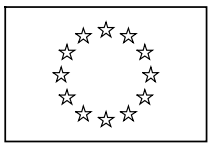

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COMMUNICATION FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT

Update on the EC Programme for Action

Accelerated action on HIV/AIDS, malaria and tuberculosis in the context of poverty reduction

Outstanding policy issues and future challenges

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EXECUTIVE SUMMARY

The Commission adopted its Programme for Action (PfA), entitled *Accelerated action on HIV/AIDS, malaria and TB in the context of poverty reduction* in February 2001. The PfA entailed a series of actions to **increase the impact of existing interventions**, **increase the affordability of key pharmaceuticals**, and **encourage research in and development of specific global public goods** to tackle HIV/AIDS, malaria and TB at the national, regional and global level. The PfA has been in place for two years and it is now an appropriate juncture at which to assess its implementation, outstanding policy issues and future challenges.

The PfA, and its implementation, is important above all because the number of people affected, infected and dying from HIV/AIDS, malaria and TB is still on the increase. In 2001 alone, some three million people died from AIDS, while another five million were newly infected by HIV. The burden of malaria and tuberculosis continues also to increase. In 2001, some two million people died from TB and 1 million from malaria. Current trends indicate that by 2020 nearly one billion people will have become infected with TB, 200 million will have developed the disease and 35 million of them will have died. Both TB and malaria are contributing factors in another two to four million deaths annually.

There is a consensus within the international community about the urgency of the need to tackle HIV/AIDS, malaria and TB in developing countries and about the mechanisms by which this can be achieved. All members of the international community have signed up to the Millennium Development Goals (MDGs). HIV/AIDS, malaria and TB targets feature prominently, highlighting the link between overall poverty reduction and health investments. The WHO-initiated Commission on Macroeconomics and Health (CMH) presented convincing evidence of the need to focus on the three diseases and demonstrated why investments in health are an effective strategy for reducing poverty. The debate over Global Public Goods (GPGs) has also advanced and appropriate incentives are being considered for the production of specific GPGs, such as controlling the HIV/AIDS, malaria and TB epidemics. There is still no HIV/AIDS, malaria or, effective, TB vaccine available and many of these global public goods depend on international action.

With regard to **'increasing impact'**, progress has been slow in terms of increased support for health. Notwithstanding the large price reductions obtained since the adoption of the PfA, only few have access to anti-retroviral medicines, effective TB and malaria interventions. The desired increase of health spending in developing countries to at least USD 30-40 per person per annum, will require, by 2007, approximately USD 27 billion per annum in donor grants

and an additional budgetary outlay from developing countries of USD 23 billion. An estimate of annual financial needs to cover HIV/AIDS, malaria and TB alone totals USD 9.2 billion. The results of the effectiveness of the PfA at country level need to be assessed over a longer time-scale. However, EC spending on social infrastructure is planned to rise, dormant programmes have been re-directed, and spending better focused on those priorities established by the PfA. At EU level several resolutions have been adopted by Council and Parliament confirming the priorities established by the PfA. The Commission has also adopted a Communication on Health and Poverty, which identifies four broad approaches toward improving health outcomes, and proposed a Regulation on Poverty Diseases (HIV/AIDS, malaria and TB). The latter includes a substantial increase in financial resources.

With regard to '**increasing affordability'**, intellectual property rights and the TRIPs Agreement have caught a lot of attention in the launching of the new WTO Development Round. At the Ministerial meeting of WTO Members at Doha in 2001, the adoption of the Declaration on relations between the TRIPs Agreement and Public Health was a significant step forward. The Commission's strategy towards tiered pricing for improved supplies of essential pharmaceuticals to developing countries has also yielded tangible results. During the last two years the tiered pricing concept has gradually become widely accepted within the EU as an effective way forward in the quest for access to key pharmaceutical products for people living in poverty. In this regard, the Commission has adopted a proposal for a Council Regulation to prevent trade diversion into the EU market of pharmaceuticals sold at tiered prices in developing countries.

In terms of '**increasing investment in research and development'**, substantial resources have been allocated from the Research Framework Programmes for HIV/AIDS, malaria and TB research, including the establishment of the new European and Developing countries Clinical Trials Partnership (EDCTP) initiative. The EDCTP clearly constitutes a new step forward as it contributes to a unified voice to represent European research contributions in the fight against the three diseases in developing countries. Additional direct and indirect incentives for research and development of specific global public goods to fight the three diseases require primary focus in the coming years.

Globally, the EC has been proactive in addressing the issues covered by the PfA, for example, in the context of the G8, in particular at Okinawa, at EU/US summits, the EU/OAU forum. The Commission is an active Board Member of the Global Fund to fight AIDS, TB and Malaria (GFATM). Developing countries have a strong voice in the GFATM Board and the Fund's overall governance arrangements. Important policy areas, which had previously not been successfully addressed in other fora such as tiered pricing, are being addressed here. These can, however, not be dealt with in the GFATM alone. Renewed efforts are needed to work jointly at the European level as well as with specific partners, in particular the US, on these issues.

Two years after its adoption the PfA remains a comprehensive, forward looking and coherent EU policy framework aimed at making a significant contribution towards improved country, regional and global action against the three communicable diseases. There is, however, still an urgent need for large-scale collective action. Where progress has been less visible, it is mainly the result of the lack of appropriate resources within the Commission and/or within the Member States to take forward large scale action in areas such as local -production- capacity, technology transfer, incentives for innovative research and development by the private sector, and working through true partnerships in particular with the developing countries concerned.

The PfA has demonstrated that a strong EU voice is crucial, and, as a result of the PfA, EU positions on targeted HIV/AIDS, malaria and TB actions have been significantly strengthened on a global level jointly with other partners. Nevertheless, more efforts are needed to provide regular and structured consultation with developing countries. It is proposed that this be further developed through the creation of a **Stakeholders Forum on Communicable Diseases in the Context of Poverty Reduction**.

Major challenges lie ahead for the EU in getting developing countries, other OECD members, their industry and civil society to adopt and apply the different mechanisms needed to fight the three diseases.

1. INTRODUCTION

The *EC Programme for Action on Communicable Diseases in the Context of Poverty Reduction* (hereinafter Programme for Action or PfA) is based on the policy framework presented in the September 2000 Communication on "*Accelerated Action targeted at major communicable diseases within the context of poverty reduction*"[1]. It establishes, as part of an expanded international effort, a broad and coherent Community response, over the period 2001 to 2006, to the global emergency caused by the three major communicable diseases, HIV/AIDS, malaria and tuberculosis (TB). These diseases affect the poorest populations most and undermine global health and sustainable development. The Community response entails a comprehensive and mutually reinforcing set of actions to increase: (i) the impact of existing interventions, (ii) the affordability of key pharmaceuticals, and (iii) research and development of specific global public goods to confront HIV/AIDS, malaria and TB at the national, regional and global levels.

This Communication assesses the implementation of the PfA over the first two years of its existence. It is intended primarily for Council and European Parliament. It is also important for the broader public committed to contributing to improved sustainable development outcomes to be aware of the progress made in the joint fight against the three diseases in developing countries. The document addresses the overall context and the outstanding challenges globally, and presents results in the areas of impact, affordability and research. A separate section is devoted to 'monitoring and evaluation', followed by recommendations for the future.

2. CONTEXT AND CHALLENGES

In all, over the past two years, more than 160 million healthy life years have been lost to HIV, 80 million to malaria and nearly 72 million to tuberculosis

1. The **number of people affected, infected and dying from HIV/AIDS, malaria and TB is still on the increase.** In 2001 alone, some three million people died from **AIDS**, while another five million contracted HIV. Half of all new HIV infections - over 6,000 daily - occur among 15-24 year olds. The areas with the most rapid spread are in Eastern Europe, Central Asia, China and India. Most new infections in these areas are among injecting drug users. Yet overall, AIDS remains a major factor in all regions.

2. The development burden of **malaria and TB** also continues to increase. Current trends indicate that by 2020 nearly one billion people will have become infected with TB, 200 million will have developed the disease and 35 million of them will have died. One-third of the world's population is currently infected with tuberculosis. In 2001, some two million people died from TB and 1 million from malaria. Both TB and malaria are contributing factors in another two to four million deaths annually. The majority of malaria deaths occur among young children living in Sub-Saharan

[1] COM (2001) 96 of 21.2.2001 and COM(2000) 585 of 20.9.2000.

Africa. TB is predominantly linked to the large prevalence of AIDS and is a major factor in South East Asia, East Asia, the Pacific and the Americas.

2.1. Unprecedented international agreement - starting to reconcile the contradictions

1. The past two years have been marked by a widespread consensus within the international community about the urgency of the need to tackle HIV/AIDS, malaria and TB in developing countries and about mechanisms through which this can be achieved. More than ever before, government officials, politicians, policy and decision-makers, civil society actors and business executives, have become aware of the burden caused by these diseases, and how it will develop if we do not scale up our efforts to fight them. This consensus has led to a new political momentum, which has garnered **unprecedented international agreement** on the interventions that will make the greatest difference.

2. All members of the international community have signed up to the **Millennium Development Goals** (MDGs – Annex 3). Central to these goals is a reduction in the proportion of people living in extreme poverty by 50% by 2015. Health targets feature prominently, highlighting the link between overall poverty reduction and health investments. The specific Goal 6 related to *'HIV/AIDS, malaria and other diseases'* indicates a strong commitment, acknowledging that without addressing these diseases the central outcome of global poverty reduction will not be met. Specifically, the aim is to halt and reverse the spread of HIV/AIDS and the incidence of malaria and TB by 2015. It is now generally accepted that the PfA has directly contributed to the international consensus reached on MDG Goal 6.

3. Other **more specific targets** have been agreed upon globally or regionally for the three diseases: for HIV/AIDS at the UN General Assembly Special Session on HIV/AIDS in June 2001, for malaria at the African Summit on Roll Back Malaria in Abuja in April 2000, and for tuberculosis, inter alia at the World Health Assembly of May 2000. The goals, targets, accompanying indicators and measures for the three diseases are also being addressed in the newly established Global Fund to fight HIV/AIDS, malaria and tuberculosis (GFATM).

4. Another important global turning point during the past two years was the work undertaken by the **WHO Commission on Macroeconomics and Health** (CMH)[2]. The report presents clear evidence of how a heavy disease burden[3] reduces economic growth and limits the resources available to governments to invest in public health and poverty reduction efforts. It demonstrated why increased investments in health constitute an effective strategy for reducing the number of people living in poverty and estimates the return on health investments in developing countries at 18% per annum. The CMH helped strengthen a global consensus on the need to reduce the disease burden of people living in poverty through concentrating on these three diseases.

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2 WHO *Commission on Macroeconomics and Health, Final report* December 2001.

3 The impact of ill health on individuals, and on their societies, is measured by estimating the number of years of healthy life they lose as a result of each illness. Cumulatively, the total number of healthy life years lost as a result of the illness can be described as the "disease burden" that it causes. The total disease burden in a society represents the gap between the actual health of the population and an ideal situation where everyone lives into old age in full health.

5. Since the adoption of the PfA the debate over **Global Public Goods** (GPGs) has advanced further in different fora. The PfA was a clear statement of the need for a global GPG policy approach based on the understanding that investments in health and development are in the interests of all, poor and rich. This policy approach goes far beyond mere "aid". Since providers of public goods may not be adequately compensated through market-based negotiations or through existing public financing mechanisms, the EC and the EU Member States are now working on developing **appropriate incentives** for the production of specific GPGs (products, services, knowledge) able to help controlling epidemics such as HIV/AIDS, malaria and TB.

6. A growing body of evidence shows that **prevention, treatment and care** are parts of a continuum. Equally, it is increasingly apparent that it is possible to deliver care and treatment for people with AIDS in resource-poor settings, which is an important part of efforts to make prevention more effective. This growing perception was apparent during the UNGASS on HIV/AIDS in June 2001, and resulted in a consensus that prevention and treatment should be addressed as complementary, not competing priorities during the XIV International Conference on AIDS, in July 2002. The essential link between prevention and care is also common knowledge in the field of TB control since only 80% cure rate in a highly endemic community can control transmission. There is increasing evidence that a similar link is strong in the field of malaria, in particular for malaria control in pregnant women, as it is often fatal for the mother or the child.

7. There continues to be strong public interest in the need to promote and improve **access to medicines** in poor countries. An important focus of public campaigning has been to establish a better relationship between the protection of public health and the protection of intellectual property rights enjoyed by pharmaceutical manufacturers. At the Doha Ministerial Meeting in 2001, World Trade Organisation (WTO) members successfully negotiated a Declaration regarding the interpretation and implementation of the relationship between the TRIPs Agreement and Public Health "…in a manner supportive of WTO Members right to protect public health and in particular to promote access to medicines for all". The European Community and its Member States played a decisive role in achieving agreement on this Declaration, and continue to lead subsequent negotiations on outstanding issues.

2.2. Globally slow progress on 'access' and 'resource mobilisation'

1. Despite the above, however, progress has been slow in terms of the urgency of delivering quality prevention, treatment and care services, including commodities and supplies. This was one of the central elements of the PfA. There is overall agreement that appropriate use of condoms and prevention of mother to child transmission with anti-retrovirals could halt the spread of the HIV/AIDS pandemic, while Highly Active Antiretroviral Treatment (HAART) has proven to be life-saving in many cases and an incentive for effective prevention through an increased uptake of voluntary counselling and testing, and through health information and education in general. Whilst during the last two years the prices of anti-retroviral drugs (ARVs) and some drugs against opportunistic infections have started to fall, in some cases by large margins (annex 4), and countries such a Brazil have progressed substantially in providing overall access to pharmaceuticals for HIV infected people, it remains the case that only 0.3% of the people living with HIV/AIDS in developing countries have access to ARVs. Therefore more effective, better-adapted and simplified treatments need to be developed.

Interventions to prevent the spread of TB still lack the desired efficacy, yet Direct Observed Treatment by Short regimes (DOTS) has shown how high cure rates and a reduction in incidence, morbidity and mortality can be achieved. Although a total of 148 countries currently use the DOTS strategy, access is only offered to about 55% of the world's population. In several countries, nation-wide commitment to the DOTS strategy has succeeded in reversing an increasing trend in the prevalence of TB and putting the country on track to halving new cases or the incidence of TB every 10 years.

Insecticide-treated nets and intermittent preventive treatments can significantly reduce a large proportion of the burden of disease from malaria. Despite the fact that more than five million insecticide-treated nets were distributed during 2000-2001, the proportion of children under five in Africa sleeping under insecticide-treated nets remains below 10%, and the average use of bednets is still only 1% of the African populations at risk. It is only in Vietnam where the child mortality rate due to malaria has declined over the last decade. In Sub-Saharan Africa the incidence of malaria has increased. The rapid increase in drug resistance suggests that malaria deaths may be poised to rise sharply. Progress on phasing out DDT for malaria control has been made with the adoption of the Persistent Organic Pollutants (POPs) Convention in Stockholm May 2001. Exemptions have been given to developing countries on the condition that research for safe and alternative chemicals and non-chemicals would continue in order to find an equally efficient and affordable tool for malaria prevention.

A particularly important issue for HIV/AIDS is the current focus by the international community **on instability and insecurity** whereby a series of measures, which are not always built on the **defence of fundamental human rights** are being proposed and taken further. The respect or non-respect for human and civil rights and the non-discrimination or discrimination against people with HIV/AIDS are of increasing concern in many countries but are not always sufficiently addressed. The debate goes well beyond the right to health and includes non-discrimination in the workplace and society, the right to inheritance, freedom of movement, and the right to marry. Frequently, legislation discriminates against HIV-infected people.

2. **Financial resources remain derisory.** The CMH calculated that current actual spending on health in the least developed countries[4] (approximately USD 13 per person per annum) need to be increased to at least USD 30-40 per person per annum. This will require approximately USD 27 billion per annum in donor grants by 2007, compared with the USD 6 billion per annum currently available, and an additional budgetary outlay from developing countries of USD 23 billion by 2007. The CMH also provided a detailed estimate of annual financial needs to cover HIV/AIDS, malaria and TB, totalling USD 9.2 billion. This is a minimum estimate for

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[4] The Least Developed Countries are presently 49: Afghanistan, Angola, Bangladesh, Benin, Bhutan, Burkina Faso, Burundi, Cambodia, Cape Verde, Central African republic, Chad, Comoros, Democratic Republic of Congo, Djibouti, Equatorial Guinea, Eritrea, Ethiopia, Gambia, Guinea, Guinea Bissau, Haiti, Kiribati, Lao People's Democratic Republic, Lesotho, Liberia, Madagascar, Malawi, Maldives, Mali, Mauritania, Mozambique, Myanmar, Nepal, Niger, Rwanda, Samoa, Sao Tome and Principe, Senegal, Sierra Leone, Solomon Islands, Somalia, Sudan, Togo, Tuvalu, Uganda, United Republic of Tanzania, Vanuatu, Yemen and Zambia (UNCTAD 2001 - http://www.unctad.org/en/pub/ldcprofiles2001.en.htm).

investments with immediately possible levels of delivery with an emphasis on expanding the lower levels of district health systems, such as health posts and outreach services. African countries have agreed to allocate 15% of their national budgets to health (Abuja, April 2000). Some, such as Nigeria, are using debt relief for substantial renewed investments in health, in particular HIV/AIDS. Countries with a high disease-burden are demonstrating their commitment to TB control by financing 60% of TB treatment budgets themselves. Nevertheless, considerable resource mobilisation challenges remain - particularly for Africa, and most particularly for HIV/AIDS. The Global Fund to Fight AIDS, TB and Malaria (GFATM) aims at an additional outlay of USD 2.3 billion for 2003 and USD 4.6 billion for 2004; to date a total of USD 2.1 billion has been committed for the forthcoming five years.

3. PROGRESS OF THE PFA TO DATE

The PfA was designed to link **country-level actions** aimed at increasing people's access to existing interventions, goods and services, with **enabling global action on affordability and investment in the development of specific global public goods**. Three areas for action were identified: **impact, affordability and research**. These areas for action are inter-related and complementary. Implementation requires coherent, collective and simultaneous action.

3.1. Impact

3.1.1. Optimising the impact of Health, AIDS and Population interventions targeted at major communicable diseases and poverty reduction

The ambitious target in the Programme for Action to increasingly **prioritise in-country / regional allocations for improved 'health' outcomes**, in partnership with developing countries and other partners, has so far brought relatively indistinct results. A longer time-scale will be needed before real impact becomes clearly visible. 'Health' allocations are traditionally and proportionally higher in the EC-funded programmes in Asia, Latin America and the Mediterranean, than in the European Development Fund (EDF). A more coherent focus on reaching the MDGs within the RELEX family is needed, especially for countries where the HIV/AIDS epidemic is advancing rapidly (India and China). The establishment of an **EC Programme for Action Interservice Group** (November 2002) is intended to take the PfA forward across the Commission and in all developing countries.

1. At the end of 2001 **Programming Guidelines** for Health, AIDS and Population were shared with Commission Delegations. All EC Country Strategy Papers/National Indicative Programmes (except for the 'non-notified ACP countries') have been finalised at the end of 2002[5]. **The current level of allocations for 'health as a focal sector' programmed under the 9th EDF is 3.7% (€ 280 million).** 22.3% from the 9th EDF (€ 1.6 billion) is programmed for 'macro-economic support with social development conditionalities'. During 2002, regional and intra-ACP funds have been programmed for 'health' in ACP countries from the 6th - 9th EDF (€ 104 million in total: € 60 million for the GFATM from the 6th and 7th EDF and € 44 million for reproductive health / malaria from the 8th and 9th EDF). Additional funding from the

[5] Commission staff working paper: 'Progress report on the implementation of the Common Framework for Country Strategy Papers, SEC (2002) 1279, 26.11.2002. See Annex 2 for multi-annual financial provisions.

9th EDF intra-ACP regional funds and from 9th EDF reserves is currently being discussed with the ACP countries. MEDA programming for 'health' for 2002-2004 represents 2%, Asia (2002-2004) is 14.1% and Latin America (2002-2006) 1.9%. The current multi-annual provisions for all developing countries total € 423.2 million for 'health and population', less than 3.3% of total EC development aid programming. EU Member States - FI, DE, UK, B, FR, S and NL - have moved towards a greater focus on the MDGs for health in their aid programming.

2. At the beginning of 2002, the Commission agreed with the European Parliament Committee on Development to ensure that, for **development spending from the EC Budget**, at least 35% will be allocated to 'social infrastructure'. This benchmark is an indicator for health and population, education, water supply and sanitation and government and civil society, following DAC sector category 1. The current multi-annual provisions for all developing countries for 'social infrastructure' represents **€** 4.651 billion, i.e. 36.3% of total EC development aid programming.

3. During 2001 the Commission revisited 22 **dormant 'health' programmes** (ACP and ALAMEDA) and de-committed or redirected funds where appropriate[6]. The reform of the Commission's External Relations services, helped speed up disbursement levels substantially. In February 2001, the total ongoing Health, AIDS and Population portfolio **disbursement** rate was set at 17% (i.e. disbursement versus total commitments). This is set to date at 23% for the same portfolio (1995-2000). Yet figures for 2001 and 2002 are more promising with, throughout the past two years, a clear improvement in the overall budget execution performance, including an increase of 20% in 2001 payments compared to 2000.[7] The new information system (CRIS) has been phased in during 2002 and is expected to be fully operational by beginning 2003.

4. The European Community and its Member States are increasingly working towards the **harmonisation of policies and procedures** to improve impact in-country. Joint European Commission/European Union missions to a number of pilot countries (Mozambique - Morocco - Vietnam - Nicaragua) were launched in September 2002 with the aim of assessing the potential for better harmonisation in the areas of health and education. It is clear that closer donor co-ordination should be based on a step by step approach, moving from joint consultation and information exchange to joint situation analyses, programming and implementation structures, including an effective information flow between HQ and delegations/embassies. The Commission has established a **Task Force** to work on a detailed **Harmonisation Action Plan** for health, HIV/AIDS and education. As a result, the current in-country work on the use of specific indicators and on measuring progress towards the MDGs should be improved.

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6 While not all dormant 'health' projects have been closed, the mass of "dormant" funds against "active" resources is 27% for health in general, 10.3% for HIV/STI related projects and 6.8% for programmes targeting control of communicable diseases.

7 COM(2002) 490 final Annual Report 2001 on the EC Development policy and the Implementation of the External Assistance, 12.09.2002.

5. Throughout 2001 several resolutions on the Programme for Action were adopted: the Council resolution on 14 May 2001; the EP resolution on 4 October 20018; the ACP-EU Joint Parliamentary Assembly resolution on 1 November 2001. The Commission's proposal for a legal base for the EC contribution to the Global Fund to fight AIDS, Tuberculosis and Malaria (GFATM) was adopted on 23 October 2001, and on 19 December 2001 the Council and EP adopted the contribution by the EC to the GFATM9.

6. The Commission has reformulated the **regulation** creating a special budget line (B7-6311) for HIV/AIDS, malaria and TB, in line with the follow-up to the Programme for Action.[10] Throughout 2002 this regulation has been thoroughly discussed in Council and Parliament.[11] The Commission proposed an almost threefold increase in allocations (from € 25.27 to € 73.35 million). It is expected that the regulation will be adopted by the EP and Council beginning 2003.

7. In March 2002 the Commission adopted a Communication on **Health and Poverty**[12] and a subsequent Council resolution was adopted on 30 May 2002. Council's resolution referred to **increasing the volume and improving the delivery of aid**. It stated: […] *in view of reaching better health outcomes and attaining the internationally agreed health development goals, the EU will strongly support those developing countries who agreed to work towards the targets set by themselves for investments in health, such as in Abuja (15% of national budgets)* […] and […] *In this context, the Council recalls its conclusions on the UN Conference on Financing for Development in Monterrey, agreed by Foreign Ministers on 14 March and endorsed by the European Council in Barcelona whereby the Member States collectively commit themselves, as a first significant step, to increasing their overall ODA volume in the next four years.* ***A substantial share of that increase should go to support for social development in developing countries with special emphasis on improving health and education outcomes.*** […] Discussions in the European Parliament on the Health and Poverty Communication started in October 2002 and remain in progress.

8. At the OECD/DAC in 2001 the Commission declared its determination to increase the participation of contractors from developing countries in the execution of Community development programmes and projects through an initiative in favour of the **increased untying of Community aid**. The Commission proposed to use

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8 On 15 March 2001 a European Parliament Resolution on access to drugs for HIV/AIDS victims in developing countries noted the inclusion of a commitment to tiered pricing in the Commission's Programme for Action and called for a system allowing developing countries equitable access to medicines and vaccines at affordable prices.

9 Decision No 36/2002/EC of the European Parliament and of the Council of 19 December 2001 concerning the Community contribution to the Global Fund to fight HIV/AIDS, tuberculosis and malaria, *Official Journal L 007 , 11/01/2002 P. 0001 - 0002.*

10 Proposal for a Regulation of the European Parliament and of the Council On aid for poverty diseases (HIV/AIDS, malaria and tuberculosis) in developing countries. COM/2002/0109 final - COD 2002/0051.

11 In parallel, the Commission proposed the revision of the regulation for the special budget line (B7-6312) on 'aid to population programmes' to include 'reproductive and sexual health and rights'.

12 COM(2002) 129 final, 22.03.2002. This Communication details the relationship between health and poverty. It outlines critical elements of a coherent development approach to improve health and well-being and establishes, for the first time, a single Community policy framework to guide investment in health, AIDS, and population within the context of overall European assistance to developing countries.

medicines and supplies/products for HIV/AIDS, malaria and TB as a pilot exercise. The first EC dossier to benefit from untying was an international tender in Zimbabwe. On 18 November 2002, the Commission adopted a Communication on untying of aid, which further clarifies the approach taken by the Community in light of the OECD/DAC decision related to aid untying.

3.1.2. Strengthening of pharmaceutical policies and capacity building

1. The **strengthening of pharmaceutical policies** has been substantially reinforced for ACP countries. The EC programmed, through a partnership with the WHO, € 25 million (9th EDF) for regional co-operation and capacity building including enhanced and improved essential drug policy and regulatory schemes. The financing proposal has been discussed at the EDF Committee in November 2002 yet adoption will only take place once the 9th EDF is formally ratified. Additional efforts are ongoing to develop and finance a broader strategic partnership[13] with the WHO.

2. In April 2002, the WHO Expert Committee on essential drugs decided on the **12th WHO Model List of Essential Medicines** (the first having been adopted in 1977). It contains 325 medicines, including 12 ARVs[14] for the treatment of HIV. Along with the model list, the WHO released guidelines on scaling up ARV treatment. The action is seen as a breakthrough in a comprehensive "prevention through care" package that could contribute to wider access to treatment over the coming years.

3. Discussions are under way between the Commission and ACP countries, Roll Back Malaria, Médicins Sans Frontières and other partners relating to existing **malaria national protocols**. There is a need for a change of protocols to include artemisine combination therapies, especially in East Africa[15].

3.1.3. Developing local manufacturing capacity

1. It is becoming apparent that there is an emerging need to **consider global manufacturing capacity** for many essential medicines and pharmaceutical starting materials. If the scale of the epidemics continues to grow, it is not impossible that the current capacity of pharmaceutical production will be insufficient. There are finite amounts of raw materials for some ARVs, for example, due to the limited numbers of manufacturers. The Commission will examine the extent of such production capacity constraints as tiered pricing and public tendering increase, affordability is promoted and demand rises.

2. Several initiatives for the development of **local production capacity** are in progress. One, for example, is for the local production of condoms in South Africa, linked with social marketing. The European Investment Bank (EIB) is taking this analysis forward and is considering financial support. The EC is also exploring other partners

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13 A Strategic Partnership could include: involvement of EC in governing, statutory and political bodies of the selected partner; contribution to policy debates; financial cooperation in operational activities; financial support for core capacities *(15.7.2002 DG DEV A/2 note to Joint Management Meeting*).

14 They include nevirapine and zidovudine - previously listed for prevention of mother-to-child transmission but now also recommended for treatment of HIV in adults and children. The new medicines in the EML are abacavir, didanosine, efavirenz, indinavir, lamivudine, lopinavir, nelfinavir, ritonavir (low-dose), saquinavir, and stavudine.

15 The new EML includes Artemether-lumefantrine (Co-artem) as a combination artemesin product.

in priority areas for technology transfer and local production of pharmaceuticals, for instance anti-retrovirals, artesunate and an oral polio vaccine.

3. The **transfer of high volume production capacity** to poor countries as well as building up of R&D capacity, is an important part of a strategy to create sustainable access to medicines. These developments must run in parallel as no technology can be mastered without significant adaptations and increasing local technical competence. Moreover, it will not necessarily disadvantage Europe's pharmaceutical industry. For some products, freeing production capacity for what may be more profitable production may create a win-win situation. However, in some cases, such as vaccines, it is important that manufacturing capacity be developed well before the lowering of production in OECD markets. There is now a real shortage of some low-profit traditional vaccines, such as the oral polio vaccine and the yellow fever vaccine, as producers in developed countries have tended to focus production capacity on more profitable – and expensive – vaccines.[16]

3.2. Affordability

3.2.1. Tiered Pricing

1. Europe's **advocacy of the tiered pricing concept** has been successfully pursued**.** The PfA, the May 2002 Council Conclusions and the EP Resolutions on the subject, all include clear references to the need to introduce tiered pricing as the norm for key pharmaceuticals destined for the poorest developing countries, while at the same time seeking to prevent imports of the tiered priced products to the EU market. Discussions on taking the tiered pricing agenda further forward, along with other PfA actions, have taken place with the Member States and with civil society. Tiered pricing is also consistently addressed by the EC in discussions relating to the procurement of goods and services funded by the GFATM. There is, in general, broad consensus in favour of tiered pricing and support for the mechanism is on the increase in Europe. Yet discussions with the US have, so far, only gradually led to tangible results.[17]

2. On 30 October 2002 the Commission adopted a proposal for a **Council Regulation to avoid trade diversion** into the European Union of certain key medicines originally destined for the poorest developing countries and sold at very reduced prices[18]. This regulation provides for increased protection against import to the EU of pharmaceutical products which have been sold to least developed and low income developing countries at prices reduced by at least 80% compared to OECD average ex-factory price or, alternatively, sold at direct manufacturing cost plus a maximum of 10%. The draft regulation is a novelty as it aims at protecting both products covered by intellectual property rights and non IP-protected goods and is also identifying a target to be achieved in price reduction. In practise producers and exporters are invited to notify to the Commission the products for which they wish the additional protection offered. The list will, together with appropriate

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16 See WHO, UNICEF, The World Bank, *State of the World's Vaccines and Immunisation*, November 2002.

17 During the GFATM Board Meeting in October 2002 the US agreed to use tiered pricing as a mechanism for GFATM procurement.

18 Proposal for a Council Regulation to avoid trade diversion into the European Union of certain key medicines, COM/2002/0592 final - ACC 2002/0257

identification in the form of a mandatory logo and possibly additional voluntary differentiation, enable the customs authorities to suspend the release of suspected tiered priced products at the borders of the EU market. Industry participation in the scheme is entirely voluntary. The draft regulation invites also non-European producers to notify their products. The regulation will hopefully serve as a model for other developed countries to follow. The more pharmaceutical products are submitted for approval under the regulation, the more likely it is that other countries, including the US, will become receptive to the idea of definitively preventing the flow of low-priced medicines back to their market.

3.2.2. Tariffs and taxes

The Commission commissioned a study on tariffs and other duties paid when pharmaceuticals are imported into developing countries. Preliminary results show **great differences in the application of tariffs, other duties and fees**. Customs duties vary from 0% to 35% for compounds as well as for medicines and vaccines in the 57 countries reviewed. It is clear that populations in a number of developing countries which apply high rates, would benefit from cuts. In the Doha tariff negotiations on non-agricultural goods, the need to improve the situation on tariff cuts for pharmaceuticals could be addressed.

3.2.3. Intellectual Property Protection

1. Throughout 2001 and 2002 the EC and other WTO Members advanced substantially on discussions relating to **intellectual property rights (IPRs) and public health.** These efforts were most apparent in the results of the negotiations in Doha, by the adoption of the Doha Declaration on TRIPs and Public Health. The Declaration usefully clarifies the rights, obligations and flexibility available under the TRIPs Agreement. In addition it allows LDCs to defer implementation of patent law with respect to pharmaceuticals until 1 January 2016. Presently, discussions take place in the TRIPs Council relating to paragraph 6 of the Doha Declaration. In March 2002 the EC presented a position paper discussing two possible 'expeditious solutions' to the difficulties faced by WTO Members with insufficient or no manufacturing capacities with regard to making effective use of compulsory licensing provided for under the TRIPs Agreement. The EC approach is that article 31(f) should be amended to include a clearly circumscribed exception to the export restriction imposed by the same article. Outstanding issues were expected to be resolved before the end of 2002,but this deadline could not be met because of the US refusal to endorse a draft decision on which all other WTO Members had agreed. In order to break this deadlock, the EU tabled a compromise proposal on 7 January 2003. As a result, discussion resumed in Geneva.

2. The Commission is also developing a work plan for **reinforced technical assistance** in the areas of trade and development, which includes support to the efforts of developing countries to participate in trade negotiations, support to building developing countries' capacity to implement trade agreements and support for the necessary policy reforms and investments[19]. Several countries, such as Mauritius, requested specific studies on IP and a general study on TRIPs implementation in Sub-Saharan Africa is being contracted. Less progress has been made on work with the **World Intellectual Property Organisation** (WIPO), but partnerships with key

[19] Trade and Development Communication COM (2002) 513 final.

civil society groups, such as Oxfam and MSF, and with the pharmaceutical industry (in particular with regard to tiered pricing) have been further developed.

3. Some Member States, in particular the UK and NL, organised **special fora to discuss Access to Medicines and IP issues**. In November 2002, the UK High Level Working Group on Access to Medicines, in which the Commission took part, presented a set of recommendations to support specific action on the R&D agenda, and to facilitate a voluntary system of widespread tiered pricing as the operational norm.[20]

3.2.4. Corporate Social Responsibility (CSR)

The area of **Corporate Social Responsibility** (CSR) was not specifically highlighted in the PfA yet its rising importance has been an opportunity to further the PfA's overall objectives. In September 2002 the Commission launched an implementation strategy with respect to CSR following the July adoption of a specific Communication[21] and laying the basis for a special CSR Stakeholder Forum, established on 16 October 2002. Different corporations and NGOs are planning to participate actively in the specific Round Table (scheduled for 2003) on "CSR and Development" which will promote the international dimension of CSR, and during which thematic areas such as health, HIV/AIDS (developing sound workplace policies and private sector advocacy responsibilities), education, gender and **core labour standards** will be examined. It is often argued that corporate businesses are not empowered by shareholders to make substantial financial contributions to development, yet many are increasingly concerned about developing or preserving their reputations through being developmentally responsible. A number of examples of **businesses becoming involved in providing for HIV infected employees** are now emerging and more efforts will need to be undertaken to further encourage the corporate sector (not just the pharmaceutical industry) and shareholders to become socially involved, acknowledge their responsibility for achieving the MDGs and participate in the international development agenda. In this context, the provision of malaria and TB treatment to workers by businesses in the agricultural and mining sectors are being explored as well.

3.3. Research and Development

With the Programme for Action, the European Community agreed to support new approaches that will stimulate the development of **specific global public goods** targeting HIV/AIDS, malaria and TB. The support will be given through **direct as well as indirect incentives** by providing much higher levels of public funding for Research and Science & Technology (S&T) capacity building.

3.3.1. Strengthening of research in poverty related diseases

1. The **Fifth Framework Programme** for Research, Technological Development and Demonstration Activities (FP5, 1998-2002) allocated more than € 109 million to research on HIV/AIDS, malaria and TB. More than 77 research projects were funded, under the Quality of Life Programme (QoL) or the International Cooperation (INCO) Programme. 32 of the projects were on HIV/AIDS (with a budget of around

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[20] Report to the Prime Minister, High Level 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

[21] Corporate social Responsibility: a business contribution to Sustainable Development, COM (2002) 347.

€ 49 million), 24 on malaria (€ 29 million) and 21 on tuberculosis (€ 30 million). Research includes methods to increase DOTS uptake and the long-term validity of ITN use. The research projects were implemented in partnerships between research institutions from EU Member States, Associated Countries, countries in Africa, Latin America, and Asia, and the USA. Projects funded under the QoL Programme aimed to develop new vaccine candidates and new lead substances. Impressive scientific results have been achieved by some of the projects, giving hope that new preventive and/or therapeutic interventions against HIV/AIDS, malaria and tuberculosis can be developed.

2. Poverty related diseases have become one of the priorities of the **Sixth Framework Programme** of Research, Technological Development and Demonstration Activities (FP6, 2002-2006). FP6 was adopted in July 2002 and a substantial budget increase of € 400 million has been allocated to HIV/AIDS, malaria and TB research. The overall research strategy for R&D in FP6 is built on two components:

i) the support for large research consortia which integrate different disciplines and approaches and which generate new partnerships between the different players involved. Different phases of the R&D development process from discovery to safety testing in humans shall be covered. Roughly € 200 million are earmarked for such activities.

ii) the establishment of a clinical trials programme to unite and support Europe's clinical trial activities specifically targeted at interventions for use in developing countries (EDCTP). The Commission earmarked € 200 million for this initiative.

3.3.2. European and Developing Countries Clinical Trials Partnership (EDCTP)

The overall goal of the EDCTP is to **accelerate the development and evaluation of new vaccines, drugs, and other preventive or therapeutic tools against HIV/AIDS, malaria and TB**. Discussions in the European Parliament and Council are currently ongoing to use for the first time Article 169 of the Treaty to establish and implement the EDCTP[22]. The EDCTP has three major objectives:

1) networking and co-operation between national programmes to ensure their efficiency and impact;

2) acceleration of the development of new products by supporting clinical trials in developing countries;

3) strengthening clinical research capacities in developing countries.

The EDCTP will have a target budget of € 600 million. One third of the budget will be contributed by the Community, whereas another € 200 million will be provided by Member States and Norway with an additional € 200 million expected from the private sector, R&D industry, foundations and charities, and Community development funds (EDF or special budget line).

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[22] Article 169 enables the Community to participate in research programmes undertaken jointly by several Member States, thereby creating incentives for co-operation of national activities and creating added value and critical mass at the European and Developing Countries level.

The EDCTP is expected to be operational during the second half of 2003. In line with the Doha declaration, the developing countries should have access to the products developed by the EDCTP. A carefully balanced management structure ensures that the developing countries are important stakeholders and equal partners in strategic decisions. In line with this, African partners will both participate in prioritising new interventions and in the development of strategic clinical trials action plans.

3.3.3. Capacity building for R&D in developing countries

1. Clinical testing and introduction of new drugs and vaccines in developing countries require **training of national health workers**. Within the EDCTP budget € 150 million is therefore earmarked for capacity building in developing countries. Activities include support to South-South, North-South networking and co-operation, technology transfer, strengthening and upgrading of facilities and services at research institutes and clinical institutes in developing countries. To ensure sustainability, mechanisms have shall be developed for retention of well-trained and qualified staff in Africa.

2. Most importantly, support for capacity building in clinical trials shall be linked with **more general support measures for infrastructures** in developing countries. Mechanisms still have to be developed to ensure this. The prioritisation of health investments by the countries concerned is one important component. Continued efforts to support infrastructures and investments through institutional capacity building in developing countries are essential in this regard.

3.3.4. Indirect incentives to increase R&D investments of private sector in specific Global Public Goods

1. The EC intends to increase the overall R&D expenditure in the EU up to 3% of GDP.[23] To achieve this, the EC will particularly explore various initiatives to stimulate investments by the private sector. **Indirect incentives** to increase the private sector's research in HIV/AIDS, malaria and TB have so far focused on ways to facilitate market access and increase profitability. In line with this, the introduction of a special regulatory procedure to obtain a marketing authorisation for poverty-related products shall be further explored.

2. Such an approach has been successfully used for rare (so-called orphan) diseases. The expectation that the **EU orphan drug regulation**[24] would also stimulate the development of medicines for poverty-related diseases (which falls below the prevalence thresholds in Europe set by the orphan drug regulation, such as malaria), has not as yet been fulfilled and was neither the regulation's prime objective. Yet, **-other- specific legislative instruments to encourage the clinical development** of new therapies for poverty-related diseases will therefore have to be re-examined or further explored. This could include specific provisions for fast track approval, and extended marketing authorisation exclusivity. Next to other indirect subsidies for research, product development and testing - such as corporate taxation - the extension of patent protection and / or the transfer of patent rights were identified in the PfA as an alternative way forward and shall be further explored. Scientific advice

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23 COM(2002) 499 final, 11.09.2002.

24 EU Regulation on Orphan Medicinal Products COM 141/2000.

to develop medicines for resource poor settings, and advice leading to GMP/GCP certification shall be considered. As a first step, the EC has revised its pharmaceutical regulation to allow CPMP, the body giving scientific evidence to EMEA, to provide scientific advice on medicinal products destined for exclusive use in third countries.

3. In June 2002 the EC **AIDS Vaccine Task Force** reviewed preliminary results of the World Bank studies on ability and willingness to pay for a vaccine. Following this meeting contacts have been reinforced with the South African AIDS Vaccine Initiative (SAAVI) and the International AIDS Vaccine Initiative (IAVI). The Commission has also committed an additional € 1.35 million to the Medical Research Council in South Africa in order to consolidate lessons learned and intensify an ongoing EC-funded vaccine preparedness programme, providing the required enabling environment for expanded HIV vaccine development activities in South Africa. The Commission is part of the IAVI policy advisory board and the country preparedness advisory group of the International Partnership for Microbicides.

4. The during the past two years the Commission has discussed several ways of increasing and enhancing partnerships with existing global alliances directly or indirectly linked to the three major communicable diseases. In May 2002 discussions were held with the **Global Alliance for Vaccines and Immunisation (GAVI).** GAVI works towards having 80% of the poorest countries with adequate delivery systems capable of introducing hepatitis B vaccine by 2002 and by 2005 having at least 80% coverage with routine immunisation in all districts. The Commission is considering how to assist countries develop plans to sustain GAVI-funded vaccination programmes after their five-year grant ends (*inter alia* through linkages with budget support for poverty reduction strategies that include immunisation coverage as an indicator). GAVI is considered an important partner in consolidating efforts to prepare the ground for a future AIDS vaccine. The Commission will also need to consider how best to encourage further private sector participation.

3.4. Participation in Global Partnerships: Policy and Political Dialogue

1. Throughout 2001 and 2002 the European Community and its Member States have been proactive in addressing the specific issues addressed by the Programme for Action in **global fora** such as G8[25] Summits, the EU/US Summits in Queluz, Washington and Gothenburg, the EU/Canada and EU/Japan Summits in 2001, the follow-up to the Cairo Plan of Action within the EU/OAU forum (leading to the EU/AU Summit in Lisbon in 2003), the LDCIII Conference in Brussels in 2001, the UNGASS on HIV/AIDS in 2001, the Barcelona AIDS Conference in 2002, and the Doha WTO Ministerial, the Monterrey Conference and the Johannesburg Summit.

2. At the **Barcelona European Council** (and the Monterrey Conference) the EU Member States agreed to increase their ODA in order to approach the 0.7% ODA/GNI UN target by raising average contributions from 0.33% to 0.39% by 2006. Together with the EU Member States Health and Education Experts the Commission

[25] The EC / G8 EU Member States consensus was clearly demonstrated during the negotiations leading to the G8 Summits in Okinawa (2000), Genoa (2001), Kananaskis (2002) and now preparing for Evian (2003), with the Okinawa Communiqué presenting the most comprehensive global approach to tackling the three diseases.

will further develop a framework for the increased ODA focused on social development with an emphasis on improved health and education outcomes.

3. From the outset the Commission has been an active partner in the establishment and operation of the **Global Fund to fight HIV/AIDS, TB and Malaria (GFATM)**. After having participated in a series of informal meetings to establish the GFATM, the EC hosted a stakeholders forum in Brussels (in July 2001). This led to the establishment of a **transitional working group** (TWG) and a **technical support secretariat** (TSS). The final TWG meeting took place on 13-14 December 2001 and the first Board Meeting, on 28-29 January 2002, marking the official hand-over from the TWG to the **Board of the Global Fund**. The Commission, in a constituency including Belgium and Austria, holds a seat on the Board[26]. So far the European Community has contributed € 120 million (€ 60 million from the 6th and 7th EDF and € 60 million from the EC Budget). In view of the need to boost the EU contribution to the Fund, the Commission is currently examining the scope for additional future contributions from both the EC budget and the EDF (reserves).

At the GFATM Board Meetings (three so far) the EC has insisted on upholding the previously agreed **principles for the GFATM**, including a) the Fund is a financing mechanism and should not become a UN body or new international institution; b) the structure should remain 'lean and mean' with no new entities established in country; c) the interests of developing countries are the key determinants for decisions and the poverty focus is non-negotiable; d) decisions should be made transparently and on merit rather than through political lobbying and should be based on high-quality proposals; e) the Fund should deliver improved health outcomes while fully taking into account national frameworks and ownership, and building on existing mechanisms - i.e. the Fund is not a 'vertical' instrument; f) monitoring and evaluation indicators and criteria must be well defined and programme and financial accountability clarified before the first disbursements are made. Other specific agenda items agreed in the Programme for Action and taken forward in the GFATM are: working in innovative ways with the private sector through new partnerships, increasing financial resources, poverty focus, price transparency and tiered pricing, the consistent reference to the TRIPs flexibility instruments reinforced by the Doha Declaration, preference for locally produced products, discouragement of in-kind medical donations.

In-country the GFATM works through Country Co-ordinating Mechanisms (CCM) which incorporate all relevant stakeholders. The set up and functioning of CCMs are unique and have great potential for working in true partnership at country level. At the October 2002 Board meeting consensus was reached on policy principles for procurement and supply management, with the US and the private sector agreeing to tiered pricing, price transparency and restrictions on in-kind donations, in line with the EC/EU position. The Fourth Board meeting will be held at the end of January 2003, and the Fifth is to coincide with the **Evian G8 Summit.**

One of the biggest challenges the Fund will face is in maintaining its momentum. There is also an ongoing need for close co-ordination among EU participants in the Fund, currently spread among several different "constituencies" represented on the

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[26] For more information about the GFATM and EC contribution see the EC DEV/RELEX/AIDCO and DELEGATIONS STAFF BRIEFING NOTE - September 2002.

Board. The need for co-ordination is likely to increase over time rather than diminish.

4. Over the past two years a series of activities has been undertaken to foster stronger partnerships with EU Member States, civil society and the private sector, UN agencies, funds and programmes, the World Bank and the EIB. Discussions started with the latter on local condom production in Africa. The World Bank is a strong partner in different global fora for capacity building and specific activities such as research into willingness to pay for a vaccine and community preparedness for an AIDS vaccine. Work with UNAIDS and the WHO has been reinforced at different levels and in different fora, with the shared key priority for forthcoming years of better partnership at the country level. Dialogue with civil society has been institutionalised through the 'trade and public health' debate but is, as yet, less strong in the other areas of the Programme for Action. Pharmaceutical companies are increasingly involved as partners in policy and implementation, in particular in areas such as tiered pricing and research and development. Other private sector partners are also increasingly committed and ready to work with the EC/EU on fighting communicable diseases in developing countries. Partnerships with the developing countries (in particular the LDCs and the LICs) are likely to grow in significance, once these are brought together in a Stakeholder Forum on Communicable Diseases in the Context of Poverty Reduction which the Commission intends to establish.

4. MONITORING AND EVALUATION

The PfA stipulated that appropriate mechanisms, resources and partnerships will be put in place to **monitor implementation and to participate in a global monitoring system encompassing the efforts of all international partners.** Efforts are being made by a number of international partners, including EU Member States and the EC, to agree on impact and high-level outcome indicators as part of a joint pro-poor, global and gender- sensitive monitoring system to assess progress towards the MDGs. These efforts must be consistent and complement the Commission's efforts to strengthen country ownership and national statistical capacity to monitor pro-poor health outcomes and health systems performance.

1. **Coherence with the PRSP process and country programming.** The shift of EC co-operation towards macro-economic support linked to social sector outcomes and sector-wide approaches has led to increased efforts towards consistency in country programming. The work on sectoral indicators is co-ordinated with the development of overall Development Indicators in the context of PRSPs and macro-economic support[27]. The intention is for the 2003 EC Annual Report to include reporting on the MDGs based on a limited number of indicators (12 impact/outcome and output) drawn from the list of 48 indicators associated with the MDGs. Countries that have opted for a sector-wide approach in health have developed a set of about 20 sector-wide indicators. In Ghana for example, the Commission has directly supported the process of selection and application of these indicators through its own Technical Assistance[28]. More efforts are under way to measure pro-poor health sector performance and to disaggregate data by social sector, gender and regions.

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27 DG DEV 2002, *Guidelines for the use of indicators in country performance assessment*.

28 Accorsi, S. 2002, *Measuring Health Sector Performance through indicators: towards evidence-based policy. A review of the experience monitoring in the framework of sector-wide approach in Ghana.*

2. **OECD/DAC.** The Commission is, as are most EU Member States, taking active part in the DAC Network on Poverty Reduction / Subgroup on Poverty and Health and contributed a sub-chapter on Monitoring and Evaluation to the Draft Guidelines on Poverty and Health drafted by the Subgroup. The Guidelines have formulated a set of key principles for monitoring health systems performance towards pro-poor health outcomes.[29]

3. **Partnerships with DfID, the WHO, the World Bank, the private sector and civil society**. The Commission and other EU Member States have joined a DfID-led working programme for monitoring health systems performance and pro-poor health outcomes. Others taking part in this joint programme (2003-2009) are the WHO, the World Bank, USAID, the Rockefeller Foundation and others. The aim of the programme is to improve the capacity to measure poverty and health, to monitor health system performance, and to evaluate PRS and health sector reforms in achieving pro-poor health outcomes. The programme will run, on demand, in 8-12 selected countries in Africa, Asia, Latin America and transition countries. Country-led processes are expected to allow a sector- wide approach in co-ordinating external support for performance and outcome monitoring and statistical capacity building[30]. The private sector and civil society could be significant interlocutors and partners in monitoring and evaluation.

4. **GFTAM.** Within the Global Fund, the Commission and EU Member States have supported the Monitoring, Evaluation and results-based disbursement working Group. Here the attempt is being made to apply results-based disbursement to a range of indicators that has to respond to a variety of proposals financed by the GFTAM. Proposed indicators are output, process and outcome indicators, ranging from the improvement of reproductive health knowledge in school settings to actual HIV prevalence rates.[31]

5. CONCLUSIONS

1. Two years after its inception the Programme for Action remains a **comprehensive, forward-looking and coherent EU policy framework** making a significant contribution towards improved country, regional and global action against the three major communicable diseases. The PfA is strongly supported by Council and Parliament, as well as by civil society and the private sector.

2. The case for targeting these three diseases remains valid and has even become clearer than before with respect to HIV/AIDS. It remains the case that general opinion is not yet fully mobilised around a clear sense of the global crises that these three diseases constitute, and **there is still an urgent need for large-scale collective action.** The European Community and its Member States are committed to keep the momentum going in the fight against the three diseases as demonstrated above, particularly by

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29 DAC & Subgroup on Poverty and Health 2002 *draft Guidelines on Poverty and Health, 4 October 2002.*

30 DfID, M. 2002, *Final draft for consultation on a programme of work: "Measuring, monitoring, and evaluating health systems performance to achieve pro-poor health outcomes".*

31 GFATM 2002, *Report of the Monitoring, Evaluation and Results-based disbursement Working Group* - October 2002.

the vast scale of parallel and, in the case of the EDCTP, joint EC-MS actions at the EU level presented in this report.

3. Many global public goods will not be achieved through domestic policy action alone and depend fundamentally on concerted international action including significant increase on R&D activities. The mobilisation of resources from national health and other sectoral budgets and from the private sector will increasingly be necessary to ensure full and reliable funding for global health concerns. **GPG policy needs to be further developed to ensure co-operation and equitable burden sharing** in this respect.

4. A number of actions spelled out in the PfA has been taken forward at the **country, EU and global level.** Where progress has been less visible, this was either due to a lack of appropriate resources within the Commission and/or within the Member States, in particular in-country resources, to take forward large-scale programmes in areas such as local manufacturing capacity, technology transfer, social marketing partnerships with civil society, innovative research and development and working through true partnerships in particular with the developing countries concerned. **Outstanding areas will be further addressed mainly but not exclusively through the use of the EC poverty diseases budget line (2003 to 2006).** All PfA actions are directly or indirectly linked to other Community policies and actions working on improved health, AIDS and population outcomes in developing countries.

5. The increase in ODA towards 0.7% ODA/GNI UN target by 2007 raises the need for an EU framework for **increased ODA focused on social development** with an emphasis on improved health and education outcomes.

6. A **strong EU/EC voice** is clearly key with respect **to each area of action – impact, affordability and research**, and at global, EU and country level. EU positions on targeted HIV/AIDS, malaria and TB actions have been significantly strengthened at the global level, jointly with other partners, as a result of the PfA. Nevertheless, more efforts are needed to **provide regular and structured consultation with developing countries** at all levels.

7. One way such consultation will be further developed is through the creation of a **Stakeholders Forum on Communicable Diseases in the Context of Poverty Reduction**. It is intended that this forum will bring together Commission and EU Member State officials, representatives of developing countries, NGOs, industry and others.

8. In addition, **civil society partners** have an increasingly strong voice in policy debates within all EU institutions, as well as nationally and globally. Implementation of the PfA is subject to increasing monitoring by civil society and organisations and business interests. The same bodies are highly active members on the Board of the GFATM. It is important for this reason also, therefore, to strengthen existing partnerships with all stakeholders involved, and to develop new partnerships where necessary.

9. For the EC, **successful partnerships require greater flexibility** - to lead on some issues where there is a genuine institutional gap, but to devolve responsibility for other issues where the EC does not have a clear competence or is unable to bring added value. The degree of formality in these partnerships should vary, with some

partnerships requiring very precise joint agreements while others can rely on much more informal understandings and working arrangements.

10. The **Global Fund to fight HIV/AIDS, TB and malaria** is one of the PfA actions to have produced clear results in terms of resource mobilisation and innovative approaches. Policy areas, which had previously not been successfully addressed in other fora, are being addressed here. The developing countries have a strong voice in the GFATM Board and the Fund's overall governance arrangements. Important topics such as **tiered pricing and the strengthening of local manufacturing capacities** are also being addressed here. These cannot, however, be dealt with in the GFATM alone. Renewed efforts are needed to work jointly at the European level as well as with specific partners, in particular the US, on these issues. **The next G8 Summit in Evian will provide a possible forum for taking forward the Communicable Diseases agenda as reflected in the PfA as a follow up from what was adopted by the G8 in Okinawa in 2000.**

11. The Commission's advocacy of tiered pricing for pharmaceuticals has clearly yielded tangible results, culminating in the Commission's October 2002 proposal for a **Council Regulation to avoid trade diversion into the European Union of certain key medicines originally destined for the poorest developing countries and sold at greatly reduced prices**. Once adopted by Council, the Regulation should provide a real protection for exporters, which in turn should develop from increased sales and offers of low priced products to a larger number of countries. As exporters benefit from the added protection there shall be pressure made on other developed countries, including the US, to provide for similar measures. As the draft Council Regulation includes reporting of volumes sold at tiered prices, these data will be useful to improve access to data about the volumes of medicines distributed in the poorest countries.

12. The paucity of information about pharmaceutical prices and production capacity is an impediment to the development of robust pro-poor policies. **Price transparency** (ensuring that production costs of producers are kept strictly confidential for reasons of fair competition) will become increasingly important as developing countries increase their procurement of key medicines within or outside the context of, for instance, the GFATM. It is unsatisfactory for public authorities to have to piece together price information about life-saving medicines from the fragmentary data collected by NGOs or provided by just one or two companies, especially since price remains an important determinant of access, and therefore life, for millions of people. **The Commission will study what measures should be introduced to improve access to information about pharmaceutical prices. The same goes for information about pharmaceutical manufacturing capacity, especially with respect to pharmaceutical raw materials.**

13. The EDCTP is a unique opportunity to create a long-term, sustainable and genuine partnership between the EU and developing countries, which is essential to accelerate the development of new products to fight the three diseases.

14. Nevertheless, additional efforts are needed in the area of the **research and development of new specific Global Public Goods,** through the kind of partnerships described above (public/private – EU/developing countries) and new proposals for **incentives and financing mechanisms.** Increased attention should now be devoted to this area of policy, which will probably prove of particular

importance over the long term. The Commission will focus on developing proposals to incentivise R&D for diseases which are currently neglected or where R&D is lacking. Such proposals will include further examination of a number of ideas: venture capital, low-cost loans, tax credits, guaranteed markets and the extension of patent rights and/or market exclusivity including through the relationship which might be established between different products.

15. In addition, the Commission will consider the need for a **specific legislative instrument to incentivise R&D for neglected and poverty diseases**, along the lines of the EU Orphan Drug Regulation. The Orphan Drug Regulation has been a success, with a large number of applications now having been submitted to the EMEA for the authorisation of such medicines. The Commission will explore whether the environment for R&D into neglected diseases can be transformed in a similar way.

16. A final key challenge remains implementation and impact at **country level.** A series of actions related to the 'harmonisation of EU/EC policies and procedures' has started and will be further developed into **specific action plans** on a country-by-country basis.

The support of the European and International community will only be effective where countries themselves show a strong political commitment and have demonstrably ascribed high priority to public health policies, prevention, care and treatment.

Annex 1 :Acronyms

ACP	Africa, Caribbean and Pacific
AIDS	Acquired Immune Deficiency Syndrome
ALA	Asia and Latin America development cooperation programme
ARIVA	Appui Régional a l'Indépendance Vaccinale en Afrique
CMH	Commission on Macro-economics and Health
CPMP	Committee for Proprietary Medicinal Products (EMEA)
CRIS	Common Relex Information System
CSP	Country Strategy Paper
CSR	Corporate Social Responsibility
DAC	Development Assistance Committee
DDA	Doha Development Agenda
DfID	Department for International Development (UK)
DG	Directorate General
EBAS	EU-ACP Business Assistance Scheme
EC	European Community
ECHO	European Community Humanitarian Aid Office
EDCTP	European Development Clinical Trials Partnership
EDF	European Development Fund
ED/M/L	Essential Drugs/Medicines List
EIB	European Investment Bank
EMEA	European Agency for the Evaluation of Medicinal Products
ESIP	EU SADC Investment Promotion Programme
EU	European Union
FP	Framework Programme
G8	Group of G7 most industrialised countries and Russia
GAVI	Global Alliance for Vaccines and Immunisation
GCP	Good Certification Practice
GFATM	Global Fund to fight AIDS, Tuberculosis and Malaria
GMP	Good Manufacturing Practice
GPG	Global Public Good
HAP	Health, AIDS and Population
HIV	Human Immune Deficiency Virus
IAVI	International AIDS Vaccine Initiative
ITN	Insecticide-treated nets
LDC	Least Developed Country
LIC	Low Income Country
MEDA	Mediterranean countries development cooperation programme
NGO	Non-governmental Organisation
NIP	National Indicative Programme
OECD	Organisation for Economic Cooperation and Development
PfA	EC Programme for Action on Communicable Diseases in the Context of Poverty Reduction
PRSP	Poverty Reduction Strategy Paper
R&D	Research and Development
RIP	Regional Indicative Programme
SADC	Southern Africa Development Community
TRIPs	Agreement on Trade Related Aspects of Intellectual Property Rights
UN	United Nations
UNAIDS	United Nations Joint Programme on HIV/AIDS

UNCTAD	United Nations Conference on Trade and Development
UNICEF	United Nations Children's Fund
WHO	World Health Organisation
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation

Annex 2: Matrix

INCREASE THE IMPACT OF EXISTING INTERVENTIONS		
EXPECTED RESULTS	**INDICATIVE TIME TABLE**	**PROGRESS STATUS 1.1.2003**
1. The Commission will prioritise HAP interventions within overall development aid and increase support to ATM (HIV/AIDS, Tuberculosis and Malaria)		
1.1. First Round Programming CSPs/PRSPs finalised	1.1. End 2002	1.1. Done
1.1.1. Majority of CSPs (ACP/ALA-MEDA/OCTs) adopted; HAP programmed 9th EDF ACP CSPs allocation increased to 15% (Abuja target);	1.1.1. End 2004	1.1.1. Ongoing. Current level HAP allocations programmed for 9th EDF – ACP is 3.7%. ALAMEDA programming includes on average 40% for social development support. EP target of 35% of EC Budget committed to 'social infrastructure'; Renewed mid-term programming review cycle working towards expected results (starting 2003);
1.1.2. PfA issues reflected in CSPs; 1.1.3. PfA issues reflected in PRSPs		1.1.2. Ongoing. Currently less than 5% of all CSPs reflect specific HIV/AIDS, malaria, TB interventions; 1.1.3. Ongoing.

1.2. PfA and Health and Poverty policies / resolutions adopted;	1.2. End 2002	1.2. Ongoing. Council resolution on PfA adopted on 14 May 2001; EP resolution on PfA adopted on 4 October 2001; EC contribution to GFATM regulation adopted on 23 October 2001; ACP-EU Joint Parliamentary Assembly resolution adopted on 1 November 2001; EP adoption contribution EC GFATM December 2001; Health and Poverty Communication adopted March 2002 - Council resolution on Health and Poverty adopted on 30 May 2002; EP report on Health and Poverty Communication ongoing; Regulation on Poverty Diseases to be adopted latest January 2003.
1.3.1. Programming and implementation 2002 special HIV/AIDS budget line in line with PfA 1.3.2. Regulation 'Poverty Diseases' budget line revised, including increase financial allocation. 1.3.3. HIV/AIDS integral part of Reproductive and Sexual Health and Rights budget line. 1.4. EC staffing plan developed. Number of staff in HQ and delegations responsible for health, AIDS and population increased. 1.5. Partnerships with MS 1.6. Active participation in international for a	1.3. End 2002	1.3.1. Done. Call for Proposals launched August 2002. 1.3.2. Ongoing. Negotiations revised regulation Poverty Diseases B7-6311. PDB 2003 includes 180% increase for special budget line (from € 25.3 to € 73.4 million). 1.3.3. Ongoing. Text revised regulation includes clear reference to HIV/AIDS. 1.4. Ongoing. DEV B/3 HAP staff increased back to 1999 level. AIDCO social development units adequately staffed. Staffing plan delegations to be developed in light of discussions deconcentration. 1.5. Ongoing. ATM on agenda regular EU MS meetings. MS agreement to use additional ODA for health, AIDS and population. 1.6. Ongoing. Programme for Action reflected in G8, EU/US, EU/Canada, EU/Japan, Cairo Plan of Action negotiations; Durban, LDCIII, UNGASS HIV/AIDS, Doha, Monterrey, Barcelona, Johannesburg.

2. Commission services will provide specific guidance to EC geographical desks and delegations on policies, programming guidelines and the implementation of the Programme for Action		
2.1.1. Programming guidelines disseminated. 2.1.2. Proper e-correspondence network with Delegations.	2.1. End 2001	2.1.1. Done. 2.1.2. Ongoing.
2.2.1. Programming guidelines reviewed and updated.	2.2. End 2002	2.2.1. Ongoing.
3. The Commission will achieve more rapid disbursement and speed up and harmonise procedures		
3.1. All HAP dormant programmes closed or re-identified.	3.1. End 2001	3.1. Ongoing.
3.2. HAP disbursement rates increased by 50%. 3.3. CRIS fully functional.	3.2. End 2001	3.2. Ongoing. HAP disbursement portfolio (1995-2000) was set at 17% May 2001, increased up to 23%.
3.4. Four case studies on harmonisation of procedures identified.	3.3. End 2002	3.3. 'Health' coding - according to DAC - and CRIS operations ongoing
3.5. Other opportunities to direct unspent resources (EDF/Budget) identified.	3.4. End 2002 3.5. End 2002	3.4. Missions - started September 2002 - in Mozambique, Nicaragua, Morocco, Vietnam.
3.6. Opportunities for rapid resource transfers identified.	3.6. End 2002	3.5. No progress. 3.6. No progress apart from GFATM process.

4.The Commission will facilitate resources for innovative partnerships with international agencies and private sector		
	End 2006	Negotiations revised regulation Poverty Diseases B7-6311 ongoing, including proposal substantial increase financial resources for PfA 2003-2006. Additional resources programmed for 9th EDF intra-ACP
4.1. Active participation in the GFATM		4.1.Ongoing. EC GFATM Board Member. EC contribution of 120 million from 6-7th EDF and 2001 Budget.
4.2. Partnership with GAVI (TB/malaria vaccines)		4.2. Ongoing. Intense discussions in May 2002. Development plan for countries to fill financing gaps for childhood vaccines from own national budgets once GAVI has to face out;
4.3. Partnership with IAVI (HIV vaccine)		4.3. Ongoing. Discussions in June 2002. Support for Medical Research Council in South Africa through IAVI.
4.4. Strategic partnership with WHO (see 5)		4.4. Ongoing. Programmed 9th EDF.
4.5. Negotiations with UNICEF (malaria bednets - social marketing)		4.5. Initial discussions beginning 2002. Programmed from 9th EDF
4.6. Discussions with UNFPA / EIB / Condomi on condom production		4.6. Ongoing. Discussions with EIB August 2002. UNFPA no progress as yet.
4.7. Negotiations with pharmaceutical industry on tiered pricing		4.7. Ongoing. Regular discussions with industry. Lengthy interservice meeting with GSK in March 2002. Pharma industry part of TRADE consultation rounds.
4.8. Co-operative agreement with World Bank/MS/WHO-UNAIDS to provide technical input to country programming and identification processes		4.8. Little progress. Proposal for Strategic Partnership with WHO under discussion.

5. Strengthening of pharmaceutical policies		
5.1. Strategy in place for support for regional cooperation, capacity building, financial and technical assistance, including enhanced and improved essential drug policy and regulatory schemes in ACP countries. Partnership with WHO strengthened.	5.1. End 2002	5.1. Ongoing. Financing proposal € 25 million with WHO discussed at EDF Committee November 2002, pending ratification 9th EDF.
5.1.1. Regional/sub-regional quality control laboratory networks to ensure appropriate quality control of pharmaceuticals developed.	5.1.1. End 2003	5.1.1. Part of WHO partnership. Extension ARIVA
5.1.2. Malaria protocols revised.		5.1.2. Progress on discussions on the change of national malaria protocols in highly resistant countries (MSF).
5.1.3. Essential drug policies refined in favour of developing countries.		5.1.3. Ongoing. WHO pre-qualification scheme for drugs/diagnostics for AMT, revision of 11th WHO EDL includes non-generic key pharmaceuticals. Discussion ongoing within GFATM Procurement Task Force and newly-established GFATM Portfolio Management and Procurement Committee.
5.2. Other partners identified.	5.2. End 2002	5.2. GFATM work in progress

6. Untying of Community aid		
6.1. EC Memorandum on untying of aid.	6.1. End 2001	6.1. Done
6.2. Tender dossiers for ACP untied.	6.2. Mid 2002	6.2. Done. First case for Zimbabwe.
6.3. ALA regulation includes untying.	6.3. Mid 2002	6.3. Done
6.4. Communication untying discussed in Council/EP	6.4. End 2002	6.4. Ongoing. Communication adopted November 2002.
6.5. EC aid for medicines and products for ATM fully untied.	6.5. End 2003	6.5. Ongoing

7. Developing technology transfer and local manufacturing capacity		
7.1. Support identified for sector and market analyses; dialogue, identification of existing business opportunities for production of quality key pharmaceuticals - many of which are off-patent.	7.1. End 2003	7.1. Ongoing. Discussions with EIB/Condomi in August 2002 on condom production linked with social marketing.
7.2. Specific geographical focus on countries with pre-existing local production capacity (in either private or public sector).	7.2. End 2003	7.2. In progress.
7.3. Licensing agreements and business joint ventures promoted through appropriate incentives.	7.3. End 2004	7.3. Ongoing discussions with generic and R&D industry. UK High Level Working group. Establishment ISG Incentives - Nov. 2002
7.4. Importance local production addressed in other international fora.	7.4. End 2002	7.4. Value local production acknowledged in UNGASS HIV/AIDS - WHA G8 Okinawa Action Plan - AU Action Plan a/o. Negotiations ongoing in GFATM - DDA
7.5. Appropriate financing instruments identified (PROINVEST, the investment promotion programme for ACP countries, the EC-ACP Business Assistance Scheme (EBAS)[32], the private sector Investment Facility of the Cotonou Agreement through the EIB, other EC technical and financial cooperation mechanisms).	7.5. End 2002	7.5. Revised legal base for special budget line for Poverty Diseases 2003-2006 to provide for additional resources. 9th EDF programming entails provisions for local production. Other instruments to be developed.

INCREASE AFFORDABILITY OF KEY PHARMACEUTICALS THROUGH A COMPREHENSIVE APPROACH

[32] An ongoing programme for ACP businesses, which provides support to individual companies or producer associations in this sector.

EXPECTED RESULTS	INDICATIVE TIME TABLE	PROGRESS STATUS
8. Lead international efforts to establish political commitment for a wide spread - voluntary and predictable tiered pricing mechanism		
8.1. Political commitment EU MS and developing countries	8.1. End 2002	8.1. Ongoing. Two Development Council resolutions. EC participation in UK High Level Working Group on Access to Medicines and in NL Access to Medicines debate.
8.2. Industry commitments to tiered pricing	8.2. 2003	8.2. Ongoing. GSK and Novartis made public commitments.
8.3. Tiered pricing part of GFATM policies and principles	8.3. End 2002 - onwards	8.3. Ongoing. GFATM works according to 'lowest possible prices'. EC part of procurement working group. Work in progress on further definition tiered pricing
8.4. Tiered pricing as part of PfA back on G8 agenda	8.4. Mid 2003	8.4. Ongoing. Follow up to agreement in Okinawa (2000). Work in progress for 2003 Summit in France.
8.5. EU/US transnational agenda	8.5. End 2002	8.5. Ongoing. No progress on TP since Gothenburg May 2001.
8.6. EU/Canada agenda	8.6. End 2001	8.6. Done.
8.7. EU/Japan	8.7. End 2001	8.7. Done.
8.8. EU/AU - Cairo Plan of Action	8.8. End 2001	8.8. Done - ongoing preparations for Lisbon 2003
8.9. Tiered pricing in OECD	8.9. End 2003	8.9. No progress
8.10. Jburg Plan of Action	8.10 Mid 2002	8.10. No result
8.11. Close partnership with WHO/UNAIDS	8.11 Up to end 2006	8.11. Ongoing.

9. Lead international efforts to establish arrangements for a wide spread, voluntary and predictable tiered pricing mechanism		
9.1. Regulation against diversion tiered priced products into EU (US) markets.	9.1. First part 2003	9.1 Ongoing. Adopted by Commission on 30 October 2002. Council discussions with a view to adoption in first quarter 2003.
9.1.1. International concertation in place to contain the risk of product diversion.	9.1.1. End 2003	9.1.1. Discussions TRIPs Council on Doha Declaration paragraph 6.
9.2. Mechanism defined for transparency and monitoring	9.2. Mid 2003	9.2 Ongoing discussion EC/WHO, within UK high level working group and most recently within GFATM Task Force on procurement.
9.3. Lower consumer prices in developing countries	9.3. End 2003	9.3. Ongoing[33].
10. Analyse tariff data from DCs to assess basis for negotiations on reduction/abolition in Doha Round		
10.1 Study on taxes, other duties and tariffs being finalised.	10.1. Early 2003	10.1. Under preparation [34]
10.2. Information on importation, distribution and registration fees available.	10.2. End 2002	10.2. Ongoing. Discussions ongoing in the GFATM Procurement Task Force.

[33] See: 'Untangling the Web of Price Reductions' - June 2002 - www.accessmed-msf.org - Médecins Sans Frontières.

[34] See draft study 'Duties and Taxes on Essential Medicines used in the treatment of the major communicable diseases', DG TRADE F/4 July 2002.

11. Support TRIPs application and discuss links between TRIPs Agreement and Public Health protection - Follow up to Doha Declaration on TRIPs and Public Health		
11.1 Broker different positions - get development deal for Doha Round;	11.1. End 2002	11.1 Done. Doha Declaration on TRIPs and Public Health, subsequent decision to allow LDCs to defer implementation of pharma patents until 2016. Compulsory licenses export prohibition regulated by end 2002. EC position on Doha para's 6 and 7 developed and currently discussed in TRIPs Council.
11.2 Work plan for reinforced TA on TRIPs implementation for developing countries. 11.3 Technical assistance provided upon request / according to plan. 11.4. Cooperation with WIPO reinforced.	11.2. End 2003 11.3. End 2003 11.4. End 2002	11.2. Ongoing. Study on TRIPs implementation in Sub-Saharan Africa on tender stage. Mauritius requested a study on IP and TRIPs at contract stage. 11.3. Ongoing. 11.4 No progress.

INCREASE INVESTMENT IN RESEARCH AND DEVELOPMENT OF SPECIFIC GLOBAL PUBLIC GOODS		
EXPECTED RESULTS	**INDICATIVE TIME TABLE**	**PROGRESS STATUS**
12. Strengthening support for Research and Development through increased support for basic and strategic research and the creation of a European Development Clinical Trials Partnership		
12.1 Sixth Framework Programme adopted.	12.1 Mid 2002	12.1 Done. Commission proposal for 6th Framework Programme adopted by EP and Council in first reading. Large support for considerably increased earmarked R&D budget (€ 400 in total for ATM, including € 200 million for EDCTP). DC countries can participate with COM funding in all projects on the three diseases.
12.2 EDCTP launched - essential EC development policy principles reflected in set-up.	12.2 End 2002	12.2 Ongoing. Preparation phase launched in April 2002. COM proposal adopted in August 2002. Council and EP discussion end 2002. Steering Committee of the EDCTP will define modalities for implementation based on development principles and with significant involvement of DCs.
12.3. Fifth Framework Programme prioritises ATM.		12.3. Fifth Framework Programme includes more than 77 ATM R&D projects and programmes for more than € 109 million.

13. Capacity building in Developing Countries		
13.1 Sixth Framework Programme includes focus on capacity building including support for collaborative molecular and clinical, epidemiological, operational and social studies, strengthening the base for health-related research. Emphasis put on gender balance and poverty focus.	13.1. End 2001	13.1 Ongoing.
13.2 EDCTP includes issues of capacity building measures such as: a) support for facilities and services at research institutions and clinical institutions in developing countries, b) human resources development,	13.2 Mid 2003	13.2. Ongoing. EDCTP foresees capacity building in the areas: networking and cooperation; technology transfer; strengthen clinical research capacities; initiate and develop clinical testing facilities; finance training schemes for African scientists. € 150 million earmarked for capacity building.

14. Incentives for the development of specific global public goods		
14.1. The reform of the international financial architecture to foster increased availability and development of global public goods promoted.	14.1. End of 2002	14.1.1 Ongoing work in relation to UN special task force on GPGs 14.1.2 OECD work on GPGs for health 14.1.3 Work within GFATM progressing rapidly
14.2 Incentive package examined and developed (extension of patent protection/marketing rights – venture capital - low cost loans – tax credits – guaranteed markets, etc.).	14.2 End 2003	14.2 Ongoing discussions with industry. Work with UK High Level Working Group on Access to Medicines.
14.3 Regulatory aspects developed.	14.3 End 2002	14.3 No progress. Discussions on involving regulatory bodies in DCs in the EDCTP.
14.4 Economic research demand completed.	14.4 End 2002	14.4 Ongoing research with the World Bank. First results discussed in June 2002.
14.5 Joint financing mechanisms developed.	14.5 End 2003	14.5 Ongoing. GFATM effort. Little progress on additional efforts (linked to special GPG task force)
14.6 EU AIDS Vaccine Task Team strengthened.	14.6 End 2003	14.6 Ongoing. Last meeting June 2002.
14.7 Partnership with IAVI strengthened.	14.7 End 2003	14.7 Ongoing
14.8 Partnership and continuing co-operation with EMEA	14.8 End 2003	14.8 Ongoing

Annex 3: The Millennium Development Goals

Millennium Development Goals (MDGs)	
Goals and Targets	**Indicators**
Goal 1: Eradicate extreme poverty and hunger	
Target 1: Halve, between 1990 and 2015, the proportion of people whose income is less than one dollar a day	**1.** Proportion of population below $1 per day **2.** Poverty gap ratio [incidence x depth of poverty] **3.** Share of poorest quintile in national consumption
Target 2: Halve, between 1990 and 2015, the proportion of people who suffer from hunger	**4.** Prevalence of underweight children (under-five years of age) **5.** Proportion of population below minimum level of dietary energy consumption
Goal 2: Achieve universal primary education	
Target 3: Ensure that, by 2015, children everywhere, boys and girls alike, will be able to complete a full course of primary schooling	**6.** Net enrolment ratio in primary education **7.** Proportion of pupils starting grade 1 who reach grade 5 **8.** Literacy rate of 15-24 year olds
Goal 3: Promote gender equality and empower women	
Target 4: Eliminate gender disparity in primary and secondary education preferably by 2005 and to all levels of education no later than 2015	**9.** Ratio of girls to boys in primary, secondary and tertiary education **10.** Ratio of literate females to males of 15-24 year olds **11.** Share of women in wage employment in the non-agricultural sector **12.** Proportion of seats held by women in national parliament
Goal 4: Reduce child mortality	
Target 5: Reduce by two-thirds, between 1990 and 2015, the under-five mortality rate	**13.** Under-five mortality rate **14.** Infant mortality rate **15.** Proportion of 1 year old children immunised against measles
Goal 5: Improve maternal health	
Target 6: Reduce by three-quarters, between 1990 and 2015, the maternal mortality ratio	**16.** Maternal mortality ratio **17.** Proportion of births attended by skilled health personnel
Goal 6: Combat HIV/AIDS, malaria and other diseases	
Target 7: Have halted by 2015, and begun to reverse, the spread of HIV/AIDS	**18.** HIV prevalence among 15-24 year old pregnant women **19.** Contraceptive prevalence rate **20.** Number of children orphaned by HIV/AIDS
Target 8: Have halted by 2015, and begun to reverse, the incidence of malaria and other major diseases	**21.** Prevalence and death rates associated with malaria **22.** Proportion of population in malaria risk areas using effective malaria prevention and treatment measures **23.** Prevalence and death rates associated with tuberculosis **24.** Proportion of TB cases detected and cured under DOTS (Directly Observed Treatment Short Course)
Goal 7: Ensure environmental sustainability*	
Target 9: Integrate the principles of sustainable development into country policies and programmes and reverse the loss of environmental resources	**25.** Proportion of land area covered by forest **26.** Land area protected to maintain biological diversity **27.** GDP per unit of energy use (as proxy for energy efficiency) **28.** Carbon dioxide emissions (per capita) [Plus two figures of global atmospheric pollution: ozone depletion and the accumulation of global warming gases]
Target 10: Halve, by 2015, the proportion of people without sustainable access to safe drinking water	**29.** Proportion of population with sustainable access to an improved water source
Target 11: By 2020, to have achieved a significant improvement in the lives of at least 100 million slum dwellers	**30.** Proportion of people with access to improved sanitation **31.** Proportion of people with access to secure tenure [Urban/rural disaggregation of several of the above indicators may be relevant for monitoring improvement in the lives of slum dwellers]

Goal 8: Develop a Global Partnership for Development*	
Target 12:Develop further an open, rule-based, predictable, non-discriminatory trading and financial system Includes a commitment to good governance, development, and poverty reduction – both nationally and internationally **Target 13**:Address the Special Needs of the Least Developed Countries Includes: tariff and quota free access for LDC exports; enhanced programme of debt relief for HIPC and cancellation of official bilateral debt; and more generous ODA for countries committed to poverty reduction **Target 14:** Address the Special Needs of landlocked countries and small island developing states (through Barbados Programme and 22nd General Assembly provisions) **Target 15:** Deal comprehensively with the debt problems of developing countries through national and international measures in order to make debt sustainable in the long term	*Some of the indicators listed below will be monitored separately for the Least Developed Countries (LDCs), Africa, landlocked countries and small island developing states.* *Official Development Assistance* **32.** Net ODA as percentage of DAC donors' GNI [targets of 0.7% in total and 0.15% for LDCs] **33.** Proportion of ODA to basic social services (basic education, primary health care, nutrition, safe water and sanitation) **34.** Proportion of ODA that is untied **35.** Proportion of ODA for environment in small island developing states **36.** Proportion of ODA for transport sector in land-locked countries *Market Access* **37.** Proportion of exports (by value and excluding arms) admitted free of duties and quotas **38.** Average tariffs and quotas on agricultural products and textiles and clothing **39.** Domestic and export agricultural subsidies in OECD countries **40.** Proportion of ODA provided to help build trade capacity *Debt Sustainability* **41.** Proportion of official bilateral HIPC debt cancelled **42.** Debt service as a percentage of exports of goods and services **43.** Proportion of ODA provided as debt relief **44.** Number of countries reaching HIPC decision and completion points
Target 16: In cooperation with developing countries, develop and implement strategies for decent and productive work for youth	**45.** Unemployment rate of 15-24 year olds
Target 17: In cooperation with pharmaceutical companies, provide access to affordable, essential drugs in developing countries	**46.** Proportion of population with access to affordable essential drugs on a sustainable basis
Target 18: In cooperation with the private sector, make available the benefits of new technologies, especially information and communications	**47.** Telephone lines per 1000 people **48.** Personal computers per 1000 people *Other Indicators TBD*

* *The selection of indicators for Goals 7 and 8 is subject to further refinement*

Annex 4: Price and price reductions for certain HIV/AIDS and Malaria products

The Programme for Action recognises that the price of pharmaceuticals is only one element in the fight against HIV/AIDS, malaria and TB. Complementary action is needed in all other areas identified in the Programme for Action, including sustainable financing, the strengthening of health systems, and the focus on improved health outcomes through sectors other than health.

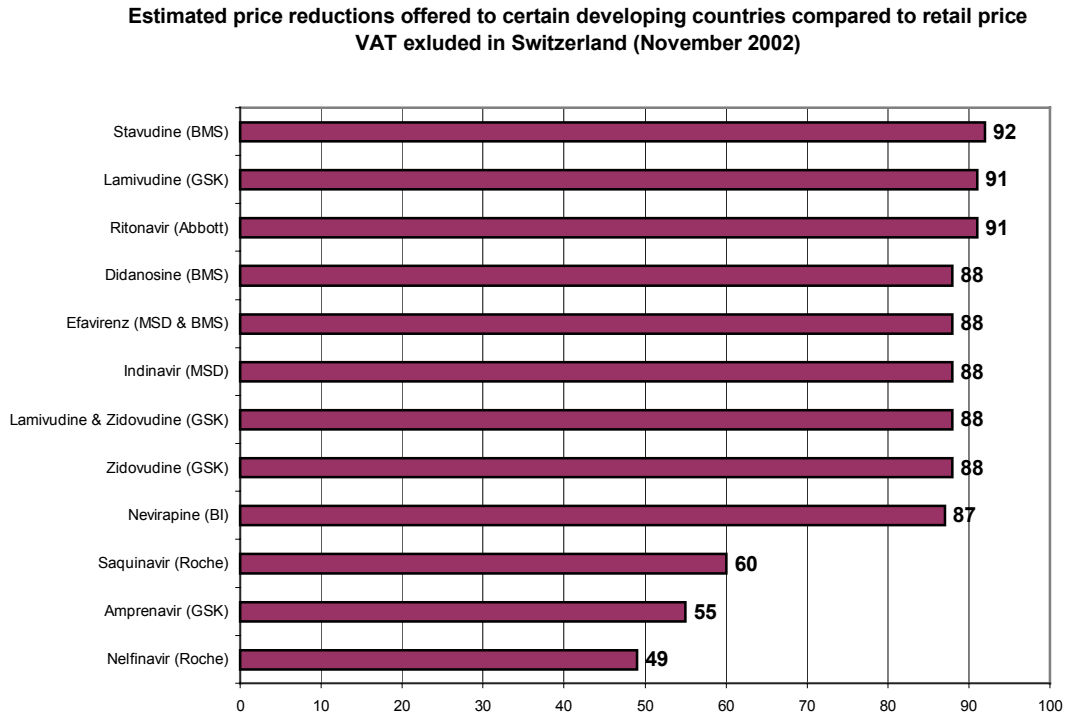
The last two years many pharmaceutical manufacturers reduced their prices for pharmaceuticals sold in developing countries. This change has been generated by the global and public focus, including by the EU, on 'affordability of medicines', as well as by the prospect of competition by generic manufacturers. Price reductions have included not only pharmaceuticals for HIV/AIDS but also for malaria and other diseases.

Price reductions are the result of number of factors such as 1) voluntary bilateral agreements, 2) bulk purchasing, 3) voluntary licensing, 4) compulsory licensing / or threat to use compulsory licensing, and 5) generic production.

Examples of voluntary agreements include; those between six participating firms and countries to supply anti-retrovirals drugs, through the UN sponsored Accelerated Access Initiative (launched in 2000 and currently covering about 1% of those needing treatment); agreements between the pharmaceutical company Novartis, South Africa and WHO currently on a pilot basis (24,000 people covered) for the tiered priced malaria medication, Coartem; and a partnership coming on stream between GSK and WHO for the Anti-malarial LAPDAP[35].

[35] See for more detail: Background paper to the UK High Level Working Group 'Differential Pricing of Essential Medicines in the Developing World', London, 26 July 2002.

The table below gives estimated price reductions for anti-retroviral drugs (ARVs).



Source: MSF, November 2002

Coartem has been registered under two different brand names with different prices and different packaging. It segments the market providing a drug for OECD markets, one for the *private* sector of malaria endemic countries and a third product available through WHO for use in the *public* sector. The likely constraint to reaching scale may be i) that the substantially reduced price is only available through the public sector, patients (including the poor) access malaria medications primarily through the private sector, and ii) the incentive and feasibility for leakage from poor to wealthy markets *within* poor countries.