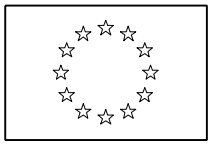

COMMISSION OF THE EUROPEAN COMMUNITIES

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

## Accelerated action targeted at major communicable diseases within the context of poverty reduction

# TABLE OF CONTENTS

# EXECUTIVE SUMMARY

This is a Communication to the Council and the European Parliament on the need for accelerated action targeted at major communicable diseases within the context of poverty reduction. It explains the issue of communicable diseases as a burden on the poorest and an obstacle to development, analyses the major policy issues involved, reports on the rationale for continuous Community involvement, and sets out a framework with three broad areas for targeted action.

**Communicable diseases: a burden on the poorest and an obstacle to development**

Investments in health can make a major contribution to poverty reduction and economic growth. In developing countries, communicable diseases, particularly HIV/AIDS, malaria and tuberculosis continue to limit human development. World wide, these three diseases cause the deaths of more than five million people each year with the greatest impact on morbidity and life expectancy in developing countries.

The failure to reduce the burden from these diseases and evidence of their increasing impact has brought them to the centre of the development debate and has led to calls for urgent action and a series of international initiatives.

The Commission has made a commitment to support an accelerated response against what has become a global emergency. There is a need for additional selective and targeted approaches to complement long standing and ongoing Community support to strengthen health systems to deliver services that benefit the poor.

**The rationale for accelerated European Community action**

The goal of the new EC Development Policy is poverty reduction. One of the priority areas for EC development aid is the support to macroeconomic policies in developing countries with an explicit link with poverty reduction strategies, in particular sector programmes in social areas (health, education) [1]. The European Community has an unique mandate to do so, being able to coherently address humanitarian, development, trade, health, education and research issues. Since 1990, Community investment in Health, AIDS and Population (HAP) assistance has reached more than 100 developing countries through a variety of complementary instruments for a total amount of Euro 3.4 billion. The Commission will strengthen its support to the health sector in developing countries, and calls for complementary actions in the areas of optimising impact, affordability and investment in research and development. Focus on disease prevention, promotion of health and improved health systems shall remain the EC´s main long-term response in improving health and reducing poverty in developing countries.

The Commission has become increasingly active in the international debate to increase developing countries' access to affordable key pharmaceutical products. This has involved extensive consultation and review of multiple issues including; infrastructure, financing mechanisms, international pricing and licensing mechanisms, intellectual property rights, tariffs

[1] COM (2000) 212, p. 25.

and appropriate incentives to increase investment in global health, including key pharmaceuticals[2].

In addition, Europe can build upon a long-standing tradition of excellence in communicable disease surveillance and control and in health research. European industry produces more than 60% of the vaccines used in developing countries and is among the largest producers of anti-infective drugs. The Community has increased investment in particular in communicable disease research over recent years, and plays an important role in facilitating new public–private partnerships for research and development of drugs and vaccines that are of particular importance to the health of people in developing countries.

**A framework for Community action should contain three broad areas for targeted action.**

***1. Reaching optimal impact of existing interventions, services and commodities targeted at the major communicable diseases affecting the poorest populations.***

The major communicable diseases are, in principle, largely preventable/and or readily treatable using existing low cost, effective interventions. However, often these do not reach the most vulnerable people where developing countries struggle to deliver essential health care with less than USD 5 per capita per year. Optimising impact of existing interventions, services and commodities requires both increased support to strengthen prevention and basic care efforts, health systems and scaled up targeted support through innovative partnerships that reach beyond the traditional health sector.

***2. Increasing affordability of key pharmaceuticals through a comprehensive and synergistic global approach.***

Improving access to key pharmaceuticals can only be achieved through a comprehensive global approach which addresses a global emergency.

Developing countries, in particular poor populations, have inadequate access to affordable services and key pharmaceuticals. The reasons why are complex and beside the main ones highlighted in area 1, they include the effects of international and national pricing policies, tariffs and taxation and implementation of intellectual property rights agreements. Options to further improve access and affordability include: exploration of the use of differential pricing (tiered pricing), voluntary licensing agreements, parallel trading, technology transfer and increase in local capacity for production, use of both generic and patented products and review of tariff and taxation options at country level.

***3. Increasing investment in research and development of global goods targeted at the three major communicable diseases.***

Research and development in the pharmaceutical industry is generally determined by the demands of industrialised countries´ markets. Those diseases prevalent in developing countries where markets are perceived to be small are neglected. Only 10 per cent of global health research efforts target those diseases which comprise 90 per cent of the global disease burden.

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[2] Key or essential pharmaceuticals are those medicines, including vaccines, which are essential to the public health of a population. Certain medicines for major diseases in developing countries may well be 'essential or key' but may not appear on the WHO or country-specific essential drugs list (EDL)

There is need to create global mechanisms and incentives to direct research and development to diseases that disproportionately affect developing countries. Progress will require expansion of the research portfolio, greater willingness to support risk investments, and a move from serial to parallel testing of candidate products. Closer co-operation of the strong public research tradition with the extensive capabilities of the European pharmaceutical industry could bring significant benefits. A priority should be increased investment in the capacity of science and technology institutions and personnel in developing countries.

**The way forward**

An accelerated Community response to the major communicable diseases should be seen as part of and complementary to ongoing Community investments in health and poverty reduction. For the response to be effective, coherent efforts of the Commission in conjunction with the EC Member States, partner countries, international and civil society partners and other stakeholders are required, as are greater innovation and more rapid action than traditional development assistance allowed for so far.

The policy framework set out in this Communication is the Community's first response to the recommendations of the G8 summit held in Okinawa in July 2000. The framework will be broadly discussed during a high level Round Table with all interested parties, in particular developing countries, EU Member States, European Parliament, international development agencies, civil society, researchers and the pharmaceutical industry. The results of the Round Table will provide valuable input to the Commission in formulating a programme for action.

## 1. INTRODUCTION

The complex interactions between the health of a population and poverty are now well recognised. There is evidence that investments in health can make a major contribution to poverty reduction and economic growth and that ill health is closely linked to poverty, poor education and weak health systems[3]. In developing countries, communicable diseases, particularly HIV/AIDS, malaria and tuberculosis, contribute disproportionately to high levels of ill health and increasingly limit human development. World wide these three diseases continue, despite existing efforts, to increase, and cause the deaths of more than five million people each year with the greatest impact on morbidity and life expectancy in developing countries.

These diseases can be partially controlled through improved living conditions and effective public health and education systems. In principle each disease is preventable and/or readily treatable using existing, effective and often low cost interventions including access to information, health commodities (condoms, bednets) and services (treatment of sexually transmitted and opportunistic infections, malaria and tuberculosis). However, too often existing interventions fail to reach the most vulnerable. There is also insufficient investment in developing new and more effective interventions at all levels.

The lack of progress in reducing the burden of HIV/AIDS, malaria and tuberculosis through support to strengthen health systems has brought these diseases to the centre of the development debate and has led, in recent years, to the launch of a series of major initiatives. These include: the International Partnership against AIDS in Africa (IPAA), the International AIDS Vaccine Initiative (IAVI), the Global Alliance for Vaccines and Immunisation (GAVI), Roll Back Malaria, the Malaria Medicines Initiative (MMV) and the Stop TB Initiative. A new momentum has been generated and has been backed by increased financial commitments from Governments[4] and philanthropic groups[5]. New working approaches between the public and private sectors are under formulation, such as the initiative of five pharmaceutical companies and UNAIDS, to provide anti-retroviral drugs at more affordable prices.

This Communication proposes a policy framework to guide a coherent, comprehensive and accelerated EC response to the three major communicable diseases as part of global efforts to improve the health of the poorest as reflected in the recommendations of the G8 summit held in Okinawa in July 2000.

This Communication briefly outlines the threats to global health and development, posed by these diseases, and the challenges and opportunities in addressing them. It defines the role of the Community in the context of new international initiatives. Finally, it identifies three core

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3 World Bank 1993 World Development Report. The Commission on Macroeconomics and Health (CMH January 2000) is producing a series of studies on how concrete health interventions can lead to economic growth.

4 The G8 in Okinawa committed to accelerated action against the major communicable diseases. Specific pledges were made by Japan (USD three billion) and The United Kingdom (USD 160 million). The International Development Association (IDA) announced a total credit of USD 1 billion to combat AIDS, Malaria and TB.

5 In 2000 only, the Bill and Melinda Gates Foundation has provided grants of USD 90 million for malaria, USD 90 million for HIV/AIDS actions and more than USD 100 million for TB related actions.

areas for increased Community action and recognises that effective action will require integrated efforts of the Commission in collaboration with partner countries, international partners and Member States.

This Communication will be broadly discussed during a high level Round Table with all interested parties, in particular developing countries, EU Member States, European Parliament, international development agencies, civil society, researchers and the pharmaceutical industry. The Commission will report on the results of the Round Table, and present its proposals for intervention in a forthcoming programme for action.

## 2. CHALLENGES AND OPPORTUNITIES TO REDUCE THE BURDEN OF MAJOR COMMUNICABLE DISEASES IN DEVELOPING COUNTRIES

### 2.1. Health systems are under pressure

Health systems[6] in the poorest countries are under enormous pressure and commonly lack resources to provide even a basic level of care. Health services are under-funded, short staffed, lack adequate essential equipment and supplies and often have limited institutional and management capacity. Typical annual per capita public health expenditure in sub-Saharan Africa is less than USD 5 or 2.5% of GNP.[7] This compares with a World Bank 1993 estimate of USD 12 per capita per year, or 3.4% of GNP, needed to deliver a basic selective package of care.

More recent work by WHO (World Health Report 2000) suggests that total annual health investment of less than USD 60 per capita is likely to be ineffective. Such low levels of investment are able only to sustain minimally functional services, even where efforts to reform and restructure health systems are successful. While Government health care services are usually intended to reach the poor they often disproportionately benefit the better off. The increasing impact of HIV/AIDS, malaria and tuberculosis has further exacerbated the gap between need and available resources. Recent financing reforms attempt to correct this bias.

Securing adequate resources to produce better health outcomes remains a struggle in most developing countries and progress towards the development of more efficient and equitable health systems is a slow process. Significant increases in the health share of national budgets are unlikely to materialise. Several of the poorest countries report capital expenditure of 40-50% of their total public health budget. Most of what is left goes to staff with only a very small portion remaining for maintenance and consumables. Payment for services funded through general government revenue prepayment schemes and social health insurance remains the

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6 Health systems defined broadly (WHO World Health Report 2000), include all of the non-personal, population-based or public health interventions such as healthy life styles, insecticide spraying against vector borne diseases, anti-tobacco campaigns, the protection of food and water as well as personal services.

7 Statistical data within this Communication are based on most recent figures provided by WHO, UNAIDS and DAC unless otherwise indicated.

preferred and most equitable approach to fair[8] financing of basic services and commodities for public health. This approach has led to the greatest improvements in access to care[9].

Where publicly funded care is not sufficiently available to cover basic healthcare costs, ill health exposes families to large unplanned expenditures. Such expenses can account for up to half of total monthly income and can push families into poverty. Much of this expenditure is particularly for services and pharmaceuticals.

## 2.2. Major communicable diseases are a global challenge

Communicable diseases are responsible for 60 per cent of the total burden of disease in developing countries. HIV/AIDS, malaria and tuberculosis comprise a major proportion of this burden and together they cause the deaths of more than five million people annually. Most of those affected live in developing countries and women are especially vulnerable. There is evidence that the impact of these diseases is increasing due to continuing and worsening levels of poverty, the effect of population growth, the increase in man-made and natural disasters resulting in displacement of populations, the failure of health systems, the emergence of resistance to medicines, increased injecting drug use, climatic changes and deteriorating sanitation. The global emergency caused by HIV/AIDS, malaria and tuberculosis is further detailed in Annex 1.

In addition, communicable diseases do not respect national borders and the failure of control measures in one country can put neighbours and global health at risk. Only 10% of the predicted illness and death due to HIV/AIDS have occurred to date and the full impact of this epidemic on people, communities and economies is still to come. Despite 15 years of concerted effort, the epidemic is out of control in many developing countries.

Malaria is re-emerging in areas where it was previously under control or eradicated. The most widely used and effective vector control tools, such as DDT, pose wider environmental threats to human and animal health. While recognising the need to control the use of commonly used persistent organic pollutants such as DDT, there is inadequate investment into research to develop and test alternatives. The cheapest and most used treatment for malaria is rapidly losing its effectiveness.

It has been possible to diagnose tuberculosis for more than a century, and to effectively treat the disease for at least 50 years, yet it remains a leading killer. A course of treatment for one patient costs as little as USD 11. With the present approach only half of the estimated total number of cases are detected. Less than half of those diagnosed complete treatment. Furthermore, the emergence of resistant strains of tuberculosis, linked to HIV/AIDS, poor compliance with treatment prescriptions, or irrational prescriptions, threatens to make existing drugs ineffective world-wide. TB has increased four-fold in many developing countries and has re-emerged after steady decline in parts of Eastern Europe.

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[8] Fair financing in health systems means paying according to ability to pay rather than to the risk of illness. This implies that poor people should pay less for the same services.

[9] The increase in social and private health insurance coverage and expanded drug benefits is a promising trend in countries as diverse as Argentina, the People's Republic of China, Egypt, India, the Islamic Republic of Iran, Georgia, South Africa, Thailand and Vietnam. Some programmes have special arrangements for rural and low-income populations. Drugs represent 25% to 70% of total costs for these schemes.

## 2.3. The need for an effective global response

Countries where people enjoy higher levels of health experience faster economic growth[10]. There is evidence that improvement in health accounts for a significant proportion of the rapid economic growth of much of the world in the 20th century. Effective education and public health systems are essential prerequisites for poverty reduction and development.

Research demonstrates that targeted investments in the control of communicable diseases can improve the health of the poorest. WHO calculates that doubling the projected rate of decline of common communicable diseases would disproportionately benefit the poor, leading to an increase of life expectancy of 4.1 years for the poor against 0.4 years for the rich (World Health Report 2000). The greatest potential impact on reducing the burden of these diseases could be achieved by a complementary and synergistic approach, which increases investment across three main areas.

***First,*** much of the disease burden arising from the three communicable diseases could be reduced through more effective access to, use, and impact of existing interventions. These remain underused and often do not reach the most needy; much more could be achieved with existing technologies and interventions. This requires intensified support to strengthen health systems to ensure improved access to prevention and treatment for the poorest and most vulnerable people. However, the global and national emergency created by these three diseases will not wait for the improvement of health systems; there is also a need for simultaneous actions beyond the traditional health sector. These must use innovative approaches in health as well as in other "enabling" sectors, such as education or transport, through increased partnerships and faster delivery mechanisms. WHO and UNAIDS have estimated the additional resources needed to provide specific outcomes through accelerated and more effective delivery of existing interventions including information, health commodities and services over the next five years (Table 1).

**Table 1 Proven cost-effective interventions for malaria and TB with potential for wider use through new mechanisms**

| Intervention | Resources USD | Target Group 2005 | Outcome |
|---|---|---|---|
| **Impregnated bednets** | 1.5 billion | All children in Africa protected from malaria | 600,000 child deaths prevented per year |
| **Anti-malarial drugs** | 4 billion | 100 million children reached in malaria endemic areas by 2005 | 25 % reduction in mortality due to malaria |
| **Anti-tuberculosis drugs** | 1 billion | 70 per cent of new cases of TB provided with effective treatment by 2005 | 50 per cent reduction in deaths caused by TB |

Source: WHO briefing

[10] This was first revealed in the World Bank 1993 World Development Report.

Cost estimates for HIV/AIDS prevention and care activities in sub-Saharan Africa are estimated at USD 1.5 billion yearly for prevention (including youth focused and sex worker interventions, public sector condom provision, condom social marketing, STI services, voluntary counselling and testing (VCT), blood transfusion services, mother to child transmission (MTCT), media, workplace interventions, start-up capacity development and surveillance, monitoring and evaluation) and USD 1.5 billion yearly for care programmes (including essential HIV care but not Highly Active Anti Retroviral Treatment (HAART)[11].

Most interventions are already being delivered through actions both inside and outside the formal health sector. Many are being, or could be, provided as over the counter products and services, through social marketing, through non-health workers or through franchising mechanisms.

***Second***, there is considerable potential to improve affordability of key pharmaceuticals[12]. for the poorest through global approaches and instruments. One-third of the world's population, and in the poorest parts of Africa and Asia over half of the population, do not have regular access to the most vital and essential pharmaceuticals. In developing countries, up to 90% of medicines are paid for "out-of-pocket" directly from household revenues. This expenditure can represent 50% of household spending and can contribute to impoverishment.

Affordability of pharmaceuticals is a complex issue but price of commodities, and the inability of most people to pay, is seen as a major obstacle to improving access in developing countries. Developing countries often lack the price control mechanisms which exist in industrialised countries, and the larger part of the ultimate consumer price can consist of import duties, taxes, distribution costs and dispensing fees.

Greater attention to affordability issues has led to a series of proposals for international action in the areas of implementation of intellectual property agreements, promotion of generic drug policies, pricing mechanisms, tariffs, bulk purchasing, technology transfer and increasing production capacity in developing countries.

Intellectual property rights, including patents, are addressed through the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS[13]) and bilateral agreements. Patent[14] protection aims at giving incentives for the development of new products and at ensuring publication and disclosure of new innovations to the benefit of the public. To recover costs of product research and development and to generate the necessary resources to invest in new

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11 Estimates based on cost of HAART of USD 1400 per person per year would result in resource needs for sub-Saharan Africa of at least USD 1 billion per year.

12 Key or essential pharmaceuticals are those medicines, including vaccines, which are essential to the public health of a population. Certain medicines for major diseases in developing countries may well be 'essential or key' but may not appear on the WHO or country-specific essential drugs list (EDL)

13 Agreement on Trade Related Aspects of Intellectual Property Rights –adopted after the Uruguay Round in 1994 to establish the minimum standards of patent protection that must be followed by all member countries of the World Trade Organisation (WTO). Application of the agreement is subject to the transitional arrangements contained in articles 65 and 66 of TRIPS.

14 A patent is a title granted by the public authorities conferring a temporary monopoly for the exploitation of an invention upon the person who reveals it, furnishes a sufficiently clear and full description of it, and claims this monopoly. The product should be new, involve an inventive step and be industrially applicable. Generally the invention may relate either to a product or a process including pharmaceuticals.

products, the inventors get an exclusive period of time to commercialise their new products. However, some representatives of civil society and some developing countries have expressed concerns that high prices are not always related to recovering investment costs and may delay the competitive forces of the market to reduce prices.

The Commission has initiated a dialogue with different stakeholders in order to assess the implementation of intellectual property rights. It is recognised that TRIPS provides a number of safeguards including specific exceptions to patent rights, notably compulsory licensing[15]. Together with its partners from developing countries, the Commission will further explore the existing safeguards. Experience with vaccines and contraceptives demonstrates that significant price differentials can be achieved between prices in developed and developing countries. Some pharmaceutical companies have indicated a willingness to have similar price differentials for other pharmaceuticals, including newer patented products. This has led to a recent announcement of a significant price decrease for some anti-retroviral drugs. Although the percentage of people with HIV who will be able to benefit from lower prices will initially be low, it is expected that incremental progress can be made. Such initiatives should be carefully monitored to ensure that scarce public finances that target prevention and services for the poorest and the many are not diverted to non-curative treatment for the few.

***Third,*** there is need for more effective and increased global investment in the development of new products, particularly vaccines, vector control products and drugs targeted at controlling the three major communicable diseases. Only 10% of global health research funds are presently targeted at 90% of the global disease burden. Developing countries represent less than 15% of the total value of the global pharmaceutical and commodity market; this results in extremely limited investment into new tools against those diseases with the greatest public health impact. There are particularly stark deficiencies in the development of new technologies against HIV/AIDS, malaria and tuberculosis which each kill more than one million people each year.

New vaccines, diagnostics, pharmaceuticals and insecticides will all be required for maximum impact. The cost of developing these technologies is very high, ranging from USD 100 million for a new treatment to USD 500 million for a successful vaccine. The complexity of the science, the efficacy of potential new products, the safety profile, the high development costs and the uncertain outcome of research and development all represent significant obstacles to investment. Yet the challenge and potential benefits to global health and development are massive and require increased and more effective public and private sector investment. Populations in developing countries and the global community will be the beneficiaries of increased knowledge and new products.

### 2.4. New international partnerships

Many countries are in the midst of redefining their health policies and systems. In many highly aid- dependent countries, governments and donors are moving towards a sector wide approach, setting a broad policy framework and establishing longer-term partnerships. This process takes time[16]. The scale of the communicable disease problem requires that ongoing

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15 TRIPS article 31. Compulsory licensing is the granting of a license without the consent of the patent holder on various grounds of general interest.

16 Walt and Smithson report: Before Ghana's single sector programme was endorsed by donors, the country had gone through 10 years of institution development, 4 years of policy and strategy work, 3 years of strengthening management, 2 years of negotiations, planning and design and 1 year of slippage and delays.

efforts to make health systems more effective and responsive need to be complemented by accelerated action. This has led to a series of targeted initiatives over recent years in which the European Union has largely been involved.

The UN Security Council, the World Bank Development Committee, and the G8 have recognised the threat to development and security posed by HIV/AIDS, and have questioned the adequacy of measures to confront the pandemic. Promising new initiatives include the International Partnership against AIDS in Africa supported by a coalition of UN agencies, donor governments, private and community sectors and African governments. The EC's initiatives to increase investments in developing new products, including AIDS and malaria vaccines, a microbicide and new medicines, are also encouraging. The initiative of five pharmaceutical companies and UNAIDS to provide anti-retroviral medicines for HIV/AIDS at more affordable prices is also a promising development. Donor funding for HIV/AIDS, estimated at USD 300 million in 1998 falls far short of need. Yet there are now positive signs of significant increases from Governments and the private sector. The EC is an active participant in these interventions.

A series of high level meetings in recent years have provided renewed political impetus to the fight against malaria. The G8 (Birmingham 1998, Cologne 1999, Okinawa 2000), the EU-US summit (Queluz 2000), the EU-Africa summit (Cairo 2000), the African Heads of State meeting in Abuja in March 2000 and the social summit in Geneva (June 2000) have all led to calls for accelerated action.

The WHO Roll Back Malaria initiative is now gaining momentum. The European Malaria Vaccine Initiative (EMVI) combines efforts of Commission, EU Member States and industry in malaria vaccine development[17]. The EU supported African Malaria Vaccine Testing Network (AMVTN), which generates human and institutional capacity in Africa, is instrumental in accelerated testing and deployment of malaria vaccines. The EC is also supporting large R&D project clusters on HIV, malaria and tuberculosis vaccines involving extensive industrial partnerships. Other innovative partnerships, such as the Medicines for Malaria Venture (MMV), which bring together public and private sectors, offer a promising route to the development of new drugs. The EC is involved in negotiating the control of the use of persistent organic pollutants (PoP) such as DDT[18].

The Stop TB Initiative, launched by WHO in 1998 and the Amsterdam TB conference (2000) have defined an agenda for action targeted at the most affected countries. Donors have indicated plans for scaled up and improved support to confront the disease.

There are many opportunities for the international community to explore the use of innovative financing partnerships, including with the private sector, and financing mechanisms that leverage additional investment. Several philanthropic agencies have provided substantial support to the fight against communicable diseases. Public-private partnerships are increasing, and the development banks are exploring possible new facilities to support work on communicable disease control.

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17 The initiative already produced tangible results: two European developed malaria vaccines are entering clinical trial this year. EMVI is participating in the Global Alliance for Vaccines and Immunisation (GAVI).

18 The EC accepts the continued, but time-limited production of DDT for vector control for public health purposes as supported by the African Consultation on reduction of reliance on DDT held in Harare in February 2000.

An effective future global response will require closer integration and synergy between these multiple initiatives with effective dissemination and incorporation of lessons learned.

## 3. EUROPEAN COMMUNITY´S SPECIFIC ROLE IN ADDRESSING MAJOR COMMUNICABLE DISEASES

### 3.1. The EC's current policies and ongoing activities

The EU (European Commission and Member States) together provides 55% of all development assistance and 65% of world assistance for Health, AIDS and Population in developing countries. In 1998 the European Community committed Euro 8.6 billion of development aid.

The goal of the new EC Development Policy (COM (2000) 212) is poverty reduction. One of the priority areas for EC development aid is the support to macroeconomic policies in developing countries with an explicit link with poverty reduction strategies, in particular sector programmes in social areas (health, education) [19]. The EC Health, AIDS and Population (HAP) policy and programmes are being re-formulated in relation to this goal, through a variety of complementary instruments. In 1998, Euro 700 million was allocated to the Health AIDS and Population portfolio[20] (see Annex 2).

The EC development policy is evolving in the following ways: from project to sector support, from infrastructure to systems strengthening and institutional development and towards greater integration of cross-sectoral themes. There has also been a shift in policy focus towards targeting poorer communities in developing countries. The EC's HIV/AIDS policy and programmes have mainly supported poverty reduction strategies through sustained cross-sectoral prevention efforts (53% of the activities financed 1987 - 1997 - see Annex 2) and primary health care (42% of the activities financed 1993 - 1997). Investment in knowledge generation has been at the core of research programmes, which increasingly target the priority issues of developing countries.

EC health support has strengthened systems, health services and pharmaceutical access with extensive support to improve capacity for procurement, distribution and rational management of pharmaceuticals as part of wider efforts to reform health systems. EC/WHO support has facilitated 21 African countries to work collaboratively on issues related to pharmaceutical policy. Specific contributions have been made over the past 10 years in 30 developing countries to develop sustainable and fair financing mechanisms and to the development of more efficient procurement and distribution systems, regulatory capacities and quality control for key pharmaceuticals with specific emphasis on contraceptives, vaccines and generic medicines.

The EC has supported capacity building to enable regional action against emerging and re-emerging communicable disease threats. This has included enhanced surveillance and control efforts, in co-operation with WHO. Ensuring effective risk management of communicable disease outbreaks is a key feature of EC humanitarian assistance programmes. The EC also supports WHO’s action plan for the reduction of the reliance on products such as DDT.

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19 COM (2000) 212, p. 25.

20 Figures include estimates from structural adjustment funds.

The EC HIV/AIDS programmes have made a major contribution to defining safe blood policy and practice, in particular in influencing the shift from a reliance on paid donors to a volunteer base. In Uganda volunteers now provide 60% of the national blood supply. The EC co-funded the influential Mwanza study (Tanzania), which identified that effective treatment of sexually transmitted diseases could reduce HIV transmission rates by 40% or more (see Annex 3). The findings of this study have influenced global HIV/AIDS control efforts. EC support to youth targeted education programmes in South Africa have led to significant falls in HIV transmission rates in this age group. Despite the successes, the scale and impact of HIV/AIDS interventions have been insufficient.

While the EC has not provided substantial targeted support to malaria and tuberculosis initiatives it has made an impact through a major contribution to health systems development in many countries. The EC supported ARIVAS programme has worked with ten countries in West Africa to incorporate finance of priority public health vaccines including tuberculosis vaccine into national budgets. The EC is involved in new international partnerships specifically related to malaria as detailed in 2.4.

The EC has played an active role in debates on improving access to and effective use of medicines. Assistance is provided to developing countries to ensure that national legislation and international agreements on trade are respected. The Commission has started to address questions linked to access to pharmaceuticals, such as pricing mechanisms, investment in new products, and the impact of international property rights. It is encouraging the participation of a wide range of stakeholders to achieve well-balanced solutions. These include research-based and generic pharmaceutical industries, NGOs, national governments and international organisations.

Europe has a long-standing tradition of excellence in vector control and pharmaceutical and medical research. European industries have considerable Research and Development (R&D) capital and skills. More than 60% of the vaccines currently used in developing countries are produced in Europe and several EU companies are among the largest producers of anti-infective drugs.

The Commission supports a long established R&D portfolio targeted at communicable diseases with more than Euro 50 million committed for new research under the first rounds of applications to the new 5$^{th}$ Framework Programme. More than 40 malaria projects were funded under the last framework programme. The EC has supported important new public-private co-operation projects, involving WHO, which seek to stimulate research and development of new medicines and vaccines of particular importance to the health of people in developing countries. Internationally very relevant activities were supported. Most of the possible malaria vaccine candidates have been initially characterised in EC projects. An EC funded trial in The Gambia in collaboration with US researchers and industry on a vaccine candidate is the first to show protection in a majority of vaccinees for more than a month. At least one new tuberculosis vaccine candidate is ready for preliminary testing and several new prototypes will be forthcoming very soon for HIV, including for the types most prevalent in developing countries. Research on a totally new class of anti-malarial drugs is also supported. EC funded North-South collaborative research was first to show the epidemiological links between HIV and tuberculosis in Zambia and between HIV and other STDs in Africa. Results of very detailed investigations on transmission give new explanations on how fast people are re-infected after initial cure of tuberculosis. In addition, the EC provided substantial funding for

environmentally friendly vector control research in order to develop new technologies and reduce the use of insecticides, and this could also be applied to the malaria vector.

Disease prevention and promotion of health will continue to be the main focus of all health and development efforts. The EC intends to build on past successes and increase support for proven and effective prevention interventions and to improve primary health services. Support to health reform is valid and will be continued in the longer term. However, the scale of the problem created by the continued spread of the three major diseases warrants additional accelerated and more targeted complementary responses.

### 3.2. The EC's comparative advantage in recent development strategies

Since mid 1990s those involved in development assistance have attempted to work through more effective national and international co-ordination mechanisms, through innovative partnerships and with greater focus on developing countries´ capacity building. More attention is being directed to ensure that public and private investments are made in the social and health environments of the poorest countries and populations, that these investments benefit the poorest and that they target the highest priorities. A set of ambitious, internationally shared development targets has been endorsed, setting the development agenda for the next 15 years. The EC has re-oriented its own strategies taking into account its comparative advantages and financing instruments.

With a strong poverty reduction mandate, the EC has a particular and important role to play in health, including to confront the problems of communicable diseases affecting the poor more effectively and rapidly. The range of Commission competencies and instruments across the vital areas of humanitarian assistance, development, environment, trade and enterprise, research and international health is unique and provides potential for greater synergy between many policy areas. In addition, the EC is active in all developing countries and provides substantial grant aid assistance. The developing country partners (in particular the Least Developed Countries) have a greater role in all aspects of the aid management cycle than with other most donor aid.

The following paragraphs present a policy framework. Specific proposals for action will be developed following wide consultation and will detail the legal basis and financial instruments proposed. The legal bases for further contributions include development co-operation (articles 177 et seq of the EC Treaty) including co-operation with international organisations (article 181), public health (article 152) and research policy (article 163 et seq). Special instruments applicable to this field include the Council regulation 550/97 on HIV/AIDS in developing countries, which is under review.

## 4. THREE CORE AREAS FOR INCREASED AND ACCELERATED ACTION

The Commission shall continue and accelerate its support for existing interventions in health but also reinforce promising approaches. Three broad areas for accelerated action are identified and presented below, building on the comparative advantage, policies and instruments of the EC.

These areas are to complement, and not replace, existing actions. They are proposed as mutually interdependent reinforcing actions. No action in one particular area can be efficient

without significant and sustained support in the other two areas. The mix of the areas of action offers the potential to deliver positive outcomes over the years.

This strategy mix consists of actions to:

- Optimise impact of existing interventions.
- Increase the affordability of key pharmaceuticals through a comprehensive global approach.
- Increase investment in research and development of new medicines and vaccines targeted at the three diseases.

These three areas have been highlighted because of their direct relevance to the fight against communicable diseases. However the Commission does not regard these areas as the only ones important to successful communicable diseases control. Ongoing EC interventions in areas such as good governance, conflict prevention and resolution, corruption, transport, infrastructure, education, gender equality, and the fight against the production, trafficking and use of illegal drugs, are all being pursued for their wider beneficial and development impact but will also have a positive effect on communicable disease control. Continued EC action in these areas and above all a continued commitment by partner governments to take action, are essential if the major communicable diseases are to be controlled.

### 4.1. Reaching optimal impact of existing interventions in EC development co-operation.

Public health systems have had varied success in providing effective services to the poor. Government health systems, however, will continue to serve as the largest single provider of preventive measures and curative services for the three diseases. The EC will improve its efforts to strengthen health systems, provide for key commodities and pharmaceuticals, support national budgets, scale up effective approaches and improve donor co-ordination. Delivering a major increase in access and utilisation of effective interventions will involve working through multiple complementary channels. These would include NGOs/CBOs, the for-profit private sector, and traditional providers.

There are under-exploited opportunities to scale up approaches, which have proven effectiveness and to develop innovative mechanisms and partnerships to reach the poorest. Useful experience has been gained in franchising, social marketing, use of voucher schemes, over-the-counter sales of non-prescription items, public-private collaboration, regulation and contracting. Many of these small-scale pilots could be scaled up. Others such as social marketing may need to be further refined to reach those who are presently too poor to benefit. Important elements will be the provision of information on which consumers can make informed decisions and attention to regulatory and legal frameworks to strengthen consumer rights.

Adequate and ring-fenced public finance (external and domestic) for priority preventive and curative interventions is essential if poor people are to have access to care. However, a range of financing mechanisms needs to be considered. The appropriate approach will depend on country context, and will need to be pluralistic.

The following policy orientations will guide future action:

- Focus on **preventive activities** should remain the EC´s main long-term response in addressing the three major communicable diseases.

- Encourage developing countries to establish **coherent and integrated health policies** designed at targeting major communicable diseases. This includes ensuring that an adequate balance between prevention and care is maintained in the delivery of Community assistance.

- Establish and strengthen **innovative partnerships** and national mechanisms that involve governments, but also **reach beyond the government health system**. Examples could include partnerships with civil society organisations, support for organisations experienced in the social marketing of health commodities, partnerships with private sector distribution networks and qualified private providers. Such an approach will require high quality market research on behaviour and attitudes that might affect the use of commodities or interventions.

- Develop **sustainable** mechanisms for **progressive, prepaid financing for effective prevention and care interventions**, which would exempt the poor and provide subsidies for the near-poor, thus opening up markets for low cost commodities and health interventions.

- Support the growth of **strategic purchasing**, including the use of contractual or franchising arrangements, by public fundholding bodies in the health sector for qualified providers of all types (public, private, not-for-profit). Ensure **incentive systems**, which favour rational selection and safe, economical use of technologies, which promote and improve health, by providers of all types.

- Support for **improved delivery mechanisms** and quality insurance for commodities and interventions that are effective, such as condoms, bednets, prevention of mother to child transmission, voluntary counselling, HIV testing and care for people with HIV/AIDS, sexually transmitted infections (STI), tuberculosis and malaria.

- Support will be focussed on **those countries which demonstrate a commitment** to equitable access to essential services and which demonstrate positive outcomes for the poorest segments of the population. This includes the development of fair financing strategies[21] and responsive, accountable health systems.

The EC and the international community are exploring innovative financing partnerships that may also induce the private sector to mobilise additional investment. This global partnership will co-operate with specialised UN agencies, such as WHO and UNAIDS, to back country-based initiatives with demonstrated ability to increase access to, and make effective use of, key commodities and interventions, disseminate lessons learned, inspire others and catalyse more widespread and effective actions.

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[21] For the definition of fair financing, see The World Health Report 2000, p. 35-39.

## 4.2. Increasing affordability of key pharmaceuticals through a comprehensive approach

Almost 90% of the products on WHO's "essential drug list" are not patented and therefore are subject to generic competitive tendering and local production. In principle they are available at lower prices from generic or original producers. Yet still many of these products do not reach people in developing countries for reasons highlighted in 4.1.

Several key products to prevent, diagnose and treat HIV/AIDS, malaria and tuberculosis are largely produced in industrialised countries, under patent, are still too expensive for the poor. Consumer prices can vary widely within, as well as amongst countries, because of differences in market demand, intellectual property rules, purchasing capacity, tariff levels, differences in local incomes, the lack of a sustainable market, price setting and the degree of competition among generic and the R&D-based pharmaceutical industry producers. The Brazilian government has recently started to produce 7 of the 12 drugs used to assist people with HIV/AIDS. The prices of those drugs have fallen 70% on average, while prices of medicines bought in international laboratories, have fallen less than 10% in the same period [22].

Affordability of key pharmaceuticals can only be increased and accelerated through a comprehensive synergistic approach. The EC recognises that the price of essential drugs and key pharmaceuticals needed to prevent or to treat the three major communicable diseases is one of the major obstacles, but not the only barrier, to improving access to health and health care for the poor in developing countries.

The following policy orientations will guide future action:

- The EC will increase its present support to countries to **strengthen national pharmaceutical policies and practice** including procurement, tendering, distribution, quality assurance and technical capacities to improve the availability of essential and key medicines at country level.

- The EC recognises the need for the careful **review of pricing** of key pharmaceuticals for the three major communicable diseases and the **impact of import tariffs and taxes,** taking into account effects on the tax base and on public expenditure. Greater transparency regarding the breakdown of consumer prices on key pharmaceuticals will also be pursued.

- The EC also advocates that industry use **tiered pricing** to allow manufacturers to offer the lowest possible prices to the poorest countries without threatening profits in developed countries.[23] This should build on a volume/price trade off. Where lower income countries benefit from (low) preferential prices, effective measures need to be in place to prevent parallel exporting to (higher price) developed countries. The EC will further examine the impact of **parallel trading**,[24] taking into account that the general principles of community law allow patent holders to oppose parallel trade from outside the EEA.

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22 Government of Brazil: Report to International AIDS conference, Durban, July 2000.

23 Tiered pricing has long been practised in relation to childhood vaccines.

24 Parallel trading involves cross-border trade in a product without the manufacturer's permission – i.e. helps lower drug prices by enabling buyers to shop around for the cheapest drug sources, whether they are patent holders or not. For parallel trading from outside of the EU and exhaustion of rights (for

- Other possibilities could be through engagement in **voluntary licensing agreements** to facilitate local production of key pharmaceuticals and to ensure that developing countries benefit from technology transfer.

- The generic and R&D based pharmaceutical industry are invited to develop and co-operate with the local pharmaceutical industry and research institutions in developing countries, provided effective competition is ensured on domestic markets. This would contribute **to increasing capacity for local production of generic drugs** and enable fair competition from generic drug manufacturers. The EC will also work with the governments from developing countries to facilitate local production.

- The EC acknowledges that developing countries can use, when appropriate, the flexibility within the **TRIPS Agreement** to provide compulsory licensing[25] (article 31 of TRIPS) **to address public health concerns and emergency crises. In doing so the EC also takes into account the need to respect the property rights of the patent holders.** Together with its partners from developing countries, the EC will explore the flexibility provided by the TRIPS Agreement to address public health concerns and emergency crises.

The EC will provide technical assistance for countries to implement the TRIPS Agreement. The EC and their Member States should co-ordinate and enhance their technical assistance with developing countries aiming at their full compliance with the TRIPS Agreement.

### 4.3. Investment in research and development of global goods targeted at the three diseases.

Actions identified in the previous sections seek to address access and affordability issues that can make an impact on communicable diseases in the short to medium term. They are to increase the attractiveness of the market and protect the environment and intellectual property rights. However, more attractive markets alone will not provide adequate incentives for new investment. This will also require measures targeted at the various stages of the research and development process. They are to overcome obstacles from the past: insufficient co-ordination between players, insufficient identification of the means necessary and lack of institutional capacity building in the countries hardest hit by the epidemic.

The EC proposes to address the multiple barriers for further investment in research and development through three complementary strategies consisting of larger scale and more effective public investment, development of an incentive package for private investment and participation in a global partnership.

**Larger scale and more effective public investment.** The Community has made a significant past contribution to the research agenda through the Biomed Specific Programme of the 4th Framework Programme and through key actions on 'control of infectious diseases', and 'quality of life', as well within the INCO programme in the 4th and 5th Framework Programme (see Annex 4). Recent initiatives have increasingly focused support on confronting communicable diseases in developing countries. The EC proposes to scale up the different

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trademarks), see the following ECJ cases: Silhouette International (Case C-355/96) and Sebago (Case C-173/98) .

[25] The granting of a license without the consent of the patent holder on various grounds of general interest.

components of the R&D process and to further increase coherence between Community and other R&D activities. The goal is to rapidly enlarge the R&D pipeline, to accept a greater degree of investment risk and to accelerate the process through a move from serial to parallel testing of candidate products. Reinforced co-ordination with Member States on common strategic R&D will be the key to this acceleration.

Under the new European Research Area policy framework (ERA), the EC proposes to increase support for capacity building of research institutions and personnel in developing countries. It seeks to ensure that researchers from developing countries are more involved in early priority setting within the EC R&D process and that countries which host clinical trials see their communities and scientists both participating adequately in the exercise and benefiting from the results. Most rigorous ethical standards need to be established and observed. A specific Communication on research against major communicable diseases is being prepared.

**Development of an incentive package for private investment.** Accompanying measures to build capacity and further develop innovative public-private partnerships are needed. Increased private investment in R&D will be encouraged through appropriate incentives. The EC intends to explore options to improve the expectations of companies that a future market will enable return of their investment costs for R&D.

Possible incentives which require further study are two-fold: low cost loans and other incentives for venture capital especially important for small biotechnology firms doing most of the early research and development of vaccines and drugs; and purchase funds. The international debate on possible operationalisation of such funds is ongoing[26]. Producers of newly licensed vaccines could be granted rights for limited patent extension on unexpired drug or biological patents for which the owner is the holder of the exclusive license. Innovative public-private licensing agreements already tested for HIV/AIDS vaccine development could also be extended more widely.

There is great scope to improve availability of information at all levels. Developing country partners need easier access to complex but publicly available patent information. Pharmaceutical companies need improved information on potential markets for products; this could be provided through market exercises such as that performed by the EC for microbicides, condoms and an HIV/AIDS vaccine. Early sharing of intellectual property rights related to extensive research partnerships will be encouraged.

**Participation in a global partnership,** to make the health research agenda more responsive to the global needs in the next decade. The EC together with WHO, the World Bank and other main partners in health and development will come together to influence a more responsive health research agenda for the next decade. The effort will seek to reorient health research, both public and private, from the present ratio of 10% investment in 90% of the global burden of disease towards a more favourable 20/80 ratio. This shift appears to be a realistic goal and further monitoring tools need to be developed.

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[26] Here the distinction is often made between 'push' and 'pull' mechanisms. Examples of push mechanisms are public investment in research and tax breaks linked to investment for research by private companies. Examples of pull mechanisms are purchase funds and transfer of patents. It is argued that without sufficiently strong pull mechanisms, the new drugs and vaccines will not be developed and be put into use, even if the 'push' is successful in developing candidate vaccines.

## 5. CONCLUSIONS AND RECOMMENDATIONS

A new international effort to reduce the impact of the key diseases that keep the poor in ill health and poverty and hold back development is long overdue. The international environment is supportive and the new and evolving partnership with WHO and closer collaboration between stakeholders, including the World Bank and UNAIDS, offer a new opportunity that should be built upon. The Community proposes to make a substantive contribution to the international effort using the various instruments at its disposal.

The policy framework set out in this Communication is the Community's first response to the recommendations of the G8 summit held in Okinawa in July 2000. The Commission will elaborate a programme for action along the lines of chapter 4 above. In formulating the programme for action the Commission will benefit from additional consultations with important stakeholders, including developing countries, Member States, Members of European Parliament, international development agencies, civil society, researchers and the private sector, at a high level Round Table to be held in Brussels on 28 September 2000.

The Council and the European Parliament are invited to work with the Commission to take forward the ideas in this Communication.

## Annex 1

## Global emergency cause by HIV/AIDS, malaria and tuberculosis

***HIV/AIDS***

- HIV/AIDS kills over 2 million people in Africa alone each year – more than 10 times the number that perish in wars and armed conflict during the same period.
- In 1999, 33.6 million people world-wide were estimated to be living with HIV/AIDS with over 16 million people deaths since the start of the epidemic.
- 95% of infections are in developing countries with two-thirds in sub-Saharan Africa where HIV prevalence has reached 30% of the adult population in seven countries.
- In 1999 an additional 5.6 million people were infected including 570,000 children born to HIV positive mothers.
- Women are particularly vulnerable to HIV infection due to both social and biological factors.
- 11.2 million children are orphaned due to AIDS.
- HIV/AIDS spreads fastest in conditions of poverty, social instability and powerlessness. Such conditions are at their most extreme during emergencies.
- HIV/AIDS is reversing important developmental gains; in parts of Southern Africa, infant mortality has increased by 25% and life expectancy has fallen from 64 to 47 years over a period of just three years.
- HIV/AIDS affects adults in their economically productive years; per capita income may be reduced by as much as 0.5% per year where more than 8% of adults are infected.
- Prevention by reducing vulnerability and curbing transmission of the virus remains the most effective strategy to control the spread of the epidemic.
- The availability of care and medicines for HIV/AIDS has significantly reduced disease and mortality caused by HIV/AIDS in industrialised countries; the vast majority in developing countries are deprived of all drugs including those for treatment of common opportunistic infections.

***Malaria***

- Malaria kills at least 1 million people each year and infects 500 million people.
- 90% of cases occur in Africa while 40 percent of the world's population is at risk.
- The major impact is on women and children - 700,000 children will die from malaria this year - one death every 30 seconds. Women are four times as likely to suffer malaria attacks during pregnancy.
- Malaria control and treatment costs African countries 1.5% of GDP or USD 2 billion in 1997.
- A malaria-stricken family spends over one quarter of its income on malaria treatment. Families pay prevention costs and suffer loss of income from repeated attacks.
- Complex emergencies and natural disasters increase malaria risk.
- Malaria is curable if promptly diagnosed and adequately treated.

***Tuberculosis***

- Tuberculosis (TB) each year kills 2 million people with 95% of deaths occurring in developing countries. TB is the leading cause of death among the HIV positive.
- TB infection is increasing across the globe with a four-fold increase in several African countries over the past decade and new outbreaks in Eastern Europe after 40 years of steady decline.[27]
- Over the next 20 years nearly one billion people will be newly infected, 200 million people will get sick, and 35 million will die from TB.
- A person with infectious TB infects 10-15 people every year.
- TB affects the weakest and traps people in a cycle of poverty and disease. Most of those affected are in the economically active population with women less likely to be detected and treated.
- A highly effective cure exists and a course of treatment costs as little as USD 11.
- The emergence and spread of multi-drug resistant TB due to inappropriate treatment or compliance with treatment prescriptions represents a global threat.

[27] While recognising the scale of the TB problem in the countries of Eastern Europe in transition, the focus of this initiative will be on developing countries.

## Annex 2

## EC Health, AIDS and Population Portfolio

Poverty reduction has become the overarching aim of EC development policy with assistance to health, HIV/AIDS and population programmes (or HAP) playing an increasingly important role. As a result, aid to these themes and sectors has grown continuously and from barely 1% of total EC aid in 1986 now represents more than 8 %. The OECD average support to HAP is around 5.5 % in 1998.

EC commitments to health, AIDS and population in 1998 amounted to well over Euro 700 million (figure 1) for more than 100 developing countries.

Between 1993 and 1997, 22% of HAP support in ACP countries was used for construction, 17% for technical assistance, 13% for equipment, 11% for consumables and 11% for human and institutional development (figure 3). Since 1998 the shift towards sector wide approaches in partnerships with Government, civil society and other donors has continued. Less funds are channelled to construction and equipment, while the focus on human and institutional development has significantly increased. Figure 7 shows EC commitments on HAP 1994 - 1998 for Asia, Latin-America, ACP countries and the Mediterranean.

The EC's HIV/AIDS policy and programmes have mainly supported poverty reduction strategies through sustained cross-sectoral prevention efforts (53% of the activities financed 1987 – 1997 – figure 4) and primary health care (42% of the activities financed 1993 - 1997).

Overall accumulated EC commitments to HAP related activities in developing countries between 1990 and 1998 amount to around Euro 3.4 billion. A forthcoming portfolio review and overall evaluation (programmed for 2001) will define the nature of commitments, countries/regions, partners, levels of interventions and type of budgetary instruments. Taken together, EC and EU Member States now provide more than half of all development assistance to health related programmes around the globe.

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Figure 1. Commitments to Health, AIDS and Population

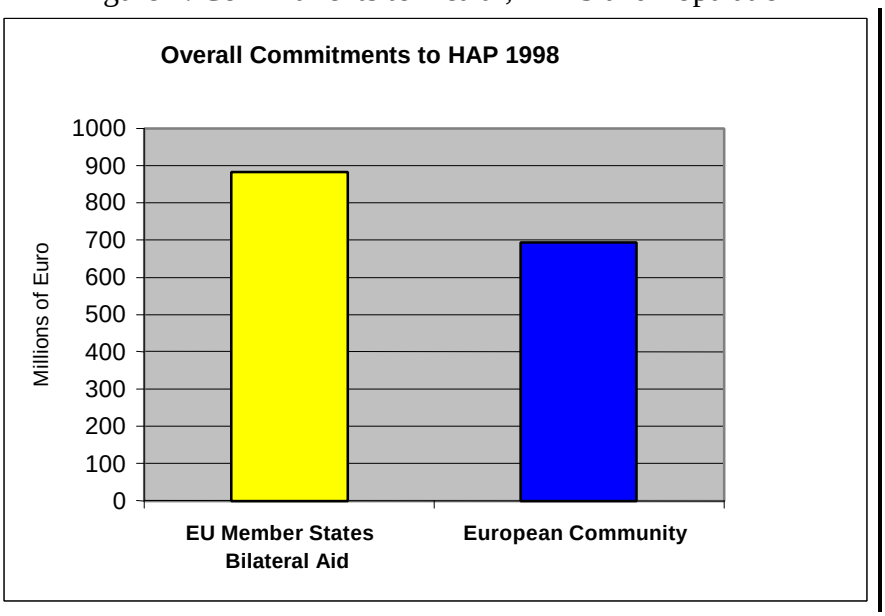
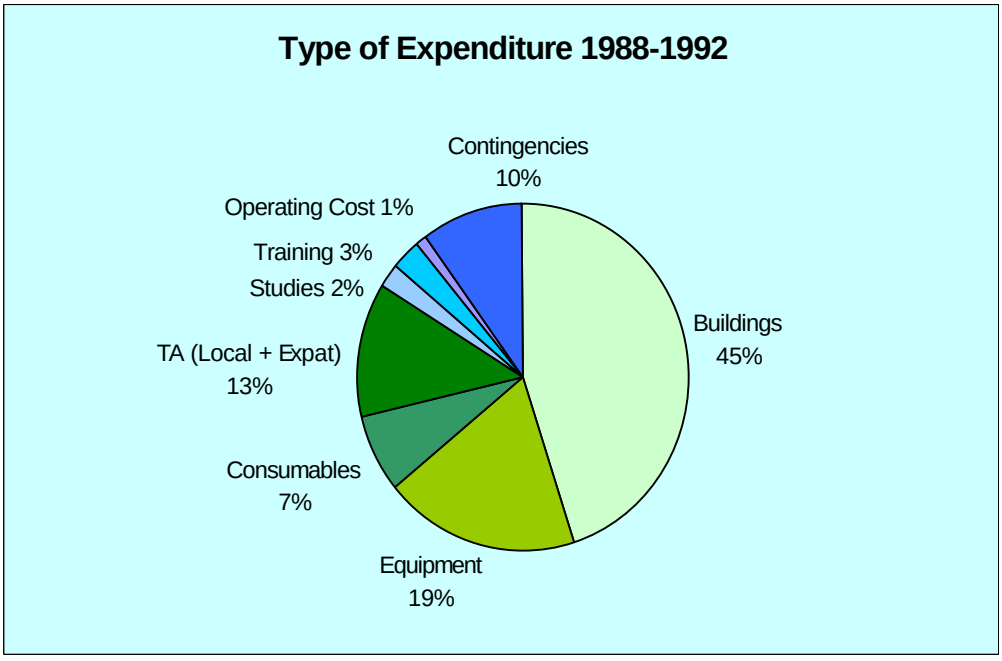



Figure 2. Evolution of type of expenditure and project focus in Health, HIV/AIDS and Population interventions (1988-1992)



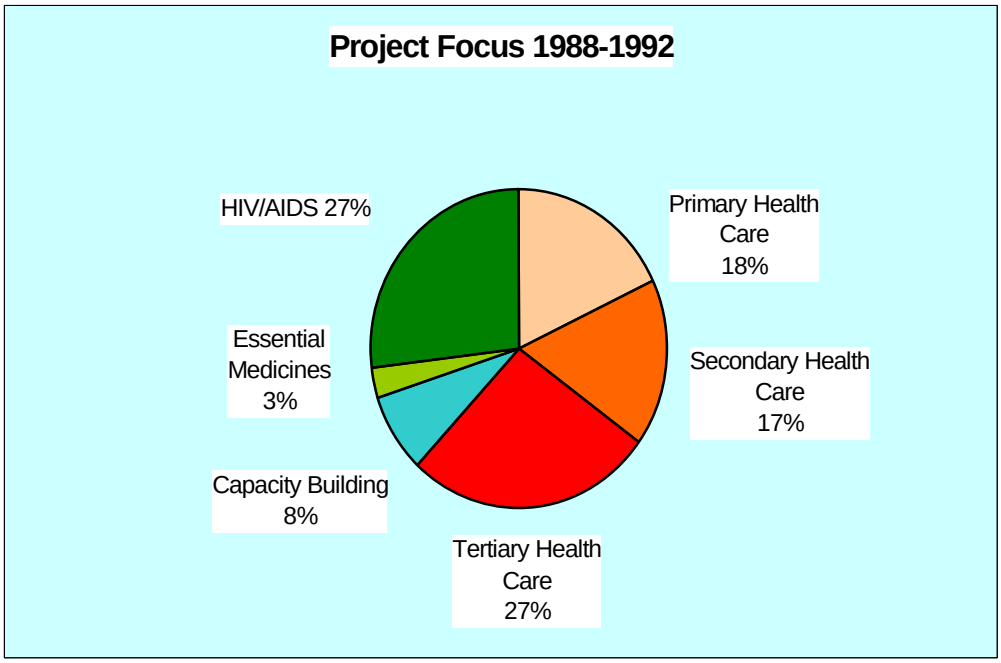
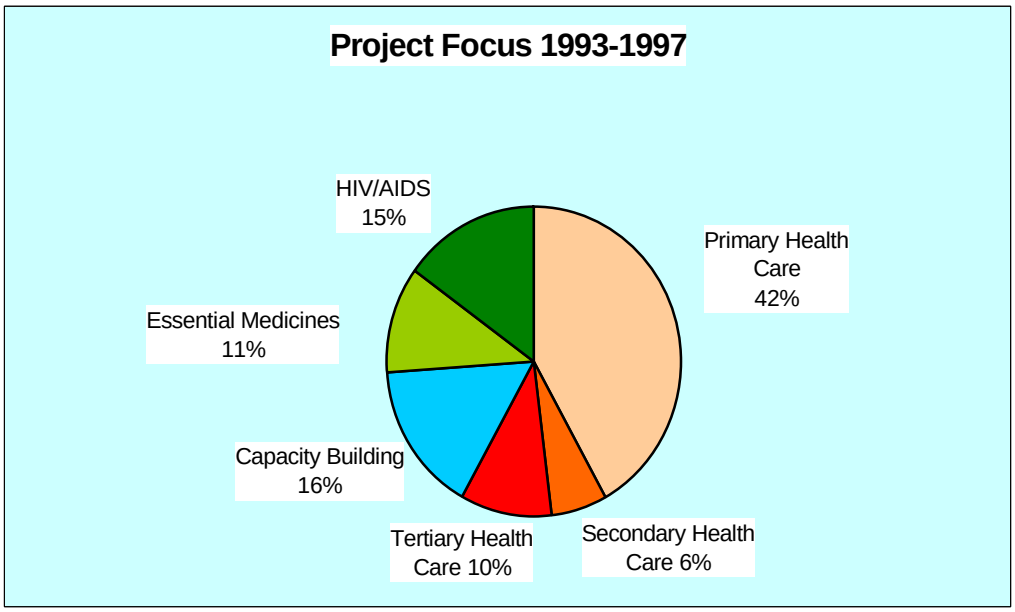

Project Focus 1988-1992
HIV/AIDS 27%
Primary Health Care 18%
Essential Medicines 3%
Secondary Health Care 17%
Capacity Building 8%
Tertiary Health Care 27%

Figure 3. Evolution of type of expenditure and project focus in Health, HIV/AIDS and Population interventions (1993-1997)



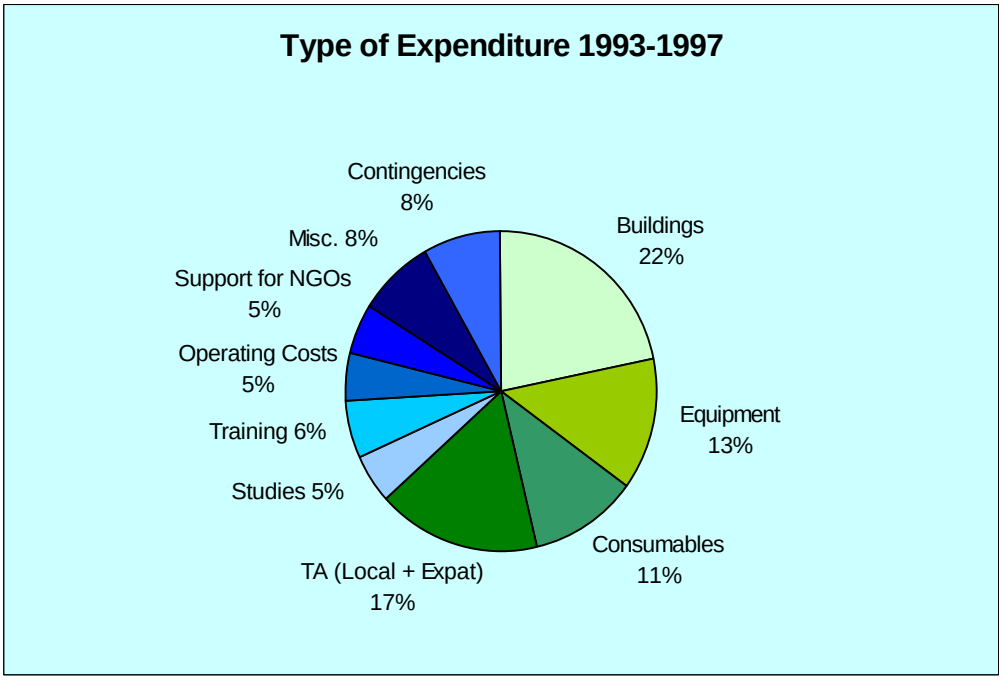



Figure 4. Commitments to HIV/AIDS interventions (1987-1997)


Figure 5. Commitments to HIV/AIDS interventions by region (1987-1997)

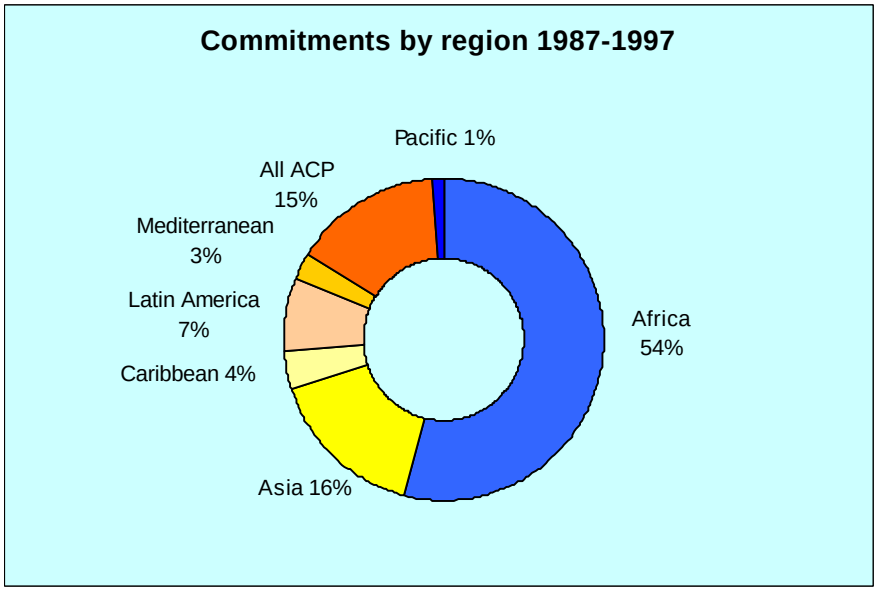


Figure 6. Commitments to HIV/AIDS interventions by partner type (1987-1997)

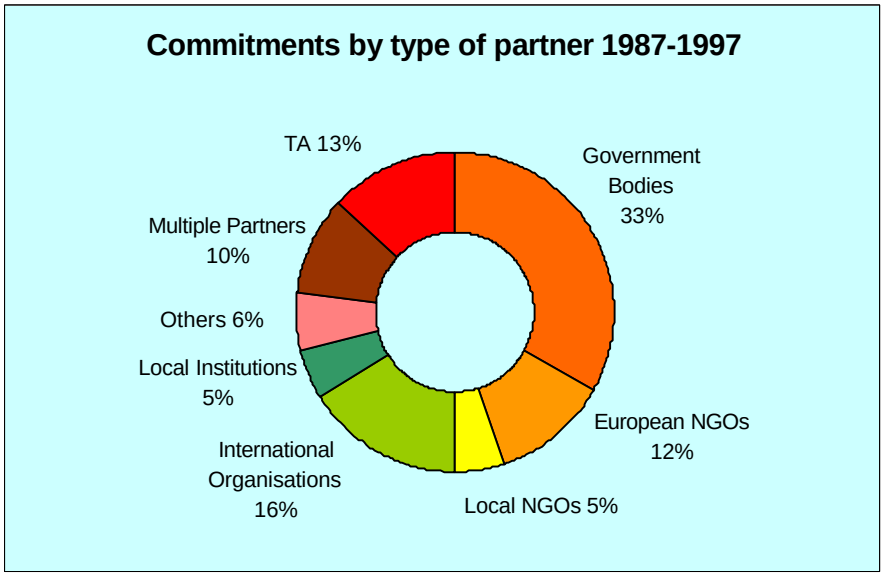
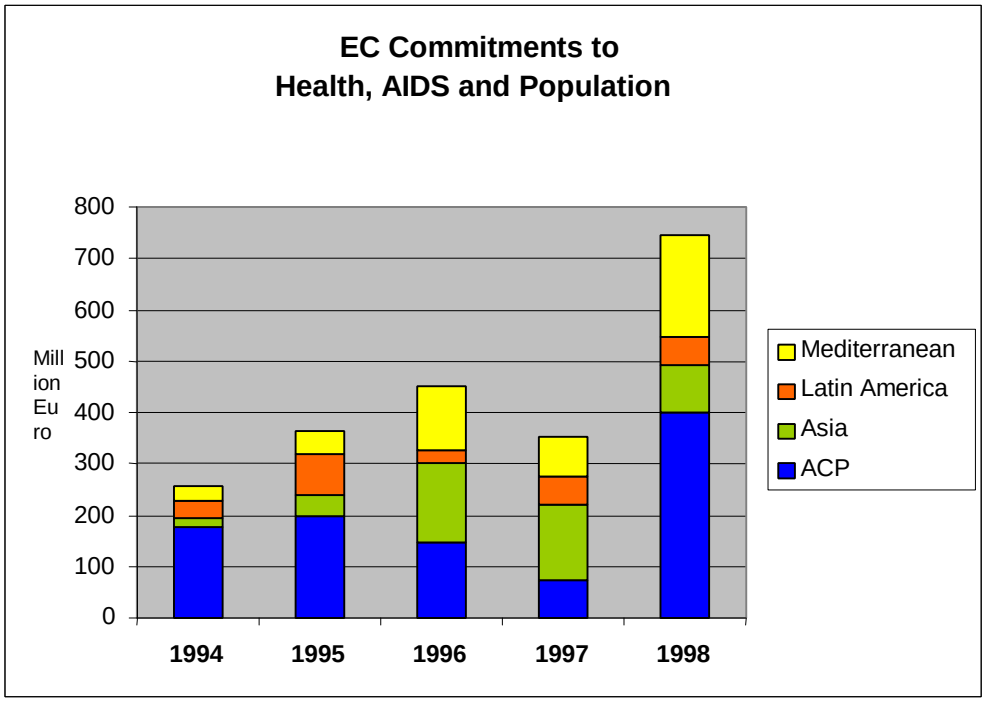



Figure 7. Overall EU Commitments to Health, AIDS and Population 1994 - 1998.




**OVERALL COMMITMENTS RELATED TO HAP PROJECTS/PROGRAMMES FOR 1995-1999 FUNDED THROUGH EDF & ALAMED FINANCIAL & TECHNICAL COOPERATION INSTRUMENTS**

| Region | Commitments Total[28] |
|---|---|
| Asia | Euro 444.215 million |
| Latin America | Euro 173.550 million |
| Mediterranean | Euro 244.860 million |
| ACP (incl. South Africa) | Euro 497.712 million |
| **Overall Total** | **Euro 1,359.9 million** |

**COMMITMENTS THROUGH THE HIV/AIDS AND DEMOGRAPHY SPECIAL BUDGET LINES (B7-6211, B7-6212 and B7-6310)**

| Region | Amount | Year |
|---|---|---|
| All Developing Countries | Euro 18.1 million | 1995 |
| | Euro 21.9 million | 1996 |
| | Euro 20.1 million | 1997 |
| | Euro 23.9 million | 1998 |
| | Euro 24.8 million | 1999 |
| | (Euro 20 million | 2000) |
| **Overall Total** | **Euro 108.8 million** | |

[28] First review prepared by DG DEV. This list does not include interventions funded through other instruments such as budget aid (including structural adjustment), NGO co-financing, research, refugee budget lines or ECHO nor does it include funding of health programming under PHARE or TACIS.

## Annex 3

## Summary of actions taken in follow-up to the Commission Communication on increased solidarity to confront AIDS in developing countries (com-98-407)

Adopted by the Commission on July 3 1998, this Communication provided the basis for a European response to calls for more international solidarity with developing countries in confronting HIV/AIDS, and in particular, calls for increased access to care for HIV/AIDS and the need for HIV vaccines and microbicides for developing countries.

The Communication stressed the importance for the EU to build upon and strengthen existing actions in support of affordable and effective targeted preventative interventions, and the need to ***strengthen health care delivery systems*** in developing countries as a pre-requisite for improved access to drugs, especially anti-retrovirals, for people with HIV/AIDS.

In addition, the Communication explored the potential for the creation of **new solidarity mechanisms**, and examined the prospect of financing ***care, including anti-retrovirals,*** in developing countries and the possibility of supporting accelerated development of ***vaccines and microbicides***.

In line with the priorities set in the Communication for **additional and new EC efforts** - in addition to the existing substantive programmes of support for health, including HIV/AIDS, in developing countries, a number of new initiatives were launched by the European Commission. **There is no doubt that these initiatives on improved access to care and development of new vaccines and microbicides in the context of HIV/AIDS, form a useful basis for EC work under the proposed programme for increased investment on communicable diseases in developing countries.**

### Initiatives for the prevention of mother to child transmission

1. The EC supported a number of pilot projects in preventing mother-to-child transmission of HIV/AIDS in developing countries. The projects included the careful introduction of an essential package of treatment regimens for zero-positive pregnant women.

2. Under the auspices of the EC and in co-operation with UNAIDS and the main other actors in this field, the "Group of Ghent" - a think-tank of scientists and health professionals - developed a public health strategy for mother-to-child interventions and designed intervention packages to reduce mother-to child transmission as an integral part of antenatal, obstetric and paediatric care. A pilot project based on the strategy and intervention package has started in Burkina Faso.

3. Initiatives in support of the development and availability of an HIV/AIDS vaccine in developing countries.

### Initiatives to support vaccine development

1. At the initiative of the Directorate for Development a technical consultation on **making an AIDS vaccine available in developing countries: economic and financing** issues, was held in March 1999. The consultation prioritised actions to

address barriers to vaccine development, identified areas where the European Union has a comparative advantage, and led to the establishment of an Inter-Service HIV Vaccine Task Team within the European Commission, lead by DG Development.

2. **The Inter-Service HIV Vaccine Task Team** includes representatives of Directorates responsible for development, scientific research, industry and enterprise, the European Investment Bank (EIB) and European Medicines Evaluation Agency (EMEA). The Team has developed a comprehensive strategy and action plan.

3. **The EC HIV vaccine strategy and programme of action** includes the following key elements: vaccine research and development; public health and economic research; vaccine preparedness; policy dialogue; and intellectual property and regulatory issues.

**Specific sponsored actions to date include:**

1. Funding for the Eurovac cluster project, through the Commission's Directorate for Scientific Research Framework Programme. This three-year collaboration between European research institutions and industry will identify potential candidate vaccines for developing countries and develop new techniques for vaccine delivery and funding of enabling projects for HIV vaccine development.

2. A programme of collaboration between the Commission's Directorate for Development and the World Bank on "willingness to pay" studies, in order to assess the potential demand for an HIV vaccine in a range of developing countries, and on modelling the potential public health impact and cost-effectiveness of an HIV vaccine in different settings.

3. Directorate for Development financing of community preparedness research by the South African AIDS Vaccine Initiative and the South African Medical Research Council, on legal and ethical issues including community mobilisation and participation in vaccine development and clinical trials.

**<u>Initiatives in support of the development and availability of microbicides</u>**

1. The EC commissioned and supervised **a study into the market potential for vaginal microbicides** that could protect against STDs, including HIV.

2. Progress towards the development of microbicides effective against STD's, incl. HIV has been fragmentary, mainly because the pharmaceutical industry lacks confidence that such a market exists. Research carried out amongst 4000 individuals in Brazil, the Ivory Coast, Egypt France, India, Kenya, the Philippines, Poland, South Africa, Thailand and Venezuela. The results of the study show a great deal of interest from women for such a product and that there is, without a doubt, a commercial - as well as a moral - justification for further product development.

3. Furthermore, a call for proposals was launched with a specific thematic budget line (year 2000) to support innovative programmes in the areas identified in the Communication on increased solidarity.

## Annex 4

## DG Research Investments into projects related to HIV, Malaria and TB

The international collaboration[29] and life sciences[30] programmes of DG Research are investing in a complementary manner into research and development of vaccines and drugs against those communicable diseases affecting the poorest most. Catalysed through the task force on vaccines and viral diseases, the past years have witnessed a considerable increase of resources devoted to this field. Moreover, research is successively moving from discovery into preclinical and clinical validation phases. Recently, major integrated research consortia ("clusters") have been established under the life sciences programme.

### INCO-DC / INCO-DEV

Under the 4th Framework Programme INCO DC (1994-1998), EC has been funding 154 health related projects, involving some 119 research teams from 31 African countries, in a total amount of Euro 80 million. Approximately two-third are directly linked to the priority diseases HIV, TB and malaria. Research covered epidemiology, transmission and intervention strategies, drug research as well as molecular and vaccine research. INCO supports the European Malaria Vaccine Initiative (EMVI) and the African Malaria Vaccine Testing Network (AMVTN).

Under the 5th Framework Programme INCO-DEV (1999-2002), Euro 10 million were committed for vaccine research, and Euro 15 million could be allocated to drug and diagnostics development (2000). A forthcoming call (2001) will be targeted at the three major communicable diseases.

### BIOMED / BIOTECH / Key Action Control of Infectious Diseases

The 4th Framework Programme programmes BIOMED/BIOTECH pursued different strategies: BIOMED invested into European networking projects on HIV (Euro 13.7 million for 31 projects) and TB (Euro 3.3 million for 7 projects). BIOTECH gave support to underpinning vaccine research (Euro 30 million for 34 projects) and to a limited number of advanced vaccine research, including clinical trials on HIV, malaria and schistosomiasis (Euro 5.3 million 5 projects).

With the 5th Framework Programme, the Key Action Control of Infectious Diseases has embraced a global view in its programme objectives. 40% of its currently committed budget (total budget over 4 years is Euro 300 million) is on projects linked to the three major communicable diseases. A novelty is the successful implementation of large cluster projects, in particular for HIV, TB and malaria vaccines, as well as for TB drug development. So far, Euro 21.8 million have been committed for HIV, Euro 8.8 million on malaria and Euro 9.9 million on TB research, with app. 2/3 of the budget being reserved for vaccine research and 1/3 for drug development.

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29 INCO-DC (International Co-operation Developing Countries) and INCO-DEV.

30 BIOTECH, BIOMED, Quality of Life "Key Action Control of Infectious Diseases".