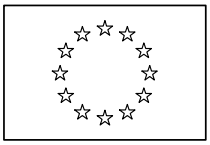

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Progress report on the implementation of the European Programme for Action to Confront HIV/AIDS, Malaria and Tuberculosis through External Action (2007-2011)

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1. EXECUTIVE SUMMARY

A European Programme for Action to Confront HIV/AIDS, Malaria and Tuberculosis through External Action (2007-2011) was adopted by the Council of the European Union in 2005 as the basis for a concerted and strong EU response and action to confront the three diseases. The 2009 progress report has been prepared in a consultative process with Member States and other stakeholders, aiming to review progress and constraints, update policy areas, stimulate joint EU[1] actions and develop recommendations on priorities for such actions.

As a result of significant investments in recent years, progress has been made in the efforts to confront HIV/AIDS, malaria and tuberculosis (TB). Overall mortality is declining slightly and in many regions and countries, fewer people are becoming infected, slowly changing the tide of steadily expanding epidemics. Affecting millions of people, the epidemics will, however, continue to pose exceptional global challenges to social growth and development for decades to come.

In a context of multiple global crises, strong and continued leadership of the EU in confronting HIV/AIDS, malaria and TB is of critical importance to ensure that the progress and investments already made are not eroded, and to prevent a return to an unabated escalation of the epidemics. Such leadership should be based on the commitments and directions set out in the European Consensus on Development and the EU Agenda for Action on the Millennium Development Goals (MDGs) and underpinned by the common values of country ownership, gender equality and human rights. The EU's commitments to increase development aid and its strong emphasis on country ownership and aid effectiveness provide significant opportunities to reinforce and sustain country-led responses. This move towards financing based on country demand and priorities also brings policy dialogue, capacity building and accountability to the centre of effective EU collaboration with partner countries on the three diseases.

Such collaboration would promote comprehensive and balanced country responses, which are based on evidence, address gender inequality and human rights infringements and ensure that the most at risk populations receive proper attention. While access to treatment must be further expanded, particular attention is needed to accelerate progress in crucial areas such as HIV prevention and care and support for people affected by the three diseases. Research and development of new tools and interventions remains crucial for effective and sustainable responses to the three diseases, and will continue to require a longer term strategic approach and investment. Greater involvement both of people affected by the three diseases and of civil society organisations in national planning, decision making, implementation and evaluation is of critical importance.

At country level, an effective EU division of labour, sharing of tools and closer collaboration with civil society and other stakeholders would strengthen capacity for policy dialogue. Innovative approaches to mobilise and engage stakeholders in the context of a stronger, broader and more comprehensive EU response could be explored, based on the recommendations for priority actions developed with Member States and stakeholders during the progress review.

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[1] In the context of this report, the reference to the EU is made on the basis of a holistic and political approach without legally prejudicing institutional competencies.

2. BACKGROUND

In October 2004, the European Commission adopted a Communication entitled *A Coherent European Policy Framework for External Action to Confront HIV/AIDS, Malaria and Tuberculosis*[2]. Welcoming this policy framework, the Council of the European Union urged the Commission and Member States to enhance their cooperation and coordination in response to the three diseases and requested the Commission to present a Programme for Action.[3]

A European Programme for Action to Confront HIV/AIDS, Malaria and Tuberculosis through External Action (2007-2011) was prepared by the Commission and adopted by the Council in May 2005, for the first time suggesting collective action on the part of the Commission and the Member States. The Council Conclusions called for enhanced cooperation and invited the Commission and the Member States to establish a roadmap for joint actions. [4]

No agreement on such joint actions was reached, however, during discussions with Member States regarding proposed joint actions, either at an informal Member States' expert meeting in Brussels in September 2005, or on joint actions on gender and HIV/AIDS proposed at an informal meeting of Member States' experts in October 2007.

Complementary to the Programme for Action, which covers external action in relation to developing and middle-income countries, a *"Communication on Combating HIV/AIDS in Europe and the Neighbouring Countries 2006 - 2009*" was adopted in December 2005[5].

This first report progress report was initially scheduled for 2008, but as the Programme for Action only commenced in 2007, participants attending the above-mentioned informal Member States' expert meeting in October 2007 suggested delaying the report to the beginning of 2009 to allow an appropriate and inclusive review process.

The participants defined the following aim, objectives and process of the progress review as being to sustain a concerted and strong EU response and action to confront HIV/AIDS, malaria and tuberculosis in all partner countries as well as at global level by reviewing progress and constraints in key policy areas of the Programme for Action, by updating policy areas and identifying new areas requiring attention in view of recent developments, by better profiling and stimulating joint EU action and division of labour in relation to the three diseases in partner countries and globally and by developing recommendations on priority joint EU actions.

It was suggested that the review should focus on the policy level and be a light process mainly based on available data. As part of the process, two stakeholder consultations took place in Brussels, on 25-26 November 2008, and in Dakar, Senegal, 6 December 2008.

In preparation for these meetings analytical briefs were developed by the Commission, Member States, civil society organisations and international organisations, and disseminated

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2 COM(2004) 726 final of 15.12.2004.

3 Council Conclusions of 23 November 2004.

4 Council Conclusions on a European programme for action to confront HIV/AIDS, malaria and tuberculosis through external action, 24.05.2005.

5 Communication from the Commission to the Council and the European Parliament on combating HIV/AIDS within the European Union and in the neighbouring countries, 2006-2009, COM (2005) 654 final of 15.12.2005.

in advance. On the basis of these documents, participants reviewed progress, gaps and constraints, made recommendations for an update of policy areas and actions and identified options and priorities for collective EU action to confront the three diseases. An agreed report of the consultations is attached as Annex 2, including a series of specific recommendations by participants to guide future EU action at country, regional and global levels in key areas of the response to the three diseases[6].

In the following sections, the *Global situation of HIV/AIDS, malaria and tuberculosis* provides an overview of the current situation, the impact of the EU and global response to the three diseases, and major trends and developments.

Progress to date in implementing the Programme for Action describes progress and constraints in key country actions – policy dialogue, capacity building, and financial resources – and in the selected areas for global and regional action – access to affordable and safe drugs, human resources for health, and research into new tools and technologies. *Lessons learnt* summarises the key lessons in each of the above-mentioned areas of action at country, regional and global levels.

The new policy context outlines the key EU and international policy developments, which in combination constitute a new paradigm for development aid and efforts to confront the three diseases. *Challenges and opportunities* then discusses the implications and options in the new policy context for EU action – doing more, better, and working together in support of country-owned efforts to confront the three diseases.

Conclusions and the way forward notes the need for a strengthened leadership role of the EU in the global response to the three diseases and that innovative approaches to mobilise and engage EU stakeholders in coordinated and collective action through an effective division of labour could be explored, based on the recommendations for priority actions developed with Member States and stakeholders during the progress review.

3. GLOBAL SITUATION OF HIV/AIDS, MALARIA AND TUBERCULOSIS[7].

As a result of improved tools and know-how and the significant investments made in recent years, progress has been made in confronting HIV/AIDS, malaria and tuberculosis (TB). Overall mortality is declining slightly and in many regions and countries, fewer people are becoming infected, slowly changing the tide of steadily expanding epidemics. The epidemics of HIV/AIDS, malaria and TB are, however, far from over, and they will continue to pose exceptional global challenges to social growth and development for decades to come.

In 2007, an estimated **33 million people were living with HIV** worldwide, 2.7 million people became newly infected, and more than 15 million children had lost one or both parents to AIDS. With 1.5 million deaths in 2007, AIDS remains the top cause of death in sub-Saharan Africa, home to two thirds of all people living with HIV and the region where three quarters of all AIDS deaths occurred in 2007. Southern Africa is the global epicentre. 35% of all new

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6 Annex 2. Agreed report of Stakeholder Consultations, Progress Review of the European Programme for Action to Confront HIV/AIDS, Malaria and Tuberculosis Through External Action (2007-2011), Brussels, 25-26 November 2008 and Dakar, 6 December 2008.

7 For a more detailed description of the current situation, progress and constraints in the response to HIV/AIDS, malaria and tuberculosis, please see the section in Annex 2.

HIV infections and 38% of all AIDS deaths occurred in this region, characterised by a hyperendemic situation with staggering prevalence rates above 15% in the general population. The epidemic is still expanding rapidly in Eastern Europe, Central Asia and South-East Asia[8].

Of an estimated ten million people in need of HIV treatment, almost four million people now have access to antiretroviral drugs in middle- and low- income countries, and are in need of continued life-long treatment[9]. For every two persons gaining access to treatment, five more become newly infected with HIV. Major gaps remain in the provision of care and support for people living with the three diseases and their families, in particular children orphaned by AIDS.

It is estimated that 3.3 billion people, half of the world's population, are at risk of contracting malaria. Nearly **one million deaths from malaria** occurred in 2006, mainly in Africa and mostly among children under 5 years. In 2008, 109 countries were endemic for malaria, including 45 in Africa. Malaria is putting health systems under severe strain; in sub-Saharan Africa an estimated 50% of hospital bed occupancy is related to malaria, and its economic impact on African economies is estimated at US$12 billion annually[10].

Malaria control has gained momentum in recent years, with currently available tools and commodities such as long-lasting insecticidal mosquito nets, effective artesimin-based treatment and indoor residual spraying of homes with insecticide proving to be effective. It will be necessary to step up procurement of long-lasting insecticide bed-nets and artesimin-based treatment in order to achieve the 2010 targets of the Global Malaria Action Plan.

While TB is preventable and curable, there were an estimated 13.7 million prevalent cases of TB in 2007, a decrease from 13.9 million cases in 2006. An estimated **9.27 million new TB cases** occurred globally in 2007, resulting in 1.3 million deaths among HIV-negative new cases of TB and contributing to an additional 456 000 deaths among new TB cases who were diagnosed with HIV co-infection. While TB incidence has declined globally in recent years, the number of cases continues to increase in areas heavily affected by drug-resistant TB or HIV. Africa and Eastern Europe in particular are lagging behind. In 2007, an estimated 500 000 cases of multidrug-resistant TB occurred worldwide, and by the end of 2008, 55 countries and territories had reported at least one case of extensively drug-resistant TB[11].

While success in TB control rests on early detection of new cases and effective treatment, 37% of the 9.27 million people detected with TB in 2007 did not have access to the effective programmes based on the Directly Observed Treatment, Short-course strategy. More than two-thirds of all people with undetected TB live in Africa and South-East Asia. Reaching them will require scaling-up of innovative interventions, notably through laboratory strengthening, engagement of all providers beyond the public sector, community involvement, advocacy and social mobilisation.

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8 2008 Report on the global AIDS epidemic, UNAIDS 2008.

9 This estimate of the number of people in treatment was provided by UNAIDS at the stakeholder consultation in Brussels, November 2008.

10 Gallup JL and Sachs J.The economic burden of malaria. American Journal of Tropical Medicine and Hygiene, 2001, 64:85-96.

11 Global tuberculosis control - epidemiology, strategy, financing, WHO Report 2009.

4. PROGRESS TO DATE IN IMPLEMENTING THE PROGRAMME FOR ACTION

At country level, the Programme for Action proposes action on policy dialogue, capacity-building and provision of financial resources. For regional and global action the Programme identifies the selected areas of affordable pharmaceutical products, regulatory capacity, human resources in the health sector, and research and development of new tools and interventions.

A summary of progress and constraints to date is provided in the following sections, while a more detailed description of actions and outputs can be found in Annex 1[12].

4.1. Policy dialogue

The Programme for Action calls upon the EU to reinforce political dialogue on key issues related to country leadership and governance – e.g. in support of balanced and comprehensive strategies for prevention, treatment and care; rights of children and women; sexual and reproductive health and rights; orphans and vulnerable children; needs of other vulnerable groups; stigma and discrimination; and greater involvement of people living with HIV.

Commission Delegations have engaged actively in policy dialogue on the situation and country responses to HIV/AIDS, malaria and tuberculosis with the vast majority of ACP partner countries, especially in the medium and high prevalence countries in sub-Saharan Africa and the Caribbean islands[13]. Since 2006, Heads of Delegations in Southern Africa have collaborated on an expanded response to the AIDS crisis in the region, including through deepened policy dialogue with partner countries and other stakeholders.

Concerns have been expressed about the quality and depth of health policy dialogue, substantiated by an alleged scarcity of technical capacity on health within Delegations and Member State Embassies [14]. According to a recent survey only 35% of Delegations took part in the Country Coordinating Mechanism of the Global Fund to Fight AIDS, Tuberculosis and Malaria (hereinafter the Global Fund)[15].

In 2008, the Commission took steps to provide better guidance and support to its Delegations in health sector policy dialogue, to strengthen their involvement in the Country Coordinating Mechanisms of the Global Fund, and to deploy additional staff with a social sector focus in fragile countries and in countries with greater and more predictable levels of budget support (MDG contracts[16]).

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12 Annex 1. Indicative Monitoring Framework for Actions 2007-2011 – Report on progress and constraints at end-2008.

13 60 of 64 approved Country Strategy Papers for the 10th EDF and 20 of 24 Joint Annual Reviews in 2007 refer to the situation and response to HIV/AIDS, malaria and tuberculosis in ACP partner countries.

14 EC Development Assistance to Health Services in Sub-Saharan Africa (European Court of Auditors, January 2009), http://eca.europa.eu/portal/pls/portal/docs/1/2470313.PDF.

15 Survey among 37 Delegations in connection with the audit of the EC Development Assistance to Health Services in Sub-Saharan Africa.

16 See also section 4.3 on MDG contracts.

4.2. Capacity building

The Programme for Action encompasses a range of activities to strengthen the country-level capacity of Delegations and the Member States, including by mapping of EU technical resources and development of plans for shared technical assistance/codes of conduct. The Programme also covers EU support to partner countries for capacity building in research (social, clinical and operational), pharmaceutical policy, and procurement of pharmaceutical products and commodities.

The regular training provided for all Commission Delegation staff and their families on HIV/AIDS awareness and prevention, in the context of the new "HIV in the workplace" programme, represents an important first step towards strengthening the capacity of all staff to recognise and systematically address HIV/AIDS as an objective in itself and a cross-cutting issue in all areas of development cooperation. Additional measures undertaken include the HIV/AIDS programming guidelines, the incorporation of HIV/AIDS in programming guidelines for health, education, humanitarian assistance and infrastructure, and the development of a mainstreaming manual and training for Delegations in Southern Africa. The Delegations have gained access to better support through the new help-desk functions created at global level and, especially appreciated, at regional level in Southern Africa.

There is little progress in sharing of resources among Member States and Delegations[17]. At this stage most technical assistance is not shared and joint resources have not yet been successfully inventoried. Ongoing efforts include mapping of EU experts on HIV/AIDS in Southern Africa, engagement of the UNAIDS Technical Resource Facility and an initiative of the Commission and UNAIDS to engage in joint support of country-led technical needs assessment, technical support planning and implementation.

Horizontal initiatives such as the European & Developing Countries Clinical Trials Partnership (EDCTP) and the Alliance of ESTHER, 'Network for Therapeutic Solidarity in Hospitals against AIDS' represent innovative approaches seeking to involve a large number of research and health institutions and civil society organisations in Member States and partner countries in capacity building through twinning programmes and networking.

The Commission is collaborating with WHO and ACP in a partnership on health MDGs, aiming to enhance national capacity in partner countries for formulation, dialogue and implementation of policies for scaling-up health programmes to achieve the MDGs. In addition, the Commission collaborates with WHO on support for local capacity building in the selected priority areas such as pharmaceutical policy development, and procurement of pharmaceutical products and commodities. In the context of health sector budget support, the Commission and the Member States are working with countries on strengthening of national drugs procurement agencies, as a key element of their health interventions.

[17] See section 4.1.3. in Commission Staff Working Document - European programme for action to tackle the critical shortage of health workers in developing countries (2007 – 2013), Progress report on implementation, SEC(2008) 2476, 19.09.2008.

4.3. Financial resources

According to the Programme for Action, the EU should aim for a contribution that helps fill the financing gap for the three diseases and meet Millennium Development Goal 6 and that reflects Europe's weight and importance as an international partner in development…The EU will contribute to providing resources to countries for confronting HIV/AIDS, malaria and TB, to be identified through appropriate mechanisms.

As the world's largest donor, the EU has collectively provided the majority of the significant increase in recent years of international financing earmarked for HIV/AIDS, malaria and tuberculosis. Collective EU contributions to the Global Fund have almost quadrupled, from a total of US$403 million in 2003 to US$1 546 million in 2008, representing around 55% of total contributions in the years 2004-2008[18].

In 2007, EU donors provided around 54% of the disbursements of earmarked financing for HIV/AIDS totalling US$4.9 billion in 2007, up from US$1.2 million in 2002. Earmarked international funding disbursements for malaria have increased from US$249 million in 2002 to US$1 127 million in 2008. With the contributions of EU donors and others, the Global Fund has provided the majority of new resources for malaria control, up from US$36 million in 2002 to more than US$427 million in 2008. Earmarked financing for TB control from international donors and governments in twenty-two high burden countries has also increased, reaching US$2.3 billion in 2008.

The Commission and other EU donors are making funds available to strengthen health systems and confront communicable diseases through a variety of financing instruments. In the case of the Commission, for the period 2007-2011 covered by the Programme for Action[19], programmed ODA financing earmarked for health is estimated to total €3.043 billion, a slight decrease from the total of €3.151 billion programmed for the preceding five years 2002-2006[20]. This financing includes support for research and technological development, where more than €200 million have already been allocated in the *7th Research Framework Programme (2007-2013)* specifically for research on the three diseases.

General budget support has increased sharply from a total of €1.425 billion in the period 2002-2006 to €2.571 billion for the period 2007-2011. General budget support can be particularly beneficial for health systems and other social sectors, as it provides longer-term and predictable financing, which strengthens country ownership and allows countries to cover recurrent costs such as salaries of health workers and teachers, buildings and infrastructures. The new *MDG contract* introduced by the Commission expands the financing cycle from three to six years, and parts of the disbursements are based on progress in MDG-related indicators.

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18 Based on data on pledges and contributions from the Global Fund to Fight AIDS, Tuberculosis and Malaria of 20 January 2009, www.theglobalfund.org.

19 Humanitarian assistance is incorporated, based on extrapolations of actual contracts 2002-2007.

20 Including earmarked financing for HIV/AIDS, malaria and tuberculosis.

4.4. Regional and global action

Among areas selected for regional and global action by the Commission in partnership with Member States and other key players, the Programme for Action identified affordable pharmaceutical products, regulatory capacity, human resources in the health sector, and research and development of new tools and interventions.

Aiming to ensure **access to affordable and safe drugs**, the Commission has introduced a tiered pricing mechanism, created a common procedure to authorise production of drugs under compulsory licence for export[21], provided support for use of TRIPS flexibilities and accepted the amendment of the WTO Agreement on Intellectual Property, which allows developing countries without manufacturing capacity in the pharmaceutical sector to import generic medicines.

The current price of first-line HIV treatment can now be below US$120 per year, and the current price of drugs for a full malaria treatment is around US$1 in the public sector. These significant price reductions may be related to a combination of factors, including the above-mentioned mechanisms introduced by the Commission as well as the sharply increased volume of drug purchases; use of pooled procurement mechanisms; increased competition with the arrival of new manufacturers; and production of fixed dose combinations.

Allowing greater transparency on drug prices, the WHO Global Price Reporting Mechanism now integrates data from the Global Fund and other donors. The WHO prequalification project has, with support from the Commission and Member States, from 2002 to 2007 prequalified 156 medicines, including antiretroviral drugs and artemisinin-based combination therapy drugs, prequalified a dozen quality control laboratories and will soon expand its activities to include prequalification of diagnostics. The Commission and Member States have been strongly involved in the development of the WHO Global Strategy and Plan of Action for Public Health, Innovation and Intellectual Property.

In December 2006, the Commission adopted a Communication entitled *a European Programme for Action to tackle the shortage of health workers in developing countries (2007-2013)*[22]. As a follow-up, the Commission earmarked €40 million to finance activities in the area of **human resources for health**. In 2007, the Commission prepared a progress report based on information from 18 Member States, which found that there was strong consensus on the policy, but that further efforts are required to translate EU policy into action. According to the report, the EU collectively supports programmes with a component on human resources for health in 51 out of the 57 countries facing critical shortages. In addition, the EU provides support for regional research, capacity-building and knowledge-generating initiatives. At global level, the EU is exploring opportunities for stimulating circular migration and other mechanisms which can address the pull factors of health worker migration. Progress is still needed, however, on coordination of activities among EU actors, on improving capacity for policy dialogue, and in developing a code of conduct for recruitment of health workers.

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21 Regulation on the compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems, (EC) No 816/2006.

22 COM(2006) 870 final of 21.12.2006

Development of **new tools and interventions** for the three diseases became one of the priorities of the *6th Framework Programme for Research and Development (2002-2006)* (FP6) and *7th Framework Programme for Research and Development (2007-2013)* (FP7). In addition, the Commission has supported the aforementioned Community research programme, the EDCTP. The significant investments by the Commission and Member States in research and development of new tools and interventions has enabled the creation of an active and competitive European research area for HIV/AIDS, malaria and TB and a strong partnership between EU and developing countries on clinical trials and local capacity building. It has also demonstrated the strong potentials of public-private partnerships in accelerating product development and ensuring the engagement of communities and partner countries. However, effective vaccines, microbicides and new drugs are yet to de developed, and there is a need for continued and long-term investment in research and development, including basic research on mechanisms of pathogenesis and protection. The conference on *Challenges for the Future: research on HIV/AIDS, Malaria and Tuberculosis* organised by the Commission in November 2008, brought together stakeholders to boost commitment and define the future priorities for funding research on the three diseases[23].

5. LESSONS LEARNT

5.1. Country level

Considering the growing importance of **policy dialogue**, an effective division of labour and deployment of staff with competence in policy dialogue related to the three diseases would help to reinforce capacity for policy dialogue in Delegations and Member State Embassies. Better guidance and tools for policy dialogue can be provided, adapted and regularly updated through collaborative efforts of the Commission and Member States at the European level. The forging of partnerships with organisations of people affected by the three diseases and other civil society organisations, as well as with UNAIDS and WHO field offices, would allow better access to strategic information related to the epidemiological situation and response in the partner countries.

The **strengthening of the capacity** of governments, civil society and other stakeholders in overall planning, management, implementation and evaluation of national health plans, and specifically in areas lagging behind such as HIV prevention, care and support for people affected by the three diseases, gender and human rights, would ensure effective implementation of the sharp increase in resources in relation to the three diseases.

With regard to **financial resources**, a shift of the policy focus away from analysis of global financing gaps and earmarked allocations for the three diseases towards identification of country-level financing gaps and resourcing strategies in the context of national health plans and budgets would serve as the basis for alignment and optimal synergy of multiple financing channels – domestic financing, Global Fund, budget support etc. – and ensure an adequate balance between disease-specific activities and health system strengthening.

[23] The recommendations stemming from the conference are published on the website http://ec.europa.eu/research/conferences/2008/poverty-related-diseases/conf-report_en.html

5.2. Global and regional action

The priority thematic areas selected for global and regional action in the Programme for Action - affordable pharmaceutical products, regulatory capacity, human resources in the health sector, and research and development of new tools and interventions – reflected the strong public support and the political commitment to **scaling up access to treatment** at a time, when treatment was still out of reach for the vast majority of people in need[24]. Given that the concept of collective EU action was new and yet to be unfolded, it also reflected the need for the Commission to focus on a few selected priority areas for action.

While access to treatment remains of critical importance and will require continued and renewed attention in the years to come, there is mounting evidence of the need to promote a broader response, and directly address **crucial areas lagging behind** such as in particular the need for **accelerated efforts in prevention** as well as comprehensive care and support for people affected by the three diseases; addressing gender inequality and reinforcing the protection of human rights; and better integration of services in the context of health system strengthening.

A broader scope of global and regional priority actions to support and promote **more comprehensive responses** to HIV/AIDS, malaria and TB at country level will require and allow for **stronger mobilisation and engagement** of Commission services, those of Member States, and European civil society and other stakeholders in the framework of coordinated and collective EU action, as initially envisaged in the May 2005 Council Conclusions. This effort would be based on the EU Code of Conduct on Complementarity and Division of Labour, and would ensure that HIV/AIDS, malaria and TB are effectively addressed within the division of labour at European and country levels.

6. THE NEW POLICY CONTEXT

Combating global poverty is not only a moral obligation; it will also help us to build a more stable, peaceful, prosperous and equitable world, reflecting the interdependency of its richer and poorer countries. In such a world, we would not stand by…while HIV/AIDS, TB and malaria claim the lives of more than 6 million people every year[25].

Following the adoption of the Programme for Action in May 2005, a series of international and European policy developments and initiatives have occurred, which influence and re-define the context of efforts to confront the three diseases.

Towards the end of 2005 the *European Consensus on Development* was adopted, bringing together for the first time existing EU policy commitments related to *the Millennium Development Goals, the Monterey Consensus on Development Assistance* and *the Paris Declaration on Aid Effectiveness* in a coherent framework of common principles for EU development cooperation policies – to do more, better, together.

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[24] Since 2003 there has been an almost tenfold increase in the number of people receiving effective HIV treatment, from 400 000 to nearly 4 million by the end of 2008 – however, still leaving behind more than 6 million in need.

[25] European Consensus on Development.

In 2006, the UN General Assembly adopted the *Political Declaration on HIV/AIDS*, where the world leaders made a commitment to support countries in scaling up towards universal access for HIV prevention, treatment, care and support in 2010. The *Global Plan to Stop TB 2006-2015* provided a comprehensive assessment of the action and resources needed to make an impact on the global TB burden. *The Global Malaria Action Plan* was launched in September 2008, reaffirming the targets of reaching and sustaining universal coverage in 2010 and beyond, and moving towards the renewed ambitious goal of malaria eradication.

In April 2007, the Council adopted *Conclusions on recently emerging issues regarding HIV*, calling for renewed focus on efforts to reverse the trend of a steadily increasing proportion of women among those affected by HIV.

In December 2007, a *Joint EU-Africa Strategy and Action Plan* was adopted at the EU-Africa Summit in Lisbon, and in this context the Africa-EU Partnership on the Millennium Development Goals (MDGs) was launched as a forum for intensified continent-to-continent policy dialogue, cooperation and joint action at all levels, with a view to achieving the MDGs in all African countries.

In June 2008, the Council adopted the *EU Agenda for Action on the MDGs*, reaffirming the EU commitments to support partner countries in achieving the MDGs, and proposing a series of actions and milestones, also in relation to HIV/AIDS, malaria and tuberculosis.

The above-mentioned EU and international policy initiatives and developments confirm a series of common commitments:

- to work towards achieving the Millennium Development Goals, including combating HIV/AIDS, malaria and other major diseases
- to provide more aid and to scale up for sustainable impact on the global epidemics
- to provide better aid, by placing country ownership, and alignment to country priorities and processes at the centre of the global response to the epidemics
- to support comprehensive country-owned responses to address the local realities of the global epidemics, based on blueprints for global action in support of such responses
- to ensure better donor coordination and complementarity in support of partner country leadership, including through implementation of the EU Code of Conduct on Complementarity and Division of Labour

7. CHALLENGES AND OPPORTUNITIES

7.1. Doing more - scaling up for sustainable impact on the global epidemics

In spite of the encouraging results achieved through the sharply increased financing for HIV/AIDS, malaria and TB, significant global **financing gaps** remain and are gradually widening[26]. These financing gaps will mean higher global morbidity and mortality and will

[26] According to estimates made by UNAIDS, Roll Back Malaria and the STOP TB Partnership/WHO, see Annex 2.

thereby greatly increase the future costs and socio-economic impact related to the three diseases. Furthermore, against a backdrop of multiple global crises, confronting HIV/AIDS, malaria and TB may be perceived as less of a priority, leading to cutbacks in financing. However, such reductions would erode the progress and investments made, and would result in the global epidemics again escalating unabated.

In the context of the EU Agenda for Action on the MDGs[27], the EU reaffirmed its commitment to increased development aid, with the expectation that this level of increased investment would allow EU to play a substantial role in helping to bridge the financing gap in health and contribute to achieving a series of specific actions and milestones related to HIV/AIDS, malaria, health and health systems. These actions and milestones represent proposals made by the EU to partner countries. Partner country ownership of measures tackling health problems remains critical if the envisaged EU support on health is to achieve the desired results.

The new Communication *Supporting developing countries in coping with the crisis*[28] emphasizes that the EU, in the context of financial and economic crisis, as a priority must pursue the 2010 milestones in its MDG Agenda for Action or risk further compromising 2015 targets. The Communication also stresses that continued support in the field of health is key to ensure that the most vulnerable are not left unprotected.

In the follow-up of the commitments made in the Programme for Action and the EU Agenda for Action on the MDGs, the Commission and the Member States are working with partner countries to ensure that increased aid for development contributes to **increased and predictable resources** to confront HIV/AIDS, malaria and TB and to strengthen health systems, including through results-based budget support modalities such as the **MDG contract** and continued strong support for the **Global Fund**.

In addition, the possibility of leveraging new resources through innovative financing mechanisms will be explored, including additional financing such as solidarity levies and private giving, frontloading long-term assets, advance market commitments and pooled purchase and procurement mechanisms[29]. The EU is working closely with African governments to enable them to fulfil their commitment to allocate 15% of state budgets to health, in line with the 2001 Abuja Declaration.

7.2. Doing better - promoting effective country responses to HIV/AIDS, malaria and TB

Working with partner countries to develop and support implementation of **national plans and budgets for health and HIV** as the basis for alignment of multiple financing instruments with country priorities and processes**,** in accordance with the principles of the International Health Partnership, would ensure adequate allocation and optimal synergy of international and domestic resources. Such national plans and budgets would also ensure an adequate

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[27] The EU as a global partner for pro-poor and pro-growth development: EU Agenda for Action on MDGs, 11096/08, 24.06.08.

[28] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on Supporting countries in coping with the crisis, COM(2009) 160 final, 08.04.2009

[29] Such mechanisms are being explored by the High-Level Taskforce on Innovative Financing for Health Systems which will present its recommendations in May-June 2009.

balance between financing for disease-specific activities, and system strengthening, e.g. by combining Global Fund grants and budget support.

The **weak health systems** in many countries are widely acknowledged as a key barrier to further progress in confronting HIV/AIDS, malaria and tuberculosis[30]. Strengthening of health systems may be achieved through continued efforts of the Commission and Member States to promote adequate fiscal space for social sectors and through **better alignment of the Global Fund** and other donors in support of country-led responses and health system strengthening. Moving from earmarked financing towards **general budget support** enables stronger country ownership and can be particularly beneficial for health systems and other social sectors, as it allows countries to cover recurrent costs such as salaries of health workers and teachers, buildings and infrastructures. The new *MDG contract* introduced by the Commission allows for greater predictability by expanding the financing cycle from three to six years, and links parts of the disbursements to progress on MDG-related indicators.

With the steep increase in financial resources for HIV/AIDS, malaria and tuberculosis, the stronger emphasis on country ownership and demand, and the move from project financing towards budget support, many countries are experiencing **capacity constraints**, undermining their ability to fully access, manage and implement these new resources effectively. System constraints also exist and require attention in relation to education, social protection and the informal sector.

Such capacity constraints may be addressed through support for **country-led** technical needs assessment and institutional **capacity building** to better develop, manage, implement and evaluate national health plans, including through horizontal technical cooperation within Africa, and between Europe and Africa, and triangular cooperation with external partners[31].

Effective country responses to HIV/AIDS, malaria and TB **require balanced and comprehensive strategies** to scale up access to prevention, treatment, care and support. Since for every two persons gaining access to HIV treatment, five more become infected, there is an urgent need to **scale-up HIV prevention** to maintain universal access to treatment as a realistic and sustainable goal. Major gaps exist in the area of care and support for people and families affected by the three diseases, including the more than twelve million children under eighteen years of age who have lost one or both of their parents to AIDS in sub-Saharan Africa. More efforts are required to ensure that prevention strategies address the local realities of the epidemics, apply evidence-based effective approaches, and promote gender equality and human rights[32].

Effective utilisation of financial resources may be further improved through promotion of **integrated approaches and services** for people affected by the three diseases based on the principles of primary health care. Such integrated services can enhance synergy, offer a better way to tackle co-infections, in particular HIV/TB, and link with services for sexual and

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30 The preliminary findings of the ongoing 5 year evaluation of the Global Fund presented at its Board Meeting 5-6 May 2009 describe its overall results as extraordinary, especially in resource mobilisation and increased service availability, coverage and reduction of disease burden, but highlights among the key constraints the need for overall health system strengthening.

31 Triangular cooperation on health, including HIV/AIDS, is identified as a priority in the Joint EU-Brazil Action Plan.

32 Please see Annex 2 for detailed analysis of the suggested priority areas, and recommendations for collective EU action.

reproductive health and rights; integrated management of childhood illnesses can also be achieved. Investment in research and development of **new tools and interventions** to confront the three diseases remain of critical importance for the development of effective and sustainable responses to the three diseases. The involvement of people living with the three diseases and **civil society** organisations in the design, implementation and monitoring of programmes and services is vital to ensure their relevance and effectiveness. Particular attention should be paid to ensuring that programmes address the needs of the **most at risk populations** such as sex-workers, men who have sex with men and injecting drug users, where necessary through flexible and targeted financing instruments.

7.3. Working together – developing effective division of labour and partnerships to confront HIV/AIDS, malaria and TB

When it comes to budget support, the actual share of resources allocated in support of country responses to HIV/AIDS, malaria, and TB ultimately depends on the **partner country's leadership and priorities**. Similarly, in the case of the Global Fund, the volume, content and balance of the grant depend on partner country interest and priorities.

The change from donor-driven earmarked financing towards financing channels based on country demand represents a major challenge for the implementation of the **ambitious and often sensitive policy agenda** for comprehensive responses to HIV/AIDS, malaria and tuberculosis. Furthermore, as financing is channelled through national budgets, and countries may lack the will or mechanisms to fund civil society organisations, the critical role of non-state actors in ensuring effective responses may be undermined with the new financing modalities.

The EU plays an important role as a global advocate for bringing attention to crucial and sensitive priority areas such as sexual minorities, harm reduction, condom programming, and integration of HIV/AIDS and sexual and reproductive health and rights. This would include a **strong European voice** at global level to oppose and confront proponents of approaches that are not based on evidence or violate human rights of people living with the three diseases and groups most at risk.

The above-mentioned challenges bring **policy dialogue to the centre of EU global and country-level actions** to confront HIV/AIDS, malaria and TB, as a key instrument in influencing country leadership and priorities, promoting approaches based on evidence, gender equality, human rights and the needs of the most at risk populations. It also raises the question of how the EU can develop and sustain its capacity for a strengthened health policy dialogue at country level in the move away from project management towards budget support modalities.

The common values and principles of the **European Consensus on Development** and the milestones set out in the **EU Agenda for Action on the MDGs**[33] provide a strong platform for a collective EU policy dialogue in support of increased country ownership and leadership of responses to HIV/AIDS, malaria and tuberculosis. The new Africa-EU Partnership on the Millennium Development Goals, which forms part of the EU-Africa First Action Plan (2008-2010), calls for intensified continent-to-continent policy dialogue in support of improved

[33] European Council: "The EU as a global partner for pro-poor and pro-growth development: EU Agenda for Action on MDGs", 18 June 2008.

access to prevention, treatment, care and support for HIV/AIDS, malaria, tuberculosis and sexual and reproductive health[34].

At **country level an effective division of labour** would allow the EU to speak with one voice, make optimal use of the strategic information and expertise that is available and utilise in full the respective comparative advantages. Policy dialogue could be further enhanced through sharing of tools, joint competence building of staff and closer collaboration with people affected by the three diseases, civil society organisations and international organisations such as UNAIDS and WHO. The division of labour can, however, only be effective if the EU collectively ensures the deployment of staff with the necessary profile, skills and competence to support a strengthened policy dialogue related to the three diseases.

Furthermore, it is equally important to ensure that national policymakers, civil society and other stakeholders have the capacity to become strong advocates for giving support to programmes and priorities related to the three diseases and are involved early in the poverty reduction strategy and development planning processes. The new thematic budget line *Non-State Actors and Local Authorities in Development* provides support for actions to **promote an inclusive and empowered society** in partner countries, in support of the MDG Agenda and coherence for development, including in areas such as human rights and HIV/AIDS. A similar budget line exists at partner country level, which also supports capacity building for non-state actors in delivery of services for HIV/AIDS, primary health care and education.

At **European level**, enhanced support for broader and more comprehensive responses will require much stronger mobilisation and engagement of Member States, European civil society and other stakeholders in the context of collective EU action, as initially envisaged in the Programme for Action and in the May 2005 Council Conclusions.

A greater mobilisation and engagement of European stakeholders can be achieved by creating **EU action teams** in the priority thematic areas, as proposed during the stakeholder consultations. Articulating a division of labour at the EU level, these EU action teams would be led by one of the Member States or the Commission, and would include other interested Member States, civil society organisations, public-private partnerships, UN and other international organisations. The role of these EU action teams would be to consider and plan how to take forward and support the implementation and further development of the detailed recommendations for action, as outlined during the progress review and described in Annex 2[35].

8. CONCLUSIONS AND WAY FORWARD

The epidemics of HIV/AIDS, malaria and tuberculosis will, in spite of the progress made, continue to pose exceptional global challenges to social growth and development for decades to come. Strong and sustained commitment is required to support partner countries in scaling up towards universal access to HIV prevention, treatment, care and support by 2010, and in reaching the 2015 targets related to HIV/AIDS, malaria and tuberculosis expressed in the Millennium Development Goals.

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[34] First Action Plan (2008-2010) for the implementation of the Africa-EU Strategic Partnership.

[35] Annex 2. Report of Stakeholder Consultations, Progress Review of the European Programme for Action to Confront HIV/AIDS, Malaria and Tuberculosis Through External Action (2007-2011), Brussels, 25-26 November 2008, Dakar, 6 December 2008.

An EU leadership role in the global response to the three diseases is required, based on the commitments and directions set out in the European Consensus on Development and the EU Agenda for Action on MDGs, and underpinned by the European common values of country ownership, gender equality and human rights. Such a leadership role would include

(1) Working with partner countries to ensure that the existing commitment of the EU to scale up aid for development contributes to increased and predictable resources to confront HIV/AIDS, malaria and TB and to strengthen health systems, including through results-based budget support modalities such as the MDG contract and continued strong support for the Global Fund

(2) In the context of the EU-Africa MDG Partnership, continuing to work closely with African governments to develop innovative health financing mechanisms and strive for fulfilment of their commitment to allocate 15% of state budgets to health, in line with the 2001 Abuja Declaration

(3) In accordance with the principles of the International Health Partnership, supporting the development and implementation of single national health plans and budgets to ensure alignment and optimal synergy of international and domestic resources for HIV/AIDS, malaria, TB and health system strengthening

(4) In accordance with the Accra Agenda for Action, supporting country-led capacity building to better develop, manage, implement and evaluate national health plans, including through horizontal technical cooperation

(5) Promoting effective country strategies to confront the three diseases through balanced and comprehensive approaches, which:

- sustain and expand access to affordable and safe medicines
- scale up evidence-based prevention strategies by ensuring access to the full range of services and commodities
- promote care and support for people and families affected by the three diseases, especially children

(6) Further supporting and promoting effective utilisation of financial resources through

- integrated approaches and services based on the principles of primary health care
- the full involvement of people affected by the three diseases and civil society in the design, implementation and monitoring of country strategies to confront the three diseases
- adequate financing of programmes for most at risk populations, where needed through flexible and targeted financing instruments

(7) Enabling effective and sustainable country responses through long term and predictable investments in research and development of new tools and interventions and work with EDCTP to engage communities and partner countries in product development partnerships, capacity building and health research policy dialogue .

(8) Intensifying a strategic and coordinated EU policy dialogue in international fora and at country level, which:

- promotes as a priority scaling up towards universal access to prevention, treatment, care and support for HIV/AIDS, malaria and TB in the context of health system strengthening
- addresses critical and sensitive priority areas such as integration of HIV/AIDS and sexual and reproductive health and rights, sexual minorities, harm reduction and condom programming
- actively opposes and confronts proponents of approaches that are not based on evidence or violate human rights of people living with the three diseases and groups most at risk.

(9) Strengthening capacity for policy dialogue at European and country levels through:

- an effective division of labour in priority areas
- sharing of tools and joint competence building for staff
- closer collaboration with people affected by the three diseases, civil society organisations, and international organisations such as UNAIDS and WHO

(10) Enabling a stronger, broader and more comprehensive EU response through innovative approaches such as the proposed EU action teams led by a Member State or the Commission, which can

- mobilise and engage the Commission and Member States services, European civil society and other stakeholders in the framework of coordinated and collective EU action;
- apply an effective division of labour at the European level for implementing regional and global activities to support country action in priority areas, based on the recommendations of the stakeholder consultations.

ANNEX 1

EUROPEAN PROGRAMME FOR ACTION TO CONFRONT

HIV/AIDS, MALARIA AND TUBERCULOSIS THROUGH EXTERNAL ACTION

INDICATIVE MONITORING FRAMEWORK FOR ACTIONS – REPORT ON PROGRESS AND CONSTRAINTS AT END-2008

Action/initiative	**Expected outputs/outcomes**	**Progress/constraints end-2008**
COUNTRY-LEVEL ACTION		
2.1. Policy dialogue	1. EU dialogue on key issues	– 60 of 64 approved Country Strategy Papers for the 10th EDF and 20 of 24 Joint Annual Reviews for 2007 in African countries refer to the HIV/AIDS situation and response. – Heads of Delegations policy initiative in Southern Africa. – According to external survey[36], most Delegations take part in health sector policy dialogue, but weaknesses in depth and quality. Only 13 of 37 Delegations in the survey take part in the Country Coordinating Mechanisms of the Global Fund.
	2. Tool kit for policy dialogue, programming and monitoring prepared for Delegations	– Set of master messages for policy dialogue on HIV/AIDS priority areas in Southern Africa developed with Delegations in 2007. – Policy background papers and analysis on socio-economic impact, prevention, financing gaps prepared for Delegations in Southern Africa in 2008. – Analysis of human resources for health in Southern African region, rapid assessment of human resources for health situation, management and capacity development (HCD) situation in Swaziland.

[36] EC Development Assistance to Health Services in Sub-Saharan Africa (European Court of Auditors, January 2009), http://eca.europa.eu/portal/pls/portal/docs/1/2470313.PDF

		– Ongoing study commissioned in 2008, aiming to develop measures and guidance to strengthen Delegations' engagement in health sector policy dialogue. – Guidelines for Delegations on partnership with Global Fund in preparation. – HIV/AIDS programming guidelines and indicators prepared in 2006 and updated in 2008. HIV/AIDS integrated in programming guidelines for health and education, and incorporated in new programming guidelines for infrastructure. – Literature review commissioned in 2008, aiming to update Health, AIDS and Population programming guidelines in 2009.
	3. HIV/AIDS, malaria and TB awareness raising and training	– Health sector policy dialogue workshop (preparation finished, actual workshop planned for 2009). – Health financing workshop (specific issues concerning the financing of these diseases addressed in the case studies). – Southern African Heads of Delegations initiative on HIV/AIDS. – Regular HIV/AIDS awareness and training provided for all Delegation staff and families in the context of the HIV in workplace programme.
	4. Sharing of EU health expertise for political and policy dialogue	– 2008 survey among EU Member States[37] indicates lack of health technical expertise in the field. In 15 of 31 developing countries one of the Member States leads on health policy dialogue, and many Member States reportedly rely on other EU donors for health policy dialogue. There are few examples of formalised arrangements of sharing of expertise for policy dialogue.

[37] Progress report on implementation of European Programme for Action to tackle the critical shortage of health workers in developing countries (2007-2013). http://ec.europa.eu/development/icenter/repository/health_progress_report_implementation_2008_en.pdf

		– 7 new positions on MDG contracts, and 4 on social sectors in fragile countries created in Delegations in 2009.
	5. Education and prevention programmes and social protection schemes for European Commission staff and families	– European Commission "HIV in workplace" policy adopted in 2007, which ensures access to training on HIV/AIDS awareness and prevention as well as care, treatment and social protection services for all staff and their families in non-EU Member States. – Support for implementation of HIV in workplace programmes in Delegations.
2.2. Capacity building	1. Shared EU resources for technical assistance (mapping, plans and code of conduct)	– Commission regional helpdesk on HIV/AIDS in Southern Africa and global helpdesk function created in 2007. – 2008 Member States survey provided scant information, most technical assistance is not shared. – Previous attempts to map and better share joint technical assistance unsuccessful; ongoing mapping in Southern Africa by Regional Helpdesk. – Mainstreaming manual developed by the Regional Helpdesk, mainstreaming training ongoing for staff in Southern Africa. – Joint Commission/UNAIDS initiative on country-led technical support planning in preparation, links forged between Delegations and the UNAIDS Technical Resource Facility (a database roster of regional experts). – The European & Developing Countries Clinical Trials Partnership (EDCTP), including 47 African countries and 16 EU Member States, has consolidated itself as a high-performing network for implementation and capacity building related to clinical trials. – The Alliance of ESTHER, 'Network for Therapeutic Solidarity in Hospitals against AIDS' engages ten Member States in collaboration with forty partner countries in an effort to strengthen the skills and capacities of health structures in developing countries for the care of people living with HIV/AIDS.

	2. Fiscal space ensured for health expenditures (Abuja target); making the case for health exceptionality in macro-economic policies; incentives and strategies developed to address human resources for health critical shortages;	– Abuja 15% target for health in national budget addressed in policy dialogue at all levels. – Many countries are still lagging well behind this target, although there are increases in some countries. – Commission/ACP/WHO Partnership on health millennium development goals (MDGs) to enhance national capacity for formulation and implementation of health policies, including an accrued engagement of the health authorities in Poverty Reduction Strategy Papers, sector-wide approaches and budget support processes, in order to scale up programmes to accelerate achievement of the MDGs. – Strong Commission position on health exceptionality in High Level Forums on Health (ceilings, budget allocations, health civil servants payroll) and other policy fora, need for better monitoring and possible interventions at country level. – Strong Commission emphasis on macroeconomic support (budget support/MDG contracts) to ensure fiscal space for social sectors and plans to link with dedicated health policy dialogue (additional staff, health and AIDS guidelines, master messages). – EU-supported health programmes with human resources for health component in 51 of 57 countries, but lack of coordinated efforts. – Country-level actions on human resources for health, High Level Inter-ministerial Consultation on Human Resources for Health in Botswana 2007. – Global Health Work Alliance/WHO supported to assist development and implementation of health workforce policies, strategies and plans to tackle critical shortage of health workers, including development of the African Observatory on Human Resources for Health. – Thematic financing to strengthen in-country capacity and involvement of civil society in advocacy, policy development and policy implementation in the area of Human Resources for Health.

	3. Increased capacity for research	– In 2007, Europe and Developing Countries Clinical Trials Partnership (EDCTP) supported 71 projects in 21 African countries on clinical trials, capacity building and networking related to HIV/AIDS, malaria and tuberculosis
	4. Increased capacity for pharmaceutical policy development through WHO support; increased capacity for procurement of pharmaceutical products	– €25 million Commission support for WHO 2004-2009 to assist ACP countries in strengthening pharmaceutical sector (including policy development on medicines, strengthening procurement and regulatory systems, capacity building, networking, best practices), now focusing on use of TRIPS flexibilities, assessment of drug distribution systems and development of procurement and supply management plans. – Study and workshop on 'Procurement policies and practices for pharmaceutical commodities', 2007-2008. – EU support for strengthening of national drug procurement agencies in the context of health sector budget support in a number of countries.
	5. Increased synergy between programmes and services on the three diseases and for children's rights and health, and sexual and reproductive health	– Strong policy consensus at European level. – Some progress in ensuring access to HIV testing in antenatal clinics and prevention of mother-to-child transmission (2007 coverage estimated 33%). – Significant gaps in ensuring sexual and reproductive health and rights for people living with HIV. – Lack of measures and indicators for progress in integration of HIV and sexual and reproductive health and rights.
	6. School safety and life skills education included in education sector programmes supported by the Commission	– School safety and life skills education included in programming guidelines for education sector programmes, and promoted in the context of joint annual reviews.

	9. Assessment of impact of the three diseases on human security and state stability; EU response for critical countries	– UNAIDS review indicates that HIV transmission patterns in humanitarian emergencies are complex and depend upon many dynamic and countervailing factors; little evidence that AIDS in itself has directly led or will lead to state failure. – Delegations Action Plan to Expand the Response to AIDS Crisis in Southern Africa launched in 2007.
	7. Mainstreaming of efforts to confront the three diseases in emergency operations	– New guidelines on HIV/AIDS in humanitarian actions adopted in October 2008.
	8. Training of peacekeeping forces to confront the three diseases	– UNAIDS office on AIDS, Security and Humanitarian Responses supports the African Union with its AIDS programmes for African Union peacekeeping forces as well as African militaries.
2.3. Financial resources to confront the three diseases	1. Adequate and predictable funding, including through the Global Fund	– In 2007, the EU collectively provided 55% of total Global Fund contributions, and 54% in 2008. – In 2007, the EU collectively provided 54% of total ODA disbursements for HIV/AIDS[38].
	2. Partnerships and specific support to finance cost-effective interventions in heavy-burden countries	– Support for specific interventions (dissemination of bednets, contraceptives and access to testing and ARV for pregnant women) only provided through comprehensive country projects supported by Global Fund, through focal sector support for health, or in the context of humanitarian action in fragile states.

[38] UNAIDS and Kaiser Foundation analysis 2008.

GLOBAL LEVEL ACTION		
3. Strengthening regional cooperation to confront the three diseases	1. Commission regional health advisers appointed	– Commission Regional Help Desk on AIDS created in 2008 for Southern Africa.
	2. Annual regional reports on country actions	– Commission report on HIV/AIDS in Southern Africa prepared in 2008 based on country progress reports.
	3. Regional cooperation established on key issues, examples of good practices shared	– Commission Action Plan on HIV/AIDS in Southern Africa adopted and implemented by Delegations.
3.1. Affordable and safe pharmaceutical products	1. Monitoring and promotion of the anti-trade diversion Regulation	– The tiered pricing mechanism introduced to avoid trade diversion into the EU of certain key medicines[39]. One company has registered medicines under the Regulation.
	2. Prices of pharmaceutical products published	– No implementation at EU level. Global Fund now provides information on drugs purchased in 80% of its grants, which can easily be incorporated into the WHO global price reporting mechanism together with UNITAID and other UN agencies purchases.
	3. EU legislation adopted to implement the WTO 2003 Decision on TRIPS flexibilities, biannual report of implementation of TRIPS flexibilities in third countries	– The Commission has allocated €25 million for a partnership with WHO to support pharmaceutical policy development in partner countries, including on the use of TRIPS flexibilities, and has stated that use of TRIPS flexibilities will not restricted by Economic Partnership Agreements[40]. – EU acceptance of amendment of the TRIPS agreement allowing import of generic drugs in 2007[41].

39 Council Regulation (EC) No 953/2003 of 26 May 2003 to avoid trade diversion into the European Union of certain key medicines.

40 E.g. in its recent answer to the parliamentary question by David Martin on Carifrom EPA – TRIPS and Access to Medicines follow up.

41 Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.

		– Rwanda first country to notify TRIPS Council in 2007 for a request to Canada for generic drugs. No request to the EU yet. – Strong engagement of the Commission and the Member States in the work of the WHO Intergovernmental Working Group, which 2008 led to the approval of the WHO Global Strategy and Plan of Action for Public Health, Innovation and Intellectual Property. The Commission is working with WHO to support the implementation and identify the most pressing needs for research and development on poverty-related, tropical and neglected diseases, which can guide EU action.
3.2. Regulatory capacity and prequalification	4. Use of Article 58 of EC Regulation 726/2005 for the evaluation of medicines for developing countries	– In 2008, three products received a European scientific opinion, for use outside the EU.
	5. Specific guidelines on key products, e.g. microbicides or vaccines, technical assistance, training	– Not implemented. Effective microbicides and vaccines yet to be developed. Large-scale trials at the earliest from 2015.
	6. Training on regulatory capacity provided by experts under Commission Framework contract and/or WHO	– Ten national drug regulatory agencies assessed and supported by WHO in 2007 in the context of the WHO-EU Partnership on pharmaceutical policy. In addition, the Commission and the European Medicines Agency have supported WHO's work with seven African national drug regulatory agencies on the development of a model technical registration package, which is now being disseminated. The seven national agencies have formed a regional network and agreed on information sharing based on the technical registration package, aiming to develop a common registration dossier.
	7. International conference organised by EMEA/WHO on regulatory issues related to microbicides	– Effective microbicides yet to be developed.
	8. Regional centres of regulatory expertise developed	– Seven national drug regulatory agencies assisted through WHO/EMEA programme, aiming to create regional network.

	9. Regional scheme of mutual recognition for marketing authorisation established	– Project with WHO and seven national drug regulatory agencies in Africa on a common dossier for drug registration in 2008, expansion to other agencies through regional economic communities
	10. Needs and opportunities for setting up an international advisory committee fully explored	– No progress.
	11. Continued and expanded EU funding for WHO prequalification project	– Great increase of capacity through support from EU and other partners. – 156 medicines prequalified from 2001 to 2007. 12 quality control laboratories prequalified.
	12. Annual report on prequalification progress in relation to production map in developing countries	– No progress regarding production map in developing countries. – Preparatory action on pharmaceutical-related transfer of technology in favour of developing countries, to be launched in 2009, through WHO.
3.3. Addressing the human resource crisis for health providers	1. EU support for AU-NEPAD in tackling the human resource crisis	– Joint work with Global Health Workforce Alliance on development of a programme for strengthening the capacity of the AU in the area of human resources for health to be financed under the AU capacity strengthening facility. – Possible additional financing through thematic programme Investing in People where €40 million has been earmarked for human resources for health between 2007 and 2013 to complement country programmes.
	2. Commission Communication on human resources for health adopted, and ways forward explored with EU Member States	– European Programme for Action to tackle the shortage of health workers (2007-2013), adopted in 2006. – 2008 progress report on implementation, including recommendations on ways forward.

3.4. Research and development of new tools and interventions	1. Commission and Member States' funding leads to results	– Significant research and capacity building results achieved through FP7 and EDCTP, which has enabled the creation of an active and competitive European research area for the three diseases. However, effective vaccines, microbicides and new drugs are yet to be developed.
	2. Research collaboration with disease-endemic countries strengthened	– Significant progress through the partnership of European scientists, industrial partners and researchers from diseases endemic countries in the context of EDCTP, which takes over the most promising candidate products and helps to accelerate the development of new vaccines and drugs for the three diseases by supporting clinical trials in African partner countries.
	3. Key areas of research (basic, preclinical and clinical) funded under FP7 and results effectively used in EU policy development and implementation	– In FP7, €104 million have so far been allocated to HIV research projects in the areas of vaccines inducing broadly-reactive neutralizing antibodies; platforms to support harmonization of vaccine adjuvant testing; drug discovery and pre-clinical development; and paediatric formulations of drugs. The third call of FP7 includes topics on microbicides, mucosal and transcutaneous vaccines, and translational vaccine research in terms of support for phase I and IIa clinical trials. In addition, a call for HIV/AIDS ERA-NET, the network of the European research area, will be published in 2009. Such projects involve funding institutions from Member States, to promote cooperation in the European Research Area to combat HIV/AIDS. – Through the first three calls of FP7 several actions to tackle the problem of emerging extensively drug resistant TB strains and also research on new drug targets are funded. So far €29 million have been allocated to the projects of the first two calls. – International conference in 2008, defined research priorities for HIV/AIDS, Malaria and Tuberculosis in remainder of FP7. – Need for continued longer-term investment in research and development of HIV vaccines, microbicides, female condoms, drugs and on the impact of treatment on HIV transmission.

		– In FP7 a support platform for the development of vaccines for poverty-related diseases will be established to support TB researchers in carrying forward promising vaccine candidates into proof-of-principle testing, and further support will be provided for projects aiming to identify new targets and provide basic knowledge of pathogen-host interactions, and, in addition, research areas such as diagnostics, biomarkers and epidemiology of TB. – The new organisation of the European malaria research community may enhance synergy among the three major projects and boost European malaria research in general through joint implementation of a series of cross-cutting and horizontal research activities. Collaboration with other international organisations and private-public partnerships is well advanced in areas such as malaria vaccines, and has already made an impact, but is yet to be fully developed in areas such as malaria drugs development. A major research effort focusing on interventions to control the mosquito vector that transmits malaria is envisaged for the near future. – Need for more research in areas such as health systems, epidemiology, behavioural change communication, health delivery as well as operational and intervention research.
	4. Studies on effectiveness and potential costs of implementing 'pull incentives' for private-sector engagement in research and development	– No progress.
	5. EU support for public-private partnerships and global initiatives working on HIV/AIDS vaccines and microbicides	– The Commission has contributed €200 million to the EDCTP and Member States have provided additional €200 million. EU has provided a total of €84.2 million, including €5 million from the Commission to IPM to strengthen the capacity of clinical trial personnel and to increase community and political support for clinical trials in developing countries; the Commission has provided €5.6 million to IAVI to establish clinical and social research capacity, community preparedness, training opportunities and exchange mechanisms to support the successful conduct of AIDS vaccine trials in East and Southern Africa. IAVI has also received support from Denmark, Ireland, the Netherlands, Spain, Sweden and the United Kingdom.

ANNEX 2

Report of Stakeholder Consultations

Progress Review of the European Programme for Action to Confront HIV/AIDS, Malaria and Tuberculosis Through External Action (2007-2011)

Brussels, 25-26 November 2008

Dakar, 6 December 2008

Introduction

In the context of the progress review of the European Programme for Action to Confront HIV/AIDS, Malaria and Tuberculosis Through External Action (2007-2011), two stakeholder meetings were organised in Brussels, 25-26 November 2008, and in Dakar, Senegal, 6 December 2008.

The stakeholder consultation in Brussels brought together some 70 participants from Member States, civil society organisations, UN and other international organisations. Setting the scene for the discussions, representatives of UNAIDS, STOP TB/WHO and the Roll Back Malaria Partnership provided updates to participants on the current situation, progress, constraints, challenges and opportunities for country responses and global action related to the three diseases. The Head of the Delegation in Lesotho described the situation and impact of hyperendemic HIV/AIDS in Southern Africa, the work being done by the Delegations to foster an expanded response, and urged Member States to engage in intensified and concerted efforts to address the AIDS crisis in the region. A representative of the International Community of Women Living With HIV stressed the gravity of the AIDS crisis, in particular for women of childbearing age, and urged Member States and the Commission to take immediate action to step up concerted efforts.

The special two-hour stakeholder consultation in Dakar, on 6 December, brought together some 100-120 participants, mainly from Africa, including policy makers, experts and, in particular civil society representatives. At the meeting presentations were made on the wider policy context of EU development cooperation, the Programme for Action, and conclusions and recommendations of the above-mentioned meeting in Brussels. Subsequent discussions focused on the role of budget support/MDG contracts in support of country responses to the three diseases, strengthened partnerships and engagement of civil society organisations, and how to ensure financing for civil society organisations and work with vulnerable groups.

In preparation for the meetings a series of analytical briefs were developed by the Commission, the Member States, civil society organisations and international organisations, and disseminated in advance. On the basis of these documents, participants reviewed progress, gaps and constraints, provided recommendations for an update of policy areas and actions and identified options and priorities for collective EU action to confront the three diseases. It should be noted that it was not possible during the stakeholder consultations to discuss all key commitments and analytical briefs prepared.

The following report seeks to capture and summarise the main conclusions and recommendations of the participants at the two stakeholder consultations. These

recommendations may also form the basis for the work of suggested follow-up mechanisms in the shape of working groups which, led by Member States or the Commission will bring Member States, civil society organisations and international organisations together in efforts to foster collective EU action in key areas identified through the review process.

Current situation, progress and constraints in the response to HIV/AIDS, malaria and tuberculosis

HIV/AIDS

Fewer people are dying from AIDS, and, in several regions and countries, fewer people are becoming infected with HIV as a result of improved tools, know-how and the significant investments made in HIV prevention efforts and treatment services. The global AIDS epidemic is, however, far from over, and will remain a daunting and devastating challenge for decades to come.

With almost 75% of the estimated 2.7 million new HIV infections in 2007, Sub-Saharan Africa remains the continent most affected by the epidemic, with South Asia next in rank, while the most rapid expansion of the epidemic is happening in Eastern Europe, Central Asia and South-East Asia, especially among vulnerable groups such as young people who inject drugs, men who have sex with men, and sex workers.

There are a number of encouraging results reflected in indicators such as declining HIV prevalence in young women attending antenatal services; behavioural changes with regard to delayed sexual debut; reduced numbers of sexual partners; and increased use of condoms. There are a growing proportion of HIV-positive pregnant women receiving antiretroviral prophylaxis, which is leading to a reduced number of new HIV infections among children. There is an impressive increase in the number of people gaining access to antiretroviral treatment, now approaching 4 million, and mortality related to HIV/AIDS is declining slightly.

However, the majority of people in need still lack access to treatment, and AIDS remains the top cause of death in Africa. There is an urgent need to accelerate, scale up and target prevention efforts, as for every two persons gaining access to HIV treatment, five more get infected. Such efforts should reflect the great diversity which exists among countries with regard to dominant HIV transmission patterns and key populations. This diversity can be found even among countries, which are perceived as hosting similar epidemics. Equally important, the evolution of the HIV epidemics should be closely monitored within countries, as changes in HIV transmission patterns may be considerable over time. Country knowledge of the epidemic and the state of the response is critical to successful efforts.

Scaling up towards and maintaining universal access will require predictable and sustainable financing, and low income countries in particular will be in need of substantial international support. Substantial efficiency gains can be made by ensuring that financing for prevention targets key populations most at risk, and by bringing national strategies more into line with evidence-based approaches. Stigma, discrimination, gender inequality and infringements of human rights remain key barriers to effective scaling-up. There is an urgent need to address constraints such as human resource shortages and weak health systems by encouraging country ownership, introducing health service reforms, enhancing synergies and addressing common constraints.

Tuberculosis

While tuberculosis (TB) is preventable and curable, an estimated 9.2 million cases occurred globally in 2006, resulting in 1.65 million deaths. The greatest numbers of TB cases occurred in Asia, while the highest prevalence rate is in Africa, reaching 363 per 100 000 population. Globally, case rates were rising during the nineties, but are now stable or falling slowly. In Africa, case rates doubled during the nineties, but are now stabilising. Cases of multidrug-resistant TB (MDR-TB) have reached almost half a million worldwide, and cases of extensively drug-resistant TB (XDR-TB) are now estimated at around 50 000 cases worldwide. By October 2008 fifty countries reported confirmed cases of XDR-TB. The estimated number of HIV/TB co-infections was more than 700,000 in 2006, and TB is the leading cause of death among people living with HIV.

Globally, significant progress has been made in reducing mortality, but Europe and especially Africa are not on track to reach the targets of the Global Plan to STOP TB 2006-2015 of halving TB deaths by 2015 in relation to the 1990 baseline. The number of TB cases detected and treated under DOTS-based programmes[42] has increased substantially, but the situation is now stagnating.

Current tools for TB control are old, but major efforts in research and development have resulted in a steady growth in the clinical trial pipeline of new diagnostics, drugs and vaccines, and is expected to result in the roll-out of new diagnostics, for instance for rapid detection of MDR-TB, within the next two years.

One of the keys to reaching the targets of the Global Plan is to ensure that all the cases detected will have access to DOTS-based programmes, considering that 38% of the 9.2 million cases detected in 2006 did not have access. Furthermore, more than two-thirds of undetected cases are located in Africa and South-East Asia. Reaching these cases will require scaling up of innovative interventions, notably through laboratory strengthening, engagement of all providers beyond the public sector, community involvement, advocacy and social mobilisation.

There is an urgent need to control the spread of drug-resistant TB through effective TB control, to promote nationwide scaling up of integrated TB and HIV services, and to strengthen health systems, e.g. the workforce, laboratories and infection control. Many countries, however, lack the capacity to initiate this process and see it through, and are in need of access to well-coordinated quality technical support from local and international experts.

Malaria

109 countries were endemic for malaria in 2008, including 45 in Africa. There was an estimated total of 247 million malaria cases among 3.3 billion people at risk in 2006, causing nearly one million deaths. 90% of these preventable deaths occurred in Africa and mostly among children under 5 years. Malaria is putting health systems under strain - in sub-Saharan Africa an estimated 50% of hospital bed occupancy is related to malaria.

Malaria control has gained momentum in recent years, with the currently available tools and commodities such as long-lasting insecticidal mosquito nets, effective artesimin-based

[42] Programmes which are based on the Directly Observed Treatment, Short-course Strategy.

treatment and indoor residual spraying of homes with insecticide proving to be effective. International financing for malaria control has increased substantially from US$249 million in 2004 to around US$1.1 billion in 2008, currently representing 47% of malaria spending from all sources.

As a result, some countries are now reporting significant progress. Rwanda reported a 66% reduction in malaria cases and deaths in 2006 in one year through expanded coverage of bed nets and effective treatment. Similarly, Eritrea, Ethiopia, Sao Tome and Principe, and Zanzibar experienced a 50% decrease in the malaria burden from 2000 to 2006/7.

Significant financial gaps remain, however, and large countries remain a challenge. The increasing success rate of malaria proposals to the Global Fund, notably in round 7 and 8, demonstrates the importance of ensuring quality technical support for resource mobilisation and overcoming implementation bottlenecks.

It will be necessary to step up procurement of long-lasting insecticide bednets and artesimin-based treatment in order to achieve the 2010 targets of the Global Malaria Action Plan. Significant progress has been made in implementing indoor residual spraying, which in 2003 was only done in 12 countries (29%) in Africa, but had been extended to 28 African countries (60%) by 2008. Implementation, however, remains hampered by logistical and implementation difficulties, limited financing and concerns about insecticide resistance. Data collection remains a significant challenge, underscoring the need to strengthen information systems. It is critical to strengthen the local response through behaviour change communication or other means, which can ensure that coverage of bed nets is translated into effective usage.

Safe and affordable medicines – challenges, opportunities, way forward

In spite of the significant progress made in scaling up access to treatment for HIV, malaria and tuberculosis, the majority of people in need still do not have access to affordable and safe medicines. Of an estimated ten million people in need of HIV treatment, almost four million now have access to antiretroviral drugs in middle- and low-income countries, and are in need of continued lifelong treatment[43]. As more people are becoming infected, the number of people in need will continue to grow. Consequently, treatment will require sustainable and predictable financing for decades to come, in terms of domestic financing and, for low-income countries, continued international assistance.

Children living with HIV have only about a one in three chance of receiving antiretroviral therapy compared to adults living with HIV, which indicates a need to develop new strategies to improve treatment uptake among children, and to develop and make available paediatric diagnostic tests and appropriate dosing tables.

Persistent efforts are required to reduce prices, and there is a need for a critical review of the price reduction approaches suggested in the Programme for Action, notably tiered pricing, the TRIPS flexibilities and local production, aiming to assess impact and pave the way for their optimal use. There is a need to ensure accessibility and affordability of newer drugs, especially second- and third-line drugs for HIV and TB. This is becoming particularly

[43] This estimate of the numbers of people in treatment was provided by UNAIDS at the stakeholder consultation in Brussels, November 2008.

pertinent as big producers and exporters of generic drugs such as India and China have become WTO members. It is widely recognised that the process for use of TRIPS flexibilities is complex.

The effectiveness of new approaches to address price and intellectual property rights issues and attract new and cheaper producers should be explored, including global negotiation, pooled procurement and the new global mechanisms such as the international drug purchase facility UNITAID (airline tax), the Affordable Medicine Facility for Malaria AMFm (global buyer co-payment facility), and the Reproductive Health Supplies Coalition (minimum volume guarantee, pledge guarantee). At the level of service delivery, efforts should be made to ensure access to free drugs and services through pre-payment schemes, community-based initiatives, health insurance schemes, tax-based health financing, etc.

With the rapid scaling up of access to treatment, there is an urgent need to strengthen drug quality assurance and monitoring of drug resistance, including through strengthening of laboratory systems. It is equally important to support effective and rational utilisation of essential medicines (including drugs for HIV/AIDS, malaria and tuberculosis) through health system strengthening (forecasting, procurement and distribution systems) and by supporting the role of civil society in providing adherence training and addressing treatment illiteracy.

Furthermore, it should be noted that accessibility to female and male condoms, currently the only commodities available for preventing sexual transmission of HIV, remains limited and should be scaled up in the context of efforts to accelerate prevention. The EU's strategy for affordable and safe products may include work with the Reproductive Health Supply Coalition to explore approaches to strengthen quality assurance and promote price transparency and reductions similar to those applied for medicines.

Participants stressed the continued importance of ensuring access to affordable quality drugs and other pharmaceutical products, and the need to closely monitor and address new developments and challenges,. They gave the following recommendations for consideration by the Commission and the Member States in the context of the Programme for Action:

- to closely monitor and address positive and negative implications for effective drug procurement of the move from earmarked financing towards budget support modalities, aiming to ensure continued access to quality technical support and an effective division of labour in this area;

- with the rapid scaling up of access to treatment, to address the urgent need for drug quality assurance and monitoring of drug resistance, and facilitate access to affordable second- and third-line drugs;

- to support effective and rational utilisation of essential medicines (including drugs for HIV/AIDS, malaria and tuberculosis) through health system strengthening (forecasting, procurement and distribution systems) and by supporting the role of civil society in providing adherence training and addressing treatment illiteracy;

- to review the effectiveness of the price reduction mechanisms currently proposed in the Programme for Action, in particular tiered pricing and the use of the Doha TRIPS flexibilities;

- to consider new approaches to address price and intellectual property rights issues, especially for new and recent drugs such as second-line antiretroviral drugs and drugs for treatment of multidrug-resistant TB, including:

  – global initiatives such as UNITAID, the Green Light Committee, Affordable Medicines for Africa (AMFA) and the "Minimum volume guarantee" of the Reproductive Health Coalition;

  – initiatives to ensure access to free drugs and services at point of delivery, pre-payment schemes, community-based initiatives, health insurance schemes, etc.

- the Commission and the Member States should invest in research and development of better and new diagnostics and drugs, e.g. in the areas of paediatric diagnostics and treatment, and for multidrug-resistant TB.

New tools and interventions – challenges, opportunities, way forward

While significant results, capacity and insights have been achieved through large-scale clinical trials, the inherently scientific 'trial and error' process is yet to produce effective vaccines or microbicides for HIV/AIDS. In relation to HIV vaccine, a return to more basic research on mechanisms of pathogenesis and protection is required, before new candidates can be developed and brought into trials. Research into microbicides is likely to lead to effective tools for HIV prevention within a shorter timeframe. Great advances have been made in managing HIV infection, but an effective cure is not in sight. People on antiretroviral treatment are still confronted with problems of drug resistance and a host of side effects, underlining the need for continued research and development of new drugs for HIV treatment. Continued and longer-term investment in research and development of HIV vaccines, microbicides, female condoms, and drugs, and assessment of the impact of treatment on HIV transmission remains of critical importance for the efforts to stop and reverse the HIV/AIDS epidemic and develop sustainable programmes.

The interaction between the HIV/AIDS epidemics in sub-Saharan Africa and the spread of multidrug-resistant and extensively drug-resistant TB strains is of great concern and represents further evidence of the need for continued investment in research on TB vaccines and drugs. In the area of vaccines, it is unlikely that a single vaccine will work for all, while different vaccine formulations for adults and children may be effective.

In the area of TB treatment, a combination of new drugs rather than a single drug will most likely provide the most effective treatment, similar to combination treatment for HIV. Consequently, there is an urgent need to ensure that sufficient candidates for new drugs and new vaccines are available and can enter the clinical trial pipelines. Renewed global efforts targeting eradication of malaria are coordinated under the Global Malaria Action Plan, supported by the Gates Foundation, the EU and other key global players. The pharmaceutical research and development process is, however, complex, risky and expensive, and a new medicine or vaccine for low-income countries is unlikely to be developed without significant support from the public sector.

There is a need to introduce push and pull mechanisms to increase innovation and the engagement of private-sector actors capable of translating of research into innovative products. Partnerships involving academic institutions, major pharmaceutical and

biotechnology companies, and leading non-governmental and international organisations have a critical role in accelerating product development and ensuring the engagement and preparedness of communities and partner countries for large-scale application.

The longer-term agenda for research and development of new tools and technologies, e.g. HIV vaccines, will entail a critical review of the roles and interactions between specific product development partnerships and the EDCTP, aiming to optimise the speed and quality of product development and large-scale application, make optimal use of resources and build sustainable and comprehensive capacity for research and development in partner countries.

Overall, there is a need for more research in areas such as health systems, epidemiology, behavioural change communication, health delivery as well as operational and intervention research. In relation to the European research area for poverty-related diseases, there is a need for better coordination between the EU and other donor countries to bring the EU's work fully into line with other global efforts.

Participants took note of the following conclusions and recommendations of the "Challenges for the Future: Research on HIV/AIDS, Malaria and Tuberculosis" conference, which provide guidance for the future directions and priorities of the EC Framework Programme on the three diseases in the context of the European Programme for Action:

- In the area of basic and clinical research, there is a need to move current leads forward, but also for renewed attention to basic research in terms of identifying/developing:

  – new drug candidates and targets; new vaccine antigens and adjuvants; alternative diagnostics and biomarkers;

  – better understanding of the links between biology, immunology and latency;

  – more intelligent design of protective vaccines, curative drugs and 100% reliable diagnostics and markers of disease, protection and latency.

- There is a strong need to strengthen intervention and operational research, and improve the evidence base through clinical, epidemiological and analytical studies, especially related to vector biology and control for malaria and other endemic infectious diseases, treatment impact on HIV transmission, and sustainable scaling up of strategic health interventions;

- Within the European research area for poverty-related diseases, there is a need to intensify coordination and collaboration between the Commission, the Member States and other donor countries and development cooperation;

- In the area of financing, there is a need for more flexible co-funding of joint programmes, more transparency and better rationality of calls for research proposals, an appropriate balance between support for large networks and support focused on innovation;

- Efforts should be made to ensure integration of new Member States in research programmes and to link the EU with global networks;

- It is of critical importance to ensure that both capacity building and research are strengthened in developing countries;

- The EU should jointly develop a coherent and comprehensive health and development research agenda aiming:

  – to intensify research on prevention, treatment, transmission and public health research with adequate balance between basic research, translational research and epidemiology;

  – to bring the work of the EU fully into line with other global efforts;

  – to recognise and reflect the importance of the European and Developing Countries Clinical Trials Partnership and product development partnerships.

Promoting integrated and comprehensive care and support for people living with the three diseases

While access to treatment is expanding, major gaps remain in the provision of care and support for people living with the three diseases and their families, in particular children. It is estimated that twelve million children under eighteen years have lost one or both parents to AIDS in sub-Saharan Africa, yet in eleven countries with high HIV prevalence only fifteen percent of households caring for orphans receive support from outside their communities.[44]

As more people gain access to antiretroviral treatment, HIV is changing from being a fatal disease to a chronic condition, requiring new forms of care and support services on a lifelong basis for the growing number of people living with HIV and their families. Comprehensive care and support should be based on a family and community approach, and should include the domains of psychosocial support, sexual and reproductive health and rights, clinical care, social and economic support, nutrition support, human rights and legal support, support for children, families and communities affected by the three diseases.

Under-funding of care and support services has left the bulk of caregiving in the hands of poor communities, especially women and girls. In this context public and community-based care services should be strengthened to alleviate the demands made on women and girls to provide unpaid care services, and resource allocations should be increased to strengthen and support home-based care providers. The well-being and support of carers must also be addressed, including carers' exposure to infections, particularly TB.

There is an urgent need for better integration of approaches and services to address co-infections such as HIV, TB and hepatitis C, and for better collaboration and clear systems of referral between the public and private health sectors, community home-based care programmes and care providers in the home to ensure a continuum of care and support.

TB, and increasingly in its multidrug-resistant and extensively drug-resistant forms, represents the leading cause of death for people living with HIV. Urgent action is required to scale up access to integrated and high-quality services for TB/HIV care, including diagnosis, treatment, preventive therapy, and infection control.

Participants wanted to see more being done to ensure integrated and comprehensive care and support for people living with the three diseases and made the following specific

[44] 2008 UN Secretary General's report on Progress towards achieving Universal Access.

recommendations for consideration by the Commission and the Member States in the context of the Programme for Action:

- to reinforce policy dialogue with countries to promote an increased focus on care and support through the preparation of toolkits/guidelines for policy dialogue and sharing of expertise with partner countries to ensure the inclusion of comprehensive care and support in relevant national plans and policies;

- to ensure implementation of workplace policies on HIV, TB and malaria for health promotion and disease prevention among staff and to ensure that staff living with HIV, TB and malaria and their families are fully protected and enjoy the benefits of social security programmes and occupational schemes;

- aiming to strengthen government and donor technical and financial support for community care, the Commission and the Member States should support development of research capacity in partner countries to document and disseminate evidence-based good practices;

- to actively promote integration of HIV/AIDS and TB services and programmes at national and subnational levels as a priority in health system strengthening;

- to ensure technical support, capacity building and financing for development and implementation of policies on comprehensive care and support, including 'care for carers' (financial compensation schemes for community carers), cash transfers and social protection programmes for the most vulnerable populations, improved care and support for orphans and vulnerable children in terms of protection from abuse and access to education, social welfare and legal protection services, and capacity building for community–based organisations and networks of people living with the three diseases;

- to engage in sector and policy dialogue on ways to improve school attendance of children affected by HIV/AIDS; support initiatives to increase treatment literacy for people on treatment and within communities; and provide technical support and guidance to increase access to legal support and advice services for people affected by the three diseases.

Accelerating comprehensive HIV prevention

For every two persons gaining access to treatment, five more become newly infected with HIV. Accelerated prevention efforts can help avoid the human and social costs associated with lifelong HIV infection and are critical to the achievement of MDG 6. Scaling up prevention can maintain universal access to treatment as a realistic and sustainable goal, and ensure effective use of the great increase in financing.

The high rates of HIV transmission result largely from failure to make accessible the available and effective prevention strategies and tools, and from poor coverage of HIV prevention programmes. There is strong evidence of the effectiveness of sustained, comprehensive and gender-sensitive prevention programmes which identify and address the local realities of the epidemics[45].

[45] Based on the principles promoted by UNAIDS, "Know Your epidemic and your current response – match and prioritize the response".

Behavioural change communication, sexual education programmes and large-scale condom programmes are crucial to reduce the risk for the large numbers of young people who are sexually active at an early age, are not monogamous, and do not use condoms regularly. Scaling up prevention of mother-to-child transmission can effectively and dramatically reduce the number of children infected with HIV.

Although prevention programmes must be made available to all, steps must be taken to ensure that specialised and focused prevention programmes are developed among key populations at higher risk of exposure to HIV. Sex workers, men who have sex with men, injecting drug users and prisoners tend to have a higher prevalence of HIV infection than the general population, because they engage in behaviour that puts them at higher risk of becoming infected and are among the most marginalised and discriminated-against populations in society.

In countries with low-level and concentrated epidemics, well-designed and adequately funded HIV prevention programmes among these populations have proved decisive in slowing or even stopping the epidemic in its tracks. Countries with generalised epidemics that place a high priority on HIV programming for these populations will ensure the most effective use of resources.

Many other populations are also vulnerable to HIV and their needs as regards prevention should also be addressed. These key populations include women and girls, children and orphans, young people, indigenous people, migrants and mobile workers, peacekeepers, health workers, refugees and internally displaced people. Furthermore, there is a need to include people living with HIV as key partners in HIV prevention efforts, and to address the specific prevention needs of people with disabilities.

The hyperendemic epidemics in countries in southern Africa require exceptional efforts and resources to mobilise entire communities to change their sexual behaviour as well as social norms.

All sexually active adults must be considered at risk of HIV infection and reached by nationwide promotion of behavioural change, including male and female condom use, delayed sexual debut, abstinence and partner limitation along with programmes on gender equality, stigma, discrimination, etc.

All modes of unsafe behaviour must be addressed regardless of the social sensitivities or political difficulties involved, including by challenging gender norms and stereotypes that promote unsafe behaviour; campaigns raising awareness of the risks of multiple, concurrent partnerships and intergenerational sex; campaigns and laws against sexual coercion and gender-based violence along with concerted efforts to ensure the that young people, especially young women and girls, are protected from all forms of sexual exploitation. Key populations such as men who have sex with men, injecting drug users and sex workers should also in hyperepidemic countries be included in the comprehensive prevention response.

Universal access to provider-initiated HIV testing and counselling is needed in healthcare settings, complementing client-initiated counselling and testing services. Access to services for prevention of mother-to-child transmission, sexual and reproductive health and rights, TB screening, preventive therapy and treatment, and "positive prevention" counselling is crucial to address the needs of the large and growing number of people living with HIV.

Continued, longer-term investment and product development partnerships to accelerate research, development and availability of new preventive approaches and technologies such as vaccines, microbicides, female condoms, pre-exposure treatment and 'treatment for prevention'[46] remain of critical importance. The progressive expansion of new evidence-based approaches such as male circumcision[47] should be carefully monitored to ensure rights-based implementation and to deal with possible adverse consequences such as risk compensation.

The EU is particularly well placed to take a global lead in advocating and supporting scientifically sound and right-based prevention approaches in sensitive areas of sexuality, gender, and drug use, including evidence-based and comprehensive sexuality education, addressing the gaps in male and female condom programming, applying the full set of effective harm reduction methods in relation to HIV and injecting drug use, and supporting HIV prevention among men who have sex with men.

Referring to the EU as a 'sleeping giant', the participants called upon it to lead by example, unleash its full potential and comparative advantages, overcome consensus-seeking architectural constraints and take the major opportunity to demonstrate proactive global leadership through:

- a strong and bold EU stand in international fora to support evidence-, rights- and gender-based prevention approaches such as harm reduction for injecting drug users, joint programming on HIV prevention and sexual and reproductive health and rights, male and female condom programming, and more financing for prevention among the most at risk populations;

- EU action to actively oppose and confront groups and countries which promote ideological approaches that are not based on evidence such as criminalisation of sexual transmission and approaches violating human rights of drug users;

- EU flagship programmes and initiatives on prevention and reduction of stigma and discrimination including (through high-level political commitments) support for comprehensive and appropriately-funded, evidence-based prevention interventions;

- greater engagement in policy dialogue and collaboration with ACP countries to strengthen leadership and commitment to prevention, and to ensure that national AIDS strategies and programmes:

  – become based on evidence and 'Know Your Epidemic';

  – tackle stigma and discrimination;

  – support prevention amongst men who have sex with men, sex workers, injecting drug users and prisoners;

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[46] The preventive impact of reduced viral load as a result of scaling up towards universal access to treatment.

[47] WHO/UNAIDS recommend access to safe male circumcision to be progressively expanded in countries with a hyperendemic situation, with priority given to adolescents and young men.

- the Commission overseeing a concerted EU effort where Member States take lead roles in specific areas, with strong and better leadership of key agencies such as UNAIDS, especially on stigma and discrimination, and support for relevant organisations such as the Global Network of People Living with HIV and the International Community of Women Living with HIV;

- linking HIV, malaria and TB programmes, as well as prevention, treatment, care and support, including 'positive prevention' and services on sexual and reproductive health and rights for people living with the three diseases;

- support for research on how to maximise impact of behavioural change and communication programmes, coupled with sustainable and longer-term commitment to support research and development in new prevention technologies.

Human rights and HIV/AIDS, malaria and tuberculosis

Human rights remain essential for the global response to HIV/AIDS, malaria and tuberculosis, and are recognised in the European Consensus on Development as a cross-cutting issue, which should be mainstreamed in all areas of development cooperation, including efforts to confront HIV/AIDS, malaria and tuberculosis[48].

There are strong and inextricable links between human rights and HIV, as human rights infringements are fuelling HIV transmission in women and among vulnerable and marginalised groups such as men who have sex with men, injecting drug users and sexworkers. Such infringements include sexual violence and coercion experienced by women and girls, denial of the right of young people to information on HIV transmission, dismissals of staff found to be HIV-positive and travel restrictions for people living with HIV.

Draconian and discriminatory legislation related to homosexuality, injecting drug use and sexworkers remains a major impediment to effective HIV/AIDS programmes in many countries. The current trend of criminalisation of HIV transmission, where an increasing number of countries are broadly applying criminal law to people living with HIV who transmit or expose others to HIV infection, may neither achieve criminal justice nor prevent further infections. On the contrary, it may risk undermining public health, exacerbating stigma and discrimination, jeopardising HIV prevention strategies currently in place, and compromising basic civil rights such as the right to privacy, especially among the most vulnerable.

While anyone can contract TB, the disease thrives among the most vulnerable – the most marginalised, discriminated-against populations, and people living in poverty. Migrant and refugees, prisoners, substance users, the homeless and people living with HIV are among the groups most vulnerable to TB. People with TB often suffer from discrimination and stigma, rejection and social isolation, which in turn perpetuates misunderstanding about the epidemic and prevents proper treatment.

The failure of many countries to ensure access to prevention, treatment, care and support for the groups most susceptible to HIV/AIDS, malaria and tuberculosis represents a serious

[48] A Communication on Dealing with Cross-Cutting Issues in EU Development Policy is currently in preparation, and will also address HIV/AIDS mainstreaming in greater detail.

mismanagement of resources and a failure to respect fundamental human rights, including the right to health[49]. In addition, many countries still fail to address the stigma experienced by people affected by the diseases and do not ensure their meaningful involvement, which is of crucial importance for effective responses.

People with disabilities are often deprived of their right to services for prevention, treatment, care and support meeting their specific needs. In view of the particular vulnerability of children and pregnant women to malaria, more efforts are required to protect the health rights of children and women by scaling up access to malaria prevention and treatment interventions.

This situation underlines the urgency of EU collective action and systematic approaches to promote full adherence to human rights and rights-based approaches to HIV/AIDS, malaria and tuberculosis in the framework of the Programme for Action. Considering the EU's weight as an international partner in development, its common values and strong track record on human rights, the EU has a central and vital role to play as a protector, catalyst and a driver of change globally with regard to advancing a human rights agenda for HIV/AIDS, malaria and tuberculosis.

Participants called upon the EU to assume a global leadership role in promoting full protection of human rights, considering its strong track record on human rights, and requested the European Commission to act as a protector, catalyst and driver of change for concerted efforts within the EU and globally in advancing the human rights agenda for HIV/AIDS, malaria and tuberculosis.

They made the following specific recommendations for developing a more systematic and coherent EU strategy to advance human rights and rights-based approaches in the context of the Programme for Action:

- to develop a mechanism for sharing of best practices among EU Member States in advancing human rights and promoting rights-based approaches to HIV/AIDS, malaria and tuberculosis;

- to break the silence and engage in a strong, concerted and inclusive policy dialogue on human rights with partner countries and international partners, paying particular attention to the right to health (universal access), violence against women, country-level indicators/bench marks for the reduction of HIV-related stigma, HIV/AIDS workplace policies and lifting of travel restrictions;

- to develop joint guidelines and an effective division of labour among Member States to address human rights in the policy dialogue;

- to ensure targeted funding of HIV prevention measures and anti-stigma and discrimination interventions for the most at risk populations;

[49] As stipulated by international human rights agreements such as Article 12 of the Universal Declaration of Human Rights and Article 12 of the International Covenant on Economic, Social and Cultural Rights.

- to support capacity building and fora to facilitate civil society involvement and greater involvement of people living with HIV/AIDS, malaria and tuberculosis in national planning processes;

- to ensure that human rights issues related to the three diseases and the creation of a supportive legal and policy environment are reflected and addressed in Country Strategy Papers and national health and HIV plans;

- to review and strengthen the effectiveness of budget support and other financing instruments in relation to the needs of groups most at risk and the response to HIV/AIDS, malaria and TB in general;

- to attend to the needs and human rights of people living with malaria and tuberculosis, displaced people, refugees (including in relation to mandatory testing for HIV), people with disabilities, orphans and vulnerable children.

Gender and HIV/AIDS, malaria and TB

As stated in the European Consensus on Development, gender equality is a cross-cutting issue, and gender aspects should be addressed in all areas of development cooperation, including efforts to confront HIV/AIDS, malaria and TB.

The April 2007 Council Conclusions on HIV/AIDS - Recently Emerging Issues, and May 2007 Council Conclusions on Gender Equality and Women's Empowerment in Development Cooperation underline the strong link between gender and AIDS. Gender inequality is a major driver of the epidemic, particularly in relation to issues of violence, economic dependence, intergenerational and transactional sex and multiple concurrent partnerships. Nearly sixty percent of all adults living with HIV in Southern Africa are women, and among young people (15-24 years) living with HIV, nearly three out of four are female. There is limited access to prevention information, commodities and services for prevention, and care and support which work for women. Women and girls are not only disproportionally affected by HIV/AIDS, they also provide the backbone of family and community care and support for people living with HIV and orphans.

Progress in addressing gender issues and HIV/AIDS remains severely hampered by a number of constraints. At government level, there is often weak leadership and limited capacity and coordination on gender equality issues. There is an abundance of policy statements and good projects, but actions lack the scale and intensity required to impact the epidemic. There is little willingness to invest in and strengthen efforts to empower and build capacity of women's groups.

Pregnant women are the main adult group at risk for malaria, and have a fourfold higher average risk of suffering from malaria due to immune deficiency during pregnancy. With an estimated 10 000 pregnant women dying each year from falciparum malaria, malaria is the leading indirect cause of maternal mortality and has many serious adverse health effects for mothers and infants.

Malaria in pregnancy can be effectively addressed by ensuring provision of long-lasting insecticidal nets and intermittent preventive therapy to the mothers, but coverage remains limited. According to a 2006 survey in 18 African countries, only 27% of pregnant women

slept under a bednet, and only 18% of women received preventive therapy during pregnancy, the lowest coverage of all recommended interventions during pregnancy.

Pregnant women are also particularly vulnerable to the potential lethal consequences of dual infection with HIV and malaria. HIV-infected pregnant women are more likely to develop clinical malaria, and HIV infection reduces the effectiveness of malaria treatment. Conversely, malaria increases the load of the HIV virus and may contribute to disease progression and increased HIV transmission.

For effective TB control it is important to identify and overcome gender-related barriers. Poor men and poor women each face different barriers in different contexts, which need to be assessed and addressed locally. Women, particularly in poor or remote populations, very often consider their disease symptoms in terms of their reproductive health. They may therefore seek reproductive health services where awareness of TB may be low. Men tend to consider their disease symptoms in terms of their ability to perform manual labour. They may therefore be very reluctant or unable to seek health services until very ill. In such cases it may be necessary to take diagnostic and treatment services to the places where poor men work.

Given that more than 75% of HIV infections are acquired sexually or through transmission during pregnancy, labour, delivery or breastfeeding, that women are particularly vulnerable to HIV and malaria, and that women require better access to TB screening and treatment, there is an obvious and urgent need to promote women-friendly and pro-poor health systems, which link and integrate programmes and services for HIV/AIDS, malaria and TB in the context of expanded access to services for sexual and reproductive health and rights, including antenatal care. The EU can play an important role in promoting expanded access to such integrated services through policy dialogue at all levels and technical support.

The EU may consider how to take a stronger stance through collective action to address the causes that make women vulnerable to HIV/ADS, malaria and TB, including efforts to engage men and boys, change harmful gender norms, role behaviour and norms about sexuality that perpetuate gender inequality and violence against women, and to ensure women's access to integrated programmes and services for HIV/AIDS, malaria, TB and sexual and reproductive health and rights.

Integration of programming and service delivery in the context of health system strengthening

There is growing evidence and recognition that further progress in confronting HIV/AIDS, malaria and tuberculosis will depend substantially on the strengthening of health systems, especially in Africa, including through better integration of disease-specific programming and service delivery in public, private and informal sectors of the health system. Such integrated services would, for example, include services for HIV/AIDS, malaria, tuberculosis, sexual and reproductive health and rights; and integrated management of childhood illnesses.

This integration should be context-specific, oriented towards concrete results in response to the needs of affected people and communities, and closely monitored to identify and address adverse consequences. In accordance with the primary health care principles of equity in access, there is a need for substantial additional resources in support of health system strengthening and basic health services, especially at district level.

Such additional financing may become available from internal sources (fiscal space, tax revenues, innovative financing, health insurance schemes, private/public partnerships, community involvement and participation) and external sources (ODA, soft loans from financial institutions, and innovative financing mechanisms)[50]. It will require a shifting of instruments from project financing towards programme and budget support.

Country leadership, ownership and capacity for planning and management constitute the key to better integration of disease control and health system approaches through donor harmonisation and alignment with country priorities and processes, e.g. in the framework of the International Health Partnership.

The participants recognised the role of the EU in promoting and supporting integration of programming and service delivery in the context of health system strengthening, with its strong commitment to the principles of aid effectiveness and its policy basis of health system strengthening.

They also noted the significant increase in international health financing which has been mobilised for HIV/AIDS, malaria and tuberculosis, and, embracing the primary health care principles of equity in access, they underlined the need for substantial additional resources in support of health system strengthening and basic health services, especially at district level.

They also called for strengthening of systems beyond the health sector, such as education, social protection and community systems, and noted that effective responses to HIV/AIDS have to be broad-based and multisectoral.

They stressed, consequently, that effective integration of HIV/AIDS services in the context of health system strengthening does not imply a re-medicalisation of the AIDS response. On the contrary, participants saw the AIDS response as an agent for change and called for health system reforms which would fully recognise, support and draw in resources of the informal sector/civil society, communities, volunteers and the private sector.

In this context, participants suggested that the EU should develop mechanisms to ensure the ongoing participation of civil society, including vulnerable and marginalised groups, in the governance, coordination and prioritisation of funding allocations and in monitoring and evaluating the implementation of national health plans.

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[50] The Commission is currently preparing a new *Communication on Social Protection in Health and Reform of the Financing of Health Systems in Developing Countries*, expected to be adopted in autumnl 2009.

Financing

Participants took note of the significant increase in financing for HIV/AIDS, malaria and tuberculosis, which has occurred in recent years in the context of increased total financing for health. They noted that there does not appear to be any indication of a 'crowding out' effect for health in general and other basic health services, although there has been a drop on financing for the area of sexual and reproductive health and rights.

As stated in the Programme for Action, the EU collectively has provided contributions to help fill the financing gaps and meet the MDG6, which reflects Europe's weight and importance as an international partner in development. The EU is providing the majority of funds for the Global Fund, and the majority of earmarked HIV/AIDS financing as reported to the OECD/DAC.

The participants recognised, however, the challenges of maintaining and verifying the EU's position as the dominant donor for the three diseases in the future, in view of the plans of the US and other emerging donors to scale up earmarked support, the impact of the financial crisis, and the partial transition of the Commission and other EU donors from earmarked project financing to budget support modalities based on results management. However, the commitment reiterated in the EU Agenda for Action on the MDGs to significantly scale up ODA, and to ensure resources for health, including the three diseases, signals the potential for a continued strong leadership role of the EU in financing.

In spite of the increased resources, participants noted that, according to UNAIDS, Roll Back Malaria and the STOP TB Partnership/WHO, significant global financing gaps remain in regards to scaling up towards universal access for HIV prevention, treatment, care and support and achieving the targets both of the MDG6 and of the Global Malaria Action Plan and the Global Plan to STOP TB.

They also noted, however, that only with the Global Fund round 8 have countries with successful proposals hit the ceiling of available funding for the first time and have been requested to make a 10% cut in their budgets. This may only signal a lack of ambitious proposals in the past, and does not in itself indicate that sufficient financing is available for effective country responses. However, in this situation there is a clear need to pay more attention to country-level financing gaps and resourcing strategies.

They stressed that in the context of the financial crisis it is imperative to ensure effective use of financial resources through synergy and integrated approaches, which may lower transaction costs, efforts to ensure that national strategies address 'the right people and the right approaches', and other financing strategies such as price reductions and innovative financing mechanisms.

Reviewing the European Community's financing instruments, they noted that specific financing in support of country strategies to confront HIV/AIDS, malaria and tuberculosis is channelled through the Global Fund. They also observed that only 3.5% of the 10th European Development Fund will be allocated to Country Strategy Papers as health focal sector support. In addition, limited contributions may be available from the non-state actor budget line and through HIV/AIDS mainstreaming in focal sectors.

The participants recognised the potentially important contributions of general budget support and the MDG contract to the development of country-led and sustainable responses to the three diseases. Such financing modalities provide longer-term and predictable financing, strengthen country ownership and allows countries to cover recurrent costs such as salaries of health workers and teachers as well as buildings and infrastructure costs.

Participants, however, recommended the Commission and the Member States to closely monitor and address potential gaps, challenges and shortcomings in budget support approaches, in particular:

- to consider responses to the three diseases and health system strengthening as priorities in defining indicators and in political and policy dialogue related to budget support, especially in countries with a high prevalence/burden or rapidly emerging epidemics;

- to strengthen the capacity of the Commission and the Member States for policy dialogue through competence building and implementation of an effective division of labour;

- to strengthen the capacity of partner countries to develop, manage and implement robust and evidence-based national plans for health and HIV/AIDS, e.g. in the context of the International Health Partnership;

- to ensure the full involvement of people living with the three diseases and civil society in the development, implementation, monitoring and evaluation of Country Strategy Papers, proposals for the Global Fund and national plans for health and HIV/AIDS, and to ensure oversight of civil society and national parliaments;

- to consider additional and more flexible financing mechanisms, and, where needed, targeted funding for work with populations most at risk or to address stigma and discrimination.

Discussing the role of the Global Fund as a financing entity, the participants recommended to Delegations that they should:

- take an active role and responsibility in strengthening country-level coordination among donors;

- ensure technical assistance through country-led need assessment and technical support planning;

- be actively engaged in the Country Coordinating Mechanisms;

- promote synergy between Global Fund projects and budget support modalities.

EU collective action

There was a strong consensus among participants about Europe's significant role and contribution to the global response to the three diseases, but also recognition that the full potential of the EU - Member States and the Commission - is far from being realised. In this respect the EU was referred to as a "sleeping giant" in comparison with other global players.

In the global context the EU may have a specific role and comparative advantages in the areas of:

- promoting principles of social protection and equity in health;
- strengthening of legal frameworks, gender equality and human rights;
- policy dialogue to better link and address the three diseases and social drivers in the wider context of socio-economic development;
- choice of financing instruments, which allow long-term predictable financing and alignment with partner country priorities and processes.

Participants recognised that the full realisation of the potential of the EU in confronting HIV/AIDS, malaria and tuberculosis will require a move towards more coordinated and concerted EU action at country and global level, including through:

- a common European voice and enhanced capacity for policy dialogue at global and country level;
- more focus on capacity building within Member States and the Commission as well as with partner countries and civil society, including through networks such as the European ESTHER Alliance and the European and Developing Countries Clinical Trials Partnership;
- support for meaningful engagement of civil society at all levels and in all stages of the responses to the three diseases;
- development, implementation and monitoring of an effective division of labour among EU Member States and the Commission;
- development of more flexible financing instruments in support of bottom up initiatives, civil society engagement and work with vulnerable groups.

In this context participants agreed to explore the possibility of creating specific task forces or 'EU action teams' in priority areas such as access to drugs, comprehensive care and support, prevention, and human rights. The role of these 'EU action teams' would be to consider and plan how to take forward, implement and develop further the recommended actions and approaches. Each team would be led by one of the Member States or the Commission, and would include other interested Member States, civil society organisations, public-private partnerships, UN and other international organisations.