industry initiatives and partnerships and by providing increased financing to support commodity purchase. Building on this experience to date, the Working Group examined a variety of mechanisms that could systematically, and sustainably, bring down the price of medicines and increase affordability and coverage.²

9. Based on initial analysis, the Group focused on the potential offered by establishing an international framework that would facilitate voluntary, widespread, sustainable and predictable differential pricing as the operational norm. While potentially an important tool, it is recognised that differential pricing mechanism alone would not be a panacea. The analysis also revealed the important effect of mechanisms such as bulk purchasing and competition, and recognised that in some cases even at dramatically discounted prices, medicines may not be affordable. Additional financing would be required. Medical donations when provided in accordance with voluntary WHO/interagency Guidelines for Drug Donation were also recognised as important. To support this, in April 2002, the UK Government introduced a new tax relief to encourage responsible donations of medical supplies and equipment to developing countries, in support of those countries' own health strategies and the needs of their people. This relief will allow companies to deduct from their taxable profits the cost of donations made for humanitarian purposes together with the cost of transport, delivery and distribution of donated goods. In implementing this measure, the Government will encourage adherence to the voluntary WHO/Interagency guidelines on donations.

² Voluntary bilateral or multilateral agreements for differential pricing, donations, bulk purchasing, competition, voluntary licensing, compulsory licensing, the Global Fund to Fight HIV/AIDS, TB and Malaria.
10. Reliable access to essential medicines also requires continued investment in research and development (R&D) for diseases that affect poor people in the developing world. Rapid scientific advances have brought hopes for new treatments and vaccines closer to reality, but the challenges are enormous. It is estimated that only 10% of R&D spending is directed at the health problems of 90% of the world’s population. The relative lack of private sector R&D for diseases specific to the developing countries results from low expected returns on investments due to the inadequate purchasing power of affected populations and the weak health systems in the developing world. It is clear that to increase R&D expenditure on neglected diseases will require a continued commitment for protection of intellectual property, developing health systems and sustainable markets and increase public–private partnerships. A variety of policy options and partnerships were put forward that could provide incentives for increased R&D.

**POLICY OPTIONS TO TAKE FORWARD**

**International commitment to differential pricing as the operational norm**

11. Within the differential pricing agenda an international partnership approach is essential. The Working Group laid out specific areas for actions along with roles and responsibilities and set these out in a framework vision that the international community can work toward. We made excellent progress and have a strong basis for continuing this work with the international community over the next year.

12. **Public Pledge.** Participants in the Working Group committed themselves to taking the necessary action to realise an approach to differential pricing of essential medicines that would result in widespread, predictable and sustainable access for the developing world as an operational norm. We agreed to monitor the impact of our efforts and to monitor the changes in poor peoples access to medicines over time. We placed as a central short-term goal gaining international commitment from a cross section of key stakeholders internationally (industry, developed and developing country governments, NGOs and global institutions). We felt that the G8 Summit in France in June 2003 might provide an opportune forum, building on the health and access to medicines commitment since the Okinawa Summit in 2000.
13. **Framework.** As a Working Group we were able to reach agree on all significant parameters and concepts. Like most working groups we could not agree on all details. The framework below represents a vision of what we as an international community can work toward. Bringing together the separate elements of the framework represents an important step forward. Gaining international agreement around this framework we believe makes an important contribution to the present environment in which differential pricing takes place – making way globally for more widespread agreements, with more affordable medicines and greater coverage. The framework below is supported by a short-term action plan (Annex 1).

14. **Scope.** Geographic scope would in principle cover all least developed countries globally (LDCs) and all Sub-Saharan Africa\(^3\). Within LDCs providing differential priced medicines through to all locally appropriate procurement and delivery channels greatly enhances access for the poor\(^4\). Within middle-income countries in Sub-Saharan Africa a distinction would be made, limiting differential pricing to public and not-for-profit entities so that viable industry markets could be preserved. Gaining international commitment for the vision of differential pricing as the operational norm would be greatly facilitated by limiting it in the first instance to the disease conditions for HIV/AIDS (including opportunistic infections), TB and malaria and then extending as needed to products for other disease conditions – bringing more companies and products on board.\(^5\)

15. Differential pricing has been shown to be economically and commercially viable. For the purpose of this framework we have not agreed a single formulaic approach to calculating prices but rather an objective whereby differential pricing for the developing world results in **prices close to the cost of manufacture.** Calculating price and costs is complex, and this objective could be achieved in a number of ways, but by definition would exclude R&D, marketing and sales and corporate administration costs. We believe that this definition provides an important conceptual baseline and represents a significant step forward. To ensure confidentiality of commercially sensitive information, an Independent Audit where needed, would establish whether a product met such criteria. We recognise that further work on the role and scope of audit needs to be done, and we commit ourselves to this task.

---

\(^3\) LDCs (currently 48 countries UNCTAD: 2000)

\(^4\) Reaching the poor through the private sector can be achieved through a number of strategies. Poor people in LDCs access the upward of 2/3rds of their medicines through the private sector. Limiting differential pricing to the public sector in LDCs results in a continued lack of access for poor people. The viable market in LDCs is limited, yet the cost to government of segmenting the market and preventing internal leakage could be considerable. In the world’s poorest countries, drug price differences between the public and private sectors result in internal leakage. The price differences provides an incentive for rural health workers or poor patients to sell medicines from the public sector on the private market in order buy food or other essential items.

\(^5\) In the short term we recognise that this disease scope covers only a limited number of products. But gaining international commitment for this framework and operationalising it is an important first step. Some companies already differentially price products within and outside this product scope, and this should be encouraged.
16. **Assurances.** An EU regulation to prevent diversion or “leakage” of cheaper products from LDCs to the EU is set to be tabled in end 2002. Other high-income country markets will need to be encouraged to undertake similar measures. LDCs themselves can commit to preventing diversion out of their countries. The prevention of diversion is an important assurance for both industry and poor people in LDCs for whom medicines are intended. Increased financing for strengthened health systems will be needed from development partners and developing country governments. Other measures such as using different branding and packaging are also effective at preventing leakage. The UK Government has given its assurance not to use benchmark or reference LDC prices. Negotiating the removal of tariffs on differentially priced products in LDCs will also be important and some appropriate forums for this have been identified. Developing countries will require the assurance that agreements will be widespread (sufficient coverage), transparent, long term (sustainable), predictable and focused on the poor. Principles to guide how agreements can be strengthened should be developed. It is important to clarify that commitment and action to the differential pricing agenda does not substitute for action in other areas. It is a variety of complementary strategies, pursued by different stakeholders that will succeed in providing access to essential medicines for the world's poor.

17. **Monitoring.** We agreed to monitor our efforts and whether differential pricing is making a significant and measurable difference to poor peoples access to medicines. This was an important outcome of the Working Group. Systematic monitoring will need to take place on the basis of product scope, price, population coverage, countries, pro-poor nature, product leakage, health systems strengthening and the overall commitment of stakeholders. This requires: 1) overall global monitoring (methodology and databases strengthened) according to the parameters outlined above, 2) supported by monitoring changes in country access (perhaps through a set number of annual case studies per year). These elements could be brought together in an annual report. WHO has agreed to further develop the monitoring framework in cooperation with industry and other stakeholders.

18. **Action.** The action agenda leading to the G8 in France, on 1-2 June 2003 is ambitious (Annex 1). Early engagement with the French Government to ensure this is on the G8 agenda will be important. The EC has laid much of the groundwork for this agenda in Europe through their Plan for Action, resulting in a European Parliament Resolution. Further work will need to be done to secure the commitment of European governments and Industry to work in partnership on this agenda. Working with the US Government and gaining their support will be particularly critical given the importance and size of the US Industry. Continued dialogue directly with US Industry may be a promising way forward. There may be scope for tabling this agenda through regional and global industry associations.

---

6 The European Commission has just published a draft Regulation aimed at preventing diversion of certain key medicines from some poorer countries back into the EU. The Working Group did not take a view on the draft as our Report was finalised before the draft was published. The Commission proposal will require careful negotiation.
Increasing R&D into diseases of poor people in the developing world

19. The Working Group concluded that there is an urgent need for stepped up investments in new and improved technologies to address diseases of the poor. Creative public investment –policies can help resolve market failure and re-shape incentives for industry.

20. The UK Government announced in the April 2002 that it would extend tax relief to companies engaged in R&D for HIV/AIDS, TB and malaria relevant to the developing world. This tax relief will extend to companies operating in the UK and qualify for expenditure sub-contracted overseas by UK companies. R&D carried out in developing countries is also important for capacity development within those countries. The new measure provides relief for R&D partnerships between industry and universities and bio-techs.

21. The Group recognised that under-investment in R&D for childhood diseases, especially for vaccines for acute respiratory illness, diarrhoea and six additional tropical diseases remains critically short. The Department for International Development currently invests in a number of R&D partnerships in this area and will continue to look at policy options that can further increase R&D for neglected diseases. The Group recommended that the UK Government look further at the potential that modified Orphaned Drug legislation might offer to stimulate R&D investments for neglected diseases. A paper was commissioned on this and it will be considered further in light of EC legislation.

22. It is clearly important that investment by the pharmaceutical industry on R&D for diseases of poor people in the developing world is monitored. In partnership with the industry and other stakeholders, the Government will explore options for establishing a rigorous and independent monitoring mechanism, to inform policies that will address bottlenecks and constraints to under investment.

CONCLUSIONS

23. The achievements of this Group, in a short, amount of time has been impressive. The agreements laid out in this report represent a starting point, rather than a solution. The way forward requires ambition but is achievable.
ANNEX 1: Recommended Actions following the UK Working Group on Access to Medicines

### DIFFERENTIAL PRICING

<table>
<thead>
<tr>
<th>GOAL: 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</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GB</strong></td>
</tr>
<tr>
<td><strong>OTHER HIGH INCOME MARKETS</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>EU</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Developing Countries</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>UN</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Pharmaceutical Industry</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Other Trade issues</strong></td>
</tr>
</tbody>
</table>

### RESEARCH AND DEVELOPMENT

<table>
<thead>
<tr>
<th>GOAL: Policies that will increase level of UK R&amp;D into essential medicines for poor people in the developing world</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>UK Government</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

---

7 These actions stem from discussion in the Working Group and official papers and cover roughly the next 12 months. The Group recognises that these actions focus on only some of policy options for increasing access to essential medicines – facilitating a voluntary system of differential pricing (combined with a strengthened capacity for bulk purchasing), donations, and increasing UK R&D into essential medicines. These actions can make a significant difference but they are not a panacea. Complementary action and international support for other policy options such as strengthened health systems, or dialogue through trade agreement, for example will need to be maintained.
Annex 2: PARTICIPANTS

Chair: Clare Short Secretary of State for International Development

Government

Lord Hunt, Parliamentary Under-Secretary of State (Lords), Department of Health

Baroness Symons, Minister of State for Trade and Investment, Department of Trade and Industry and Deputy Leader of the House of Lords

Paul Boateng Financial Secretary, H M Treasury

External

Mr. E J Fullagar Esq., President, Association of British Pharmaceutical Industry
Professor Trevor Jones, Director General, Association of British Pharmaceutical Industry

Dr Tom McKillop, CEO, AstraZeneca
Dr John Patterson, Executive Vice President, Product Strategy and Licensing, AstraZeneca
Ms. Frances Charlesworth, Director, Global Government Affairs and Policy, AstraZeneca

Mr. Paul Vandoren, Head of Unit for TRIPS and New Technologies, DG Trade, European Commission

Dr Lieve Fransen, Head of Unit for Human and Social Development, DG Development, European Commission

Sir Richard Sykes, Chairman, GlaxoSmithKline
Ms. Chrissie Kimmons, Senior Vice President, Global Government Affairs and Public Policy, GlaxoSmithKline
Mr. Chris Strutt, Vice President External Relations, GlaxoSmithKline
Mr. Simon Sargent, Vice President, Industry Affairs, GlaxoSmithKline

Professor Richard Feachem, Director, Institute for Global Health, UC San Francisco/UC Berkeley

Professor Gordon R Conway, President, Rockefeller Foundation
Dr. Tim Evans, Director, Health Equity, Rockefeller Foundation

Dr. T Michael Dexter, Director, Wellcome Trust
Dr Richard Fuller, Director of Science Funding
Dr Richard Lane, Head of International Programmes,

HE Professor George Kirya, Ugandan High Commissioner, Uganda High Commission London

Dr Yasuhiro Suzuki, Executive Director, Health Technology and Pharmaceuticals, WHO
Dr. Jonathon Quick, Director, Essential Drugs and Medicines Policy, WHO
Dr. Andrew Creese, Economist, Essential Drugs and Medicines Policy, WHO

Mr. Adrian Otten, Director, Intellectual Property Division, World Trade Organisation

8 Now Executive Director for the Global Fund to Fight HIV, TB and Malaria
ANNEX 3: PRIME MINISTER’S STATEMENT 18/07/01

The Prime Minister announced today that he has asked Clare Short, Secretary of State for International Development, to set up and chair a small high level working group with the pharmaceutical industry and representatives of international organisations to find ways of improving access to medicines in developing countries.

The Financial Secretary to the Treasury, Paul Boateng, will join the Group, and will report to the Chancellor on the implementation of the Budget proposals to extend new tax credits for R&D on diseases of poverty – in line with new commitments from the industry to respond to new incentives. The Working Group will also include Ministers from DFID, Department of Health and other relevant Departments, and senior representatives of the UK pharmaceutical industry. It will seek senior representatives of international organisations to join in its work.

Commenting on the establishment of the Group the Prime Minister said: "We are all committed to working together in partnership to improve access to medicines to help meet the health targets set at the G8 Okinawa Summit in July 2000."

The Working Group will look at a range of issues on access to medicines. Its initial priorities will be on:

- Ways of improving access to medicines through measures such as facilitating differential pricing arrangements and encouraging appropriate donations.
- Measures to encourage companies to increase R&D into medicines and vaccines for diseases prevalent in developing countries, namely TB, Malaria and relevant strains of HIV/AIDS, taking forward implementation of the R&D tax credits announced in the budget.

The Working Group will also discuss other key issues on the international health agenda - such as the development of the Global Health Fund - and related trade issues.

The Prime Minister added: "There is agreement that there is a range of obstacles to access to medicines in poor countries. These include the absence of sustainable financing for medicines, their affordability, the lack of reliable health and supply systems and inappropriate use and selection of medicines. In addition there are issues around incentives for R&D investment that influence access to future medicines. There is action ongoing in many of these areas by industry and the international community. The work of Clare Short’s Group is intended to complement other work, especially the establishment and development of the Global Health Fund, and to facilitate international discussions and actions around this vital international public health agenda."
ANNEX 4: INDEX OF ALL WORKING GROUP PAPERS

GENERAL

1. Prime Minister’s Launch Statement and Terms of Reference
2. Report to Prime Minister by the Secretary of State for International Development
6. Overview of DFID Support to Increase Access to Essential Medicines, DFID
7. UK Government Statement reaffirming commitment to areas of the wider context of actions necessary to support increased R&D and product development, Produced subsequent to 2nd Meeting
8. Global Fund Update, 2nd Meeting, DFID

R&D

11. Context Setting Paper: Investing in R&D for Diseases of the Poor, Professor Richard Feachem and Carol Medlin
12. Chancellor’s Initiative to Stimulate R&D into Diseases of the Poor, HMT
13. Industry Investments and Initiatives, Association of British Pharmaceutical Industry (ABPI)
15. Encouraging R&D into the diseases of poverty: the role of Orphan Drug Legislation (ODL), Paper Produced for HLWG

DIFFERENTIAL PRICING

19. Preventing Parallel Trade of Differentially Priced Patented Drugs, 2nd Meeting, DTI
22. Tiered Pricing: an NGO Consultation Paper: 2nd Meeting, NGOs
23. Trade Measures to Prevent Diversion of Differentially-priced Pharmaceuticals: Relevant WTO Provisions, Adrian Otten, WTO