COMMISSION OF THE EUROPEAN COMMUNITIES



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

A European Programme for Action to Confront HIV/AIDS, Malaria and Tuberculosis through External Action (2007-2011)

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#### 1. THE POLICY CONTEXT AND SCOPE OF THE PROGRAMME FOR ACTION

In October 2004, the European Commission (EC) adopted a Communication entitled "A Coherent European Policy Framework for External Action to Confront HIV/AIDS, Malaria and Tuberculosis (TB)" – COM(2004) 726 final<sup>1</sup> This was prepared based on a second progress report on the "EC Programme for Action: Accelerated action on HIV/AIDS, malaria and tuberculosis in the context of poverty reduction" that highlighted key results and areas where the EC needs to reinforce or take further action.<sup>2</sup>

The Council welcomed the policy framework, urged the EC and the EU Member States (EU MSs) to enhance their cooperation and coordination to confront the three diseases and requested the Commission to present a **Programme for Action (PfA)**.<sup>3</sup>

This PfA responds to the Council Conclusions on harmonisation,<sup>4</sup> by proposing **collective EU (EC and EU MSs) action to support country-lead programmes** to confront the three diseases<sup>5</sup> and **action at global level** in selected areas where the EU can add value.

The PfA will cover **developing and middle-income countries**. It is based on the general principle of benefiting from best practices and experience in the external actions and from the relevant Community policies. Later this year, the Commission will adopt a Communication on how to confront HIV/AIDS within the EU and in the neighbouring countries. Country strategy programmes (CSPs) and European Neighbourhood Policy Action Plans will define an appropriate strategy and set of actions.

**The response to HIV/AIDS, malaria and TB is still underfunded**. Additional funds will mainly have to come from external sources – public and private. The projected annual external resource gap will continue to grow and is estimated to reach US\$14.9 billion by 2007 – US\$11.5 billion for HIV/AIDS, US\$2.6 billion for malaria, and US\$0.8 billion for TB.<sup>6</sup> These figures only partly include resources for strengthening of the health system in partner countries, which is a prerequisite for

<sup>&</sup>lt;sup>1</sup> COM(2004) 726 final

<sup>&</sup>lt;sup>2</sup> SEC(2004) 1326

<sup>&</sup>lt;sup>3</sup> Council Conclusions of 23 November 2004 (doc. 15158/04)

<sup>&</sup>lt;sup>4</sup> Council Conclusions of 24 November 2004 (doc. 15159/04)

<sup>&</sup>lt;sup>5</sup> References to common action in countries are made under action points 1, 3, 5, 6, 9, 10, 13, 15, 16 and 18 and to common action at global level under action points 19, 23, 26, 27, 28, 29 and 30.

<sup>&</sup>lt;sup>6</sup> The Global Fund, Addressing HIV/AIDS, Malaria and Tuberculosis: The Resource Needs of the Global Fund 2005-2007, 2005

progress, and the need for further investment in the research and development of new tools and interventions.

A major objective of this PfA is to **increase efforts to scale up interventions** that have shown results. The EU should aim for a contribution that helps to fill the financing gap for the three diseases and meet the Millennium Development Goal (MDG) 6 and that reflects Europe's weight and importance as an international partner in development.

#### 2. EU ACTIONS AT COUNTRY LEVEL

Country leadership is the key to confront these diseases and their consequences through broad-based strategies. The participation of civil society – including people affected by the diseases – and partnership with public and private stakeholders, donors and international agencies are essential for scaling up efforts that lead to success. (See Annex 1.)

# 2.1. Political and policy dialogue to support country-led strategies to confront the three diseases

- (1) The EU will reinforce its **political dialogue** with countries on key issues relating to leadership and governance. The dialogue will address the need for a comprehensive strategy with an appropriate balance between prevention, treatment and care, depending on the situation in each country. Other subjects for dialogue include **children's rights, women's rights**, and sexual and reproductive health and rights. The dialogue should also address the needs of **orphans and vulnerable children.** The "Framework" adopted in July 2004 should be used by EC staff for this purpose.<sup>7</sup> The dialogue should address **other vulnerable groups, such as injecting drug users, prisoners, elderly people, people with disabilities, refugees and internally displaced populations**, as well as issues around **stigma and discrimination**. The application of the Greater Involvement of People Living with AIDS (GIPA) principle needs to be extended to the three diseases.<sup>8</sup>
- (2) To help implement policy, the EC will prepare a **toolkit** for Delegations and services which will include guidelines for policy dialogue, programming guidelines offering advice concerning indicators and monitoring of country efforts, and reference documents. It will be reviewed and updated periodically. Awareness raising and training will be provided for EC staff.
- (3) The EU will **share expertise** to ensure that the EU collectively has a critical mass of expertise to play a constructive role in the policy and technical dialogue, including in PRSP reviews, sector policy dialogue and in the Country Coordinating Mechanisms (CCMs) of the Global Fund. In countries where the EC does not have specific expertise, Delegations will work actively with EU MS experts and other partners, including UN agencies. Such

<sup>&</sup>lt;sup>7</sup> The Framework for the Protection, Care and Support of Orphans and Vulnerable Children Living in a World with HIV and AIDS, July 2004

<sup>&</sup>lt;sup>8</sup> For further information on the GIPA principle, see UNAIDS, 2004 Report on the Global AIDS Epidemic

arrangements may include shared programming, monitoring and reporting, and will make optimum use of EU regional expertise.

(4) EC Delegations will promote **health and disease prevention amongst staff**, particularly for HIV/AIDS, building on the ILO Code of Practice on HIV/AIDS, while also addressing relevant issues concerning TB and malaria. In staff training, Delegations will be encouraged to use the training manual developed by ILO.<sup>9</sup> Delegations will assist and support staff and their families through adequate social protection schemes.

# 2.2. Capacity building to confront the three diseases

- (5) The EU will **map TA resources** available to countries with a view to developing a **plan for shared TA**, governed by a code of conduct for collective action. Such assistance should be provided, e.g. by UN agencies, at the request of broad-based national or regional bodies such as the CCMs and sector coordination platforms.
- (6) The EU will support the case for **health** being treated as **an exceptional case** in public sector reform programmes, increasing public spending to allocate a sufficient share of public expenditure to health (e.g. the 15% Abuja commitment for African countries), and will maintain its dialogue with the Bretton Woods institutions on the appropriate fiscal space for action on the three diseases.
- (7)The EC will strengthen national programmes to build clinical research capacity through the European and Developing Countries Clinical Trials Partnership (EDCTP). General support for life science research will be provided through the 7<sup>th</sup> Framework Programme for Research and Technological Development (FP7). The EC will also support synergy in the approach to health research (EDCTP) and health care activities at country level, in a selected number of partner countries. Synergies between capacity building for research and training of staff for health care should be fully explored. The EDCTP should play an integrating role by contributing to national and regional human resource plans for clinical research. Further efforts are needed to support complementary health care activities, including improving local or regional health services at clinical trials sites, reinforcement of human resources, building of new infrastructures such as hospital wards, and ensuring access to medical care coverage for the population during clinical trials.
- (8) The EC will provide further technical support to improve countries' capacities to develop pharmaceutical policy, including through its strategic partnership with WHO. The EC will encourage WHO to identify key issues that pharmaceutical policy needs to address.
- (9) The EU will support countries in developing sound and efficient procurement policies and practices for pharmaceutical products and

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http://www.ilo.org/public/english/protection/trav/aids/code/codemain.htm

**commodities**, such as condoms, long-lasting insecticide-treated bed nets (LL-ITNs) and anti-retrovirals.

- (10) The EU will strive to **exploit mutual synergies** between programmes and measures to implement the Convention on the Rights of the Child, the Beijing agenda on gender equality, the Cairo agenda on sexual and reproductive health and rights (SRHR), and UNGASS and other UN strategies and programmes to confront HIV/AIDS, malaria and TB.
- (11) In countries where the EC supports the education sector, the EC will pursue through sector and policy dialogue the inclusion of lifeskill education and **safe schools for children**, especially girls, to increase protection against rape, pregnancy or infection with HIV/AIDS and other sexually transmitted diseases (STDs). The EC will help to establish and support codes of conduct, training of school staff, and community protection mechanisms.
- (12) In emergency situations and protracted crises, the EC Humanitarian Office (ECHO) will help to reduce the transmission of the three diseases, and the human distress and mortality they cause by mainstreaming basic HIV/AIDS preventive and palliative measures, both in its humanitarian programmes and via its implementing partners. This will include awareness-raising, information, training and the provision of prevention tools for humanitarian workers. Preventive and curative measures against malaria and TB already form an integral part of the humanitarian response supported by ECHO. Consultations on the three diseases with other donors and EC departments will become an essential part of the Linking Relief, Rehabilitation and Development (LRRD) process.
- (13) To help national initiatives to counter rape, violence against women, childtrafficking and the spread of the three diseases in conflict-resolution, peacekeeping, and post-conflict situations, the EU will ensure that **guidelines** are developed and **awareness-raising**, **information**, **training and prevention tools are provided for participants in such operations**, in line with the UN Security Council Resolution of July 2000.
- (14) The EC will **analyse the impact of HIV/AIDS, malaria and TB on human security**, e.g. in terms of access to basic services and stability at state-level, including the impact of these diseases on governance and institutional performance. The results will feed into a response strategy to support countries affected.
- (15) The EU will support countries in collecting and monitoring sex- and agedisaggregated data on HIV/AIDS, malaria and TB. The EC will promote the use of indicators that can be meaningfully monitored on an annual basis through national health information systems, including through behavioural surveillance surveys. In line with the "3 Ones", as extended to malaria and TB, and ongoing efforts at donor harmonisation around country-led strategies, the EU will work with countries, WHO (building further on the Second Generation Surveillance Project, the Health Metrics Network, and the Roll-Back Malaria (RBM) and StopTB partnerships), UNAIDS and the

Global Fund towards joint monitoring and performance assessment based on common indicators and shared reporting.

#### **2.3.** Financial resources to confront the three diseases

- (16) The EU will continue to provide resources to countries for confronting **HIV/AIDS**, malaria and **TB**, to be identified through appropriate mechanisms.
- (17) The EC will use partnerships and specific support to help finance highly costeffective interventions likely to yield rapid results, including:
  - **Targeted distribution of free LL-ITNs** and complementing social marketing strategies which encourage local production capacity
  - **Targeted distribution of free contraceptives** linked to increased investment in health promotion, and building capacity for social marketing
  - Provision of universal free access to voluntary counselling and testing (VCT) and antiretroviral drugs for HIV positive pregnant women.

To achieve maximum impact, these should be delivered as part of a **comprehensive package of interventions**.

(18) The EU will work with countries to address concerns identified in the High Level Forum on Health MDGs and the review of the MDG focus of PRSPs. Despite strong MDG commitments, there has not yet been a significant shift in resources to actions capable of accelerating progress towards the health MDGs. The EC will support further work and action linking national policy commitments to the MDGs more closely with financing decisions to reward investment in evidence-based strategies for accelerating progress towards the MDGs, in particular MDG 6.

#### **3. EU** ACTIONS AT GLOBAL LEVEL

The EC will also undertake action at regional and global level to confront the three diseases, in partnership with EU MSs and other key players. Selected areas for action include affordable pharmaceutical products, regulatory capacity, human resources in the health sector, and research and development of new tools and interventions. Global efforts to promote prevention, treatment and care remain a cornerstone for confronting the three diseases.

(19) The EC will further develop its regional capacity through the use of regional health advisors, with specific focus on the three diseases. Tasks will include setting up a network of EU and partner expertise to exchange experience, share best practice, and promote regional cooperation in the fields of regulatory and procurement capacity.

# 3.1. Affordable and safe pharmaceutical products

- (20) The EC will monitor the implementation and the results of the EC Regulation to avoid trade diversion into the EU of certain key medicines.<sup>10</sup> Through its dialogue with industry, the EC will encourage more companies to register a wide selection of their products under the rules established through the Regulation.
- (21) The EC will promote **price transparency on pharmaceutical products and commodities used to confront the three diseases** by asking countries to publish prices on products purchased by country programmes funded by the EC and by the Global Fund. Prices will be made available on the EC web site facilitating price comparisons, as a way of monitoring the impact of untying of aid.
- (22) The EC will uphold the principles reflected in the 2001 Doha Declaration on TRIPs and public health and in the **August 2003 Decision by the WTO** General Council. The EC has proposed the legislation needed by European companies to issue a compulsory licence in response to the procedure described in the Decision.<sup>11</sup> The EC will monitor the implementation of the August decision by exporting and importing parties, identify bottlenecks and provide assistance to solve them. The EC will actively participate in negotiations with the aim of incorporating the Decision into the TRIPs Agreement through a formal amendment.

# **3.2.** Regulatory capacity and prequalification

- (23) The EC will cooperate with WHO, the European Medicines Agency (EMEA) and interested national regulatory bodies of EU MSs in support of the development of the capacity of national and regional bodies to perform scientific and regulatory tasks with respect to the evaluation and marketing authorisation of pharmaceutical products. This will include, in particular, scientific assistance in the framework of the so-called 'Article 58',<sup>12</sup> plus specific guidelines on key products.
- (24) The EC will help to establish regional cooperation networks of regulatory consultants and **regional schemes of mutual recognition for marketing authorisation**. EC support will include a feasibility study, in cooperation with the African Union (AU) on the setting-up of an African mutual recognition scheme for marketing authorisation. Cooperation should also help to establish **regional centres of regulatory expertise** in countries with potential in this field e.g. Brazil, South Africa and Thailand. The EC is ready to join forces with WHO to help set up an **international advisory committee**

<sup>&</sup>lt;sup>10</sup> Regulation (EC) 953/2003. OJ L 135, 3.6.2003, p.5

<sup>&</sup>lt;sup>11</sup> Proposal for a Regulation of the European Parliament and of the Council on compulsory licensing of patents relating to the manufacture of pharmaceutical products for exports to countries with public health problems. COM(2004) 737

<sup>&</sup>lt;sup>12</sup> Article 58 enables the EMEA to give a scientific opinion, in the context of cooperation with WHO, for the evaluation of certain medicinal products for human use intended exclusively for markets outside the Community. Regulation (EC) No 726/2004 (31 March 2004), Article 58, OJ L 136, 30.4.2004, p. 1

of impartial experts to provide technical, scientific and policy support for partner country regulatory agencies.

(25) The EC will support the **WHO prequalification project** in its efforts to expand the geographical coverage and range of products. In addition to funding, EC support will include the sharing of expertise and human resources, and targeted support for local production initiatives in developing countries to upgrade Good Manufacturing Practices and submit proposals (bioequivalence and stability studies).

### **3.3.** Addressing the human resource crisis for health providers

- (26)The lack of trained health providers undermines efforts to scale up the provision of prevention, treatment and care services. The EU will support a set of innovative responses to the human resource crisis. At regional level, the EC will use its support for the AU and the New Partnership for Africa's Development (NEPAD) to help ensure strong African leadership in the formulation and coordination of a response to the human resource crisis. The aim should be to increase incentives for health workers to remain in or return to developing countries or regions where the need is greatest rather than to create barriers to migration. Actions will include strengthening AU and NEPAD capacity to map the scale of the problem and facilitate regional dialogue on country, regional and global action needed to increase training and to retain and sustain increased human resource capacity. Improved opportunities for research may also help to prevent brain drain. Engaging the local communities in research activities, which could contribute to improving the overall level of health care, will also be encouraged. Strengthened synergy between EC supported research and health resources at local and regional level can further help improving health care.
- (27) By 2006, the EC will present a **policy document on human resources within the broader health context**, which will help to formulate specific measures and thus also have an impact on the implementation of this PfA. This strategy will include a discussion of the following topics:
  - a **European Code for ethical recruitment** practice, drawing upon and learning from experience in EU MSs with voluntary codes;
  - compensation for partner countries (e.g. through taxation by the EU MSs on recruitment) to make up for the recruitment of trained nationals from countries with a human resource crisis;
  - supporting the development of national plans for human resources through policy dialogue on sectors, CSPs and PRSPs; and
  - a Declaration of Global Solidarity, issued by the Council and the EU MSs, stating the key principles and objectives for supporting action on human resources in the health crisis.

# **3.4.** New tools and interventions

- (28)The EC will support the research and development of new tools and interventions through projects designed to accelerate the development of new vaccines, drugs, microbicides and diagnostic tools for resource-poor settings. The EC will encourage the participation of research organisations and institutions from disease-endemic countries in collaborative research projects with European partners. The EC will provide support for the EDCTP while urging European countries, private charities and industry to provide significant funding and expertise for this initiative. In its dialogue with participating countries and companies, the EC will advocate the inclusion of clauses on affordability, intellectual property rights (IPR), manufacturing and regulatory approval. The EC will provide support for social-behavioural research, epidemiology and operational, healthsystems and applied research, and cost projection studies - including community capacity and preparedness to participate in clinical trials and to introduce new tools and interventions rapidly, once developed and approved.
- (29) The EU will undertake studies to **establish a priority list of "pull incentives"** to engage private industry in the research and development of new tools and interventions, based on a cost-benefit analysis and on their feasibility. The studies should, in particular, analyse advanced markets mechanisms, cash premiums, an international financing facility for vaccines, and transferable privileges – such as IPR extensions or fast-track approvals.
- (30) The EC will support a selected number of **public-private partnerships** (**PPPs**), and global initiatives. The aim will be to establish the coordination and synergy that are necessary and the appropriate level of resources required to accelerate R&D efforts, to estimate the health, social and economic benefits that could be derived from the development and use of new diagnostic, preventive and therapeutic technologies, and to prepare communities for the introduction of HIV/AIDS vaccines and microbicides. The EC will enhance cooperation within Europe to ensure the viability and progress of innovative research initiatives towards the development of priority products.

# **3.5.** Strengthened partnerships

The EC will consult and involve a wide group of partners in ongoing dialogue through the **EC Stakeholder Forum** and regional consultations. The Stakeholder Forum will invite representatives of civil society, including people directly affected by the three diseases to enhance their role and voice in the policy dialogue at global level. The involvement of the private sector, including industry (e.g. Private Investors for Africa) and private foundations, remains crucial.

The EC will collaborate with and further support key organisations and global initiatives through effective global partnerships sharing efforts, risks and benefits to translate a common vision into a common voice and common action. The EC will assess the relative merits of working in global partnerships by assessing what the partnership offers in terms of:

- **unique expertise, wide presence in countries, key resources** that make it a particularly useful partner to make EU action more effective and efficient;
- whether the **benefits for the EU outweigh the input** in terms of resources, staff and time; and
- whether the **EC** as an organisation offers the partner **specific comparative advantages** and what the position of EU MSs is towards the potential partner.

In addition to the stakeholders mentioned under 3.4, and based on an assessment of these three criteria, the EC proposes to work with the following partners at global level. WHO (under the EC-WHO strategic partnership) and UNAIDS – are key partners for the EC. These organisations offer both technical expertise, e.g. on pharmaceutical policy, regulatory issues and health monitoring, and disease-specific expertise through RBM and Stop TB. The EC will also cooperate closely with UNFPA to ensure that synergies are explored between initiatives in this field and those focusing on the Cairo agenda, with ILO, under the EC-ILO strategic partnership, and with UNICEF on mother-and-child health and education issues.

#### **3.6.** A strong European voice

The EC has a strong role and responsibility, together with the EU MSs, in terms of establishing, representing and defending the European vision and commitments internationally. Political dialogue with countries is crucial to addressing and defending basic principles and to raising and discussing sensitive issues at the highest political level.

At global level, the EC voice may be due to a formal mandate, e.g. in trade policy, or to the EC taking the initiative or being asked by EU MSs to take on such a role. This is sometimes also the case in UN processes, where it is the EU MSs that are fully represented and have a formal voice. Examples include preparations of UNGASS, follow-up to the MDGs, and UN conferences on gender equality and SRHR – all of which are intimately linked to the policy issues discussed in this PfA. The EC can play a constructive role both by projecting and defending an EU position internationally and by offering non-EU members a credible partner for dialogue. Close cooperation between the EC and EU MSs remains crucial in the UN as well as in the G8 context. The EC also needs to be able to co-fund international conferences and seminars where progress is assessed and new policy and practice discussed.

#### 4. NEXT STEPS

Programming decisions and **budget allocations** with respect to actions proposed in this PfA will be made in accordance with the structure of instruments determined for the next financial perspectives.

EU MSs are invited to work closer together with the EC in taking **specific actions forward at country level**, e.g. sharing expertise, reflecting the EU common vision in policy dialogue, mapping and planning technical assistance for capacity building, and formulating joint measures to support countries in addressing human resource

constraints. The EC will take the decisions required to promote synergy and provide a **coherent response** to the three diseases across relevant policy areas.

The EC will **monitor and report** on the implementation through annual and midterm reviews of country specific instruments, FP7, and monitoring and evaluation mechanisms of the Global Fund. The EC will work towards agreement with partners in countries on the use of one monitoring and evaluation framework with common indicators. In 2008 and 2010, the Commission will present comprehensive progress reports to Parliament and the Council on the implementation, outputs and impact of the PfA.

# Annex 1 – Principles for country strategies to confront the three diseases

Civil society, in particular people infected and affected by the diseases, together with representatives of the social partners and the private sector should be active partners in policy dialogue, priority setting, and the design, implementation and monitoring of strategies.

Strategies should be evidence-based and represent an appropriate policy-mix, including information, prevention (e.g. condoms and LL-ITNs), harm reduction (e.g. needle exchange for injecting drug users), vector control measures against malaria (e.g. environmental and sanitation measures and intra-door residual spraying with DDT), treatment and care, and impact alleviation. Information and prevention remain crucial components of any strategy aiming to halt the spread of HIV/AIDS, malaria and TB. These strategies should also help to increase human security and the protection of human rights – including women's rights and the rights of the child. They should also help to overcome stigma and discrimination among those infected and affected, including groups at higher risk of HIV/AIDS infection e.g. commercial sex workers, men having sex with men, injecting drug users and prisoners, and protect the rights of such people while at the same time providing access to essential services based on equity.

The translation of policies into strategies requires sufficient and predictable financing based on solid costing and gap analyses, adequate allocation of domestic resources according to capacities and topping-up by external aid to support the strategy.

Strategies should be cross-sectoral and be both an integrated part of, and reflected in comprehensive actions for developing health and other social services to improve health outcomes. Synergies should be explored with strategies to promote SRHR and gender equality. All sectors should consider the impact of the three diseases and how their sector can contribute through an appropriate response.

Inclusion of strategies into MDG-based poverty reduction programmes should be promoted in developing countries.

Gender equality should be promoted through these strategies, and reflect the fact that girls and women carry a heavier burden and are affected more often and at an earlier age by HIV/AIDS than men. HIV/AIDS strategies must be designed to address the constraints that make it difficult for girls to use prevention tools, treatment and care services. The role and responsibilities of men in HIV/AIDS prevention should also be highlighted, including in terms of norms and responsible sexual behaviour.

Strategies should reflect the fact that family-based and community-based care often plays a crucial role in alleviating the burden of the disease, including as an alternative to institutional care for orphans and vulnerable children. The age dimension also needs to be taken into account, with a particular focus on children affected by malaria, orphans and vulnerable children affected by HIV/AIDS and elderly people who have higher rates of TB infection (often undiagnosed) and who are also often left to take care of such children and may need support to this end in terms of social protection or allowances. Inheritance and social rights for widows and orphans need to be protected through legislation and put into effective practice.

Strategies should address other specific vulnerable groups, e.g. workers in unhealthy environments, refugees, migrants, internally displaced people, minority communities, and people with disabilities, who are often placed in vulnerable situations.

	ACTION/	PARTNERS	MONITORING AND OUTCOMES
	INITIATIVE		
	COUNTRY ACTION		
1.	Political dialogue	EC	- Political dialogue on key issues relating to leadership, governance, human rights, vulnerable groups,
		EU MSs	and stigma and discrimination.
2.	Develop a toolkit for policy	EC	- Toolkit prepared and distributed to Delegations.
	dialogue, programming and	EU MSs	- Training at HQs organised.
	monitoring for EC/EU	WHO (+UNAIDS, RBM,	- HIV/AIDS, malaria and TB, including the critical issues, raised in the dialogue in more countries;
	delegations; and for awareness	StopTB)	reports by social sector experts.
	raising and training at		- HIV/Malaria/TB analysis, where relevant, included in CSP programming and review exercises.
	headquarters (HQ)		
3.	Sharing health expertise between	EC Delegations, EU MSs	- Mapping of EC/EU health experts.
	EU MSs		- Arrangements for joint working or sharing of EU health expertise.
			- EU health experts present in policy and political dialogue in PRSP, health sector, and disease-specific
			reviews, as reported annually by EC Delegations.
			- Shared situation analysis, programming, monitoring and reporting increasingly used.
			- Development of a joint framework for analysis and reporting.
4.	Social responsibility for EC staff	EU MSs	- Education and prevention programmes in EC delegations.
	and their families	ILO	- Adequate social protection schemes for EC Delegations and RELEX services, which support staff and
			their families affected by the diseases, in line with good practice developed by EU Member State
			development agencies.
5.	Sharing resources for technical	EC	- Plan for shared TA and code of conduct agreed in countries with high presence of EU donors, based
	assistance	EU MSs	on mapping of resource persons.
		WHO (+UNAIDS, RBM,	
		StopTB)	

# Annex 2 – Indicative monitoring framework for actions 2007-2011

	ACTION/	PARTNERS	MONITORING AND OUTCOMES
	INITIATIVE		
6.	Supporting national human resources for health policy and strategies which build HR capacity	EC Delegations (in particular in countries with EC sector or macroeconomic budget support) EU MSs and their health professions councils Dialogue with IMF, AU, NEPAD	<ul> <li>Incentives and strategies developed and supported by the EU to retain health providers and to strengthen research capacities through training of professionals and the creation of more attractive career conditions and perspectives.</li> <li>Bretton Woods institutions acknowledging the exceptional situation in terms of human resources in the health sector and contributing to an enabling environment to address this.</li> </ul>
7.	Building capacity for clinical research	EC EU MSs EDCTP	<ul> <li>Capacity increased for research (social, clinical, operational), including training of human resources, in several African countries with heavy burden for the three diseases and accompanied by adequate institutional capacity strengthening.</li> <li>Support by EC, EU MSs, EDCTP and other global stakeholders for further scientific and technical cooperation between health care and health research, complementing EC supported clinical trials activities.</li> </ul>
8.	Building capacity for pharmaceutical policy	WHO (+UNAIDS, RBM, StopTB)	<ul> <li>Support provided through WHO, including on the following key issues on pharmaceutical policy: , including Multi-Drug Resistant TB; substitution therapy for injecting drug users; affordable, rational and supervised use of relevant malaria treatment, including Artemisinin-based combination therapy; provision of second-line treatment for HIV/AIDS; treatment guidelines for women of reproductive age and children; and guidance on drug quality.</li> <li>Improved and more rational use of pharmaceutical products in developing countries.</li> </ul>
9.	Building capacity for procurement of pharmaceutical products and commodities	WHO (+UNAIDS, RBM, StopTB)	<ul> <li>Prices on pharmaceutical products and SRH commodities published.</li> <li>Lowest prices paid by least developed countries by end of 2011, as seen from prices published.</li> </ul>
10.	Increase synergy between programmes and services on the three diseases and for children's rights and health, and sexual and reproductive health	EC EU MSs	- Child health programmes and SRH services increasingly providing information and preventive commodities for the three diseases.
11.	Making schools safe for children and including prevention of the three diseases in curricula	International organisations, e.g. UNICEF and UNFPA, and teachers and parent organisations	<ul> <li>School safety raised in policy and political dialogue, reports by EC delegations with education as focal sector, taking into account the work done by e.g. UNICEF and UNFPA on rights-based, child-friendly schools and involve children, parents and teachers in their design and implementation.</li> <li>Codes of conduct established and respected by teachers.</li> </ul>

	ACTION/	PARTNERS	MONITORING AND OUTCOMES
	INITIATIVE		
12.	Assessing the impact of the three	EC	- Study on human security and stability.
	diseases on human security and		- EU response proposed for critical countries.
	stability at state level		
13.	Mainstreaming efforts to	EC	- ECHO guidelines for HIV/AIDS and malaria finalised.
	confront the three diseases in		- Training and tools provided for humanitarian workers.
	emergency operations		- The three diseases addressed in the situation of CSPs subject to LRRD.
14.	Training of peacekeeping forces	EC	-Accompanying measures of EC support for the AU Peace facility.
	to confront the three diseases	AU	
		EU MSs	
15.	Collecting of relevant data for	EU MSs	- Sex- and age-disaggregated data collected and analysed to monitor meaningful indicators on the three
	annual monitoring of progress	WHO (+UNAIDS, RBM,	diseases.
	indicators <sup>13</sup>	StopTB)	- Capacity of national monitoring and reporting systems strengthened, including to monitor essential
		Health Metrics Network	services.
16.	Financial resources to confront	EU MS	- Adequate and predictable funding of the Global Fund, including a significant EU contribution.
	the three diseases	GLOBAL FUND	
17.	Highly cost-effective	UNICEF	- EC support and funding provided for these interventions through relevant organisations in partnership
	interventions likely to yield rapid	UNFPA	with heavy-burden countries.
	results	WHO/UNAIDS	
		Other agencies	
18.	Promoting MDG-6 focused	EC	- MDG rating analysis for PRSPs developed.
	PRSPs	EC Delegations	- PRSPs increasingly focused on achieving the MDGs with increased resources allocated to MDG6.
		EU MSs	

<sup>&</sup>lt;sup>13</sup> Examples include: Voluntary Counselling and Testing (VCT) coverage, Prevention of Mother-To-Child Transmission (PMTCT) coverage, and Highly Active Anti-Retroviral Therapy (HAART) coverage (for HIV/AIDS); use of LL-ITNs for under-fives and pregnant women, and Intermittent Preventive Treatment (IPT) during pregnancy and possibly childhood (for malaria); and DOTS detection and cure rate (for TB).

	ACTION/	PARTNERS	MONITORING AND OUTCOMES
	INITIATIVE		
	GLOBAL ACTION		
19.	Strengthening regional	EC	- EC regional health advisors appointed.
1).	cooperation to confront the three	EC	- Annual regional reports on country actions.
	diseases in Southern Africa and		- Regional cooperation established on key issues and examples of good practice shared.
			- Regional cooperation established on Rey issues and examples of good practice shared.
	South-East Asia, expanding to		
20.	other regions Monitoring and promoting of the	EC	- Monitoring reports published with meaningful and transparent price data.
20.	anti-trade diversion Regulation	Dialogue with industry	- Monitoring reports published with meaningful and transparent price data.
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21.	Promoting price transparency	WHO (including RBM and	- Prices of pharmaceutical products and commodities purchased through EC support published.
		StopTB) and UNAIDS	
		MSF	
		GLOBAL FUND	
		(see action point 9)	
22.	Implementing the August 2003	EC	- EC legislation to implement the August Decision adopted by Council and Parliament.
	decision of the WTO	EU MSs,	- August Decision fully incorporated into the TRIPs Agreement through a formal amendment.
		Dialogue with WTO	- Biannual report of implementation of the August agreement in third countries.
23.	Developing scientific and	EC	- Use of Article 58 of Regulation (EC) No 726/2004 for the evaluation of medicines for developing
	regulatory capacity of partner	WHO, EMEA, EU MSs	countries.
	countries	<b>Regulatory bodies</b>	- Specific guidelines developed on key products, e.g. microbicides and vaccines – consistent with the
			risk-benefit profile of products in the country context, and age and gender aspects when assessing
			safety and efficacy. Support will be given through TA, training and exchange schemes.
			- Training on regulatory capacity provided by experts under EC Framework contract and/or WHO.
			- International conference organised by EMEA and WHO focusing on regulatory issues relating to
			microbicides.
24.	Establishing regional schemes of	EC	- Regional capacity developed in terms of centres of regulatory expertise.
	mutual recognition for marketing	AU, WHO	- Regional scheme of mutual recognition for marketing authorisation established.
	authorisation	×	
	Setting up an international		- Needs and opportunities for setting up an international advisory committee fully explored.
	advisory committee on regulatory		
	matters		
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	ACTION/	PARTNERS	MONITORING AND OUTCOMES
	INITIATIVE		
25.	Support for WHO	EC	- Continued and expanded EC funding for the WHO prequalification project.
	prequalification project	EIB	- Annual report on prequalification progress in relation to production map in developing countries.
		WHO	
26.	Innovative responses to the	EU MSs,	- EC support for AU-NEPAD in tackling the human resource crisis, ultimately leading to increased
	human resource crisis among	AU, NEPAD, HL Forum on	training, improved working conditions and better availability of health providers in Africa.
	health providers	the Health MDGs	
27.	Preparing new EC policy on a	EC	- EC Communication on "HR-diversion" adopted and ways forward explored with EU MSs.
	European response to the human		
	resource crisis among health		
	providers		
28.	Supporting research and	EC	- EC funding leading to results in terms of new tools and interventions (e.g. EDCTP).
	development of priority tools and	EU MSs	- Research collaboration with and participation of disease-endemic countries further strengthened,
	interventions, including clinical	Private sector	through excellence centres in disease-endemic countries.
	trials and non-medical research		- Key areas of research (basic, preclinical and clinical) funded under FP7 and results effectively used in
			EC policy development and implementation in the fight against the three diseases.
29.	Evaluating the effectiveness and	EC	- Studies finalised and EC policy proposal in terms of new incentives presented.
	potential cost of implementing		
	pull incentives within EC		
	competence		
30.	Support for priority tools	EC	- EC and EU support for PPPs and global initiatives working on priority tools and interventions, e.g.
	through public-private	EU MSs	HIV/AIDS vaccines and microbicides.
	partnerships (PPPs) and global	PPPs and global initiatives	
	initiatives		