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A Review of European Commission Funding for HIV/AIDS, Tuberculosis and Malaria Health Technology R&D

IAVI Public Policy Department

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A Review of European Commission Funding for HIV/AIDS, Tuberculosis and Malaria Health Technology R&D

Policy Research Working Paper
December 2006

IAVI's Policy Research Working Paper series disseminates the findings of works in progress to promote the exchange of ideas about the effective development and global distribution of vaccines to prevent HIV infection.

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Acronyms and Abbreviations

ACP	African, Caribbean and Pacific countries
AIDCO	European Aid Cooperation Office
AIDS	Acquired Immunodeficiency Syndrome
ATM	AIDS, Tuberculosis and Malaria
CA	Coordination Action
CD4	Cluster of Differentiation 4
DG	Directorate-General
EC	European Commission
EDF	European Development Fund
EDCTP	European and Developing Countries Clinical Trials Partnership
FP6	Sixth Framework Programme
GAVI	Global Alliance for Vaccines & Immunization
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
HIV	Human Immunodeficiency Virus
IAVI	International AIDS Vaccine Initiative
IFH	International Family Health
IP	Integrated Projects
IPM	International Partnership for Microbicides
MRC	Medical Research Council
NoE	Networks-of-Excellence
PDP	Product Development Public-Private Partnership
PPP	Public-Private Partnership
PMTCT	Prevention of Mother-to-Child Transmission
R&D	Research and Development
SME	Small and Medium-sized Enterprises
SSA	Specific Support Action
STREP	Specific Targeted Research Projects
TB	Tuberculosis

Executive Summary

AIDS, Tuberculosis and Malaria (ATM) are recognised as three of the world's most devastating communicable diseases affecting many of the world's poorest people. While prevention and treatment services for ATM have improved significantly in recent years, these diseases continue to spread.

The European Commission (EC) has drawn up a political framework and a programme for action to increase the impact of existing interventions, make key pharmaceuticals more affordable, and support research and development (R&D) of specific global public health technologies to confront ATM. These efforts include directing public sector funding to support R&D and Product Development Public-Private Partnerships (PDPs).

This paper reviews the EC's financial support with respect to PDPs, its support of pre-clinical and early human testing of promising new candidates to treat and prevent ATM, and its establishment of a programme to support clinical trials in Africa. The purpose of this paper is to provide an informational resource that documents the level of financial engagement that the EC has made in recent years.

While the EC does not have a specific mechanism with a primary function of funding PDPs, ad hoc funding directed towards PDPs from EC development budgets over the period 2002-2009 total € 12.5M. These commitments have been made to PDPs concerned with the prevention of HIV/AIDS and specifically organisations conducting R&D of AIDS vaccines and microbicides.

Funding commitments on all ATM-related R&D via the EC's research and clinical trials programmes (FP6 and the EDCTP respectively) over the period 2002-2006 total between € 372M and € 400M. Excluding the EDCTP, EC commitments to ATM R&D currently total € 172M and are expected to rise to more than € 200M by the end of 2006 (when funding for the fourth and final call for proposals is finalised). Overall, 22% of the current ATM R&D funding is directed towards “discovery” research, whilst the remaining 78% is allocated to “translational” research.

The € 172M committed to date is currently distributed amongst ATM such that 44% is committed to AIDS-related research (26 HIV/AIDS projects with a total funding allocation of € 74.3M), 31% is committed to TB-related research (12 TB projects with a total funding allocation of € 55.1M) and the remaining 24% is committed to malaria-related research (10 malaria projects with a total funding allocation of € 43.1M).

Of the 26 HIV/AIDS research projects, 12 projects (€ 26.7M and 34% of HIV/AIDS funding) pertain to vaccine research, whilst 8.5 projects (€ 22.2M and 28% of HIV/AIDS funding) are related to treatment research and another 2.5 projects (€ 15.5M and 20% of HIV/AIDS funding) are for microbicide research. The remaining 3 projects (€ 13.7M and 18% of HIV/AIDS funding) are directed at general HIV/AIDS disease research.

In the case of the EDCTP, the € 200M committed has not yet been translated into actual expenditures. Published data on EDCTP grants awarded suggests that only € 8.3M (<5%) of the € 200M committed has been disbursed. This € 8.3M is distributed amongst ATM as

follows: 18% on HIV/AIDS (3 HIV/AIDS-related clinical trials with a total funding allocation of € 1.5M), 53% on TB (4 TB-related clinical trials with a total funding allocation of € 4.4M) and 23% on malaria (3 malaria-related clinical trials with a total funding allocation of € 2.4M).

This review underscores the EC's commitment to the search for health technologies to combat HIV/AIDS, tuberculosis and malaria. The use of development aid to fund the efforts of HIV/AIDS-related PDPs in the past five years has been a valuable contribution by DG Development in the global effort against HIV/AIDS. Furthermore, the focus of DG Research on basic discovery and translational research for vaccines, microbicides and drugs is notable. That said, the combined investment of the EC and member states in AIDS vaccine R&D is less than 10% of the global total.[1] While these funds have been important, in light of the recognised gap in funding that would optimise the search for a much needed vaccine against HIV/AIDS, there is scope for the Commission and its member states to expand their contribution to the global AIDS vaccine effort. Additionally, clinical research activities funded by the EDCTP should be used to test promising new prevention and treatment tools, helping to stimulate and raise the pace of disbursements from the EDCTP. In the meantime, the EDCTP could be used to further expand clinical trials capacity in developing countries and test health technologies to treat and prevent other neglected diseases emerging from national and international research.

[1] HIV Vaccines and Microbicides Resource Tracking Working Group. "Adding It Up: Funding For HIV Vaccine and Microbicide Development 2000 to 2005". New York (August 2006): p5-6.

I. Introduction

AIDS, Tuberculosis and Malaria (ATM) are recognised as three of the world's most devastating communicable diseases affecting many of the world's poorest people.

While prevention and treatment services have improved significantly in recent years, ATM continue to spread, highlighting the need for novel health interventions to combat these diseases. However, people living in the areas of greatest need (developing regions) are often least able to access and to afford the health services necessary to prevent or treat ATM. Furthermore, the search, particularly for new preventive technologies, remains hampered by a series of basic scientific challenges, and the expectation of potentially lengthy development times. As a result, little incentive exists for private sector involvement in health research and development (R&D) in the fight against ATM.

The post-war period has seen increasing public sector input to drug and vaccine development especially where basic scientific (and applied research) questions remain.[2,3,4] These trends suggest that public sector funding of R&D activities (particularly for preventive technologies for ATM) will continue to be a critical success factor towards a comprehensive response to these diseases. More recently, the involvement and collaboration of public and private sectors in health technology discovery and development have been formalised through the emergence of a new type of organisation known as a Product Development Public-Private Partnership (PDP).[5] PDPs may be one of a number of crucial innovative responses to ATM and neglected diseases in general. Recent evidence has confirmed that PDPs, along with public sector funding of basic and translational research, are likely to be some of the most effective and efficient ways in which health interventions for neglected diseases can be developed and their launch accelerated.[6]

As a public sector multilateral institution interested in supporting development efforts, the European Commission (EC) addresses a wide range of policy areas including trade, international development and health care technology R&D. During the past 5-6 years, the EC has drawn up a political framework and a programme for action related to ATM with a number of policy dimensions. These include supporting R&D for health technologies to combat ATM.[7,8,9]

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[2] Kettler, H. and A. Towse (2002). "Public-Private Partnerships for Research and Development: Medicines and Vaccines for Diseases of Poverty". London, Office of Health Economics; p29.

[3] Maxwell, R., Eckhardt, S. (1990), "Drug Discovery: A Case Book and Analysis". Humana Press, Clifton, NJ.

[4] Cockburn, I. and R. Henderson. (1997). "Public-private interaction and the productivity of pharmaceutical research". Cambridge: National Bureau of Economic Research.

[5] Buse K. & Walt G. (2000). "Global Public–Private Partnerships: Part I – A New Development in Health". Bulletin of the World Health Organization.78 (4): pp549-561.

[6] Moran M., A. Ropars, J. Guzman, J. Diaz and C. Garrison. (2005). "The New Landscape of Neglected Disease Drug Development". Pharmaceutical R&D Policy Project; London: p64.

[7] Brussels, 26 October 2004. [COM(2004) 726 final]. A Coherent European Policy Framework for External Action to Confront HIV/AIDS, Malaria and Tuberculosis

[8] The Commission of European Communities. Programme For Action: Accelerated action on HIV/AIDS, malaria and tuberculosis in the context of poverty reduction. Brussels, 21 February 2001 [COM(2001) 96 final]. Available at: http://eur-lex.europa.eu/LexUriServ/site/en/com/2001/com2001_0096en01.pdf

[9] The Commission of European Communities. Update on the EC Programme for Action - Accelerated action on HIV/AIDS, malaria and tuberculosis in the context of poverty reduction: Outstanding policy issues and future challenges. Brussels, 26 February 2003. [COM(2003) 93 final]

This report assesses the EC's financial support (funding commitments and expenditures) with respect to:

- PDPs via the EC's development aid/assistance programme;
- pre-clinical and early human testing of promising new candidates to treat and prevent ATM; and
- its establishment of a programme to support clinical trials in Africa.

The purpose of this paper is to provide the ATM communities with an informational resource that documents the EC's contribution[10] to the search for innovative ATM health technologies.

[10] Separate from that of the individual member states

II. PDP Commitments and Expenditures

For the purposes of this paper, PDPs have been defined as not-for-profit organisations working to develop technologies to combat communicable diseases, and in particular, HIV/AIDS, TB or Malaria. These organisations receive funding from public, philanthropic and private sector sources and use these funds to partner with academic researchers, government institutions and private industry in product R&D efforts. It is recognised that this definition excludes other public-private collaborations that receive funding from Directorate-General (DG) Research to undertake ATM-related R&D projects. For example, all of the translational research activity that are financed by DG Research and undertaken as Integrated Projects[11] (IP) involve Phase I clinical trials and all involve industry collaboration (either SMEs[12] or large multinational pharmaceutical companies), in addition to academia. The distinction between these types of research efforts and associated financial contributions are captured in section IV of this report, separately from the analysis of PDP-related commitments described in this section.

The EC does not have a specific mechanism to fund PDPs for AIDS, TB or malaria. However, between 2002 and 2006, it made three AIDS-related grants to PDPs through DG Development and the European Aid Cooperation Office (AIDCO): one to the International AIDS Vaccine Initiative (IAVI) for € 3M over the period 2004-2006, one grant to the International Partnership for Microbicides (IPM) for € 0.87M over the period 2005-2007, and a third to the International Family Health (IFH) public-private partnership (PPP), totalling € 1.45M for the period 2002-2006. IFH was disbanded in 2005 and the balance of this grant was transferred to PATH. Whilst not directly involved in product development, the IFH/PATH grant is included in our analysis of EC PDP funding since work done by these PPPs has focused on accelerating the development and eventual access to new preventive technologies.

In late 2005, the EC committed an additional € 3.0M for IAVI's work in Southern Africa for disbursement over the period 2006-2008, and € 4.2M to IPM (likely to be disbursed over the same period). These grants aim to:

(1) build and strengthen capacity of clinical trial personnel in developing countries;
(2) increase community and political support for clinical trials in developing countries; and
(3) enhance capacity of regulatory agencies in developing countries.

This takes total EC commitments on PDPs to € 12.52M over the period 2002-2009.

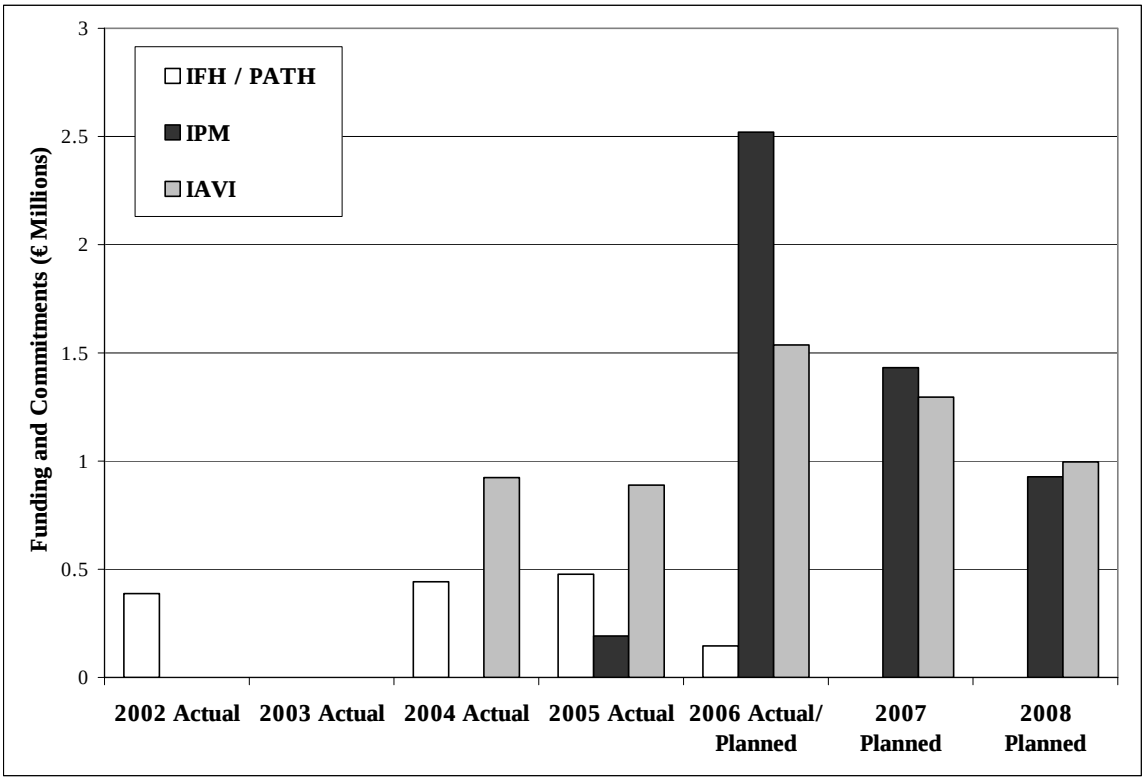
In addition to funding IPM, IAVI and IFH/PATH, the very first EC commitment (€ 1.35M) for AIDS vaccine development was made in 2002 to the UK public sector institution, the Medical Research Council (MRC), for capacity building work in South Africa. EC AIDS vaccine and microbicide funding is delineated in Table 1 and illustrated in Figure 1. The annual phasing of these commitments is described in Table 2.[13]

[11] See section IV for definition and further discussion.
[12] Small and Medium-sized Enterprises (SMEs) are companies whose headcount or turnover falls below certain limits. The EU currently categorises companies with fewer than 50 employees as "small", and those with fewer than 250 as "medium."
[13] Because the MRC is not a PDP, this commitment is not included in Figure 1 or Table 2 below.

Table 1. Contributions by the EC to AIDS vaccine and microbicide research, development and preparedness

Technology	Grantee Institution	Purpose of Grant	Amount (€)
AIDS Vaccines	IAVI	Partnerships for Preparedness: Southern Africa	3,000,000
	IAVI	Partnerships for Preparedness: building local capacity and ownership in the development of AIDS vaccines in East Africa	3,000,000
	MRC	Consolidation and expansion of AIDS vaccine preparedness in South Africa	1,350,000
Microbicides	IPM	Microbicides development	4,200,000
	IPM	Country-level analyses to accelerate access to microbicides by women in developing countries	870,000
	IFH/PATH Europe	Microbicide Awareness, Investment and Demand: advocacy and networking to accelerate microbicide development and availability to vulnerable people, particularly women, in developing countries	1,450,071

Figure 1. HIV/AIDS-related PDP funding and commitments (2002-2009)



Source: Communications with Directorate-General (DG) Development representatives (2004-2006)

In addition, DG Development may also support specific PDP projects through country-level funding. However, no data on PDP projects financed through country-level grants were available at the time of writing. Additionally, no information was available on *actual expenditures* relative to the commitments described above at the time of writing.

Table 2. Annual EC contributions to PDPs (2002-2009)

	2002 Actual	2003 Actual	2004 Actual	2005 Actual	2006 Planned	2007 Planned	2008 Planned	2009 Planned	TOTAL (2002-2009)
IFH / PATH	€ 386,685	-	€ 441,721	€ 476,594	€ 145,071	-	-	-	**€ 1,450,071**
IPM	-	-	-	€ 191,368	€ 2,520,000[1]	€591,632 + €840,000[A]	€ 87,000 + € 840,000	-	**€ 5,070,000**
IAVI	-	-	€ 923,112[B]	€ 888,444	€ 888,444 + € 648,750[C,D]	€ 300,000 + € 995,625	€ 995,625	€ 360,000	**€ 6,000, 000**
Total	€ 386,685	-	€ 1,364,833	€ 1,556,406	**€ 4,202,265**	**€ 2,727,257**	**€ 1,922,625**	€ 360,000	**€ 12,520,071**

Source: Communications with DG Development representatives (2004-2006)

[A] These installments reflect the € 4.2M committed by AIDCO in 2005. IPM expects the disbursement to run beyond 2006, estimating that it may last for three years with the first disbursement of € 2.5M (60% of the grant) in late 2006. Disbursements in 2007 and 2008 will likely see € 0.8M (20% of the grant) spent each year, based on IPM's best estimates of how the money will be disbursed and spent.

[B] East Africa grant

[C] Southern Africa grant

[D] 2006 installments of grant already received

Finally, the EC has provided a total of € 522M in funding for the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), and € 44M over the 4 years (2003-2006) to the Global Alliance for Vaccines and Immunization (GAVI). Roughly half of the aforementioned GAVI funding comes from the EC budget with the remainder coming from the European Development Fund (EDF),[14] a funding tool for development assistance to the African, Caribbean and Pacific (ACP)[15] countries. These funding commitments are mentioned here because GFATM and GAVI are PPPs, albeit not directly involved in product development.

[14] The European Development Fund (EDF) is the main instrument for providing Community aid for development cooperation in the ACP countries (see below). Even though a heading has been reserved for the Fund in the Community budget since 1993 following a request by the European Parliament, the EDF does not yet come under the Community's general budget. It is funded by the Member States, is subject to its own financial rules and is managed by a specific committee. The aid granted to ACP States and OCTs will continue to be funded by the EDF, at least for the period 2008-2013.

[15] *List of ACP countries:*

AFRICAN	Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroun, Cape Verde, Central African Republic, Chad, Comoros, Congo (Brazzaville), Congo (Kinshasa), Djibouti, Equatorial Guinea, Eritrea, Ethiopia, Gabon, Gambia, Ghana, Guinea, Guinea Bissau, Ivory Coast, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Mozambique, Namibia, Niger, Nigeria, Rwanda, Sao Tome & Principe, Senegal, Seychelles, Sierra Leone, Somalia, South Africa, Sudan, Swaziland, Tanzania, Togo, Uganda, Zambia, Zimbabwe;
CARRIBEAN	Antigua and Barbuda, Bahamas, Barbados, Belize, Cuba, Dominica, Dominican Republic, Grenada, Guyana, Haiti, Jamaica, St.-Kitts & Nevis, St.-Lucia, St.-Vincent, Suriname, Trinidad & Tobago;
PACIFIC	Cook Islands, East Timor, Federated States of Micronesia, Fiji, Kiribati, Marshall Islands, Nauru, Niue, Palau, Papua New Guinea, Samoa, Solomon Islands, Tonga, Tuvalu, Vanuatu

III. Commitments and Expenditures on ATM R&D (outside of PDPs)

In 2005, the public sector dominated funding for AIDS vaccine R&D, accounting for 88% of total global investment. Of this investment, European national governments and the EC together accounted for 10%.[16]

EC commitments on ATM R&D for the period 2002-2006, are funded by DG Research via the Sixth Framework Programme (FP6) instrument and by the European and Developing Countries Clinical Trials Partnership (EDCTP). The FP6 funding instrument for ATM is focused on basic research (discovery and translational research activities), while the EDCTP funds clinical research activities.

Over the period 2002-2006, total ATM commitments are expected to reach between € 372M and € 400M. Further information on the Framework Programmes and the EDCTP can be found on the following websites respectively:

- http://cordis.europa.eu/fp6/dc/index.cfm?fuseaction=UserSite.FP6HomePage
- http://www.edctp.net/default.asp?cid=1

Excluding the EDCTP, EC commitments through the FP6 alone currently total € 172M (see Table 3 and Appendices 1 and 2). Commitments made through the end of 2006 (the final year of FP6) are expected to increase the overall funding allocation to more than € 200M. The additional commitments expected in 2006 will provide the funding for projects endorsed through the fourth and final call for proposals (deadline November 2005, approved in April 2006). As contract negotiations between the EC and recipient research institutions were still ongoing at the time of writing, no details are currently available on the projects expected to receive funds under the fourth call for proposals. However, it is anticipated that the EC may finance at least 14 new HIV/AIDS projects, with total commitments in the region of € 50M. For the most up-to-date information on the EC's commitments to ATM health research, please see the DG Research electronic book of abstracts at:

- http://www.ec.europa.eu/research/health/poverty-diseases/projects/l_fp6_en.htm

[16] HIV Vaccines and Microbicides Resource Tracking Working Group. "Adding It Up: Funding For HIV Vaccine and Microbicide Development 2000 to 2005". New York (August 2006): p6.

IV. Commitments and Expenditures on ATM Health Discovery and Translational Research

The aforementioned € 172M in existing commitments support discovery and translational research.

Discovery projects: Discovery projects are small-scale, high-risk projects with a high degree of innovation.[17] Individual projects selected have typically lasted two to three years with budgets of between € 1 and € 2M. The projects are categorised amongst Specific Targeted Research Projects (STREP), Specific Support Action (SSA) and Coordination Action (CA).[18] STREP projects involve research focused on particular disease/vector targets or identification of new vaccine/drug candidates. SSA projects focus on supportive research such as standardisation of assays or definition of common treatment efficacy markers. CAs refer to clinical networks that monitor epidemiological or patient outcomes to inform the future scientific research.

Translational Research: These projects focus on the development of promising drug and vaccine candidates from discovery phases to early human testing. They are undertaken via large multidisciplinary research consortia that are organised as integrated projects (IP). In addition, networks-of-excellence (NoE) provide coordination among experts and structural support to research and undertake clinical activities in ATM.

These instruments can also be classified into three different groups on the basis of their purpose:

- The first group comprises the instruments aimed at generating, demonstrating and validating new knowledge through research and development, and is composed of IPs and STREPs.
- The second group is composed only of the NoEs, instruments aimed at the durable integration of the participants' activities.
- The third group comprises the instruments aimed at supporting collaboration, coordination and other activities such as conferences and studies and is composed of CAs and SSAs.

Given the nature of these activities, commitments for translational research are larger than those for discovery activities while commitments for clinical development are larger still.

[17] The Poverty Related Diseases website - About FP6 Funding http://ec.europa.eu/research/health/poverty-diseases/fp6projects_en.html

[18] CAs are not classified by DG Research as discovery or translational research. However, for the purposes of this report, CA projects have been included within the definition of discovery projects. CAs only relate to AIDS research; there are only 4 such projects and these total € 8.2M of all commitments on discovery projects. See Appendix 1 for further details.

Table 3. EC funding commitments on ATM-related R&D (2002-2006)

	Discovery Projects	**Translational Research**	**TOTAL Translation and Discovery commitments by disease (ATM)**	**Percentage of Total**
FP6 instrument (defined in section III)	**STREP, SSA, CA**	**IP, NoE**		
AIDS research contributions	€ 20,204,413	€ 58,010,500	€ 78,214,913	45%
TB research contributions	€ 8,255,405	€ 42,920,000	€ 51,175,405	30%
Malaria research contributions	€ 10,086,534	€ 33,000,000	€ 43,086,534	25%
TOTAL EC contribution	€ 38,546,352	€ 133,930,500	€ 172,086,852	
(Percentage of Total)	(22%)	(78%)	(100%)	

Source: Adapted from DG Research Poverty-Related Diseases website (http://europa.eu.int/comm/research/health/poverty-diseases/fp6projects_en.html). Also, see Appendices 1-3.

V. Commitments and Expenditures on R&D Between AIDS, TB and Malaria

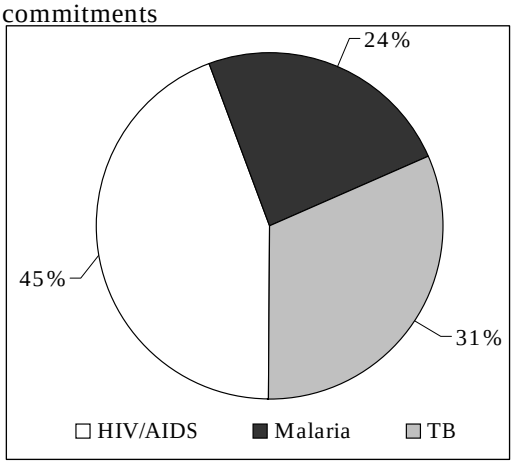
The FP6 research programme (excluding the EDCTP) to address HIV/AIDS, TB and malaria has funded roughly 26 HIV/AIDS projects, 10 malaria projects and roughly 12 TB projects over the research programme period (2002-2006).

Comparing funding commitments (excluding the EDCTP) for ATM, it is clear that both AIDS vaccine commitments and HIV/AIDS funding commitments in general are relatively large. The latter accounts for 45% of all EC research funding commitments across the three diseases from the first three FP6 funding rounds. Malaria and TB commitments account for 24% and 31% respectively of the EC research funding from the first three FP6 funding rounds (see Figure 2).

Of the 26 HIV/AIDS research projects, 12 projects (€ 26.7M and 34% of HIV/AIDS funding) pertain to vaccine research, whilst 8.5 projects[19] (€ 22.2M and 28% in funding) are related to treatment research and another 2.5 projects (€ 15.5M and 20% in funding) are for microbicide research. The remaining 3 projects (€ 13.7M and 18% in total funding) are directed at general HIV/AIDS disease research. (See Figure 3 and Appendix 1 below.)

Of the 10 malaria research projects, 5 projects (€ 22.4M or 52% of malaria funding) pertain to treatment-related (anti-malarial) research, while 3 projects (€ 18.3M or 42% of malaria funding) are related to disease research and the remaining 2 projects (€ 2.3M or 5% of total funding) are for vaccine research. (See Figure 3 and Appendix 2 below.)

Figure 2. EC ATM research funding commitments

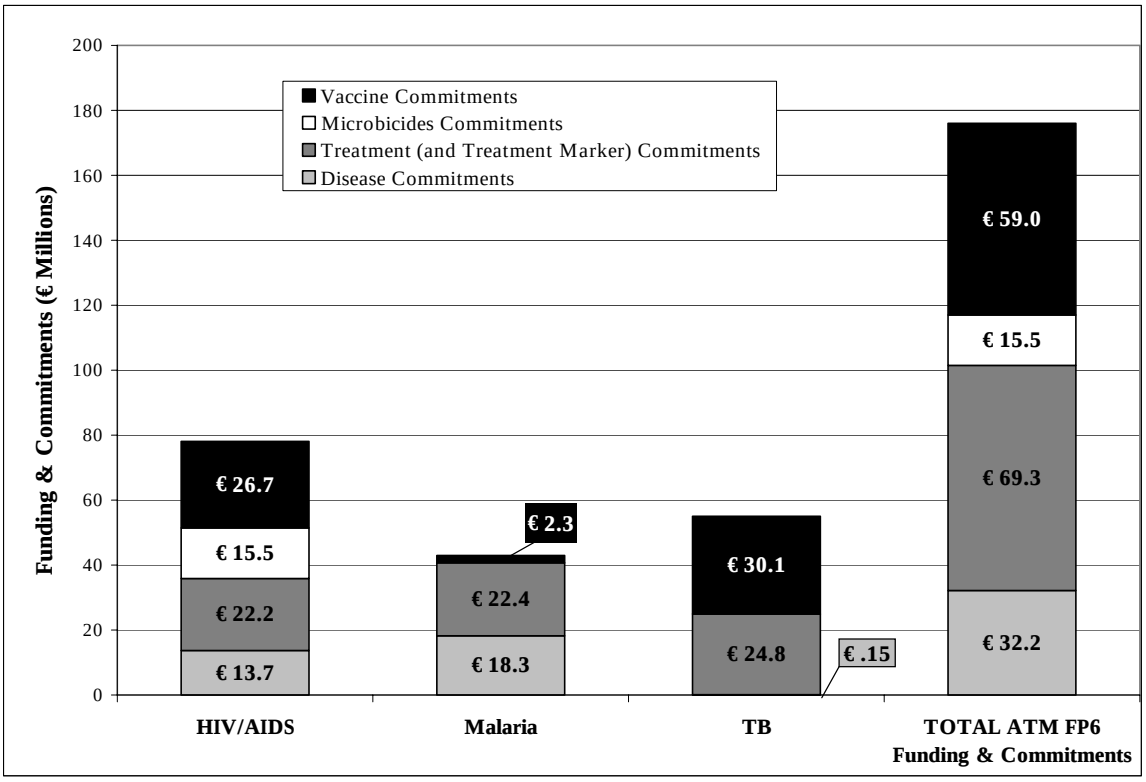


Source: Adapted from DG Research Poverty-Related Diseases website (http://europa.eu.int/comm/research/health/poverty-diseases/projects/l_fp6_en.htm). Also, see Appendices 1-3.

Of the 11.4[19] TB research projects, 3.7[19] projects (€ 30.1M and 55% of TB funding) pertain to vaccine research, while 4.8 projects (€ 24.8M and 45% total funding) are related to TB treatment research and TB treatment marker research. The remaining project (€ 0.15M and 0.3% total funding) relates to disease research. (See Figure 3 and Appendix 3 below.)

[19] The decimals for the number of projects reflect the fact that some projects have dual applicability; i.e. for treatment and microbicides or for TB and HIV/AIDS. See Appendices 1 and 2 for further details.

Figure 3. EC ATM research funding commitments by disease area and health technology



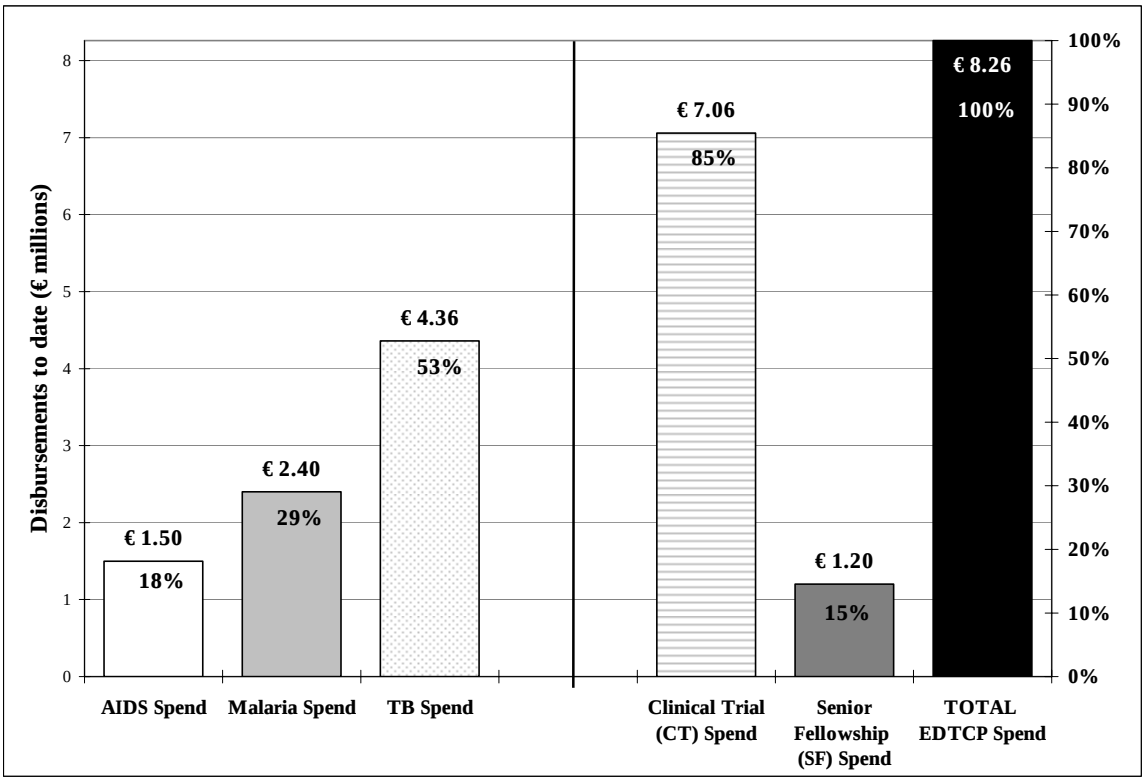
Source: Adapted from DG Research Poverty-Related Diseases website. (http://europa.eu.int/comm/research/health/poverty-diseases/projects/l_fp6_en.htm). Also, see Appendices 1-3.

Funding for projects endorsed through the fourth and final call for proposals of FP6 is in the process of being determined. It is expected that an additional € 50M will be spent on HIV/AIDS research projects. However, the EC provisionally expects that the total FP6 budget (of over € 120M), will have been divided such that around 40% will have been committed for R&D into new therapeutic approaches, 42% to vaccine research and 18% to microbicides. Neither these splits nor the new funding allocations are represented in Figures 2 and 3 because of the provisional nature of this information. No information was available on *actual expenditures* relative to the commitments described above at the time of writing.

VI. Commitments and Expenditures on ATM Health Clinical Research (EDCTP)

In the case of the EDCTP, the € 200M commitment has not yet translated into actual expenditure. The published data on EDCTP grants awarded suggest that only around € 8M of the € 200M committed has been disbursed to date. The grants awarded for ATM projects under the EDCTP are shown below in Figure 4.

Figure 4. EDTCP disbursements



Source: Adapted from the EDCTP website (http://www.edctp.org/default.asp?cid=98). See Appendix 4.

VII. Comments

This review underscores the EC's commitment to the search for health technologies to combat AIDS, Tuberculosis and Malaria. The use of development aid to fund the efforts of HIV/AIDS-related PDPs in the past five years has been a valuable contribution by DG Development in the global effort against HIV/AIDS. Furthermore, the focus of DG Research on basic discovery and translational research for vaccines, microbicides and drugs is notable. That said, the combined investment of the EC and member states in AIDS vaccine R&D is less than 10% of the global total. While these funds have been important, in light of the recognised gap in funding that would optimise the search for a much needed vaccine against HIV/AIDS, there is scope for the Commission and its member states to expand their contribution to the global AIDS vaccine effort. Additionally, clinical research activities funded by the EDCTP should be used to test promising new prevention and treatment tools, helping to stimulate and raise the pace of disbursements from the EDCTP. In the meantime, the EDCTP could be used to further expand clinical trials capacity in developing countries and test health technologies to treat and prevent other neglected diseases emerging from national and international research.

VIII. APPENDICES

Appendix I: Classification of EC-funded HIV/AIDS-related research

PROJECT NAME	CLASSIFICATION OF RESEARCH			EC FUNDING COMMITMENT (€)
	Co-ordination Action (Discovery), Discovery or Translational Research	STREP, SSA, CA, IP or NoE	Disease, Microbicides, Treatments or Vaccines	
CASCADE	Co-ordination Action (Discovery)	CA	Disease	1,700,000
Teach CD4	Discovery	SSA	Disease	426,449
TRIoH	Translational	IP	Disease	11,610,500
EMPRO	Translational	IP	Microbicides	11,700,000
SHIVA	Translational	IP	Microbicides	3,800,000
Europe HIV Resistance	Co-ordination Action (Discovery)	CA	Treatment	1,499,336
Euro SIDA 2005-2009	Co-ordination Action (Discovery)	CA	Treatment	3,000,000
HIDDEN HIV CHALLENGE	Discovery	STREP	Treatment	657,998
NEW HIV TARGETS	Discovery	STREP	Treatment	550,000
PENTA/ECS	Co-ordination Action (Discovery)	CA	Treatment	2,000,000
Pox-gene	Discovery	STREP	Treatment	1,180,000
UNITE-MORE	Discovery	SSA	Treatment	375,000
VirApt	Discovery	STREP	Treatment	450,000
			Microbicides	450,000
PHARMA-PLANTA	Translational	IP	Treatment	3,000,000
Auto/AlloCell-HIV	Discovery	STREP	Vaccines	1,700,000
AVIP	Translational	IP	Vaccines	10,000,000
DEC-VAC	Translational	IP	Vaccines	3,400,000
EPI-VAC	Discovery	STREP	Vaccines	911,050
HIV VIROSOMES	Discovery	STREP	Vaccines	973,930
HIVAB	Discovery	STREP	Vaccines	950,000
MUVAPRED	Translational	IP	Vaccines	5,032,500
NeutNet	Discovery	SSA	Vaccines	299,000
RMVHIV	Translational	IP	Vaccines	5,500,000
TIP-VAC	Discovery	STREP	Vaccines	951,650
VaccTIP	Discovery	STREP	Vaccines	1,000,000
VIAV	Discovery	STREP	Vaccines	1,000,000
			Disease commitments	13,736,949
			Microbicides commitments	15,950,000
			Treatment commitments	12,712,334
			Vaccines commitments	31,718,130
			TOTAL HIV/AIDS commitments	**74,247,413**

Notes on Funding Included in Classification of EC-funded HIV/AIDS-Related Research:

1) A two-week Advanced Course of Vaccinology known as the ADVAC-EC project organised annually (2005-2007) by Mérieux Foundation and University of Geneva at the Veyrier-du-Lac Conference Centre received € 390,000 in funding through FP6. However, since this SSA project was relevant to AIDS, TB and Malaria, one-third of the total (i.e. € 130,000) has been assigned to each of the three diseases' total EC commitments.

2) Under the 'Treatment' classification of research, the following has been included:

- a cohort network which monitors HIV drug resistance;
- a network which monitors clinical and virological patient outcome;
- standardisation of testing and monitoring HIV resistance; PMTCT research; and
- research into recombinant pharmaceuticals from plants and identification of novel classes of HIV inhibitors to treat HIV infection.

Two projects have also been assigned to the treatment-related research, although they could also have been assigned to vaccine research. These are:

- A combined pox-virus/lentiviral vector system to treat HIV infection, immunisation and direct in vivo gene transfer in T-lymphocytes, i.e. basic research for treatment, immunisation and cure (€ 1,180,000) and
- Understanding the block on transcriptional reactivation to eradicate infection, i.e. basic research for a therapeutic vaccine/cure (€ 657,998).

3) Based on the advice from officials within DG Research, 25% of the research budget for the translation of recombinant pharmaceuticals from plants (PHARMA-PLANTA) has been assigned to HIV/AIDS treatments and the remaining 75% to TB treatments (see Appendix 2). Similarly, 33% of the budget from the study looking at mucosal vaccines for poverty related diseases (MUVAPRED) has been assigned to HIV/AIDS vaccines and the remaining 67% to TB vaccines (again, see Appendix 2).

4) The Antiviral Aptamers project (VirApt) has been included as 50% treatment-related and 50% microbicide-related since aptamers could be developed as both drugs and microbicides.

5) Under the 'Disease' classification of research, the following projects have been included:

a) Concerted Action on Sero-Conversion to AIDS and Death in Europe (CASCADE);
b) International CD4 (Cluster of Differentiation 4) T-Lymphocyte training programme for the support of HIV clinical trials networks (Teach CD4); and
c) Targeting replication and integration of HIV (TRIoH).

Appendix 2: Classification of EC-funded Malaria-related research

PROJECT	CLASSIFICATION OF RESEARCH			EC FUNDING COMMITMENT (€)
	Discovery, Translational	STREP, SSA, CA, IP or NoE	Disease, Antimalarial (treatments) or Vaccines	
Anti Mal	Translational	IP	Antimalarials	€ 17,500,000
Malaria Porin	Discovery	STREP	Antimalarials	€ 885,534
READ-UP	Discovery	STREP	Antimalarials	€ 2,000,000
VITBIOMAL	Discovery	STREP	Antimalarials	€ 1,000,000
SENSITIVE TARGETS	Discovery	STREP	Antimalarials	€ 1,000,000
Bio Mal Par	Translational	NoE	Disease	€ 15,500,000
Malaria Age Exposure	Discovery	STREP	Disease	€ 1,800,000
SIGMAL	Discovery	STREP	Disease	€ 984,000
MALINV	Discovery	STREP	Vaccine	€ 587,000
SME Malaria	Discovery	STREP	Vaccines	€ 1,700,000
			Disease commitments	**€ 18,284,000**
			Treatment commitments	**€ 22,385,534**
			Vaccines commitments	**€ 2,287,000**
			TOTAL Malaria commitment	**€ 43,086,534**

Notes on funding included in classification of EC-funded malaria-related research:

1) One-third of the € 390,000 total committed under FP6 for the two-week ADVAC-EC course (relevant to AIDS, TB and malaria) has been assigned to each of the three disease's total EC commitments (i.e. € 130,000 has been added to TOTAL TB commitments in Appendix 3).

Appendix 3: Classification of EC-funded TB-related research

PROJECT	CLASSIFICATION OF RESEARCH			EC FUNDING COMMITMENT (€)
	Discovery, Translational	STREP, SSA, CA, IP or NoE	Disease, Treatments, Treatment Markers or Vaccines	
Tuberculosis China	Discovery	SSA	Disease	150,000
MM-TB	Discovery	STREP	Treatment Markers	976,000
TB Treatment Marker	Discovery	SSA	Treatment Markers	375,104
NEWTBDRUGS	Discovery	STREP	Treatments	1,800,000
NM4TB	Translational	IP	Treatments	10,870,000
scrIN-SILICO	Discovery	STREP	Treatments	1,000,000
TB-DRUG OLIGOCOLOR	Discovery	STREP	Treatments	770,856
PHARMA-PLANTA	Translational	IP	Treatments	9,000,000*
Neotim	Discovery	STREP	Vaccines	2,000,000
TB-VAC	Translational	IP	Vaccines	16,800,000
Vaccines4TB	Discovery	STREP	Vaccines	1,053,445
MUVAPRED	Translational	IP	Vaccines	10,217,500**
			Disease commitments	**150,000**
			Treatment Marker commitments	**1,351,104**
			Treatment commitments	**23,440,856**
			Vaccines commitments	**30,070,945**
			TOTAL TB commitment	**55,142,905**

*Based on the advice from DG Research officials, 75% of the research budget has been assigned for the translation of recombinant pharmaceuticals from plants (PHARMA-PLANTA) to TB treatments and the remaining 25% to HIV/AIDS treatments (see Appendix 1).

**Similarly, 67% of the budget from the study looking at mucosal vaccines for poverty-related diseases (MUVAPRED) has been assigned to TB vaccines and the remaining 33% to HIV/AIDS vaccines (again, see Appendix 1).

Notes on funding included in classification of EC-funded TB-related research:

1) One-third of the total € 390,000 committed under FP6 for the two-week ADVAC-EC course (relevant to AIDS, TB and malaria) has been assigned to each of the three diseases' total EC commitments (i.e. € 130,000 has been added to TOTAL TB commitments above).

Appendix 4: Classification of EDCTP ATM-related research

Description of Research Project	AIDS, TB or Malaria	Grant Amount (€)	Percentage of TOTAL EDCTP Spend	Clinical Trial (CT) or Senior Fellowship (SF)
CHAPAS Trials - Children with HIV in Africa: Pharmacokinetics and Adherence of Simple Antiretroviral Regimens	AIDS	1,100,070	13%	CT
Development and evaluation of high throughput, cheap and reliable assays for monitoring HIV-1 and HIV-2 viral loads in ARV programmes and clinical trials in developing countries	AIDS	200,000	2%	SF
Preventing peri-partum transmission of HIV-1 in Africa: tenofovir-based alternatives to single dose nevirapine in the light of future treatment options	AIDS	200,000	2%	SF
TOTAL AIDS Spend		**1,500,070**	18%	
Evaluation of four artemisinin-based combinations for treating uncomplicated malaria in African children	Malaria	1,999,990	24%	CT
Assessment of the public health benefit of artemisine-based combination therapies for uncomplicated malaria treatment in Mali	Malaria	200,000	2%	SF
Understanding the mechanism of piperaquine resistance	Malaria	200,000	2%	SF
TOTAL Malaria Spend		**2,399,990**	29%	
Rapid Evaluation of Moxifloxacin in the treatment of sputum smear positive tuberculosis: REMoxTB	TB	2,987,875	36%	CT
Surrogate markers to predict the outcome of anti-tuberculosis therapy	TB	973,033	12%	CT
BCG-induced immune correlates of protection against tuberculosis	TB	200,000	2%	SF
The burden of tuberculosis in eastern Sudan: epidemiology and drug resistance patterns of Mycobacterium tuberculosis isolates	TB	200,000	2%	SF
TOTAL TB Spend		**4,360,908**	53%	

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