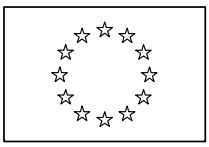

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Second Progress report on the EC Programme for Action: Accelerated action on HIV/AIDS, malaria and tuberculosis in the context of poverty reduction

{COM(2004)726 final}

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1. EXECUTIVE SUMMARY

The death of more than 6 million people in the world from HIV/AIDS, malaria and tuberculosis (TB) each year constitutes a global crisis. In 2000, the European Commission (EC) redefined its role and accelerated its response in a coherent and comprehensive framework.[1] In 2001, the EC adopted its Programme for Action[2] (PfA) based on this framework, which defined key actions to accelerate the impact, affordability and research and development of new tools. It is now an appropriate time to assess the progress made, build on achievements and face new challenges.

This progress report illustrates that the main achievement under the area for action on accelerating impact has been a four-fold increase in EC resources allocated specifically to confronting the three diseases, with an annual average of €259.02 million programmed for 2003-2006 as compared to the €59.32 million annual average committed for 1994-2002 (including a significant increase in research funds). In the action on affordability, there has been a reduction of up to 98% in the price of some key pharmaceutical products in developing countries. Under the research and development action, a key achievement has been the establishment of the European and Developing Countries Clinical Trials Partnership, which focuses on clinical trials for the development of new interventions confronting the three diseases, especially in sub-Saharan Africa. The active EC role in terms of leadership, coordinating positions and mobilising resources among the EU Member States and other donors is a key achievement under the partnership action. Examples of this include a strong European voice in the Global Fund to Fight HIV/AIDS, TB and malaria (to which the EU contributes more than half of the budget), and in international fora on key issues such as Trade-Related Aspects of Intellectual Property Rights and sexual and reproductive health and rights.

The main outstanding challenges include how to increase the prioritisation of, and resources to, health and social services in third countries; how to boost ailing health infrastructure and overburdened human capacities, especially in the current context of brain drain; how to support regulatory capacity in third countries; how to further increase affordability of key pharmaceutical products, and improve access to pharmaceutical products in general; how to develop new tools to confront the three diseases; and how to continue coordination with partners in third countries, civil society and the private sector. New challenges include how to maintain coherence and harmony in an increasingly complex and divergent global institutional set-up, and how to respond to the evolving epidemiology, geography and demography of the diseases in the context of an enlarged EU.

This progress report illustrates how the policy framework and the PfA remain valid. The overall framework of poverty reduction is still the main focus, especially in the

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1 *Accelerated Action Targeted at Major Communicable Diseases within the Context of Poverty Reduction* (COM(2000) 585)

2 *Programme for Action on Communicable Diseases in the Context of Poverty Reduction* (COM(2001) 96)

context of achieving the Millennium Development Goals by 2015. The focus on the three diseases, with an appropriate and comprehensive policy mix to confront the diseases, including prevention, treatment and care, remains valid. EC action at both country and global levels should continue and expand, given that simultaneous actions reinforce each other and allow for increased effectiveness. The synergy and coherence of different policy areas within the EC should be further strengthened, in order to push the momentum forward, reinforce commitment and shape key actions for the future. An updated and comprehensive policy framework for confronting HIV/AIDS, malaria and TB globally will be presented in an EC Communication to follow this progress report.

Acronyms and abbreviations used in this document

ACP	African, Caribbean and Pacific
ACT	Artemisinin-based combination therapy
ALA	Asia and Latin America
AMANET	African Malaria Network Trust
ARVs	Anti-retrovirals
CCM	Country Coordinating Mechanism
CIS	Commonwealth of Independent States
CLS	Core Labour Standards
CSP	Country Strategy Paper
DAC	OECD Development Assistance Committee
DFID	Department for International Development (UK)
DOTS	Direct Observed Therapy Short-course
EC	European Commission/European Community
EDCTP	European and Developing Countries Clinical Trials Partnership
EDF	European Development Fund
EEIG	European Economic Interest Grouping
EMEA	European Medicines Agency
EU	European Union
FDA	Food and Drugs Administration
FDC	Fixed-dose combinations
FP(RTD)	Framework Programme for Research and Technological Development
FTA	Free Trade Agreement
GAVI	Global Alliance for Vaccines and Immunizations
G8	Group of 8
HIV/AIDS	Human Immunodeficiency Virus/ Acquired Immunodeficiency Syndrome

IAVI	International AIDS Vaccine Initiative
ICPD	International Conference on Population and Development
IP	Integrated Project
IPM	International Partnership for Microbicides
IPPF	International Planned Parenthood Federation
ITN	Insecticide-treated Nets
MEDA	Mediterranean countries
MDGs	Millennium Development Goals
MSF	Médecins Sans Frontières
NGO	Non-governmental Organisation
NoE	Network of Excellence
ODA	Official Development Assistance
OECD	Organisation for Economic Cooperation and Development
PEPFAR	US President's Emergency Plan for AIDS Relief
PfA	Programme for Action
PRSP	Poverty Reduction Strategy Paper
SME	Small and Medium-sized Enterprise
SWAps	Sector-wide Approaches
TB	Tuberculosis
TRIPs	Trade-Related Aspects of Intellectual Property Rights
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNFPA	United Nations Population Fund
WIPO	World Intellectual Property Organisation
WHO	World Health Organisation
WTO	World Trade Organisation

2. INTRODUCTION

Substantial progress has been made since the groundbreaking European Commission High-Level Round Table on HIV/AIDS, malaria and tuberculosis took place in September 2000, and the adoption of the policy framework for a comprehensive and accelerated approach to confront HIV/AIDS, malaria and tuberculosis (TB). It is now time to take stock, reflect on progress made and new challenges, and to accelerate and readjust actions where needed. The coherent and comprehensive policy framework remains valid in the context of the Millennium Development Goals (MDGs) and the overarching objective of poverty reduction. The need to focus on HIV/AIDS, malaria and TB is clearly reflected in Millennium Development Goal (MDG) 6 – "Combat HIV/AIDS, malaria and other diseases" which includes associated targets and indicators – and other inter-linking MDGs on health and poverty.[3] Confronting the three diseases remains high on the agenda for EU Presidencies, both current (the Netherlands) and future (Luxembourg, the UK, Austria and Finland).

However, despite efforts made and resources allocated, the number of people affected, infected and dying from HIV/AIDS, malaria and TB continues to rise. In 2003, almost 3 million people died of HIV/AIDS; this is rapidly becoming the worst infectious disease catastrophe in recorded history, surpassing in absolute numbers the bubonic plague of the fourteenth century and the influenza epidemic of 1917, each of which killed around 20 million people. Malaria kills more than one million people every year, including an African child every 30 seconds.[4] TB kills about 2 million people every year.[5]

2.1. The EU policy framework and programme for action on HIV/AIDS, malaria and tuberculosis

A comprehensive policy framework: HIV/AIDS, malaria and TB collectively undermine global health, poverty reduction and human security. In 2000, the European Commission (EC) redefined its role and accelerated its response to the global emergency in a coherent and comprehensive framework on *Accelerated Action targeted at major communicable diseases within the context of poverty reduction.*[6] This Communication was discussed at a High-Level Round Table with a large number of stakeholders, held in Brussels in September 2000.

Cooperation, coherence and synergy: In the policy framework, the EC highlighted the value and importance of harnessing several key policy areas and instruments to work towards a common goal. Different policy areas within the EC redirected some

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3 MDG Target (7): Have halted by 2015, and begun to reverse, the spread of HIV/AIDS.
MDG Target (8): Have halted by 2015, and begun to reverse, the incidence of malaria and other major diseases. Please see web-page http://www.un.org/milleniumgoals for further information.

4 WHO "What is Malaria", from www.rbm.who.int

5 WHO "Basic Facts on TB", from www.stoptb.org

6 Accelerated Action Targeted at Major Communicable Diseases within the Context of Poverty Reduction (COM(2000) 585)

of their activities to confront the three diseases. It was recognised that the EC has a unique mandate to coherently address a range of development, humanitarian aid, trade, research, enterprise, health and education issues. This range of competences and instruments provided the potential for greater synergy across these policy areas.

Description of the Programme for Action: To formulate actions for 2001-2006 within the policy framework, the EC adopted a *Programme for Action on Communicable Diseases in the Context of Poverty Reduction* (COM(2001) 96). Council and Parliament welcomed the Programme for Action (PfA) in their resolutions of 14 May 2001 and 4 October 2001 respectively (refer to Annex 1 for further policy declarations and resolutions of relevance to the policy framework and the PfA). The PfA was later assessed and updated in a progress report adopted by the EC in February 2003.[7]

The vision of the policy framework is to accelerate the response to confront the three diseases. This requires intensified support to strengthen social sectors beyond the health sector to include enabling sectors such as education, transport and food security, and cross-cutting issues regarding human resources. The PfA focuses on three inter-related areas for action: to increase the **impact** of existing interventions, to increase the **affordability** of key pharmaceutical products, and to encourage research in and **development of specific global public goods**.

These actions are inter-related and synergistic, with each having a multiplying effect with a larger cumulative impact – one example being the interrelationship that exists between affordability of pharmaceutical products, impact through existing interventions and incentives for further research and development of new pharmaceutical products. Results are achieved by acting at two levels – through accelerating and increasing resource allocation at **country level**, and through advocating and adopting key policies and action at **global level**.

The PfA also reflects EC policy on sexual and reproductive health and rights,[8] maintaining the commitments made at the International Conference on Population and Development (ICPD) in Cairo, 1994.[9] The PfA is part of the overall EC Development Policy, which highlights poverty reduction as a priority goal.[10]

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7 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 (COM(2003) 93)

8 Regulation (EC) No 1567/2003 of the European Parliament and of the Council on Aid for Policies and Actions on Reproductive and Sexual Health and Rights in Developing Countries and Accelerated action targeted at major communicable diseases within the context of poverty reduction, COM(2000) 585.

9 http://www.un.org/popin/icpd2.htm

10 EC development policy statement by the Commission and Council (10 November 2000). The EC's Health, AIDS and Population policy, as set out in the Communication on Health and Poverty Reduction (2002), also clearly defines this poverty reduction goal. *Health and Poverty Reduction in Developing Countries* (COM(2002) 129)

The PfA is implemented using a range of instruments: geographic budget lines,[11] horizontal or thematic budget lines,[12] and the EU Framework Programme for Research and Technological Development (FP (RTD)).

2.2. The comprehensive policy mix needed to confront the three diseases

The PfA calls for new partnerships to strengthen policy advocacy and political dialogue. The PfA also calls for a **comprehensive policy framework**, taking an appropriate mix of innovative, more efficient and less costly disease responses in prevention, treatment and care. An appropriate mix depends on the nature of the disease, capacities and resources available within the country and region; but most crucially, it depends on proven best practice.

HIV/AIDS: The majority of HIV infections occur through sexual contact, and are preventable. The effectiveness of condom use in preventing transmission of HIV/AIDS through sexual contact is a proven fact. The knowledge and ability to openly discuss and negotiate an informed choice is important, and is something that many people – especially women – lack. The use of condoms by non-regular partners remains very low for several reasons, including lack of access. Gender inequalities also mean that many women in developing countries are deprived of negotiating skills to enable them to protect their own lives and the wellbeing of their families. Condoms are the only current tool available for protection from sexual transmission of HIV/AIDS, but they are controlled by men. The rapid development and introduction of effective microbicides is therefore crucial for women in developing countries and elsewhere in order for them to protect themselves against HIV/AIDS transmission. A high proportion of HIV/AIDS transmission occurs through injecting drug use. Harm reduction, through needle exchange and/or substitution therapies, is proven to reduce the transmission of HIV/AIDS through injecting drug use. However, access to harm reduction services is limited in many countries where it is most needed.

The recent price reduction in anti-retrovirals (ARVs) for treatment of HIV/AIDS has resulted in an increase in the number of people treated in developing countries. HIV/AIDS could be a chronic disease controlled by drugs instead of a life sentence, but only 2% of those in developing countries who need ARVs have access to it (and only 1% in Africa). With ARV therapy now being a significant element of an increasing number of national programmes, mobilising sufficient resources to achieve a balanced response between prevention, treatment and care in national HIV/AIDS strategies is becoming an increasing challenge. The provision of ARV therapy is also placing an increasing challenge on already ailing health infrastructures and overburdened health staff.

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[11] These are resources to Africa, Caribbean and Pacific (ACP) countries from the European Development Fund (EDF), including regional and intra-ACP; Asia and Latin America (ALA); Mediterranean (MEDA); and Eastern Europe and Central Asia (TACIS).

[12] The relevant ones being Aid to Fight Poverty Diseases, Co-funding with NGOs, Aid for Policies and Actions on Reproductive and Sexual Health and Connected Rights, and Humanitarian Aid.

Fixed-dose combinations (FDCs), which combine multiple drugs in one pill, are easier to administer and use than the cocktail of drugs which imply taking 3 times more pills per day. FDCs are mainly produced by generic manufacturers. There are still no FDCs for paediatric formulations of ARVs.

TB: A person with HIV/AIDS who develops active TB has a life expectancy of just a few weeks or months. Up to half of those with HIV/AIDS in developing countries will die of TB. For those on the lengthy waiting list to receive antiretroviral treatment for AIDS, having access to TB treatment is a matter of life and death. The cost of the pharmaceutical products for a full course treatment under the DOTS (directly-observed therapy short-course) scheme has been reduced to US$10, and TB can be successfully treated and life expectancy extended by several years. It is a challenge for health systems to effectively administer DOTS given the complication and length of treatment, and the improper use of TB drugs has resulted in a growing trend of multi-drug resistant TB. In addition, TB diagnostics tools are outdated and difficult to use. Innovative initiatives are needed to increase the detection of tuberculosis and compliance with treatment, particularly amongst the poorest.

Malaria: Malaria can be prevented using vector-control (e.g. drainage of swamps and insecticide spraying of houses), or transmission to humans can be prevented in many areas using insecticide-treated bednets (ITNs)[13]. The development of long-lasting ITNs (which last five years, the time span that newborn children are most vulnerable to malaria) offers new potential for confronting the disease. At the current price of $5 per net, long-lasting ITNs are already more cost-effective than conventionally treated nets. Treating pregnant women with anti-malarials is particularly important because of the potentially harmful effects the disease can have on their children and themselves. Treatment with new drugs, among them artemisinin-based combination therapy (ACT) is needed because of increasing resistance to traditionally used malaria medicines like chloroquine. However, ACTs are significantly more expensive than traditionally used malaria medicines.

2.3. Objective of the document

Why this progress report? The policy framework and the PfA are major initiatives for confronting HIV/AIDS, malaria and TB. The EC has seen significant achievements in confronting the three diseases over the past few years. Globally, there has also been an increase in the amount of resources channelled towards HIV/AIDS, malaria and TB. A large number of new players have joined the scene and changed the global institutional architecture. Now is therefore an appropriate time to assess progress made on the PfA, to build on these achievements and face new challenges.

This progress report outlines implementation so far on each of the three PfA areas for action – impact, affordability, and research and development. The EC's participation

[13] By 2003, 18 out of the 40 malaria-endemic countries in Africa with country strategy plans for rolling back malaria had developed strategic plans that included increasing access to ITNs. Twenty-five African countries successfully applied for funding in the second round of Global Fund applications (from Africa Malaria Report 2003, http://www.rbm.who.int/amd2003/amr2003/ch2.htm

in global partnerships is also discussed. The report integrates and builds on key findings of the 2003 progress report.

How will this progress report be used? This progress report provides input into an EC consultation where outstanding and new challenges are being analysed to define key actions for the EC and the EU. Later this year, the EC will continue its discussions with Council and Parliament on the Financial Perspectives (period 2007-2013) for the enlarged EU. At the same time, discussions are ongoing on the new instruments to be adopted for EC external action. The EC will also continue its dialogue with EU Member States and stakeholders regarding the updating of the EC Development Policy. The outcomes of these discussions are of primary importance given that one of the main challenges currently faced by the EC is how to ensure increased and sustainable financial commitments to the Millennium Development Goals, including MDG 6. This progress report will also provide timely input into the report on EU progress towards the MDGs, which is currently being prepared for presentation at the upcoming UN summit in September 2005.

3. ACHIEVEMENTS OF THE POLICY FRAMEWORK AND THE PFA

3.1. Impact

Rationale for action: Increased and accelerated efforts are needed both at country and at global level to confront the three diseases using existing interventions, while at the same time strengthening essential services and systems.

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

The PfA calls for increased funding, quick disbursement and accelerated action to provide wider access to prevention, treatment and care, especially for the poor, to confront the three diseases. In general, there has been no increase in resources allocated to health since the PfA. However, there has been an accelerated disbursement of funds to health through country and macroeconomic budget support. A major achievement has been the creation of a new and innovative horizontal budget line to confront the three diseases specifically. There has also been an increase in resource allocation through regional and horizontal budget lines over time to confront the three diseases.

Macroeconomic budget support: Macroeconomic budget support is EC support for a country's budget through a geographic budget line. A varying proportion of the macroeconomic budget support contributes to improved health outcomes in each country, depending on the Country Strategy Papers (CSPs) and national prioritisation of health. As Table 1 below illustrates, €40.42 million per year is estimated to have been channelled to the health sector in European Development Fund (EDF) countries

from macroeconomic budget support.[14] Whilst this figure seems low compared to the annual EC investment through budget support, it reflects the fact that national budget allocations to health are low in many countries, and increased national allocations to health, in line with poverty reduction strategy objectives, will be needed before there can be a greater allocation of EC macroeconomic budget support to the health sector. It is difficult to compare this figure to previous macroeconomic budget support going to health.

It is also difficult to see the health outcomes due to this financial allocation. In countries where the EC provides macroeconomic budget support, health process and output indicators are included to assess overall country performance, especially relating to the MDGs (e.g. HIV prevalence, attendance of skilled birth attendants, immunisation coverage). The inclusion of such indicators can contribute to the strengthening of in-country budget allocations or country programmes on the three diseases, assuming that agreement on targets reflects agreement on national priorities for investment. All countries, regardless of their choice of focal sector, are advised to include the MDG-related outcome indicator – "HIV prevalence among 15-24 year-old pregnant women" in their monitoring and reporting systems. In the 2004 mid-term review of all the CSPs for the EC cooperation partners in ACP countries, 32 out of the 68 countries for which the data has been analysed used exactly this indicator in their core list.[15] 23 countries included a different indicator on HIV/AIDS, while 13 did not use any HIV/AIDS indicator at all. Analysis of this outcome indicator remains limited, and cannot yet illustrate trends over time.

Specific health sector support: As Table 1 below illustrates, health sector support through country programming has decreased by a third from a €393 million annual average (commitments 1998-2002[16]) to a €246.6 million annual average (programmed support 2003-2006[17]). Although geographic support for health has decreased when comparing 1998-2002 and 2003-2006, there has been accelerated expenditure of resources through faster disbursement of money to countries This reflects a general increase in the EC disbursement rate in development coopertaion which includes a 47% increase in payments since 2000.[18].

The primary mechanism for EC partnership at country level are the Country Strategy Papers (CSPs), and policy dialogue around Poverty Reduction Strategy Papers (PRSPs). Countries have been encouraged to focus on two sectors in the CSP.[19] In the period 2002-2006, the EC provides specific funding for health for only 27 out of 106 countries. Reasons for countries not choosing health as a focal sector may include the traditional expertise of the EC being in other sectors (e.g. transport), the lack of health expertise in EC delegations able and willing to advise and argue for

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14 The proportion of the EC macroeconomic support allocated to the health sector is calculated using the percentage of the government's budget commitment to health as outlined in the World Health Report 2004.

15 Only 55 of the total 76 had data available

16 Source: Population and development mid-term evaluation

17 Source: Country Strategy Papers

18 http://europa.eu.int/comm/europeaid/reports/reform_def_en.pdf

19 The EC decided to focus on only two sectors so that it does not spread its support too thinly.

health support in discussions with the government, and – in many countries – the weak position of the Ministry of Health (relative to other Ministries) in the policy dialogue. However, participation in sector support programmes makes for more intense dialogue on health policies and how to improve them and increase support for systems.

Table 1: EC support for health from geographic line items (1998-2002 compared to 2003-2006)

Instruments	Annual average 1998-2002 (commitments, from Population and Development mid-term review)	Annual average 2003-2006 (programmed support, from Country Strategy Papers)
Macroeconomic budget support estimated input to health	Difficult to calculate from DAC records and consolidated developing countries government allocation to health, 2000-2001	€40.42 million (EDF data only, MEDA countries not included)
Specific health sector support through country programming	€393 million	€246.6 million

In contrast to the decreases in specific health sector support, the amount of money specifically allocated to confront the three diseases has increased over time. As illustrated in Table 2 below, the EC programmed €259.02 million per year to confront the three diseases (annual average 2003-2006), a four-fold increase from the annual average of €59.32 million committed between 1994-2002. The greatest amount of increase has come from the Aid for Poverty-Related Diseases budget line (which saw an 8.7-fold increase), followed by an increased allocation to the three diseases through the regional budget line (an almost 5-fold increase), and an increase by 4 times in the FP (RTD) allocation to HIV/AIDS, malaria and TB.

Table 2: EC financial commitments/programmed support specifically to confronting HIV/AIDS, malaria and TB (annual averages by instrument, in € million)[20]

Instruments		Annual average (€ million) 1994-2002	Annual average (€ million) 2003-2006
Geographic budget lines	Regional[21]	11.92	56.76
Horizontal/thematic budget lines	Aid for Poverty-Related Diseases[22]	10.10	88.25
	Humanitarian Aid	1.60	1.50
	NGO co-financing	12.60	12.51
Framework Programme for Research and Technological Development	4th, 5th and 6th FP (RTD)	23.10	100.00
TOTAL		**59.32**	**259.02**

Regional support: Support specifically for the three diseases has been channelled through regional or intra-ACP funds. As Table 2 illustrates, there was an increase from €11.92 million (average annual commitment, 1994-2002) to €56.76 million (average annual programmed, 2003-2006) to confront the three diseases. Another significant achievement since the PfA was adopted has been the more flexible use of this instrument, which allows for increased resources at country level, and for support for innovative partnerships. For example, part of the intra-ACP funds are used to support the Global Fund;[23] to support pharmaceutical policy development in countries (with the World Health Organization); health information system development through the Health Metrics Network with WHO; and to develop malaria vaccine trial capacities in Africa through AMANET (African Malaria Network Trust). This EC-funded project (for €7 million) aims to strengthen a pan-African network that will enhance the human and institutional capacity needed for clinical development and evaluation of malaria vaccines. AMANET, which is the only registered trust composed of African public health and research institutions, will

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20 Sources: (1994-2002): Population and Development Evaluation, see http://europa.eu.int/comm/europeaid/evaluation/evinfo/sector/951649_ev.htm
(2003-2006): Programming data from DG Development, see http://europa.eu.int/comm/development/body/theme/human_social/pol_health1_en.htm, updated from brochure http://europa.eu.int/comm/development/body/publications/descript/pub7_10_en.cfm
Breakdown by diseases from Global Fund, see progress reports by diseases: http://www.theglobalfund.org/en/funds_raised/reports/

21 Calculated from regional programmes and intra-ACP programmes

22 Before 2003, money for HIV/AIDS came from the AIDS and Population budget line. Breakdown after 2003 is indicative, pending first selection of proposals from 2003 call.

23 Established in 2002, the purpose of the Global Fund to Fight AIDS, TB and Malaria is to attract and disburse resources to prevent and treat AIDS, TB and malaria. www.theglobalfund.org

implement the project. The project will result in an operational network of efficacy evaluation centres in Burkina Faso, Mozambique and Tanzania, with properly skilled staff through short, long and on-site training. Four malaria candidate vaccines will undergo clinical trials under internationally accepted good clinical practice and ethical standards.

Another part of the intra-ACP budget is used to ensure continued reproductive health services in countries through support for the United Nations Population Fund (UNFPA) and the International Planned Parenthood Federation (IPPF). This has been done in response to the withdrawal of US funding following the US's re-introduction of the Mexico City policy (or 'global gag rule'), halting funding of organisations providing legal abortion services, counselling and referral for abortion, or lobbying to make abortion legal or more available in their own country.

Aid for Poverty-Related Diseases: One of the main achievements of the past three years has been the adoption of the budget line on Aid for Poverty-Related Diseases[24] in 2003 as a new instrument to implement the PfA with a financial framework of €351 million (2003-2006). This new instrument supports innovative initiatives and targeted actions that can later be scaled up through other financial instruments.

The new instrument has been a catalyst for action to confront the three diseases. The EC has harnessed non-development resources into this budget line and thus focused additional resources into development priorities. The budget line has provided for flexibility and additional impact beyond geographic programming. While geographic programmes address health interventions at national or regional level, this budget line also ensures EU action, impact and visibility at global level, while supporting demand driven proposals put forward by various in-country stakeholders. It contributes resources to the Global Fund;[25] to community preparedness initiatives for an AIDS vaccine through the International Aids Vaccine Initiative (IAVI);[26] to the International Partnership for Microbicides (IPM)[27] for microbicide development; and for second generation surveillance on HIV/AIDS through WHO/UNAIDS. In the calls for proposals for 2005 and 2006, EDCTP clinical trials sites proposals are encouraged.

One example of country impact from this thematic budget line is an EC-funded programme on HIV/AIDS treatment in Senegal, which has proven that highly active anti-retroviral therapy can successfully be administered in a resource-poor setting. The programme has set a precedent for the establishment of a national treatment programme planning to treat 7,000 people by 2006.

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24 This Regulation (EC) No 1568/2003 of the European Parliament and of Council was adopted on 16 June 2003.

25 €6.67 million was given to the Global Fund prior to 2003

26 The International AIDS Vaccine Initiative (IAVI) was created in 1996 and is working to ensure the development of safe, effective, accessible and preventive HIV vaccines for use throughout the world. www.iavi.org

27 The International Partnership for Microbicides (IPM) was established in 2002 to accelerate the discovery, development and accessibility of microbicides to prevent transmission of HIV. http://www.ipm-microbicides.org/

Other horizontal or thematic budget lines: The Sexual and Reproductive Health and Rights, NGO Co-financing and Humanitarian Aid budget lines are partly used to confront the three diseases. The Regulation on Aid for Policies and Actions on Reproductive and Sexual Health and Rights in Developing Countries[28] was adopted in 2003, and includes financial assistance to programmes on the prevention of sexual and mother-to-child transmission of HIV/AIDS, and initiatives to reduce malaria burden during pregnancy and in newborns. It sets an overall financial framework of €73.95 million for implementation during the period 2003-2006[29] (not included in Table 2).

One example of a successful EC-supported NGO Co-financing project is in Nepal, where the EC has contributed €1.9 million to a €5 million multi-NGO TB and leprosy project. This project provides cost-effective health education, early detection and treatment of TB, with 300,000 outpatient beneficiaries and 20,000 treated patients. An example of a successful EC-funded programme from the Humanitarian Aid budget line is the EC Humanitarian Aid Office's action in Burundi during the 2001 malaria epidemic, and since then with the post-epidemic response.

EC and the Global Fund – support through flexible use of several budget lines and EC leadership

An important EC achievement since 2001 has been the establishment of the **Global Fund to Fight AIDS, TB and malaria.** The EC actively supported the early Global Fund transitional working group in Brussels 2001 and continues to be a key partner working closely together with other Board members and the Global Fund Secretariat.

The EC has played a leadership role in preparing cutting-edge policies through active participation as a member of the Board and in several of the working committees advising the Board.

As the second largest individual donor, the EC has contributed more than 18% of the total Global Fund budget in 2004 and provides longer-term, predictable financing. The EC has committed €460.5 million from 2001 through 2006 – half from the EDF and half from the EC budget.[30] Europe (EC and EU Member States) is now the largest donor, having committed more than half of the total budget for the Global Fund (€2.4 billion out of the total €4.6 billion). The financial support from Europe comes fully untied (refer to Annex 2 for details on EU Member States financial contributions to the Global Fund).

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28 Regulation (EC) 1567/2003 of the European Parliament and of the Council on aid for policies and actions on reproductive and sexual health and rights in developing countries

29 The new horizontal budget line replaced two budget lines on HIV/AIDS-related operations in developing countries (AIDS and Population, and Reproductive Health).

30 Through intra-ACP funds and on the budget line linked to the Regulation on aid to fight poverty diseases (HIV/AIDS, tuberculosis and malaria) in developing countries

The Global Fund to Fight AIDS, TB and Malaria

The Global Fund is an innovative and accountable financing mechanism, which raises, manages and disburses resources quickly to beneficiary programmes based on national plans and priorities, including PRSPs and sector-wide approaches (SWAps). Global Fund programmes are developed in an inclusive and participatory process at country level through Country Coordinating Mechanisms (CCMs) and evaluated by an independent technical review panel.

The Global Fund is an effective and innovative way of making funds available to confront the three diseases at country level. Its flexibility allows for the channelling of resources to countries which may previously not have received EC funding for the three diseases, health or macroeconomic budget support through geographic instruments.

The results of the Global Fund include:

- An allocation of 56% of the funding to HIV/AIDS, 31% to malaria and 13% to TB. Approximately 70% of the funding goes to low-income countries and a further 26% to lower middle-income countries. Africa receives 60% of the total funding.
- 51% of programme allocations is for strengthening the capacity of health systems.
- The Global Fund has approved 310 programmes in 128 countries through four rounds of calls for proposals.
- The EC has worked to ensure that the Global Fund sets up procurement policies which maintain quality standards and can make pharmaceutical products available at the lowest possible prices. Working with Global Fund procurement policies, countries such as Jamaica can save up to 50% of the costs of ARV treatment.[31] The EC has achieved full transparency with regard to the prices paid for pharmaceutical products by countries.

By 2009, Global Fund programmes are expected to have achieved the following results:

HIV/AIDS: The number of people on ARV treatment will have increased six-fold to almost 1.6 million. Voluntary HIV counselling and testing services for prevention will have been provided to 52 million people. Increased access to condoms has been included in approximate 70% of all the Global Fund-approved HIV/AIDS programmes.

TB: 2.8 million people will have been immunised against TB (the coverage in 2000 was 800,000). Treatment of multi-drug resistant TB will have quadrupled. And 3.5

[31] The exact price reduction in first-line ARV treatment per person per year was from US$1,380 to $702.

million TB patients will have been treated as part of the internationally-recommended TB control strategy DOTS (directly observed therapy short-course).

Malaria: 108 million insecticide-treated malaria bednets will have been provided and 145 million artemisinin-based combination therapy treatments for malaria will have been delivered.

Further information on the Global Fund can be obtained from www.theglobalfund.org

The untying of aid: The untying of aid is an important measure to increase the value of ODA, and was identified as a key activity in the PfA. The decision was taken to untie aid for the first time in the PfA. The first country to benefit from untying was Zimbabwe, through an international tender for the provision of drugs and medical supplies. Drug procurement in Zimbabwe in 2002 and 2003 made under the Health Sector Support Programme managed to purchase drugs at prices around 40% below the prices estimated using the *International Drug Price Indicator Guide* published by WHO. The full untying of procurement through the Global Fund was a second major result of the PfA, due to pressure by the EC. This has led to significant reductions in the price of pharmaceutical products financed through Global Fund programmes. For example, Jamaica managed to reduce the cost of ARV treatment from US$1,380 to US$702 per patient/year. Honduras is another country which has reduced the price of first-line ARV from US$1,380 to US$205 per patient/year.[32]

3.1.2. Strengthening of pharmaceutical policies and capacity building

Capacity building: The PfA identified support to strengthen pharmaceutical policy and practice. In 2002, the EC programmed €25 million from the 9th EDF (intra-ACP funds) for support through WHO. This aims to enhance the capacity of ACP countries in various areas of pharmaceutical policy, including: the development, implementation, and monitoring of national drug policies; the negotiation and monitoring of international trade agreements on pharmaceutical products, and the development of supportive related legislation and regulations; the improved affordability and financing of essential drugs in both the public and private sectors; the establishment of more reliable and efficient pharmaceutical product supply management systems, including, where appropriate, development of regional pooled procurement; the strengthening of norms, standards and guidelines for the quality, safety and efficacy of key drugs (including the fight against counterfeit drugs); and training and monitoring the rational prescription and dispensing of drugs by health professionals. The overall objective of the programme is to close the huge gap between the potential that essential drugs have to offer and the reality that for millions of people – particularly the poor and disadvantaged – drugs are unavailable, unaffordable, unsafe or improperly used.

In addition to this regional cooperation on pharmaceutical policy, the EC provides support through its bilateral cooperation with several African countries to the

[32] Report on Wilton Park Conference (WP751), Scaling up Health Investments in Developing Countries: Lessons about what Works, 16-18 June 2004

development of national pharmaceutical policies (e.g. in Mozambique) and essential drug supply (e.g. in Zimbabwe). In Chad and Guinea, the health programmes have specific components on pharmaceutical policies.

Enhanced partnerships: Developing countries need to be sure of the quality and safety of pharmaceutical products they intend to purchase. To support this, part of the €25 million EC allocation in 2002 goes to the WHO prequalification project (Procurement, Quality and Sourcing Project: Access to HIV/AIDS, tuberculosis and malaria products of acceptable quality). The WHO prequalification process assesses the quality, safety and efficacy of drugs submitted by participating manufacturers. It evaluates pharmaceutical manufacturers and products according to WHO recommended standards of quality and compliance with Good Manufacturing Practice. The project was originally set up in 2001 to give UN procurement agencies the choice of a range of quality drugs, which would facilitate access. Since then, the list has increasingly been used by other purchasing agencies and organisations as well as by countries. The list of pharmaceutical products pre-qualified by WHO includes FDCs for HIV/AIDS, malaria and TB. These are recommended by WHO for patients in resource-poor countries.[33] However, many local production sites have not yet been assessed, and WHO recently removed five generic products (including three FDC drugs) used to treat HIV/AIDS patients from the list, referring to lack of evidence on bioequivalence with patented products. This leaves only three fixed-dose combination ARVs on the WHO list, which narrows the choice of affordable pharmaceutical products available for use in developing countries.

Regulatory issues, with the EMEA and WHO: The PfA specified the need to enhance and improve regulatory schemes. A key achievement has been the recently adopted revision of the EU pharmaceutical legislation. This lays down specific provisions enabling the European Medicines Agency (EMEA) to give a scientific opinion, upon request by WHO, for the evaluation of certain medicinal products manufactured in the EU intended for markets outside the EU.[34] These provisions respond to the need to protect public health and give scientific assistance to developing countries, while at the same time allowing rapid access to those countries for important new medicinal products. It should be coordinated with a gradual strengthening of national and regional capacities to progressively reduce dependency and increase ownership.

Licensing mechanisms for pharmaceutical products outside of developing countries can still affect them, even more so because their own regulatory capacities are weak. For example, the US's Food and Drug Administration (FDA) has marketing approval requirements for pharmaceutical products procured under the US President's Emergency Plan for AIDS Relief (PEPFAR). These mitigate against the purchasing

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33 http://mednet3.who.int/prequal/ Campaign for Access to Essential Medicines, Untangling the web of price reduction: a pricing guide for the purchase of ARVs for developing countries, 6th ed., April 2004

34 Regulation (EC) No 726/2004 (31 March 2004), Article 58, OJ L 136, 30.4.2004, p.1

and distribution of generic drugs in developing countries,[35] which are often cheaper than drugs produced by R&D based companies.

3.1.3. Developing local manufacturing capacity

Local production: The PfA calls for increased assistance to developing countries to develop high-quality local production of key pharmaceutical products. The EC supported a feasibility study in the local production of condoms in several African countries, which demonstrated that there is clear potential for local production in several main countries.

So far, progress has been slow. Local production is now one of three priority areas in the calls for proposals 2003-2006 for the budget line on Aid for Poverty-Related Diseases. This presents the possibility of supporting innovative actions, which could then be scaled up, potentially through other instruments such as country budget lines, the European Investment Bank and the Centre for Development of Enterprise (specified by the Cotonou Agreement).

[35] The President's Emergency Plan for AIDS Relief (PEPFAR) is a US initiative launched by the American President, which commits US$15 billion to HIV/AIDS over five years with particular focus on 15 countries (12 of those in sub-Saharan Africa). http://www.state.gov/s/gac/

IMPACT

Key results:

- A four-fold increase in EC resources allocated specifically to confronting the three diseases, at a €259.02 million annual average programmed for 2003-2006 as compared to a €59.32 million annual average committed for 1994-2002, illustrating the increased commitment to confronting the three diseases. This includes a 4-fold increase in funds from the 5th to the 6th FP (RTD) (from €109 million, 1998-2002, to more than €400 million, 2002-2006) allocated to research on HIV/AIDS, malaria and TB.

- More flexibility in funding, and accelerated disbursement, to confront the three diseases. Firstly, responsive use of the intra-ACP budget line to support new partnerships and distribute greater resources at country level (this includes EC leadership and substantial support for the Global Fund). Secondly, new instruments (the budget line on Aid for Poverty-Related Diseases) to support innovative actions at global level and faster disbursement to demand-driven proposals in countries.

- EMEA now able to evaluate pharmaceutical products intended exclusively for markets outside the EU. These provisions respond to the need to protect public health and give scientific assistance to developing countries.

Key Challenges:

- To encourage countries most affected by the three diseases to prioritise health, and investment in the strengthening of the health system and sustainable long-term financing.

- To monitor health outcomes in countries where the EC provides health and/or macroeconomic budget support. Presently, it is difficult to show impact beyond resource allocation.

- To ensure, in the new EC financial perspectives, predictable and sustainable but also flexible funding targeting the three diseases, within the context of support for strengthened health and other social services.

- To strengthen the regulatory capacity of countries (possibly through WHO support).

- To accelerate local production of some pharmaceutical products in developing countries, including by strengthening local capacity.

3.2. Affordability

Rationale for action: At the time of developing the policy framework,[36] prices of some key pharmaceutical products for the three diseases were unaffordable for households and countries. It would not have been the best use of ODA to support the purchasing of such expensive products. To give one example, in 2000 when the EC policy framework was adopted, the price of patented ARV was around US$10,000/person/year.

Political pressure and policy decisions: Various factors contributed to the price decrease in some key pharmaceutical products, the most important of which are discussed below. The EC has played a leading role in most, if not all, of them. Some were planned actions under the PfA, for example the promotion globally of tiered pricing, and issues relating to intellectual property. Other factors were the result of the synergy and interplay of PfA actions, for example the EC's partnership with civil society and developing countries on issues of global advocacy, and the increase in demand for ARVs due to Global Fund funded projects in-country.

Sustained public pressure and advocacy from civil society and international organisations, and the eventual responsiveness of the corporate community in acknowledging the importance of prices, are key reasons behind the fall in prices of pharmaceutical products.

The most important area of progress in the past few years with regard to the three diseases is the dramatic reduction in price of anti-retrovirals (ARVs) to treat HIV/AIDS. In September 2000, a major announcement made by Cipla (an Indian generic pharmaceutical product manufacturer) at the EC Round Table discussion[37] initiated the price reduction in ARVs to around US$500 per person per year. R&D based pharmaceutical companies also committed themselves to large price reductions (GlaxoSmithKline at the same Round Table) at around the same time.[38] Today, the lowest prices for first-line ARV treatment are between $100-$350 per person per year.[39]

Increasing transparency: The 2003 progress report identified the need for improved transparency in prices of pharmaceutical products. It is unsatisfactory to

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36 Affordable drugs are also included in the MDGs, Goal 8, Target 17 – "In cooperation with pharmaceutical companies, provide access to affordable, essential drugs in developing countries"; in the Amsterdam targets for TB – "By 2005, 70% of people with infectious TB will be diagnosed, and 85% cured"; and in the Abuja targets for malaria – "Ensure that by 2005 at least 60% of those suffering from malaria have prompt access to, and are able to correctly use, affordable and appropriate treatment within 24 hours on the onset of symptoms."

37 This Round table was hosted by the EC to ensure broad consultation on the Communication (2000). It was organised in partnership with WHO, UNAIDS, and 170 stakeholders, including developing countries, the European parliament, civil society, and leaders of major pharmaceutical companies. Stakeholders reached a wide level of consensus.

38 In May 2000, five pharmaceutical R&D based companies announced a new partnership (the Accelerating Access Initiative), which specified less expensive drug prices for the poorest countries and countries where HIV/AIDS prevalence is highest.

39 WHO, "3 by 5 Progress Report December 2003 through June 2004", 2004

rely on fragmentary data. One success of the past few years has been the gradual but slow increase in price transparency, especially from Principal Recipients buying pharmaceutical products under Global Fund-supported contracts. Some NGOs also show what prices they pay for procuring products, and some manufacturers have started to be themselves more transparent about prices. The increasing price transparency facilitates the comparison of prices, informs potential buyers and ensures that market competition contributes to reducing prices in developing countries. Exact details on prices remain hard to obtain; Annex 3 illustrates some prices of certain key ARVs, as published on the web-page of the Global Fund. The Global Fund has a Price Reporting Mechanism where Grant Recipients have to publish the prices they paid for pharmaceutical products purchased under Global Fund projects.

3.2.1. Tiered Pricing

EC Regulation on trade diversion: The concept of tiered pricing (that buyers in developing countries should have access to medicines at considerably lower prices than buyers in more well-off countries) is one that the EU has consistently emphasised. Pharmaceutical producers in developed countries need security that discounted products supplied in large volumes do actually reach the poor countries they are meant for and are not diverted back into high price markets. This will enable them to enter new markets and support the reduction of communicable diseases. In May 2003, the Council therefore adopted a *Regulation to avoid trade diversion into the European Union of certain key medicines.*[40]

The Regulation aims to encourage producers to significantly increase supplies of medicines at tiered prices in developing countries, while maintaining higher prices for the same products in the EU. Exporters are invited to register their products on a tiered price list established by the EC.[41] The Regulation responds to the danger of diversion of cheap imported medicines from poor countries into high price markets, and provides an incentive to reduce prices further. It also ensures that price reductions are sustainable for the producer and predictable for the purchaser. To some extent, it also enhances transparency.

Both patented and generic products can be registered, as can donated products. In order to be added to the list, medicines have to be made available either with a price cut of at least 75% off the average 'ex factory' price in OECD countries, or at the cost of production plus maximum 15%. The proposed system is simple and transparent, with products on the list bearing a logo for identification purposes.[42] The Regulation makes no differentiation between products sold to public authorities, NGOs, and private buyers. In developing countries, medicines frequently consume a significant proportion of private household expenditure. Therefore, the price of pharmaceutical products in the private market is as important as those sold to public authorities and a key determinant of access.

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40 Regulation (EC) 953/2003. OJ L 135, 3.6.2003, p.5

41 http://trade-info.cec.eu.int/cgi-bin/antritradediversion/index.pl

42 http://europa.eu.int/comm/trade.csc.med.htm

As the 2003 progress report identified, the Regulation is the start of a successful tiered pricing policy that will contribute to increased affordability. To date, GlaxoSmithKline (a leading manufacturer of ARVs which has strongly supported the tiered pricing policy from the beginning) has registered 7 HIV/AIDS products under the Regulation to be protected against trade diversion.[43] Two further applications from GlaxoSmithKline are still pending and will be processed before the end of 2004. The company is also advocating the merits of the EU Regulation to other pharmaceutical R&D based companies.[44] The first annual report of the activities under the Regulation will be published in the autumn of 2004, showing the volumes of exports of tiered priced products. In accordance with the Regulation, the EC will issue a standard form by which manufacturers and exporters registered under the Regulation will report their annual volumes. Under the Regulation, the EC is also required to periodically report to the Council on the volumes exported under tiered prices.

EC advocacy of tiered pricing: The EC is encouraging other developed countries to introduce a tiered pricing policy. As specified in the PfA, the EC is currently engaged in an informal dialogue with Japan on the issue of access to medicines. The Japanese government informed the EC that Japan did not produce or export treatments for HIV/AIDS, tuberculosis or malaria and that, therefore, a tiered pricing policy was not necessary. However, the Japanese government responded positively to the possibility of extending the current dialogue to the broader issue of increasing access to medicines for developing countries. No progress with other major countries has been achieved.

The EC policy framework (2000) argued strongly that there is an inverse relationship between the price of pharmaceutical products sold in developing countries and the number of people treated (i.e. volumes sold). This relationship appears to have been borne out in practice. The increase in treatment uptake as supported by country strategies, the Global Fund, NGOs such as Médecins Sans Frontières (MSF), the Global Alliance for Vaccines and Immunization (GAVI)[45] and calls such as the 3 by 5 Initiative are starting to increase the number of people being treated.[46] This has only been possible through price reductions, which made increased treatment a realistic possibility.

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43 Trizivir 750mg, Epivir 150 mg, Retrovir 100 mg, Retrovir 250 mg, Retrovir 300mg, Combivir 300/150mg, Epivir Oral Solution 10mg/ml 240ml

44 From DFID 'Increasing access to essential medicines in the developing world: UK Government policy and plans', June 2004

45 The Global Alliance for Vaccines and Immunization (GAVI) is a public-private partnership launched in 2000 which through the Vaccine Fund provides financial resources to countries to purchase vaccines and other supplies and to support the operational costs of immunisation. http://www.vaccinealliance.org/home/index.php

46 Launched on World Aids Day 2003 by the WHO, the 3 by 5 Initiative is a call for reaching three million people living with HIV/AIDS (including 2 million in Africa) by 2005 with antiretroviral treatment. http://www.who.int/3by5/en/

3.2.2. *Tariffs and taxes*

Another activity specified in the PfA was to work towards eliminating the hurdles of tariffs, taxes and importation, distribution, and local registration fees in importing countries. This was intended to further eliminate hurdles to access to pharmaceutical products. An EC study on duties and taxes on pharmaceutical products in 57 developing countries[47] showed that there is still scope for lowering tariffs and taxes in some countries. The range of duties and taxes currently varies from 55% on most pharmaceutical products in India to 0% in countries such as Cuba, Gabon, Indonesia, Iran, Malaysia, Nicaragua and Uganda. This issue is being addressed on a bilateral basis through EC trade and policy dialogue.

3.2.3. *Use of flexibilities within the Agreement on Trade-Related Aspects of Intellectual Property Rights*

The World Trade Organisation Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) defines minimum standards for intellectual property protection in WTO Member States. This is important for the development of research-based pharmaceutical products to allow a return on investment, which is reflected in the price of patented pharmaceutical products. From the outset, the EU has been at the forefront of efforts to ensure access to affordable pharmaceutical products for developing countries. In the WTO, the EC has played a lead role by acting as a bridge-builder to bring together the almost irreconcilable positions of the opposing sides. These efforts were most apparent in the results of the negotiations in Doha, where the WTO agreed on a groundbreaking Ministerial Declaration on the TRIPs Agreement and Public Health (November 2001), which reaffirmed existing flexibilities within TRIPs, including that the Agreement should not prevent countries from taking measures to improve public health and promote access to medicines. The Declaration affirms that these flexibilities comprise the use of compulsory licensing in order to serve developing countries' markets. The Declaration also defers the obligation for Least Developed Countries to enforce patents on pharmaceutical products until 2016.

The Doha Declaration left one issue unresolved: countries with no manufacturing capacity for pharmaceutical products, which include those in greatest need of affordable drugs, would not benefit from the use of compulsory licences. To serve the needs of their markets, those countries need to import medicines. However, Article 31(f) of the TRIPs Agreement stipulates that compulsory licences must be "predominantly for the supply of the domestic market of the Member authorising such use". Therefore, the granting of compulsory licences for the sole purpose of exportation was not allowed. The EC was strongly supportive of finding a quick solution. In this context, in April 2003, the EC organised a "Round Table on Access to Medicines".[48] One of the main objectives of the Round Table was to recommend how the G8 Summit in Evian in June 2003 could progress on this critical issue. Over 90 external participants attended, representing international organisations,

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47 http://europa.eu.int/comm/trade/issues/global/medecine/ttr.htm

48 http://europa.eu.int/comm/trade/csc.med.htm

governments of developed and developing countries, R&D based industry, generic industry, pharmaceutical associations and NGOs.

In August 2003, the WTO General Council adopted the 'Decision on the Implementation of Paragraph 6 of the Declaration on the TRIPs Agreement and Public Health'. Under certain conditions, WTO members with no or limited manufacturing capacity may now purchase drugs, in order to address a public health problem within their territory, produced under a compulsory licence in a WTO member with manufacturing capacity.

National patent laws in exporting countries need amendment to provide for this. Discussion on a formal amendment to the text of the TRIPs Agreement continues in the WTO TRIPs Council, with the aim of reaching agreement by June 2005. While this amendment remains in preparation, those developing countries wishing to use the mechanism to import essential medicines today will not face litigation (WTO dispute Settlement Mechanism) as a result. The EC is finalising a draft Regulation to implement this decision to be directly applicable in the EU. It contains the necessary safeguards and other conditions that are necessary when an EU Member State becomes an exporter under the new system.

The EC/EU attaches great importance to ensuring that the Doha Declaration is not undermined either in the formal amendment of the TRIPs Agreement, through bilateral negotiations, or through national legislation. Recently, some negotiating partners (particularly the US) have been criticised for seeking regional and bilateral free trade agreements (FTAs) in which developing countries are asked to refrain from using the flexibilities as provided by the Doha Declaration by more stringent provisions in the FTAs.[49] Criticisms have also been levelled for delaying amendments to the TRIPs Agreement pursuant to the 30 August 2003 Decision. The EC and EU Member States have voiced criticism of the US for such actions.

Another way in which the EC has been supporting adherence to the commitments made in Doha 2001 is through the World Intellectual Property Organisation (WIPO). At the WIPO General Assembly in 2003, the EC and EU Member States made a statement that the adoption of the Doha Declaration and the decision on paragraph 6 should be reflected in WIPO's technical assistance. In addition, the Commission has engaged in a dialogue with WHO on health and trade matters, resulting in more information exchange and reinforced cooperation in public health matters.

Beyond affordability to access: The reduction in the price of ARVs and other pharmaceutical products is necessary to increase access, but is not sufficient in itself. Lower prices can be a catalyst for change, and stimulate progress in other areas that are essential to promote access. These include effective procurement, regulatory control, transport and storage facilities and an efficiently functioning health infrastructure with referral mechanisms in place, essential logistics supply

[49] Undermining access to medicines: Comparison of five US FTAs – A technical note (OXFAM, June 2004). http://www.oxfam.org.uk/what_we_do/issues/health/undermining_access_ftas.htm

mechanisms and appropriately trained, employed, remunerated and effectively managed health staff to deliver the medicines and supervise treatment.

Most of the people suffering from HIV/AIDS, malaria and TB live in the poorest countries, and belong to the poorest sectors of society. Even where there are existing and effective technologies and interventions, many people do not have access to them. Further reduction in prices would increase the number of countries and the pool of people able to afford them, especially those living in least developed countries where US$150 per person per year – the cost of a first-line ARV – is still far beyond what national health budgets or individual incomes can support.

In 2000, there were still more than 2,700,000,000 people living on less then US$2/day.[50] As of June 2004, 440,000 people were estimated to have received ARVs out of a total estimated number of six million people in immediate need of treatment in developing countries (only 8%). This is an increase of 40,000 from the total number of people on treatment in 2003.[51] According to the 3 by 5 Initiative Progress Report (December 2003 through June 2004), access to ARV medicines in 2002 increased by 50% globally, and by two-thirds in sub-Saharan Africa. This excludes Brazil, which still accounts for about 33% of all people on ARV therapy in developing countries.[52]

AFFORDABILITY

Key results:

- A reduction by up to 98% in the price of some key pharmaceutical products in developing countries.
- Global acceptance of tiered pricing as a sound principle, an established definition of what constitutes a maximum threshold for a tiered price, and anti-trade diversion measures put in place for registered products.
- Agreement reached on all aspects of the Doha Declaration on TRIPs and Public Health, including Paragraph 6, which allows countries with insufficient manufacturing capacity to import less expensive pharmaceutical products to address a public health problem.

Key challenges:

- To accelerate price reductions (i.e. make tiered pricing the norm) in developing countries, and to broaden the range of more affordable pharmaceutical products.
- To reduce or eliminte import tariffs on essential pharmaceutical products to ensure lowest possible consumer prices in developing countries.

50 Global Economic Prospects 2004, World Bank www.worldbank.org/prospects/gep2004/chapter1.pdf

51 WHO, "Treating 3 Million by 2005: Making it Happen. The WHO Strategy", 2003

52 3 by 5 Progress Report – December 2003 through June 2004. http://www.who.int/3by5/publications/progressreport/en/

- To continue to improve transparency of prices of pharmaceutical products and price reductions, through the Regulation on trade diversion and through the Global Fund. Public advocacy and support for greater price transparency is an underplayed card in the affordability arena.

- To support developing countries' capacity to use flexibilities under the Doha Declaration, and to ensure that the Doha Declaration is not eroded (through bilateral agreements).

- To go beyond affordability to promote access, primarily through developing functioning health infrastructure with appropriately trained, employed, remunerated and managed staff.

3.3. Research and development of new tools

Rationale for action: The PfA calls for continued and increased support for basic and strategic research on new tools for the three poverty diseases, with greater coordination at European and international level. The PfA calls for the creation of a European and Developing Countries Clinical Trials Partnership (EDCTP) to increase the number, efficiency and coherence of clinical trials carried out in developing countries in Africa with a high disease burden. It also calls for incentives to harness the capacity of private industry to invest in and develop new tools targeting the three diseases.

The EU's support remains strong. In June 2004, at a conference bringing together a multitude of private and public partners held in Dublin and co-hosted by Ireland and the Netherlands, the EU endorsed the Global HIV/AIDS Vaccine Enterprise, and agreed on priority actions to improve and speed up the development of new preventive technologies such as HIV vaccines and microbicides.

The 6th FP (RTD) for 2002-2006 was adopted by the European Parliament and the Council in June 2002.[53] Compared to the 5th FP (RTD) for 1998-2002, the indicative budget for poverty-related diseases under the 6th FP (RTD) is substantially higher, with more than €400 million being allocated to basic, pre-clinical and clinical research in new interventions for HIV/AIDS, malaria and TB (a 4-fold increase from €109 million). Substantial efforts have since been made to gather a critical mass of private and public partners, from developed and developing countries in a limited number of relatively large project consortia, typically handling budgets in the range of €5-20 million. The Quality of Life approaches[54] have been consolidated in the 6th FP (RTD), where research in poverty-related diseases has become a specific budget item under the first priority thematic area (life sciences, genomics and biotechnology

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53 Decision No 1513/2002/EC. OJ L 232, 29.8.2002, p.1

54 The 5th Research Framework Programme ran between 1998 and 2002, and the EC provided substantial funding to a broad range of research activities relating to the three diseases, notably via specific calls for proposals. A total of 77 projects were supported with more than €109 million under two separate programmes – Quality of Life and International Cooperation. The approach in the Quality of Life programme focused on bio-medically-oriented and clear deliverables, while the International Cooperation programme used a networking approach to build up numerous North-South partnerships.

for health). The International Scientific Cooperation programme continues to support North-South collaborative research projects on health systems and policies, other neglected diseases, child survival, and reproductive health.

Currently, a number of highly significant research projects are under way and delivering results, funded by the 5th FP (RTD). These include a multicentre trial of shortening TB treatment to four instead of six months, a series of early clinigal tests for TB vaccination, and various projects dealing with new malaria drugs such as phosphidomycin. Another significant action is the support to a pioneering effort of HIV/AIDS vaccine research in China, based on the locally predominant C-strain of the HIV virus.

3.3.1. Strengthening of research in poverty-related diseases

The EC has made an important contribution to confronting HIV/AIDS, malaria and TB by pooling knowledge, experiences, human and financial resources from the different stakeholders in the research and development process. The 6th FP (RTD) has given increased opportunities to organising and funding large-scale research projects, with a high and lasting potential impact. The EC is now supporting a much wider range of research activities, expanding from early discovery to clinical trials and comprising an extensive pipeline of promising development projects. Since the launch of the PfA, European research in poverty-related diseases has become ever more visible, influential and effective on the global research agenda and in its priorities. Alliances have been created with foundations and industry, and closer interaction with national and international organisations has been implemented.

Support for large research consortia: The significant funding allows for large consortia with diversity and critical mass to undertake complete product/intervention development projects. Development of promising drug and vaccine candidates from discovery phases to early human testing is undertaken by multidisciplinary research consortia that are organised as Integrated Projects (IPs) or Networks-of-Excellence (NoEs). So far, support has been given to 6 projects with a total budget of €160 million and an EU contribution of €73 million. The 6 projects cover malaria biology (EU contribution of €15.5 million), TB and HIV vaccine development (EU contributions of, respectively, €16.8 million, €15.5 million and €10 million), as well as microbicides (EU contributions of €3.8 million and €11.7 million). During the next two years of the 6th FP (RTD), funding will be provided to drug development projects in malaria and TB, while other projects should focus on further development of HIV/AIDS and malaria vaccine candidates.

Support to several small-scale, high-risk and innovative projects: Research in poverty-related diseases is a long-term and complex activity, and innovation is needed in order to maintain a wide initial scope. The EC supports several small-scale, high-risk and innovative projects, all in the early discovery phase. Based on project results, the EC will be able to select interventions that may enter the first stages of the formal development pipeline. Individual projects have a duration of 2 years, and budgets of €1-2 million. Approximately 20 projects involving 102 research groups representing all three diseases have so far been selected for support. More projects will be added during the next 2 years of the 6th FP (RTD).

Utilising the innovative potential of SMEs: It is expected that opportunities offered to the Small and Medium-sized Enterprise (SME) sector, by means of specific calls for proposals and appropriate use of instruments of the 6th FP, could enhance their participation in this field.

Partnerships: The overarching methodology of poverty-related disease research in the 6th FP (RTD) is to consolidate genuine partnerships between European scientists, research teams from disease-endemic countries and industry. The projects described above involve a significant number of industry partners, thereby generating a synergy between academic and industrial research. Research teams from developing countries have been particularly encouraged to join the projects, and this has resulted in the active participation of 12 renowned African institutions.

Despite this progress, many research efforts are not sufficiently coordinated on the ground between the different stakeholders in the most affected endemic countries. There is little investment into the development of scientific learning, further training of health practitioners or in positive local synergies between research and routine health care programmes. There are also other research areas, such as social analysis, the analysis of new epidemiological trends and the development of methods on how to measure impact of interventions, which have not been appropriately addressed so far. These are of particular importance for vector-borne diseases like malaria.

Training fellowships: Significant efforts have been made to provide for increased training activities in the area of research on poverty-related diseases, in particular through the larger IPs and NoEs of the 6th FP (RTD). Very encouraging examples can be found in the malaria research NoE (BIOMALPAR), where the European Molecular Biology Laboratory makes its expertise available.

3.3.2. European and Developing Countries Clinical Trials Partnership

The **European and Developing Countries Clinical Trials Partnership** (EDCTP) initiative was established in 2001 in response to one of the three areas for action in the PfA – to increase research and development of specific global public goods to confront the three diseases in developing countries. The aim was to unite and coordinate Europe's clinical trial activities specifically targeting interventions for use in developing countries. The single largest budget allocation of the 6th FP (RTD) (€200 million) goes to the EDCTP. The EDCTP's mandate focuses on supporting phase II and phase III clinical trials for new interventions confronting the three diseases and on research-oriented capacity building, particularly in sub-Saharan Africa.

The EDCTP programme was adopted by the European Parliament and the Council in June 2003.[55] The programme started operations in autumn 2003 after a legal entity, the European Economic Interest Grouping (EEIG), was formed by the participating states (14 EU Member States and Norway), external from the Commission and headquartered in The Hague. The EDCTP now operates its own implementation

[55] Decision No 1209/2003/EC of 16 June 2003. OJ L 169, 9.7.2003, p.1

structures, calls for proposals and appropriate selection and evaluation procedures. An African office of the EDCTP was opened in Cape Town in July 2004.

A first **call for proposals** for clinical trial projects and senior fellowships for African scientists and clinicians has been issued in early 2004. A total of nine projects on improved treatment for HIV/AIDS, malaria and TB and six fellowships have been selected for funding through an independent scientific review procedure. A second call for proposals, targeting upgrading of research capacity of African vaccine trials sites, is currently underway.

African ownership and representation in the EDCTP is established at different levels: at the Scientific/Advisory level, the composition of the Partnership Board (North-South is 50/50); at the Structural/Organisational level with the establishment of the African EDCTP Secretariat in Cape Town, the functioning of the Developing Countries Coordinating Committee as an EDCTP external entity for the representation of the African scientific community to the EDCTP programme; at the Advocacy/External level with the role of Dr Mocumbi, the High Representative of the EDCTP; and finally, at the Project level, where in the nine selected projects from the first call, 31 partners are African institutions representing 16 sub-Saharan African countries.

Through the use of Article 169 of the Treaty, the EC is contributing €200 million to the EDCTP (for the whole time period 2002-2006). Another €200 million comes from the 15 participating European countries, the Netherlands having already committed significant funds. Further input is expected from industry, foundations and other private sector sponsors.

The EDCTP is a pilot programme and a unique initiative in research at the European and global level. Key components include:

- It contributes to the first implementation of Article 169 of the EC Treaty, which allows the participation of the European Community in EU Member States' national research and development programmes.
- It is the largest programme on clinical trials in Africa.
- It has an entrepreneurial legal entity, more flexible to take up the challenges.
- It consolidates a genuine partnership between the South and the North on a long-term sustainable basis.
- It focuses on the needs of developing countries, which are setting the priorities and are establishing strategies in close partnership with European countries.

The EDCTP is thus a concrete example of the functioning of the European Research Area and it is fully integrated within the activities of the 6th FP (RTD) (2002-2006).

3.3.3. Capacity building for research and development in developing countries

A significant proportion of the EDCTP budget contributes towards the enhancement of capacity for research and development in developing countries with a high disease

burden. Capacity building is an essential component of the EDCTP. Nevertheless, the needs largely outweigh the resources of the programme. Capacity building is needed in terms of personnel training, support for new and existing health infrastructures as well as setting up the adequate organisational, technical/scientific and institutional frameworks.

While the 6th FP (RTD) funds mobilised under Article 169 can contribute to the implementation of EDCTP programmes' clinical trials and research-related capacity building activities, additional funds from both private and public sources are needed to allow the EDCTP programme to achieve its full impact potential. Such funds are required, for example for high-quality production of medicines and vaccines, for implementation of new interventions, and for strengthening health systems and care facilities in Africa.

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

Incentives: The PfA identified the crucial role of private investors in developing tools to confront the three diseases. Since pharmaceutical R&D is complex, risky and expensive, developing new drugs or vaccines for low-income countries is unlikely to occur without significant public incentives. The 2003 progress report recommended that further work be done to increase incentives to the private sector to invest in new specific global public goods targeting these diseases. The EC has since reinforced the dialogue with the R&D based industry, European industry organisations, health economists and other stakeholders to identify those public incentives most likely to boost private investments in the development of essential pharmaceutical products, including HIV vaccines and microbicides. The menu of incentives being discussed includes the extension of patent rights and/or market exclusivity, including through the relationship which might be established between different products, venture capital, low cost loans, tax credits and guaranteed markets. Through these consultations, the EC has identified the need for further studies on:

(1) Costs and benefits of developing an AIDS vaccine, a microbicide and a malaria vaccine

(2) Impact of introducing different incentives on private research intensity, both in the large pharmaceutical and small and medium-sized enterprise sector

(3) Potential long-term impact on global public health of introducing different incentives

(4) Financial requirements, including an assessment of costs of different incentives for public authorities and individual citizens

(5) Identification of various EC instruments which could be used to provide incentives, including potential new EU regulations and related legal issues.

Community preparedness for potential vaccines and microbicides: It is imperative to test new tools in developing countries, where they are most needed. The EC is taking a parallel approach and preparing developing countries for the possibility of introducing AIDS vaccines and microbicides. This is in anticipation of

the technological breakthroughs, and will eventually ensure a smooth and fast distribution implementation mechanism. The EC is working on community preparedness directly with communities in sub-Saharan Africa, and with international partners such as IAVI, IPM,[56] and the South African AIDS Vaccine Initiative. EC work includes the funding of programmes on ethical criteria and regulatory aspects. The EC also held discussions on affordability clauses (with IAVI), regulatory aspects (EMEA), and production and distribution capacities. The discussion has not yet started on what price would be affordable and morally acceptable for AIDS vaccines in developing countries. A potential precedent for tiered pricing has already been set through the Regulation. The EC also funded a joint economic research programme with the World Bank to assess the potential demand and impact of an AIDS vaccine (see Annex 2 for information on financial support by EU Member States to IAVI and IPM).

[56] Various EU Member States are also supporting these organisations, see Annex 2.

RESEARCH AND DEVELOPMENT

Key results:

- A 4-fold increase in funds from the 5th to the 6th FP (RTD) (from €109 million, 1998-2002, to more than €400 million, 2002-2006) targeting the three diseases.
- Support for large research consortia, with strong partnerships developed between European scientists, renowned African research institutions, and industry partners.
- Support for small-scale, high-risk and innovative projects in the early discovery phase and incentives for participation by SMEs.
- The establishment of the European and Developing Countries Clinical Trials Partnership, which focuses on supporting phase II and phase III clinical trials for new interventions confronting the three diseases and on research-oriented capacity building, especially in sub-Saharan Africa. In only one year, all decision-making, organisational and managerial components of the EDCTP programme are operational. The participation in and ownership of African countries and researchers in the EDCTP programme is a significant achievement.
- The preparation of developing countries for the possibility of introducing AIDS vaccines and microbicides. Early results show that people are willing and able to pay, use and test these new tools.

Key challenges:

- To sustain EU (EC and EU Member States) funding to promote further development of key tools to confront the three diseases, including an AIDS vaccine, microbicides and TB diagnostics.
- To prioritise close coordination and increased coherence of clinical testing (recommended to be done in parallel), in order to accelerate the release of new tools. Also, to ensure better cooperation between different stakeholders on the ground.
- To ensure sustainability and increase in EDCTP support, with an appropriate mix of EC, EU Member State and private sector funding.
- To establish incentives for private industry to develop new targeted products, ensuring cost effectiveness of such interventions.

3.4. Participation in Global Partnerships: Policy and Political Dialogue

The EC has developed strong partnerships with various key players, including policy dialogue with NGOs and pharmaceutical companies and enhanced cooperation with UNAIDS and WHO, despite the lack of formal channels for such dialogue and partnerships. EC cooperation with UN agencies now includes funding (as a new component) which, in the case of WHO, is part of a formal, strategic partnership with the EC which defines areas for further cooperation.

Partnership with developing countries: The EC has worked in partnership with developing countries to confront HIV/AIDS, malaria and TB at global, regional and country level. As described above, the EC has supported programmes that directly address the three diseases at country level, both through country strategies and the Global Fund. In many of these countries, EC delegations have been active in the Country Coordination Mechanisms (CCMs) of the Global Fund. EC contributions to confronting the three diseases in other countries have come through health as a focal sector, and/or through macroeconomic budget support. In the area of research and development, the EC has formed strong partnerships with research institutions of developing countries, primarily through the EDCTP as described above.

Partnership with civil society: The EC has actively called upon the participation of civil society in policy consultation and formulation. This has resulted in a new partnership and dialogue with international and national non-governmental organisations (NGOs), including those representing women, people living with the diseases, and those representing sexual and reproductive health and rights. NGOs have increasingly become more than implementers of programmes using EC funds, and are important partners in policy dialogue.

Partnership with the private sector: A growing body of evidence suggests that if a company is investing in a developing country or in a middle-income country such as Brazil, China, Russia or South Africa, HIV/AIDS is also their business. For many businesses, investment in programmes that prevent infection and provide care and treatment for employees with HIV/AIDS makes business sense. Companies are now increasingly offering services for voluntary testing and treatment of employees and families, condom provision and education. The EC has been working with investors in Africa to encourage the provision of preventive and care programmes either directly or indirectly. Investing in such programmes improves the welfare of their employees, and makes them more productive. Such programmes also generate goodwill and raise the company's standing in society.

The EC has worked in close partnership with the private sector, including the R&D based industry, private enterprises (e.g. Private Investors for Africa) and other key stakeholders in the dialogue, development and implementation of national and global strategies. The active policy dialogue and partnership with the R&D based industry is now resulting in an improved understanding of development objectives and business incentives.

Leadership in countries: Certain developing countries have demonstrated strong leadership and successful strategies that have stopped or reversed infection rates for HIV, malaria and TB over the past few years[57]. **Peru** has attained effective TB control nationwide through integrating TB control within the health system throughout the country, and maintaining high quality service, monitoring, and management of the system. **Senegal** saw early mobilisation of government and civil society. There was also open government support for reproductive health, including sexually transmitted disease and HIV prevention, and HIV/AIDS treatment through ARVs. These measures have kept the disease prevalence low. In **Thailand**, strong prevention efforts promoting the use of condoms, production of generic pharmaceutical products, and testing and treatment have contributed to decreasing annual infection rates in certain groups by a factor of five over the last decade. Thailand's treatment and care approaches have also been supported by the distribution of generic and locally produced medicines. In **Uganda**, national prevalence of HIV/AIDS dropped from 12% in the early 1990s to 4.1% in 2003 (in the capital Kampala, this trend was even more pronounced, with a prevalence of around 8% in 2002 as compared to 29% ten years ago). This reduction was mostly due to education campaigns to mobilise various leaders, and condom promotion. However, this momentum must be continued – a recent survey suggests that young people in Uganda may have less AIDS knowledge than their counterparts in the 1990s[58]. In **Vietnam**, child mortality rates due to malaria have declined over the last decade, primarily because of the use of insecticide-treated bednets and community-based diagnosis and treatment.

The countries mentioned above have varying reasons for their success. Most notable is that of leadership, with political commitment behind strong policies, the effective mobilisation of resources to confront these three diseases, and social services and systems that deliver.

Global health partnerships: The 2003 progress report already noted success at scaling up global partnerships, reaching important international consensus on the interventions that will make the greatest difference.[59] This is most significantly illustrated by the establishment of the Global Fund in 2002 after an active transition period with the support of the EC and Belgium. Significant new partnerships have been made over the past few years with multilateral organisations such as UNAIDS and WHO, primarily on issues of pharmaceutical policy and affordable pharmaceutical products. For example, the EC is funding WHO to strengthen the capacity of countries at national level to monitor health data.

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57 WHO, UNICEF, UNAIDS, World Bank, UNESCO, UNFPA, *Health a key to prosperity: Success Stories in Developing Countries*, 2000

58 UNAIDS Fact Sheet (6/7/2004), from: http://www.unaids.org/EN/other/functionalities/Search.asp?StartRow180

59 This builds on previous agreement on specific targets for malaria at the African Summit on Roll Back Malaria in Abuja April 2000; for TB through the WHO Assembly of May 2000; and for HIV/AIDS at the UN General Assembly Special Session on HIV/AIDS in June 2001.

EC/EU Leadership: The EC has played an active role in terms of advocacy, coordinating positions, mobilising resources, and defending and representing strong and honest dialogue on the full Cairo agenda among the EU Member States. The EC has also regularly held meetings with experts on Health, AIDS and Population from the EU Member States to discuss and coordinate policy. EC leadership has been exercised as a basis for more coordinated and harmonised cooperation with other donors in developing countries and a stronger European voice in international fora – including in the WTO, and in the G8. For example, the EC is a key player in the policy debate on tiered pricing with the G8 and with the R&D based industry.

Partnership with EU Member States: There was good cooperation and agreement on the PfA between EU Member States in 2001,[60] as is indicated by the passing of various related Council resolutions (refer to Annex 1). However, the past few years have seen dispersion of strategies by Member States. This is indicative of a wider trend occurring globally – for example, as evidenced by the different initiatives to confront the three diseases. In April 2004, UNAIDS proposed a set of principles – the 3 Ones[61] to promote harmonisation at country level on HIV/AIDS. These principles are: one agreed HIV/AIDS action framework that provides the basis for coordinating the work of all partners; one national AIDS coordinating authority with a broad-based multi-sectoral mandate; and one agreed monitoring and evaluation system at country level.

60 Figures on contributions by Member States to the Global Fund, IAVI and IPM are provided in Annex 2.

61 The Three Ones, launched in 2004, is an initiative aimed at harmonising donor efforts at country level based on three principles: One agreed HIV/AIDS Action Framework that provides the basis for coordinating the work of all partners; One National AIDS Coordinating Authority, with a broad-based multi-sectoral mandate; and One agreed country-level Monitoring and Evaluation System. http://www.unaids.org/en/about+unaids/what+is+unaids/unaids+at+country+level/the+three+ones.asp

PARTICIPATION IN GLOBAL PARTNERSHIPS: POLICY AND POLITICAL DIALOGUE

Key results:

- Strong partnership with developing countries through the Global Fund, through CSP and PRSP processes, and through various research activities.
- Close partnership with a broad range of civil society, who have increasingly become important partners in policy dialogue.
- Sustained and positive dialogue with the private sector, including the R&D based industry and private enterprise, regarding corporate social responsibility, particularly on HIV/AIDS.
- Strong EC support for global partnerships in health, including with UN organisations and international consortia.
- Active EC role in terms of advocacy, coordinating positions and mobilising resources among the EU Member States. This includes a strong European voice in international fora on key issues, including on TRIPs and the Cairo Agenda (ICPD).

Key challenges:

- How to strengthen further and intensify the dialogue between key partners at county level.
- How to increase the efforts of the private sector, including the promotion of private investment and contributions to multilateral initiatives and mechanisms (such as the EDCTP and the Global Fund).
- How to minimise the negative impact of numerous and sometimes divergent initiatives through enhanced harmonisation and coordination with EU Member States and through global initiatives such as the 3 Ones.

3.5. Institutional coordination and cooperation

The policy framework and the PfA required strong coordination, cooperation and efforts across different policy areas. No specific EC institutional set-up was created to perform the tasks of coordinating, monitoring and reporting on the PfA. Despite this, the EC has managed to focus and increase attention through coherent policies, resources and efforts in a remarkably short period of time. The EC institutional set-up has not facilitated the task at hand, and the lack of clear and shared information bases has made it very difficult to track results.

The EC financial instruments are set up in a way which renders supporting global instruments difficult. Despite this, the EC has provided significant financial support and political commitment to global instruments.

The policy framework and the PfA required strong cooperation with a variety of stakeholders, outside of historical precedent. The PfA announced the creation of a Stakeholder Forum to institutionalise the regular consultation process with developing countries, civil society and the private sector. However, this never materialised. The EC still retains a great deal of good will with most of the partners in providing input and participating in a dialogue.

4. THE EVOLVING EPIDEMIOLOGY, GEOGRAPHY AND DEMOGRAPHY OF HIV/AIDS, MALARIA AND TB

In total, the three diseases constitute what is generally acknowledged as a global emergency – the death of more than 6 million people every year, most of them in sub-Saharan Africa. HIV/AIDS is rapidly becoming the worst infectious disease catastrophe in recorded history, surpassing in absolute numbers the bubonic plague of the fourteenth century and the influenza epidemic of 1917, each of which killed around 20 million people.

Diseases still increasing, and with new forms: Despite increased efforts and resources in recent years, the number of people affected, infected and dying from HIV/AIDS, malaria and TB continues to rise. In 2003, almost 3 million people died of HIV/AIDS, and there were about 5 million new HIV infections.[62] It is estimated that 38 million people (range between 35-42 million) throughout the world were living with HIV/AIDS at the end of 2003.[63] By the end of the decade, the number of people infected will have grown by another 45 million. Tuberculosis (TB) kills about 2 million people every year.[64] TB is also a major cause of death amongst people infected with HIV, and each of the two diseases amplifies the effects of the other. Malaria kills more than one million people every year, including an African child every 30 seconds.[65]

The diseases are also taking on new forms, including multi-drug resistant versions of TB, which are especially emerging in Eastern Europe due to poor use of therapy. The global picture with regard to malaria shows little sign of improvement, with sub-Saharan Africa remaining the worst affected region. Climate change, the lack of effective vector control, the increase of displaced persons and the rapid extension and increase of resistant strains have led to an overall increase in the burden of malaria.

Geographic spread: Sub-Saharan Africa carries the greatest burden of HIV/AIDS and TB; it is home to two-thirds of HIV-infected people globally, although it consists of only 11% of the world's population. An estimated 25 million infected with HIV/AIDS live in sub-Saharan Africa. In 2003, approximately 3 million people in

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62 Robert Steinbrook, 'The AIDS Epidemic in 2004', New England Journal of Medicine, 351;2, 8 July 2004

63 UNAIDS "A global view of HIV infection", www.unaids.org

64 WHO "Basic Facts on TB", from www.stoptb.org

65 WHO "What is Malaria", from www.rbm.who.int

the region became infected, while 2.2 million died of AIDS.[66] Women made up 56.7% of adults infected with HIV by the end of 2003.[67]

The populations of China, India and Russia make up half of the world's total population; in all three countries, the HIV/AIDS epidemic is spreading. In China, 10 million people may be infected with HIV/AIDS by 2010 unless effective measures are taken to prevent it; India has the largest number of people living with HIV/AIDS outside of South Africa (about 4.6 million in 2002); and in Russia, the number of new cases registered doubled between 1987 and 2000 (with 56,630 new cases registered in 2000).[68] The virus is also spreading rapidly to parts of Eastern Europe (including new EU neighbouring countries such as Ukraine).[69]

Poverty reduction remains the main framework: HIV/AIDS, malaria and TB persist in undermining global efforts to reduce poverty. The three diseases are both a consequence of, and a cause of, poverty.[70] The most disadvantaged and vulnerable in society – e.g. people with disabilities, ethnic minorities, refugees and migrants – are the least likely to have access to prevention, treatment and care. They are also exposed to more social risk factors, which increase their risks of HIV/AIDS, malaria and TB infection, for example overcrowding, malnutrition and poor hygiene. All people have the right to realise the highest attainable standard of health (regarding all aspects of care, water, food, sanitation, information and education). Poverty is more than a lack of income – it is also a condition of powerlessness and vulnerability. For poverty reduction to occur, the rights of poor people have to be realised.

HIV/AIDS also has significant repercussions on economies, reducing economic productivity and growth by decimating the workforce. A recent World Bank study illustrated how long-term effects of HIV/AIDS could result in economic collapse of the worst affected countries.[71] Another study illustrates how malaria has hindered economic growth in Africa, so much so that the GDP of African countries is currently 32% lower than it might have been had malaria been controlled two decades ago.[72] The diseases also add to the vicious cycle of poverty by inhibiting the investment climate of the country, as businesses are less likely to invest in countries where the population has a low productivity rate and low purchasing power. Morbidity from TB and malaria also negatively impact the economies of societies by increasing the burden of disease carried by the working age population.

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66 UNAIDS, Report on the global AIDS epidemic, July 2004

67 IPPF, ICPD at Ten: Where are we now?, 2004

68 UNAIDS, Report on the global AIDS epidemic, July 2004

69 A response to HIV/AIDS inside the EU and in neighbouring countries is presented in the recently finalised Commission working paper "Coordinated and integrated approach to combat HIV/AIDS within the European Union and its neighbourhood"

70 WHO, Report of the Commission on Macroeconomics and Health, December 2001, www3.who.int/whosis/cmh/cmh_report/e/report.cfm?path=cmh,cmh_report&language=english

71 World Bank, The Long-Run Economic Costs of AIDS: Theory and an Application to South Africa, 2003

72 WHO, Macroeconomics and Health: Investing in Health for Economic Development. Report of the commission on Macroeconomics and Health, 20 December 2001

Human security and human rights as a complementary framework: For all three diseases, the impact goes far beyond the individual. The effects of HIV/AIDS in particular are now challenging the basic stability of countries. As the pandemic spreads in developing countries, its negative effects on the social, economic, and political fabric of communities grow. At societal level, HIV/AIDS is decimating communities and destroying social cohesion. In seven African countries where HIV prevalence is more than 20%, the average life expectancy of a person born between 1995-2000 has declined from 62 to 49 years.[73] The awareness of reduced life expectancy on such a high proportion of society has a traumatic effect on people's minds, norms and behaviour. Although the disease is becoming more widespread, acceptance is not following suit, and stigma and discrimination against people living with HIV/AIDS still remains. Enforcement of harsh laws has the effect of marginalising and further stigmatising many people at greater risk of the diseases (e.g. commercial sex workers, injecting drug users, and men having sex with men). People whose human rights are abused are most vulnerable to HIV/AIDS.

The potential relation between HIV/AIDS and political instability is gathering increased international attention. HIV/AIDS may have links to the breakdown of institutions, and has been shown to decimate many government sectors, such as education, health and the military. Whole cadres of skilled social service professionals (including those in the education and health sectors) are affected. In Zimbabwe, for example, it is estimated that by the end of 2003 30% of all teachers were HIV positive. This contributes to a vicious circle which makes it harder to confront HIV/AIDS.

Gender dimension: The female face of the HIV/AIDS pandemic continues and grows; HIV/AIDS disproportionately affects women in terms of infection, impact and access to treatment. Women are more likely to be infected by HIV due to biological reasons but also due to inequalities in access to information, education, care, negotiation ability, societal and familial empowerment and condoms. HIV/AIDS is spreading rapidly among young girls and women, and women account for almost half of those already infected globally.[74] (In Sub-Saharan Africa, the percentage is higher, with women comprising 56.7% of adults infected with HIV by the end of 2003[75]). In terms of new infections, globally six out of ten new HIV infections occur in women. And in the young age group of 15-24, young women are more than three times as likely as young men to be infected.[76] They are also more likely to be the main care-givers for those suffering from HIV/AIDS. Women bear a disproportionate burden of malaria. Pregnant women and their children are particularly vulnerable to malaria consequences (e.g. perinatal mortality, low birth weight and maternal anaemia).

Age dimension: HIV/AIDS mostly kills people in the productive age. The legacy of orphans caused by parents dying from HIV/AIDS is shocking – there are 12 million

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73 UNAIDS, Report on the global AIDS epidemic, July 2004
74 UNAIDS, Report on the global AIDS epidemic, July 2004
75 IPPF, ICPD at Ten: Where are we now?, 2004
76 UNAIDS, UNFPA, UNIFEM, Women and HIV/AIDS: Confronting the Crisis, 2004

orphans in Africa alone, and it is estimated that there will be more than 18 million by the end of the decade.[77] Many older women are now looking after young orphaned family members, and there is increased pressure on the transmission of cultures, norms of behaviour and simple societal survival mechanisms. Malaria causes 20% of childhood deaths in Africa, and the long-term consequences of malaria, for those who survive, include debilitating disabilities.

5. CONCLUSIONS

It may sound strange to talk about progress when there are still more than 6 million people in the world dying each year from HIV/AIDS, malaria and TB. The fact that these preventable diseases are still not under control should remain the main focus when the EC and the EU Member States set priorities for external action to confront the three diseases.

Implementation of the policy framework (2000) and the PfA (2001) has seen major achievements, some of which need to be further accelerated. There have also been some issues where progress has been slow. These, and new evolving challenges, need to be addressed. Of particular significance in the achievements are:

- **Impact:** A four-fold increase in EC resources allocated specifically to confronting the three diseases, with a €259.02 million annual average programmed for 2003-2006 as compared to a €59.32 million annual average committed for 1994-2002 (including a significant increase in research funds).

- **Affordability:** A reduction by up to 98% in the price of some key pharmaceutical products in developing countries.

- **Research and development:** The establishment of the European and Developing Countries Clinical Trials Partnership (EDCTP), which focuses on clinical trials for new interventions confronting the three diseases and on research-oriented capacity building, especially in sub-Saharan Africa.

- **Partnership:** An active EC role in terms of leadership, coordinating positions and mobilising resources among the EU Member States and other donors. This includes a strong European voice in international fora on key issues, such as Trade-Related Aspects of Intellectual Property Rights (TRIPs) and the Cairo Agenda (ICPD).

Outstanding challenges remain. The EC has allocated increased resources since the adoption of the PfA to confront the three diseases. However, EC resources allocated to health as a focal sector have decreased over time. Specific support for health systems, as well as for overall social services, needs to be prioritised by countries.

It is difficult to monitor the health outcomes of macroeconomic budget support. The EC should work with EU Member States (particularly the ones that are also moving

[77] UNAIDS, Report on the global AIDS epidemic, July 2004

towards macroeconomic budget support) to assess EC funding channels. The assessment will determine whether these channels allow for increased resource flows to the social sectors, and whether this translates into improved health outcomes.

It is essential for countries to invest in ailing health infrastructure and other social services, and to strengthen the overburdened human resource capacity. This includes accelerated action on staff training, appropriate remuneration and retention of staff, and responsive management. This could also include innovative actions to help mitigate brain drain. To support this, the EC needs to ensure sustainable and long-term financing, both at country and global levels through innovative actions and flexible instruments that permit an optimal use of resources and increased impact.

The EC needs to support regulatory capacities in developing countries. In this context, the recently adopted revision of the EU pharmaceutical legislation enables the Community, in cooperation with WHO, to provide scientific assistance to non-EU countries, for the evaluation of medicines that meet their own pubic health needs.

To further increase affordability, the EC should focus on upholding the WTO TRIPs commitments. The EC needs to monitor the price of pharmaceutical products purchased by countries that receive EC funding for health or macroeconomic budget support, in an effort to increase price transparency. The EC should support a broader range of tiered price pharmaceutical products (including anti-retroviral second-line treatments, FDCs, and other products such as ACTs for malaria). Improving investments in health and other social services will also contribute to increasing access to affordable pharmaceutical products.

Other challenges include the research and development of new tools such as AIDS vaccines and microbicides, both with EDCTP and other key partners. The EC should explore the issue of incentives for private enterprise. Further involving the private sector in the promotion of private investment, contributions to multilateral initiatives and mechanisms (such as the Global Fund) and in research (such as the EDCTP) remains a challenge.

There is a continued need for cooperation with other partners, including third countries and civil society. Involving all these partners in an institutionalised Stakeholder Forum, as originally suggested in the PfA, remains important. The EC is in a unique position to promote efficiency and cooperate with EU Member States on sharing technical assistance in partner countries. Minimising the negative impact of numerous and sometimes divergent international initiatives through enhanced coordination, harmonisation and through global initiatives such as the Three Ones is important.

Moving beyond the PfA, the EC needs to respond to evolving challenges. The diseases are spreading further geographically. The enlarged EU faces a re-emergence of TB (especially multi-drug resistant variants), and a rapidly rising incidence and prevalence of HIV/AIDS. This demands a strong EC/EU response. These diseases disproportionately affect women, so there is a need to fully consider patterns and causes of the dramatic increase in HIV/AIDS transmission to women. The diseases are also prominent in children, affecting them both directly and indirectly; consideration of the impact of the diseases on different ages is imperative.

The EC policy framework remains valid, with the focus on the three diseases, and the comprehensive policy mix of prevention, treatment and palliative care. Poverty reduction remains the key rationale for action on HIV/AIDS, malaria and TB. The increasingly obvious effects of HIV/AIDS on society, the economy, and government institutions also require the consideration of a complementary framework of human security and human rights.

The EC will continue to act at both country and global levels. The simultaneous and coherent actions reinforce each other, and allow for increased effectiveness. This progress report has illustrated the value in allocating additional resources to countries faster and effectively through global instruments, for example through the Global Fund. There are also certain issues that can only be addressed at global level. The EC should therefore continue to play an important role in developing a common European response and advocating policy in international fora. The maintenance of international commitments, such as those made on sexual and reproductive health and rights and TRIPs, is paramount. The long-term vision of Europe and its partners remains the achievement of the MDGs.

The synergy of different interlinking and mutually supporting actions on development, trade and research has created a larger impact. The EC should now build further on this strength. The need for policy coherence, both within the EC and across all partners, is stronger than ever within an increasingly diverse global institutional set-up.

The moment is right for the EC to take stock of what has been achieved, reflect on what has changed, reinforce its commitments and build on existing momentum to shape key actions for the years to come. This will require identification of appropriate instruments, including the use of new financial instruments for EC external action and the 7th FP (RTD). An updated and comprehensive EC policy framework for confronting HIV/AIDS, malaria and TB globally will be presented in an EC Communication.

Annex 1: European Council and European Parliament Resolutions relating to the PfA

Council of the European Union

- Resolution on "Health and Poverty" of 30 May 2002, (Doc: 8958/02.)

http://europa.eu.int/comm/development/body/theme/human_social/docs/health/02-05_council_resolution.pdf#zoom=100

- Resolution on "Programme for action: accelerated action on HIV/AIDS, malaria and tuberculosis in the context of poverty reduction" of 14 May 2001, (Doc: 6802/01)

http://register.consilium.eu.int/pdf/en/01/st08/08495en1.pdf

- Resolution on "Communicable Diseases and Poverty" of 10 November 2000, (Doc: 12929/00)

http://register.consilium.eu.int/pdf/en/00/st12/12929en0.pdf

- Conclusions on "Communicable diseases: HIV/AIDS, malaria and tuberculosis" of 18 May 2000

http://europa.eu.int/rapid/pressReleasesAction.do?reference=PRES/00/156&format=HTML&aged=1&language=EN&guiLanguage=en

European Parliament

- Doc: PE 286.865/DEF or A5-0263/2001

Report on the Commission communication on accelerated action targeted at major communicable diseases within the context of poverty reduction (COM(2000)585 – C5-0014/2001 - 2001/2006(COS)) - Committee on Development and Cooperation

http://www2.europarl.eu.int/omk/sipade2?PUBREF=-//EP//NONSGML+REPORT+A5-2001-0263+0+DOC+PDF+V0//EN&L=EN&LEVEL=2&NAV=S&LSTDOC=Y

- Doc: PE 310.468/DEF A5-0394/2002

Report on the proposal for a European Parliament and Council regulation on aid for poverty diseases (HIV/AIDS, malaria and tuberculosis) in developing countries – Committee on Development and Cooperation

http://www2.europarl.eu.int/omk/sipade2?PUBREF=-//EP//NONSGML+REPORT+A5-2002-0394+0+DOC+PDF+V0//EN&L=EN&LEVEL=2&NAV=S&LSTDOC=Y

- Doc: PE 310.467/DEF A5-0020/2003

Report on the proposal for a European Parliament and Council regulation on aid for policies and actions on reproductive and sexual health and rights in developing countries – Committee on Development and Cooperation

http://www2.europarl.eu.int/omk/sipade2?PUBREF=-//EP//NONSGML+REPORT+A5-2003-0020+0+DOC+PDF+V0//EN&L=EN&LEVEL=2&NAV=S&LSTDOC=Y

- Doc: PE 310.512/DEF A5-0217/2003

Report on the Commission communication on Health and Poverty Reduction in Developing Countries - Committee on Development and Cooperation

http://www2.europarl.eu.int/omk/sipade2?PUBREF=-//EP//NONSGML+REPORT+A5-2003-0217+0+DOC+PDF+V0//EN&L=EN&LEVEL=2&NAV=S&LSTDOC=Y

- Doc: PE 326.769/DEF A5-0474/2003

Report on the Commission communication on the update of 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 – Committee on Development and Cooperation

http://www2.europarl.eu.int/omk/sipade2?PUBREF=-//EP//NONSGML+REPORT+A5-2003-0474+0+DOC+PDF+V0//EN&L=EN&LEVEL=2&NAV=S&LSTDOC=Y

- Doc: PE 326.776/DEF A5-0055/2004

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- RESOLUTION on health issues, young people, the elderly and people living with disabilities. The ACP-EU Joint Parliamentary Assembly, meeting in Cape Town (South Africa), 18-21 March 2002

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http://europa.eu.int/comm/development/body/theme/human_social/docs/health/03-07_draft_declaration_global_fund.pdf#zoom=100

Annex 2: Contributions by the EC and EU Member States to the Global Fund, the International Aids Vaccine Initiative, and the International Partnership for Microbicides

It is difficult to compare bilateral funding of HIV/AIDS, malaria and TB across countries because of their different categorisation (some focusing on sectors, others on regions/countries, and others on diseases). The contribution of the EC and of EU Member States since 2001 to date to the Global Fund, IAVI and IPM provides one example of their funding. It should not be taken as indicative of other funding trends, and there are other research initiatives (such as AMANET and the European Malaria Vaccine Initiative) that receive support from Europe.

Table 3: Financial commitment to the Global Fund by the EC and EU Member States to date[78]

EC and EU Member States	*Amount contributed 2001-2002 (in US$)*	*Amount contributed 2003 (in US$)*	*Amount contributed so far, 2004 (in US$)*
Austria	1,075,900	-	13,827,500
Belgium	12,207,409	7,229,938	10,270,518
Denmark	14,816,511	13,790,866	16,188,433
EC	**137,064,385**	**50,360,226**	**264,413,350**
France	58,299,236	61,084,236	180,505,415
Germany	11,955,200	37,427,325	45,944,850
Hungary	-	-	10,000
Ireland	9,835,000	11,161,430	12,299,000
Italy	108,618,673	106,541,600	-
Luxembourg	1,037,500	1,094,820	2,365,000
Netherlands	8,087,400	43,590,360	47,886,680
Poland	-	20,000	-
Portugal	-	400,000	200,000
Spain	-	35,000,000	15,000,000
Sweden	22,369,965	11,488,363	39,159,992
UK	78,215,278	40,032,750	54,980,010
TOTAL	**463,622,457**	**384,221,914**	**622,815,249**

[78] From the Global Fund web-page, http://www.theglobalfund.org/en/

Table 4: Financial commitment to the International AIDS Vaccine Initiative (IAVI) by the EC and EU Member States to date[79]

EC and EU Member States	*Amount contributed 2002-2003 (in US$)*	*Commitments 2004-2007 (in US$)*	*Total commitments (in US$)*
Denmark	3,358,525	1,617,646	4,976,171
EC	-	3,000,000	3,000,000
Ireland	7,690,288	5,800,000	13,490,288
Netherlands	25,117,124	15,600,000	40,717,124
Sweden	359,812	197,910	557,722
UK	14,339,741	9,000,000	23,339,741
TOTAL	**50,865,490**	**35,215,556**	**86,081,046**

Table 5: Financial commitment to the International Partnership for Microbicides (IPM) by the EC and EU Member States to date[80]

EC and EU Member States	*Amount contributed 2002-2003 (in US$)*	*Commitments 2004-2007 (in US$)*	*Total commitments (in US$)*
Denmark	774,355	-	774,355
EC	-	-	-
Ireland	3,812,250	3,048,250	6,860,500
Netherlands	2,325,100	7,315,800	9,640,900
UK	987,962	1,070,670	2,058,632
TOTAL	**7,899,667**	**11,434,720**	**19,334,387**

[79] Data received from IAVI (September 2004)
[80] Data received from IPM (September 2004)

Annex 3: Some illustrative prices of ARVs published on the Global Fund's web-page

The Price Reporting Mechanism is available at:

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

At present, visitors to the website can see the prices paid by 17 countries in 128 purchases of anti-retroviral drugs costing a total of US$4.8 million. Examples of prices paid include:

- Five countries purchasing 400mg doses of Indinavir between August 2003 and July 2004 paid between US$0.25 and US$0.30 per dose when purchasing from two different manufacturers in India, and paid US$0.28 per dose when purchasing from one manufacturer in the United States.

- Eight countries purchasing 200mg doses of Nevirapine between August 2003 and July 2004 paid between US$0.11 and US$0.36 per dose when purchasing from four different manufacturers in India and Cuba, and paid US$3.43 per dose when purchasing from one manufacturer in the United States.

The existence of the Mechanism produces several benefits.[81] First, countries that are preparing Global Fund proposals can develop a better sense of how much to budget for product procurement. Second, grant recipients who are negotiating procurement contracts with vendors can do so from a strengthened position as a result of knowing what others have paid. Third, grant recipients will be less tempted to enter into contracts on poor terms that have secret kick-back provisions (so long as they are required to report full details of their purchases). Finally, all stakeholders can be better informed on how Global Fund money is being used.

[81] Other sources of price data include *Sources and Prices of Selected Medicines and Diagnostics for People Living with HIV/AIDS*, which is available on the following website: http://www.accessmed-msf.org