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**COMMUNICATION FROM THE COMMISSION TO THE COUNCIL AND
THE EUROPEAN PARLIAMENT**

**A Coherent European Policy Framework for External Action to Confront HIV/AIDS,
Malaria and Tuberculosis**

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1. INTRODUCTION

In 2000, Europe made a commitment to achieving the Millennium Development Goals (MDGs) and the European Union (EU) adopted its new development policy, based on poverty reduction. At the same time, the European Commission (EC) developed a comprehensive frameworkⁱ to accelerate action targeted at the three major poverty diseases – HIV/AIDS, malaria and tuberculosis (TB). The Programme for Action (PfA),ⁱⁱ developed as a framework for implementation, remains just as valid today. The status of the PfA is illustrated in the progress report 2004.ⁱⁱⁱ Significant achievements have been made on impact, affordability and research and development through coherent action between the policy areas of development, trade and research.

The EU needs to accelerate action and address issues where progress has been slow. While maintaining the overall goal of poverty reduction, the EU also needs to respond to an increasingly changing global arena and rise to new challenges. There is a growing awareness of the effect that HIV/AIDS can have on human security and human rights. The changing nature and rapid spread of HIV/AIDS and TB globally also warrant consideration. Sustaining policy coherence regarding HIV/AIDS, malaria and TB remains a major challenge.

This Communication provides the policy framework for all EC external action on confronting the three diseases. The Communication has been prepared following stakeholder consultations with third countries, EU Member States, civil society, industry, the Global Fund to Fight AIDS, TB and Malaria (the Global Fund), UN agencies, the World Bank and others. A stakeholder consultation meeting was organised in Brussels on 14 September 2004.^{iv} Due to the re-emerging epidemic in Europe and its neighbouring countries, the Commission has highlighted the need for immediate action through a separate Working Paper adopted by the Commission on 8 September 2004. This proposes a set of concrete actions for the next eighteen months.^v These actions and recommendations to partners were endorsed in the “Vilnius Declaration” adopted by participants in the Ministerial Conference “Europe and HIV/AIDS: New Challenges, New Opportunities” (Vilnius, 17 September 2004).

2. CHALLENGES

2.1. Epidemiological, geographical and demographical challenges

Despite increased efforts and resources, the number of people affected, infected and dying from HIV/AIDS, malaria and TB continues to rise. More than 6 million people in the world die each year from the three diseases, and the effectiveness of treatment is threatened by the emergence of multi-drug resistant malaria and TB. HIV/AIDS and TB are spreading rapidly, including in (European Neighbourhood Policy) ENP partner countries (e.g. Russia); the number of people with the diseases in countries with large populations (e.g. China and India) is increasing. Malaria poses a large burden particularly on African countries. Sub-Saharan Africa continues to carry the largest burden of HIV/AIDS and is home to two-thirds (an estimated 25 million people) of HIV-infected people globally.^{vi}

Particularly with regard to developing countries, poverty reduction remains the main framework in which to confront the three diseases, as the diseases are often a consequence and a cause of poverty. HIV/AIDS, malaria and TB have a negative impact on the social and economic fabric of communities. The critical interaction between human security issues and the wider Cairo agenda (including HIV/AIDS, and gender-based violence) is becoming increasingly obvious. This demands consideration of human security and human rights. The spread of the three diseases among refugees and people living in conflict situations remains a challenge. The HIV/AIDS pandemic continues to affect women disproportionately in terms of infection rate, impact and lack of access to prevention, treatment and care. Consideration of vulnerable children, including the 12 million AIDS orphans in Africa, remains a challenge.

2.2. Challenges to maintain a comprehensive policy mix of prevention, treatment and care

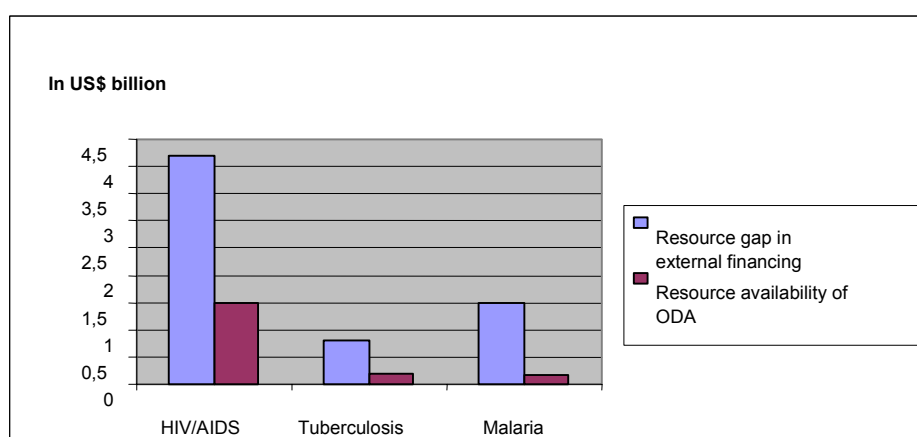
HIV/AIDS, malaria and TB can be prevented and treated, but more countries need to develop appropriate strategies with a comprehensive policy mix integrating proven prevention, care and treatment. Successful programmes contain a balanced response. Condom use, and harm reduction programmes including needle-exchange for injecting drug users, have to be promoted as methods of HIV/AIDS prevention. Many health systems are showing signs of weak infrastructures and overstretched human resources; given the growing care and treatment needs for HIV/AIDS, maintaining an adequate focus on prevention and care poses a challenge. Provision of treatment requires more predictable and long-term resources. Research into new interventions is needed to deal with changing forms of the diseases. Capacity building for research and health services is also an integral part of the strategy.

2.3. Challenges in financing

Resources allocated to HIV/AIDS have increased globally, primarily because of an increase from domestic budgets and the private contribution (see Annex 1, Table 2). There are scant global funding figures available on malaria and TB.

Despite the increase, a considerable gap remains in terms of external resources to confront the three diseases (see Table 1). The international community will need to secure appropriate funding to match demand. UN estimates of the resources needed by region to confront HIV/AIDS over the next few years are given in Annex 1, Table 3. However, this Communication does not have financial implications for the EC.

Table 1 – Estimated annual ODA and external resource gap^{vii}



2.4. Challenges in governance at country and global levels

Reaching the **affected countries, the poorest people, and the disenfranchised of all societies** remains a challenge. Populations already facing barriers to care (in particular women and the poor) have become increasingly marginalised. Many behaviours associated with increased risk of HIV/AIDS (e.g. men having sex with men, injecting drug use, commercial sex work) are often socially unaccepted; people living with HIV/AIDS and TB are often met with stigma and discrimination. This prevents open dialogue, and can lead to poor access and uptake of prevention methods, testing and treatment. Enabling youth, women and people affected by the diseases to have a stronger voice in planning, policy and implementation is crucial to address needs.

Strong leadership within countries is essential, with **political commitment** behind effective policies and consequent mobilisation of resources. Particularly in many of the poorest countries with weak government structures and in ENP partner countries, the acknowledgement among political leaders of the need to address HIV/AIDS and TB is a challenge.

The fact that **the three diseases know no institutional or national boundaries** is another challenge. Confronting them requires strong cooperation between all partners in society. Some countries have managed to establish cross-sectoral cooperation with concrete results. The Country Coordinating Mechanisms (CCMs) set up to access Global Fund support can play a strong role in catalysing cooperation between different partners, promoting harmonisation and facilitating implementation. Confronting the three diseases often requires a cross-border response, which is difficult where regional institutions are weak.

Increasing the efforts of the **private sector** to supply resources and skills is a major challenge. The private sector has significant untapped potential to invest in developing countries. Increasing private sector efforts in the area of tiered prices on their products, and in their contribution to multilateral initiatives (e.g. the European and Developing Countries Clinical Trials Partnership (EDCTP) and the Global Fund), remains a challenge.

The lack of vocal representation and the imbalance of power on global issues also represent a challenge in terms of **global governance on health**. Many countries do not have the voice, negotiation capacity or voting rights to design and implement global rules to their advantage (e.g. regarding research priorities and regulatory frameworks). The increase in the number and diversity of global initiatives and players in the HIV/AIDS, malaria and TB arena has further altered the global institutional structure, and poses opportunities and challenges in terms of harmonisation and coherence. The recent enlargement of the EU has brought the impact of HIV/AIDS and TB in ENP partner countries in Eastern Europe higher on the European agenda.

3. EU VISION

3.1. Vision for 2015

The EC will continue to respond to the evolving nature of the three diseases and their geographic spread in developing countries and in ENP partner countries. The EC and the EU Member States have made international commitments and share a long-term vision towards confronting the three diseases and reaching the MDG target date of 2015. Through its humanitarian aid, development, trade, health and external relations policies, the EU contributes to achieving the **MDGs**, including MDG 6 on “combating HIV/AIDS, malaria and other diseases”.

All EU Member States endorsed the Programme of Action adopted in Cairo in 1994 at the International Conference on Population and Development (ICPD). The Cairo agenda on **sexual and reproductive health and rights** (emphasising a voluntary, people-centred approach based on informed choice) is clearly reflected in EU policies and advocacy positions. The EC and the EU Member States were signatories to the Declaration and Platform for Action of the 1995 World Conference on Women in Beijing. The Platform stressed the need for action against world-wide obstacles to **gender equality**, and established gender mainstreaming as a main strategy.^{viii} All EU Member States have ratified the UN Convention on the Rights of the Child. The commitment to **human rights** is also clear in the EC Development Policy Statement.^{ix} The commitments to MDGs, Cairo, Beijing, human rights and human security are core pillars of the EU vision for confronting the three diseases.

Increasing resources and coordinating efforts are also part of the EU vision. The 0.7% of gross national income (GNI) remains a recognised target for EU Member States’ allocations to ODA. The EU is well on track to achieving commitments made in **Monterrey** (March 2002);^x based on current trends, the EU will provide 0.42% of its collective GNI in ODA by 2006 (€38.5 billion).^{xi} This means an increase of €10 billion per year of EU ODA. The EC and the EU Member States are bound by the Treaty to operate in **coordination and complementarity** in the field of development cooperation, a commitment reaffirmed at the High-Level Forum on Harmonisation in Rome (2003). The principles of harmonisation across strategy, agency and monitoring plan are also reflected in the 3 Ones approach to HIV/AIDS.^{xii}

3.2. Principles

Several shared principles guide Europe's cooperation with third countries. The EU closely adheres to the overall development goal of **reducing poverty**, achieving the MDGs and respecting rights. The principle of equity means that services need to reach those who are most in need. Ensuring **countrywide ownership** remains a guiding principle. Countries remain the key decision-makers responsible for formulating their strategic priorities and national frameworks. Governments are **accountable** to their electorates for their choices and for implementation. **Good governance**, with the ability to ensure transparent processes and maintain the rule of law, is an integral part of country action. Governance beyond state institutions is also important to ensure demand-driven responses with **broad participation**, including civil society and the private sector. Working with third countries also requires the **scaling-up** of actions, and increasing sustainable resources, with complementary investment in enhanced capacity.

4. EC ADDED VALUE AND EC ACTIONS

4.1. EC added value

As seen from the progress report and consultations, the EC has several attributes of comparative advantage for action on the three diseases. The majority of EC financial support instruments are, and will remain, at country level. The EC, together with the EU Member States, will also continue to address key issues at global level.

The EC has successfully cooperated across policy areas of development, humanitarian aid, trade, and research towards **coherent external action**. Activities in different policy areas can reinforce each other and produce greater synergy. This is the added value of the EC, and goes beyond what EU Member States can do individually (as has been evident from implementation of the PfA, and advocacy for ICPD and the Doha Declaration on TRIPs and public health). The EC also has added value in its ability to **convene, represent and defend a common European position globally**, thus improving coherence in global governance. Coherence between EU Member States and the EC will become increasingly important. Human security, including the links with HIV/AIDS, is an important consideration in the evolving field of a Common Foreign and Security Policy.

At country level, EC added value includes its **working presence in many countries**,^{xiii} including several neighbouring countries and those where some EU Member States are absent, as well as the ability to provide support for **recurrent costs**, e.g. salaries of health staff and commodity purchasing – a major component of health expenditure.

A final aspect of added value is the flexibility in the current EC thematic budget lines, which allow for the **financing of innovative actions** both at country and at global level. This has allowed for support to the Global Fund, to the International AIDS Vaccine Initiative (IAVI), to the International Partnership for Microbicides (IPM), and to the EDCTP sites for clinical trials in disease-endemic countries. Such flexibility should be retained in the new financial instruments for EC external action (2007-2013).

4.2. EC action at country level

The geographic spread of the diseases requires a focus beyond developing countries. In particular, multi-drug resistant TB and HIV/AIDS are spreading fast in ENP partner countries. The EC is able to provide a policy mix of country support through various financial instruments and for different social services; a country can ask for a different range of inputs depending on its needs. The **poorest countries** need the most financial resources, resources related to political commitment, technical capacity building, and policy dialogue, and close partnership. **Middle-income countries**, including the new **neighbouring countries in Eastern Europe** mostly need support in their policy dialogue and political commitment, and in technical capacity building. In areas of **difficult partnerships**^{xiv} (commonly characterised by human rights violations, political repression, high levels of corruption, or violent conflict), the EC will remain engaged and adopt specific strategies such as LRRD and working pragmatically with committed organisations inside and outside of government.

4.2.1. Increase capacities

The EC will actively focus on enhancing **human resource capacity** in national development plans, such as the Country Strategy Papers (CSPs), Partnership and Cooperation Agreements, and Poverty Reduction Strategy Papers. This will strengthen social services, including health and education. Improving human resource capacity includes accelerated action on staff training, career development, appropriate remuneration and retention of staff, and responsive management. These actions will address some of the key motivational problems faced by health staff, and might therefore dent the drastic brain drain of staff from rural to urban, from public to private, and from developing to developed countries. The EC recommends countries and donors to agree on a financing model where disease-specific initiatives contribute a defined proportion of their funds to health care delivery, including the development of human resources. The EC could also explore a European code of conduct for recruiting staff from third countries; or for organisations employing national staff to train counterpart staff within the government structure. These proposals should be further developed in the High-Level Forum on Health.

The EC encourages **capacity enhancement of broad-based national and regional (e.g. NEPAD) bodies** focusing on the three diseases with participation of government and non-government stakeholders at country level (e.g. CCMs where they are present). EC delegations will be more actively involved in capacity building and establish complementary partnerships with EU Member State representatives to provide technical assistance.

In its policy dialogue, the EC will encourage countries to develop strategies which recognise the value of **investing in people and in social services**. A comprehensive policy mix, including prevention, treatment and care, is necessary. An appropriate mix depends on the nature of the disease, capacities and resources available, and best practice. For HIV/AIDS, evidence shows that condom use and open discussion of sexual activity – rather than abstinence – are the most effective tools for preventing sexual transmission. A recent study on India illustrated^{xv} that increasing the current rate of condom use during high-risk contacts from 50% to 70% would be enough to change the direction of the epidemic in India.

The EC will strengthen **surveillance and monitoring capacity of health outcomes** through continued support of the Health Metrics Network^{xvi} and UNAIDS. The EC will emphasise the tracking of health data beyond the currently used ten MDG-linked core indicators. It will become increasingly important to demonstrate that macroeconomic support allows countries to address priorities in social services. The EC will work with EU Member States to assess whether macroeconomic support allows for increased resource flows to social services, and whether this translates into improved health outcomes.

The EC will focus on the critical interaction between **human security and the Cairo agenda** in discussions with personnel participating in conflict-resolution, peace-keeping and post-conflict operations. The full Cairo agenda – including HIV/AIDS, gender-based violence and provision of contraceptives – needs to be an integral part of the analysis of conflicts, their causes, effects and resolution.

The EC will support **local production capacity**, e.g. for raw materials and formulations of artemisinin-based combination therapies (ACT) and other new antimalarials, insecticide-treated bednets, condoms, and generic production of essential drugs – including fixed-dose combinations (FDCs) for TB and HIV/AIDS. Local production can promote competition and make pharmaceutical products more affordable. It is important to encourage technology transfer to ensure that locally produced pharmaceutical products meet internationally agreed standards. The EC will pursue this through cooperation with the European Investment Bank.

The EC will continue to strengthen developing countries' capacities to **conduct research**, particularly in clinical trials. Synergies between capacity building for research and training of staff for healthcare services should be explored, with the active involvement of partner countries. The EDCTP should play an integrating role by contributing to both national and regional human resource plans for clinical research.

4.2.2. *Increased and sustainable resources*

Countries need **increased long-term, sustainable resources**, from a variety of sources, to confront the three diseases. Countries need to invest an appropriate portion of their budget in social services to achieve improved health outcomes. The WHO-World Bank Commission on Macroeconomics and Health recommends an annual budget allocation to health of at least US\$40 per capita. The current annual gap in reaching this recommendation is over €120 billion. Private investment in third countries and official development assistance (ODA) are needed.^{xvii} The EU should continue to adhere to commitments made in Monterrey on raising ODA. The capacity of countries to absorb increased resources should be addressed, and medium-term expenditure frameworks developed that encourage flexibility in investment ceilings.

The EC will **increase funding support to confronting the three diseases through innovative action**. The Global Fund has proven to be a comparatively fast way of channelling EC funds into confronting the three diseases at country level and has already shown key results. According to Global Fund projections based on demand from the countries concerned a tripling of the annual average level of donor contributions is needed, from the current US\$1 billion to US\$3 billion by 2008.^{xviii}

The need for a substantial EU contribution, in the region of US\$ 1 billion annually, has already been discussed at the EU Thessaloniki summit. The 2005 high-level replenishment conference of the Global Fund is an opportunity for all donors to increase their contributions. If this conference re-confirms the projections made, the EU will be expected to contribute to increased funding needs. Contributions will be expected from both the EC and from EU Member States, based on a model for fair European burden sharing.

4.3. EC action at global level

4.3.1. *Affordable and safe pharmaceutical products*

The EC will continue to advocate a reduction in the price of pharmaceutical products. The EC will continue to encourage **tiered pricing** through, *inter alia*, the use of the anti-trade diversion Regulation on a broader range of products (including anti-retroviral second-line treatments, FDCs, paediatric formulations^{xix} and other products such as ACTs). The EC encourages **competition** between the R&D based industry and generic producers and public tendering based on fair and transparent procurement rules to reduce prices.

The EC will also encourage countries to **publish in a transparent manner prices** of commodities purchased, whether through the Global Fund (where prices paid are already made public), or through other mechanisms. This will become standard practice for EC-funded programmes purchasing pharmaceutical products.

The EC emphasises adherence to the **Doha Declaration on TRIPs and public health (2001), and to the August 2003 Decision**,^{xx} including assurance that the Declaration is not undermined either in formal amendments of the TRIPs Agreement, through bilateral negotiations, or through national legislation. The EC encourages developing countries to make use of TRIPs flexibility and exemptions, including compulsory licensing while stressing the importance of an adequate intellectual property regime.

The EC will provide technical assistance to improve countries' capacities in **pharmaceutical policies**, including through continued and strengthened partnership with WHO on prequalification. The EC will continue to emphasise the need for safe pharmaceutical products. The EC Enforcement Strategy Paper (June 2004) contains guidelines for EC action on the enforcement of intellectual property rights in third countries, which will be considered along with public health needs.

4.3.2. *Regulatory aspects*

The EC will support the enhanced capacity of third countries to **perform regulatory tasks**, including the approval of clinical trials and the granting of market authorisation. Regulatory challenges for new vaccines, microbicides and diagnostics need to be addressed.^{xxi} The European Medicines Agency (EMA) and national regulatory authorities in the EU, could support – in coordination with WHO – capacity building for regulatory bodies through partnerships, scientific/technical assistance or financial support. This should focus on establishing regional centres of regulatory expertise in, for example, Brazil, South Africa and Thailand. Regulatory

procedures should not be used as trade obstacles, which could make pharmaceutical products more expensive.

Assistance provided by the EMEA will build on the recent revision of the EU pharmaceutical legislation, enabling the EMEA to give a **scientific opinion for the evaluation of medicines** to be marketed exclusively outside the Community^{xxii}. This procedure, open to both R&D and generic manufacturers, should enable the Community to provide scientific support to developing countries, thereby facilitating rapid access to medicinal products which meet their own public health needs.^{xxiii}

4.3.3. *New tools and interventions*

The EC will continue to focus on **developing new, effective, safe and affordable tools and interventions**, by investing in research and development. New effective vaccines would be the most powerful and cost-efficient tool to confront the three diseases, but a comprehensive research approach will remain important, in the foreseeable future.^{xxiv} Research in new interventions should focus on vaccines for the three diseases, microbicides to prevent HIV/AIDS transmission,^{xxv} new diagnostics and treatments for TB in the context of resistance and low compliance, and improved prevention and treatment for malaria. Special attention should be given to FDCs, paediatric formulations, and treatment regimens for multiple concurrent infections.

The EC will continue to support **EDCTP** in order to increase the number of new candidate vaccines and other products entering clinical trials. The EC will encourage Member States and industry to invest in and make use of the EDCTP programme. The EDCTP will ensure coherence and synergy between clinical trials carried out by itself and by other organisations.

The results of extensive monitoring in the relevant social and economic context should be used to improve the impact of existing interventions and diagnostic tools. Epidemiology and applied research will therefore be an integrated part of the research agenda.

Following stakeholder consultations, the EC will establish **incentives** to harness the capacity of private industry, including small and medium-sized biotech enterprises, in the development of new tools targeting the three diseases. Incentives could include: the extension of patent rights and/or market exclusivity, including through the relationship which might be established between different products, simplified and faster regulatory procedures, venture capital, low cost loans, tax credits and guaranteed markets.

4.3.4. *Strengthened partnerships and a strong European voice*

The EC will continue to **cooperate closely with EU Member States** – on technical assistance, strengthening regulatory capacity in developing countries, and promoting and coordinating research. The EC will also continue to seek common European positions in multilateral institutions and mechanisms, including the Global Fund.

The EC will **continue and strengthen policy dialogue and funding to multilateral UN organisations**: the strategic partnership with WHO (on pharmaceutical policy, regulatory issues, and health monitoring), and the strong partnership with UNAIDS

(regarding the 3 Ones) and UNFPA (for the Cairo agenda). This should be seen as part of an EC response to the challenges posed in terms of global governance for health.

The EC will **continue to support demand-driven country programmes** through the Global Fund (see Annex 2 for more details).

The EC will continue to support a needs-driven global research agenda by supporting the EDCTP and by partnering with other international research initiatives, such as IAVI, IPM, GAVI, and the Global HIV Vaccine Enterprise (endorsed by G8).

The EC will continue to **present a strong voice advocating common European values** at fora following Cairo and Doha, with the ultimate goal of achieving the MDGs by 2015.

5. EC TOOLS

Coherence remains an integral component of the EC policy framework. **Coherence and coordination** need to be reflected in the EC institutional set-up, perhaps with a clearly defined lead service, to ensure EC-wide accountability. Measures will also be put in place to ensure coordination between EC services, including delegations, responsible for various parts of the programming cycle. These proposals will be developed in more detail in the Programme for Action.

The **new EC financial perspectives (2007-2013)** offer increased opportunities and scope for leadership to confront global challenges, including the three diseases. The new financial instruments benefit the poorest countries, while also supporting the EU neighbourhood. Six instruments are proposed, three supporting EU external policies (pre-accession, neighbourhood and development), and three thematic instruments to respond to political, humanitarian and financial crisis situations (See Annex 3, Table 4).^{xxvi} While this Communication does not have financial implications, a Programme for Action will be presented at a later stage specifying actions in various regions and proposing resource allocations.

The EC Round-table discussion in 2000 established a momentum for action between different stakeholders. The EC will continue to amplify this momentum, and establish a **Stakeholder Forum** to ensure continued consultation, including people living with HIV/AIDS, malaria or TB, on how to confront the three diseases and on instruments and financing needed.

6. CONCLUSION

The Policy framework (2000) and the Programme for Action adopted in 2001 achieved significant results in confronting the three diseases within the context of poverty reduction. Much of this was due to synergy between EC research, trade and development policies. Based on these experiences and following consultation with stakeholders, including developing countries and ENP partner countries in Vilnius, a coherent policy framework for all EC external action to confront the three diseases is presented in this Communication. The Communication will be brought before the Council under the Dutch Presidency, and submitted to the European Parliament.

Based on this comprehensive policy framework, new strategies and action programmes will be developed. These will refer to the use of specific instruments and resources, and will propose further coordination with EU Member States. The Commission Working Document prepared for Vilnius already outlines specific actions for ENP partner countries in Eastern Europe.

Europe has a leadership role to play in confronting HIV/AIDS, malaria and TB globally. The current EU Presidency (the Netherlands), and future Presidencies (Luxembourg, the UK, Austria and Finland) have given priority to confronting the three diseases and adhering to the full Cairo agenda. Communicable diseases remain prominent on the global agenda – in UN fora and the G8. Europe's contribution to turning the tide of the HIV/AIDS pandemic, and confronting malaria and TB, will help to achieve the ultimate aim of the MDGs – reducing poverty for millions of people worldwide.

Annex 1: Resources spent, and resources needed, for HIV/AIDS

Table 2: Resources invested in HIV/AIDS, 1996-2003^{xxvii}

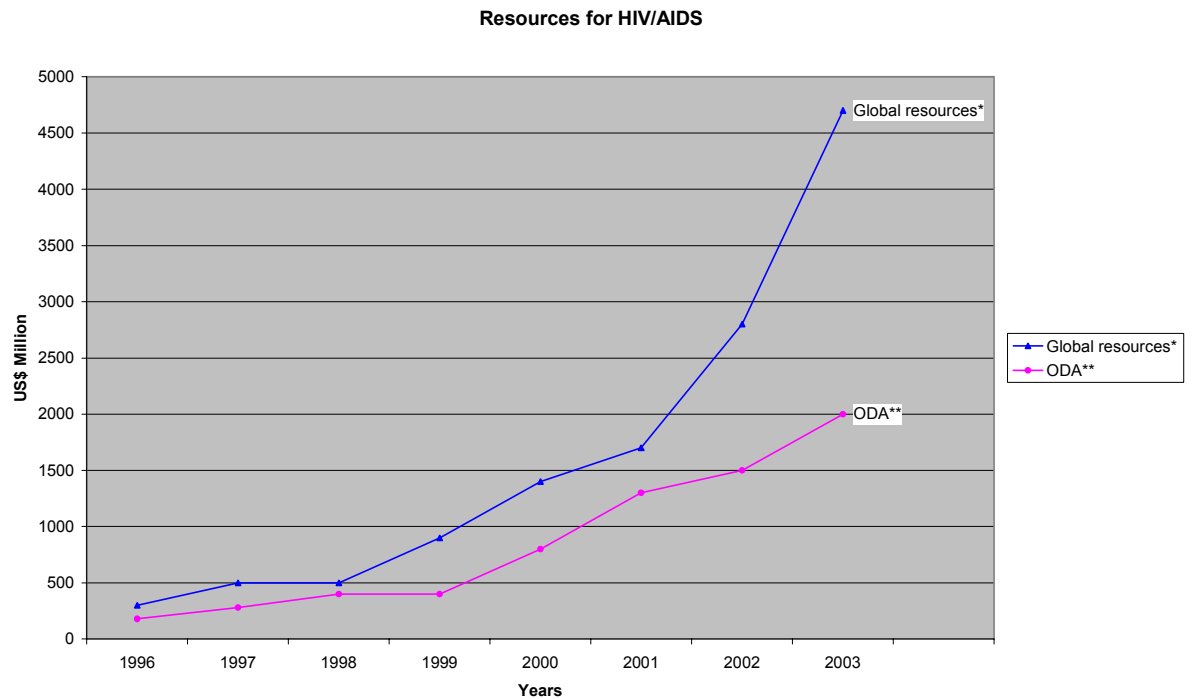
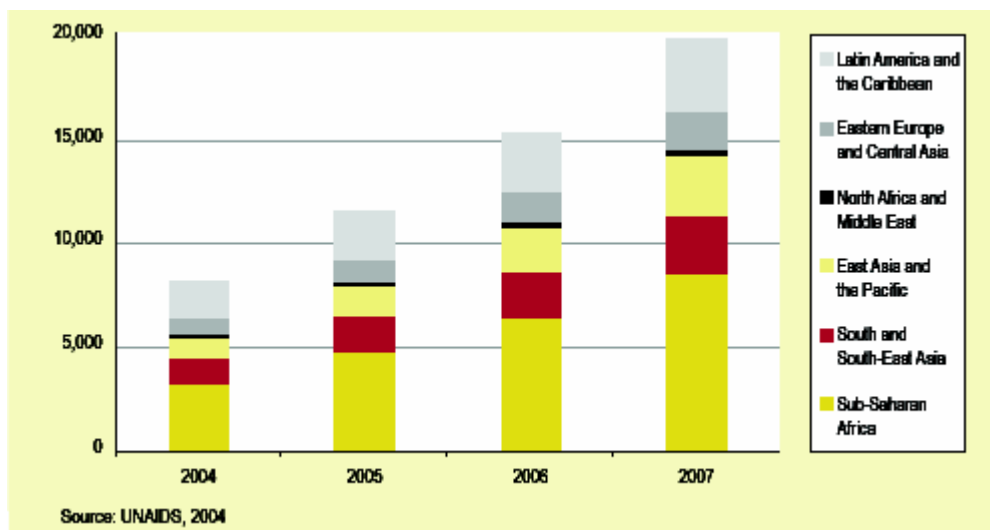


Table 3: Projected Annual HIV/AIDS financing needs (in US\$ million) by region (2004-2007)^{xxviii}



Annex 2: The Global Fund to Fight AIDS, TB and Malaria and the EU's role

The Global Fund was established to generate additional public and private resources to confront the three diseases. It departs from traditional forms of multilateral governance because non-state actors share decision-making powers and financing responsibilities with national governments. This reflects the political implausibility of raising much-needed funds through the UN, while still remaining reliant on the infrastructure and support of UN agencies, funds and programmes. For example, WHO and UNAIDS are providing technical aid and administrative support and building capacities. The Global Fund was also established to be a model of performance-based funding. While not a purchasing institution, the funding provided to support demand-based proposals made by countries, and the transparency in purchasing, can help to reduce prices of pharmaceutical products and commodities. The demand generated could also have a medium-term leverage effect on research into new tools to confront the three diseases.

A forecast of the Global Fund operations and the business model^{xxix} illustrates that, if the current business model is pursued, the Global Fund will reach an annual value of approvals, commitments and disbursements of US\$3 billion from 2008 onwards. This forecast predicts a considerable increase in both the demand for resources and the workload compared to the current levels. Although disbursements have been slow initially, they would speed up over the next three years to meet the level of approvals.

The annual average level of donor contributions to the Global Fund would have to triple from its current US\$1 billion to respond to the increase in resource demands. The 2005 high-level replenishment conference of the Global Fund is an opportunity for all donors to increase their contributions to the Fund. As tens of thousands of people begin receiving anti-retroviral treatment financed by the Global Fund, the issue of sustainable and predictable funding is even more important. Countries should gradually move towards self-sustaining financial systems. However, faced with severe resource constraints in the poorest countries, the global community will need to continue its support for many years to come.

Other future challenges to the Global Fund for the EC/EU to take a position on in the Board meetings are the difficulty of some poor countries to effectively use large sums of money, especially with the significant brain drain in developing countries, which depletes human resources, particularly in the health services most needed. It has also been discussed whether the disease-specific approach committing global finance primarily to the three diseases, instead of health services, is, in general, beneficial. The Global Fund programmes have so far been successful in delivering the demand at country level. Some countries have even exceeded performance targets and disbursements have been made faster than expected. In a recent performance review made by the Global Fund, the 25 grants that had passed one year of operations were performing above the targets set and in comparison with other donors. On average for all grants reviewed, 70 percent of the expected disbursements had been made, and the disbursement rate was climbing. Some of the programmes had achieved spectacular results. For instance, in the Global Fund TB programmes in China, Ghana, Indonesia, Mongolia, Panama and Sri Lanka, performance targets were exceeded by 32%.^{xxx}

Developing countries have expressed positive views on the Global Fund's performance and have, in particular, underlined ownership based on the national development of programmes and global representation at Board level; the flexibilities offered by Global Fund financing, especially with regard to recurrent costs, which are rarely permitted under the guidelines of most other aid agencies (with the exception of the EC); and the openness and transparency in transactions (e.g. the Global Fund's activities are accessible on its website, including the results of negotiations of pharmaceutical product pricing).

If sufficient resources are provided to meet the increase in demand, then the current business model must be adapted to make the operations more effective and reduce transaction costs. Key suggestions to streamline Global Fund procedures include:

- The Global Fund could adopt a differentiated approach based on a risk analysis, taking into account contextual considerations and past performance of grant receivers.
- The Global Fund could establish a public and a private funding channel in a country with an approved proposal. The principal recipient for the public channel would be likely to be the Ministry of Health or the Ministry of Finance, while the private channel could be NGOs and take on a country-appropriate form.
- Existing mechanisms such as the country-specific accreditation scheme (planned by the Health Metrics Network) for monitoring and evaluation systems could also be used as a standard for assessments, rather than using a parallel Global Fund assessment system.
- The Global Fund Secretariat could play a more active role in identifying needs for technical assistance, and garner support from donor agencies and other partners present in the country to improve the provision of such assistance.

Any changes in the Global Fund business model must be based on the ability to serve the Global Fund recipients, both those who will directly receive and use funding and the people and communities living with, affected by and at risk from HIV/AIDS, TB and malaria. The performance of the Global Fund programmes is measured by their ability to reach the poorest and most vulnerable.

Annex 3: New EC financial instruments (as proposed by the EC, September 2004)

Table 4 should be used for initial reflection on the potential use of EC financial instruments for external action to confront the three diseases. Specific proposals will be presented in a Programme for Action.

Table 4: Overview of the proposed new EC financial instruments and their potential to be used in confronting HIV/AIDS, malaria and TB

Instruments 2007-13 (total amounts)	Beneficiary countries	What policy mix in regard to confronting three diseases?	Channels of cooperation/financing
Development Cooperation and Economic Cooperation Instrument (DCECI) (€41 088 million)	All non-Member States (incl. their overseas territories) not covered by IPA and ENPI	Long-term development assistance. Focus on Treaty objectives (mainly Art. 177), international engagements of the EC incl. MDG	Coherence of policies; coordination with MS; coordination with international donors; sectoral and budget support; respect for HR and fundamental freedoms. Geographical as well as thematic and horizontal multi-annual programming and subsequent annual action programmes.
European Neighbourhood and Partnership Instrument (ENPI) (€13 856 million)	Algeria, Armenia, Azerbaijan, Belarus, Egypt, Georgia, Israel, Jordan, Lebanon, Libya, Moldova, Morocco, Palestinian Auth., Russian Federation, Syria, Tunisia, Ukraine	Institution building, political cooperation “Supporting policies to fight poverty and promote social development, health, education and training, employment and social protection”.	CSPs give margin for inclusion of disease-related financing. Thematic programmes “to address in a visible and recognisable way global challenges of particular importance” for all partner countries. MS can be associated for joint projects.
Instrument for Pre-Accession Assistance (IPA) (€13 271 million)	Croatia, Turkey, Western Balkans	Institution building, human resources development, cross-border cooperation, No specific provision for health systems.	Financing through instruments similar to the structural funds and PHARE/ISPA/SAPARD structure. Association agreements.
Stability instrument (€4 258 million)	All third countries (except overseas territories of EU)	Rapid response to crises; most activities DAC eligible; “major unexpected threats to public health”	Complementary to the other instruments.

Annex 4: References

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- ^{iv} http://europa.eu.int/comm/development/body/theme/human_social/pol_health3_en.htm
- ^v “Coordinated and integrated approach to combat HIV/AIDS within the European Union and its neighbourhood” This document outlines the regional epidemic, synthesises best practice in prevention, reducing the impact of the epidemic, and resources mobilisation and building partnerships.
- ^{vi} UNAIDS, *Report on the Global AIDS Epidemic*, 2004
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- ^{viii} Regulation (EC) No 806/2004 of the European Parliament and of the Council of 21 April 2004 on promoting gender equality in development cooperation
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- ^x A collective EU average of 0.39% of GNI to ODA by 2006, and at least 0.33% of GNI for each individual EU Member State to ODA by 2006
- ^{xi} *Translating the Monterrey Consensus into practice: the contribution by the European Union* COM(2004)150
- ^{xii} <http://www.unaids.org/en/about+unaids/what+is+unaids/unaids+at+country+level/the+three+ones.asp>
- ^{xiii} The EC ensures its presence throughout the world through its 128 delegations and offices.

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- xv World Bank, *HIV/AIDS Treatment and Prevention in India*, 2004
- xvi <http://www.who.int/healthmetrics/about/en/>
- xvii The current annual ODA to health is approximately €6.
- xviii Richard Feachem, Executive Director of the Global Fund Secretariat, at the 8th Board Meeting of the Global Fund, June 2004
- xix MSF, *Untangling the web of price reductions*, 2004 <http://www.accessmed-msf.org/documents/untanglingtheweb6.pdf>
- xx TRIPs stands for the Agreement on Trade-Related Aspects of Intellectual Property Rights. The August 2003 Decision refers to the World Trade Organisation ‘Decision on the Implementation of Paragraph 6 of the Declaration on the TRIPs Agreement and Public Health’
- xxi Coplan, Mitchnik & Rosenburg, ‘Regulatory Challenges in Microbicide Development’ in *Science*, Vol. 304, 25 June 2004 http://www.ipm-microbicides.org/pdfs/Reg_Chall_Dev.pdf
MSF, *Running out of Breath? TB Care in the 21st Century*, 2004 http://www.doctorswithoutborders.org/publications/reports/2004/tbreport_2004.pdf
- xxii Regulation (EC) No 726/2004 (31 March 2004), Article 58, OJ L 136, 30.4.2004, p.1
- xxiii In the US, the Food and Drug Administration has recently implemented a fast-track approval process allowing originator manufacturers to submit FDCs. Originator manufacturers have been pressured into action to produce FDCs.
- xxiv Although more than 30 HIV/AIDS vaccine candidates are currently being tested in clinical trials no breakthrough is expected in the short term. (www.aidsvaccine04.org) It is estimated that US\$1.1 billion is needed annually to develop an HIV/AIDS vaccine.
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