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Review of the problem of human immunodeficiency virus/acquired immunodeficiency syndrome in all its aspects

Letter dated 17 May 2001 from the Permanent Representative of Sweden to the United Nations addressed to the Secretary-General

I have the honour to draw your attention to the communication dated 21 February 2001 from the Commission of the European Communities to the Council of the European Union and the European Parliament, entitled "Programme for Action: Accelerated action on HIV/AIDS, malaria and tuberculosis in the context of poverty reduction" (see annex).*

I should be grateful if you would have this letter and its annex circulated as a document of the General Assembly, under agenda item 179.

(*Signed*) Pierre **Schori**
Permanent Representative

* The annex is being circulated in the languages of submission only.

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Annex to the letter dated 17 May 2001 from the Permanent Representative of Sweden to the United Nations addressed to the Secretary-General

[Original: English, French and Spanish]

Communication from the Commission to the Council and the European Parliament

Programme for Action: Accelerated action on HIV/AIDS, malaria and tuberculosis in the context of poverty reduction

Executive summary

This Commission's Programme for Action develops the policy framework presented in the September 2000 Communication on *"Accelerated Action targeted at major communicable diseases within the context of poverty reduction"*[1]. It establishes a broad and coherent Community response, over the period 2001-2006, to the global emergency caused by the three major communicable diseases, HIV/AIDS, malaria and tuberculosis, which most affect the poorest populations and which undermine global health.

The Programme, as part of an expanded global effort, targets actions to increase; the impact of existing interventions, the affordability of key pharmaceuticals, and research and development of specific global public goods to confront these diseases in developing countries.

The Commission will prioritise investment in health, aids and population in the context of poverty reduction. A greater focus on communicable diseases will be provided through options including; redirection of unspent resources, guidance on future programming exercises and the use of regional funds. More effective aid management processes will speed up the disbursement of funds to improve health. While the overall approach will be comprehensive, targeting the support for better health in developing countries, the Commission will maintain a major focus on prevention. Investment in strengthening pharmaceutical policies will include the appraisal of opportunities to develop local production capacities. The Commission will seek to work in close co-operation with the UN, the G8 partners, the World Bank, civil society and EU Member States to, based on each partner's comparative advantage, promote the reform the international financial architecture to enable greater co-ordination, complementarity and efficiency of international funding.

The European Community will seek to increase the affordability of key pharmaceuticals through attention to issues related to taxes and tariffs in developing countries. The European Community will work towards the introduction of tiered pricing as the norm for the poorest developing countries[2], while seeking to prevent re-importation to the EU market. Investment will build capacity within developing countries on health and trade-related issues, including implementation of the TRIPs Agreement.

[1] COM(2000) 585 of 20.9.2000.

[2] In the context of this Programme for Action, the poorest developing countries include the Least Developed Countries (currently 48 countries (UNCTAD:2000) and the other low-income countries with a GNP per capita of less than USD 765 (currently 24 countries DAC: 2000).

The European Community will support new approaches to stimulate the development of global public goods targeting the three major communicable diseases. Action will include increased public support to Research and Development, notably for clinical trials, appropriate incentives to encourage private investment into Research and Development, attention to early dialogue on regulatory aspects and ensuring participation of developing countries in the research process. Building increased capacity for research in developing countries will be a priority.

To meet these objectives, the Commission will explore the use of the full range of available financial instruments to implement this Programme for Action. The framework presented identifies main actions, potential partners and instruments, and will be further detailed within specific work plans following endorsement of this Programme for Action.

Appropriate mechanisms, resources and partnerships will be put in place to monitor implementation of this Programme for Action, and to participate in a global monitoring system encompassing the efforts of all international partners. Successful implementation of this initiative will make a major contribution to global efforts to address the communicable disease emergency.

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1. CONTEXT

On 20 September 2000, the Commission adopted a new policy framework presented in the Communication on **"Accelerated Action targeted at major communicable diseases within the context of poverty reduction"**[1]. The European Community policy aims to respond to what is now generally acknowledged as a global emergency: the death of five million people per year from three major communicable diseases: **HIV/AIDS, malaria and tuberculosis**. Each disease kills more than one million people a year, mainly in developing countries, posing a serious threat to global health.

The policy framework identifies three objectives for targeted action and a coherent response to the three diseases in the area of **impact of existing interventions, affordability of key pharmaceuticals, and research into and development of specific global public goods**. This approach has received a high level of political support from developing countries, EU Member States and international development agency partners, civil society and industry. It combines a **coherent and unique mix of development, trade and research policy** and draws on all available expertise within the Commission.

Taking into account the outcome of the international 'High-Level Round Table'[2] on the new European Community policy, and following the conclusions by the Council[3], the **Commission has developed a Programme for Action** targeted at the three major communicable diseases over the coming five years (2001 - 2006).

2. OBJECTIVES AND EXPECTED OUTCOMES OF THE PROGRAMME FOR ACTION

The main objective of European Community Development Policy[4] is to foster **sustainable development** designed to **eradicate poverty** in developing countries and to integrate them into the **world economy**. At the start of the twenty-first century, few investments are wiser than those in good health. Investments in health can make a major contribution to poverty reduction welfare and economic growth: countries with higher levels of health grow faster. In the poorest developing countries[5], communicable diseases, particularly HIV/AIDS, malaria and tuberculosis continue to limit development.

The European Community policy framework and this Programme for Action targeted at the major communicable diseases, are entirely in line with and at the same time a pre-requisite for achieving the objective of the European Community Development Policy. They will allow the European Community **to contribute substantially and participate fully in global and country efforts** to confront major communicable diseases. In recognition of the pivotal role of developing countries in ensuring the

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[1] Communication (2000) 585 of 20.9.2000.

[2] In order to ensure a broad consultation on the new Communication, the EC, in partnership with WHO and UNAIDS, convened a High-Level Round Table in Brussels on 28 September 2000. The Round Table brought together over 170 stakeholders, including 25 developing countries, notably ACP states, EU Member States, the European Parliament, international development agencies, civil society, researchers and leaders of major pharmaceutical companies. A high degree of consensus was reached among stakeholders on the content of the Communication. More information can be found at www.europa.eu.int/comm/development/sector/social/table.

[3] Council resolution of 10.11.2000, 2304th Council meeting.

[4] COM (2000) 212 of 26.4.2000.

[5] In the context of this Programme for Action, the poorest developing countries include the least developed countries (currently 48 countries (UNCTAD:2000) and the other low-income countries with a GNP per capita of less than USD 765 (currently 24 countries DAC: 2000).

health of their people, this Programme for Action will pay particular attention to ensuring their full participation and 'ownership' of the actions envisaged.

In line with the objectives of the policy framework, the expected outcomes of the European Community's Programme for Action are:

- optimal impact from existing interventions, services and commodities targeted at the major communicable diseases affecting the poorest populations;
- increased affordability of key pharmaceuticals through a comprehensive approach;
- increased investment in research and development of specific global public goods.

All of these will make a substantial contribution to reducing the burden of the major communicable diseases, in particular for the poorest developing countries, and will strengthen global poverty reduction efforts.

3. THE PROGRAMME FOR ACTION

The European Community's policy is designed to link country level actions aimed at increasing people's access to existing goods and services, with enabling global action on affordability and investment in the development of specific global public goods (see Annex 3). Consequently, **all three areas for action – impact, affordability and research – are inter-active and synergetic**: the development and financing of global public goods such as AIDS and malaria vaccines require more effective research, financing and new partnerships. At the same time a real and sufficiently large increase in financing for existing vaccines, for example at country level, will be needed to increase confidence in future uptake of new vaccines. Similarly a reduction in prices and concessions from the research and development industry will require a market of sufficient size, established public-private partnerships and a substantial increase in production capacity. **Implementing the European Community Programme for Action will require coherent, collective and simultaneous action.**

This Programme for Action takes into account a number of **basic principles** for European Community's Health, AIDS and Population support in developing countries, as highlighted in Annex 2.

Progress will be **monitored** at two levels. Impact and high-level outcome indicators will be monitored as part of a joint gender sensitive and pro-poor global monitoring system to be developed with international partners. Annex 1 outlines a framework to monitor implementation of this Programme for Action within the direct areas for European Community action. The framework, which identifies potential partners, instruments, will be further detailed within specific work plans and monitoring tools, including yearly progress reports, to be developed by Commission services following endorsement of this Programme for Action.

3.1. IMPACT

3.1.1. Optimising the impact of Health, AIDS and Population interventions[6] targeted at major communicable diseases and poverty reduction

(1) The Commission will prioritise within the total development co-operation budget, **health, AIDS and population (HAP) interventions** over the next five years (2002-2006). The proportion allocated to HAP stood at 8% in 2000 (approximately Euro 800 million) and will be steadily increased as delivery capacity improves. Within those interventions, increased support will target HIV/AIDS, malaria and tuberculosis, and the actions identified in this Programme for Action, in accordance with the needs of each country and region.

(2) The ongoing process of European Commission's reform is establishing more effective aid management processes and addressing bottlenecks to allow **more rapid disbursement**. The European Community's commitments to health, AIDS and population (HAP) totalled Euro 4.2 billion over the period 1990-1999 of which Euro 700 million was committed in 1998 alone. Most of this supports, will continue to strengthen of the health sector. Measures are underway to simplify payments and contracting procedures. In addition, the Commission will invite developing countries to **identify opportunities to direct unspent committed resources** within country programmes to address the communicable disease burden.

(3) The Commission will provide guidance to developing countries on communicable disease issues and options for **accelerated action within the current country, regional and thematic programming exercises**[7]. Delegations and partner countries will be encouraged to address from a poverty reduction and gender perspective, communicable diseases within the framework of Country Strategy Papers (CSPs) and Poverty Reduction Strategy Papers (PRSPs)[8]. Member States will be co-ordinated with and will be consulted in the competent committees. The Commission will maintain a comprehensive approach within which **preventive activities** will continue to receive major attention.

(4) The Commission will establish **co-operative arrangements with WHO/UNAIDS, the World Bank and Member States** to provide necessary technical and normative input to country programming and identification exercises.

(5) The Commission will consider the use of "all ACP" and other regional funds[9] for **rapid resource transfers** to partners to increase access and utilisation of existing approaches and scale up innovative practices such as social marketing of bednets, condoms, prevention and care of mothers with HIV, etc. Subject to the conditions contained in applicable instruments, funds may include the possibility for transfers to UN agencies/NGOs and CBOs and non-

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[6] EC 'Population interventions' are defined in Council Regulation on Population Policies and Programmes in Developing Countries N°1484/97, 22 July 1997.

[7] In the different elements in this Programme for Action will be adapted to 'unstable' situations or where the local component is weak (absence of functional Ministries of Health, absence of proper national health strategies, lack of means to conduct a programme).

[8] The European Community's Development Policy': COM(2000) 212 of 26.4.2000.

[9] See section 4 on instruments. The legal bases for contributions may 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 in the field include Council regulation N°550/97, 24 March 1997, on HIV/AIDS in developing countries, and Council Regulation on Population Policies and Programmes in Developing Countries N°1484/97, 22 July 1997. Commitments are subject the eligibility conditions specified in the applicable instruments.

traditional partners at the request of developing countries. Innovative practises will be scrutinised from a poverty reduction and gender perspective before they are used widely.

The Commission will continue to work with **global partners** to develop new approaches through large scale and more efficient resource transfers to developing countries. See section 3.4 for specific actions.

3.1.2. Strengthening of pharmaceutical policies and capacity building

(1) Through national and regional co-operation, capacity building, and financial and technical assistance, the Commission will support the strengthening of pharmaceutical policy and practice. The Commission will build upon existing programmes[10] where possible. Particular efforts will be directed to improving budgeting and financial management, planning, quality assurance, purchasing, tendering, distribution and optimal use of pharmaceuticals. Commission support will facilitate a review of the impact of import duties and taxation schemes on prices, address regulatory aspects and ethical standards, and lead to improved information exchange. The Commission will support the development of regional/sub-regional quality control laboratory networks to ensure appropriate quality control of pharmaceuticals. This is particularly important in the context of local production and use of generics in accordance with WHO approved standards. Developing countries will be supported in their efforts to identify actions and promote informed dialogue on pharmaceutical policies.

(2) The Commission will **enhance partnerships** with regional technical resource networks, notably with WHO as the lead technical agency in the pharmaceutical policy area. Collaboration will be extended with UNICEF, UNAIDS, the pharmaceutical industry and other partners.

(3) The European Community will work with WHO, to further **refine essential drug policies in favour of developing countries.** Actions include the progressive inclusion of (non-generic) key pharmaceuticals in the essential drug list and the implementation of appropriate, cost-effective regulatory schemes at the regional and country levels. The aim will be to accelerate registration and marketing approvals of key pharmaceuticals in developing countries based on existing registration in developed countries. Moreover, the European Community will liase with WHO for specific rules and regulatory schemes, and the provision of key pharmaceuticals in emergency situations.

(4) The European Community will work with countries and regions to **develop systems to protect against diversion of tiered priced products** (see 3.2.).

3.1.3. *Developing local production capacity*[11]

(1) The European Community will assist developing countries, at a regional or national level, to develop high-quality, local production of key pharmaceuticals, many of which are off-patent and could be produced immediately. Candidate-countries will be identified through **sectoral and market analyses,** in conjunction with **feasibility studies** to identify and assess existing **business opportunities**. In addition, **dialogue** between the private and state-owned pharmaceutical sectors in both developing and developed countries will be encouraged, and **business links** between them facilitated. **Support for local production** will go to countries

[10] For example the EC programmes ARIVA (Appui Régional a l'Indépendance Vaccinale en Afrique) and APPA (Appui a la Politique Pharmaceutique en Afrique).

[11] See Annex 3: Clarification of Terminology.

that have pre-existing capacity and necessary infrastructure. Other countries may be considered at a later stage.

(2) **Viable projects** will be supported by promoting business opportunities on the basis of **sound business plans** and **studies** focusing on public health benefits as well as profitability. **Financing** may be through PROINVEST, the investment promotion programme for ACP countries, the EC-ACP Business Assistance Scheme (EBAS)[12], the private sector Investment Facility of the Cotonou Agreement through the EIB, and other EC technical and financial co-operation mechanisms (for ALA-MEDA - see section 4 on Instruments).

(3) EU and non-EU generic and research-based industries will be encouraged to enter into **licensing agreements** and **joint ventures** with suitable developing country partners. This will require adequate **incentives**, such as securing a high standard of protection for intellectual property rights, obtaining access to developing country markets by mutual recognition of marketing approvals, and ensuring that products destined for developing country markets are not exported to the Community or other developed country markets.

3.2. AFFORDABILITY

3.2.1. Tiered pricing[13]

(1) The European Community is at the forefront of international efforts to establish a **global tiered pricing system** for key pharmaceuticals for the poorest developing countries. It remains convinced that a firm, long-term commitment from manufacturers to supply these products at the lowest possible prices would be a major contribution to the problem of access to affordable medicines. Further discussions will therefore be pursued with the pharmaceutical industry, and with the public authorities in the poorest developing countries, with a view to setting up such a system at the earliest opportunity. In future, tiered pricing for the poorest developing countries should no longer be the exception, but the rule.

(2) A successful tiered pricing system targeted at the poorest developing countries must also be able to **prevent product diversion** to other markets, thus undermining prices. It is essential, in order to preserve confidence in such a system, that **effective safeguards** are in place to ensure that all low-priced pharmaceuticals destined for specific markets are delivered to, and remain in, those markets. Such safeguards include technical measures, such as differential labelling, packaging and trademarks to identify preferentially priced products, special enforcement procedures to be applied in the importing and/or exporting country, and contractual arrangements between the exporter, importer and distributor of the medicines[14].

(3) **International concertation** (e.g. under the auspices of the UN or the WTO) will be needed to contain the risk of product diversion, but it will also require the full participation and co-operation of governments in developed and developing countries, the public and private

[12] An ongoing programme for ACP businesses, which provides support to individual companies or producer associations in this sector.

[13] Tiered pricing describes a system whereby different prices are charged in different markets. In the context of this Programme for Action, it refers to a pricing system by which producers of key pharmaceuticals, including both patented and non-patented medicines, make those products available to the poorest countries at significantly discounted prices.

[14] Measures foreseen in this regard should not affect the free movement of goods within the Community.

sectors, and of NGOs. The European Community will continue discussions with its main trading partners in order to advance this debate.

3.2.2. Tariffs and taxes

The European Community will continue to analyse the effects of **other factors**, besides the net import price, on **consumer prices** in developing countries. Such factors, which include **tariffs, taxes,** and **importation, distribution and local registration fees**, can significantly increase prices. Where appropriate, importing countries shall be encouraged to reduce or abolish these factors.

3.2.3. Intellectual property legislation

(1) The European Community is committed to **supporting WTO developing country members** in implementing the **TRIPs Agreement**. The support available includes training, assistance with legislative drafting, and setting up the appropriate institutional and administrative structures.

(2) The EC recognises that, within the TRIPs Agreement, there exists a flexibility allowing countries to issue, in certain circumstances, compulsory licenses[15] in order to address urgent public health concerns.

For its part, the EC will promote discussions, within the WTO, WIPO or WHO, to address the link between the TRIPs Agreement and public health protection issues, in order to an achieve international consensus on this issue.

3.3. RESEARCH AND DEVELOPMENT

3.3.1. Strengthening and increasing support for Research and Development

Under the current 5th Framework Programme, the Commission is expected to commit Euro 130 million for the research on HIV/AIDS, malaria and tuberculosis. More than Euro 80 million have been committed under the 4th Framework Programme (1994-1998). Recent initiatives have increasingly focused support on confronting communicable diseases in developing countries. The European Research Area[16] provides a framework for Europe to develop co-operative Research and Development strategies. Building on current investments in health research for the three major communicable diseases, a new major initiative is envisaged to support and accelerate the clinical development of new interventions. In this context, the Commission is elaborating in the first half of 2001, in consultation with all relevant stakeholders, a European research strategy for global goods to confront HIV/AIDS, malaria and tuberculosis. Guided by specific action plans for the three diseases, two directions for Community support are envisaged:

(1) continued and **increased support for basic and strategic research with greater co-ordination at European and international level.**

(2) the creation of a **European Clinical Trials Platform** to increase number, efficiency and coherence of clinical trials carried out by the public and private sectors, and involving the

[15] The granting of a licence without the consent of the patent holder, but against adequate remuneration, on various grounds of general interest. See also COM (2000) 585, 20 September 2000, paragraph 4.2.

[16] COM(2000) 6, 18 January 2000 and COM(2000) 612, 4 October 2000.

developing countries. This platform will also function as an interface for research and development with other global initiatives including those of the G8 partners.

3.3.2. Capacity building in developing countries

Developing countries will be involved at all stages of the research and development process for new public goods. Lasting impact is expected both from basic professional as well as advanced research training on science and technology capacity and health services performance.

(1) Increased **support to research activities** will include support for collaborative molecular and clinical, epidemiological, operational and social studies, strengthening the base for health-related research. Emphasis will also be put on gender balance and poverty focus. Moreover, support will be given to ensure appropriate ethical standards and review systems.

(2) Support will be provided for **capacity building** in developing countries to enable them to host and conduct large-scale population trials. Three major activities are envisaged to be co-ordinated through the clinical trials platform: a) human resources development, b) social mobilisation and community empowerment as a support measure for population trials and c) upgrading of facilities and services at research institutions and clinical institutions in developing countries.

3.3.3. Incentives for the development of specific global public goods

(1) The EU will **study and develop an incentive package** to encourage more private investment by the Research and Development based (R&D) industries in new products to confront the major communicable diseases in developing countries. Following the adoption of the new European Community's policy framework, the UK Prime Minister's office has established a working group to assess such potential incentives. The work of the UK group will take place in close consultation with the Commission and EU Member States. This will provide valuable input to the EU's examination of incentives such as the extension of marketing rights, venture capital, low-cost loans, tax credits, guaranteed markets, and so on.

(2) The Commission will encourage and support initiatives for an **early dialogue on regulatory aspects** in relation to new products for the three major communicable diseases. This will be essential in avoiding delays in the approval of new products. The **Commission will ensure that regulatory bodies in developing countries** where clinical trials are taking place or envisaged **are part of such early dialogue** in respect of these new products.

(3) The Commission will increase its support for **economic research** into the demand for specific global public goods for developing countries. The Commission is already involved with the World Bank in research on public demand and willingness to pay for an AIDS vaccine. This includes support for studies to improve market understanding and to assess the potential health impact and affordability of an HIV vaccine. The results of this research will yield much-needed information for policy makers in developing countries as well as for donors.

(4) The Commission will participate in the development of financing mechanisms to address the need for specific global public goods and to ensure that these become available to people in developing countries as quickly as possible, particularly for AIDS and malaria vaccines, tuberculosis diagnostics and vector control products.

(5) The work of the **Commission AIDS Vaccine Task Team and co-operation with Member States and other partners such as UNAIDS, IAVI, GAVI will be continued and strengthened.** The AIDS Vaccine Task Team is working on the various actions listed above with the aim of accelerating the development and availability of an AIDS vaccine for developing countries as soon as possible.[17]

(6) The **European Clinical Trials Platform** will act as an incentive by removing important scientific, technological and operational hurdles to product development. It is intended to extend the platform to developing countries.

3.4. PARTICIPATION IN GLOBAL PARTNERSHIPS: POLICY AND POLITICAL DIALOGUE

The European Community will continue to **participate in global initiatives** targeting action against the major communicable diseases in the context of poverty reduction. To this end, the European Community will:

(1) **promote the reform of the international financial architecture** to foster increased availability and development of specific global public goods (see Annex 3) and to support greater co-ordination and efficiency of international funding. The European Community will pay particular attention to ensuring that global support **unites around comprehensive approaches to health at country level** and is based on the full participation and ownership of developing countries. To this end, the Commission will continue to **actively participates in the working group of G8 members** which will examine how best to organise increased spending and targeting of global resources towards the three communicable diseases. In the lead up to the Genoa G8 meeting (July 2001) the group evaluate the lessons learnt from existing international mechanisms. These will provide important input to the Commission's own examination of the opportunities to fund global mechanisms;

(2) **strengthen partnerships with the UN organisations, in particular with the WHO[18] and UNAIDS.** Particular aims will be to co-ordinate global efforts more efficiently and to monitor the accelerated response through resource flows and health outcomes;

(3) **continue close co-operation with the US and Japan** in order to garner support for adequate global burden sharing, financing mechanisms and the development of a global tiered pricing system for key pharmaceuticals for the poorest developing countries (see Section 3.2.1.). With the US this should be part of the co-operation which has been set up by the EU-US Summit Leaders on the three communicable diseases and will take place in the framework of the New Transatlantic Agenda[19] and in the context of the G8 discussions.

(4) **this approach will benefit the European Community, the international community and recipient countries.** It will facilitate more streamlined technical support from the UN and other important donors, establish a more effective financial mechanism to speed up delivery, and

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[17] The EIB and EMEA are already part of the team and there is substantial interest from EU Member States and IAVI participants.

[18] Over the past year the EC and WHO have intensified their co-operation. Letters have been exchanged covering a memorandum with a framework for co-operation, signed in December 2000. The memorandum defines principles and objectives, outlines areas of co-operation, establishes procedures and defines priority areas for action, including those related to the three major communicable diseases.

[19] EU-US Summits Conclusions, Queluz May 2000 and Washington December 2000.

reduce transaction costs for donor and recipient. At the same time, it will ensure a stronger voice for the European Community in global policy setting.

4. INSTRUMENTS

4.1. Identifying the instruments for action

The European Commission has a large array of policy, legislative, regulatory and financial instruments which it will activate in support of the Programme for Action[20]. Which of these instruments come in to play for each action will depend on the various entry levels (national, regional, and global) and will need to be defined further, following the procedures contained in the respective instruments. **The following development assistance instruments will be used:**

a) Unspent reserves from the 8th EDF, and resources from geographic budget lines (ALA-MEDA).

i) Specific actions in support of initiatives with existing or new partners. Specific Health, AIDS and Population programming guidelines are being developed to this end.

ii) Within this context the following interventions will be envisaged for financial support as well:

- where countries agree to remove tariffs for pharmaceutical imports, technical support for fiscal reforms and additional financial incentives for countries committed to this will be examined;

- technical support for the implementation of the TRIPs Agreement.

b) Resources from the 9th EDF[21], ALA-MEDA and thematic budget lines.

i) It is proposed that a substantial amount would be allocated for partnerships with non-traditional partners, such as the local private sector in developing countries, to use innovative approaches in the area of social marketing at country level (see 3.1.1).

ii) It is further proposed that a substantial amount be allocated to form a partnership with WHO for actions envisaged for the strengthening of pharmaceutical policies at regional and country level (see 3.1.2).

iii) While advocating adequate international burden-sharing and a consensus consistent with the European Community policy spelt out in this Programme for Action, the Commission will consider a contribution to a global mechanism providing technical know-how and commodities in co-operation with other partners (see 3.4).

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[20] See footnote 9. Development assistance instruments which are proposed to be used in support of the Programme for Action include: NIPs – RIPs and other EDF instruments, such as the Regional Economic Partnership Agreements (REPAs) and the new Investment Facility under the Cotonou agreement. Technical and financial co-operation protocols for Asia, Latin-America and the Mediterranean, thematic budget lines, and Humanitarian Aid managed by ECHO should also be used. Commitments are subject the eligibility conditions specified in the applicable instruments. In addition to the development assistance instruments, the European Research Area and research framework Programmes will be used for supporting the measures envisaged.

[21] From 2004 onwards and as set out in the financial protocol to the Cotonou Agreement.

c) Several support actions, such as feasibility studies, can be undertaken in support of the development of production capacity in developing countries[22]. Business linkages may follow from the activities of the ESIP programme that will start in 2001, in co-operation with the European Investment Bank.

d) In relation to the current debate on untying aid, and with a view to enhancing local capacity and affordability, the Commission proposes to replicate the ACP regime for non-ACP regional areas, allowing partner countries' firms, as well as EU firms, to bid for tenders. Beyond that, the Commission seeks to explore the opening of calls for tender for procurement of certain services or products, like key pharmaceuticals for HIV/AIDS, malaria and tuberculosis, to all developing countries. The aim is to encourage the production and access of such goods and services within developing countries or regions, as appropriate, and to make available, with or without financial support from external partners, such goods and services at an affordable price to all developing countries.

In addition to the development assistance instruments, **Research Framework Programmes** will be used for supporting the measures envisaged under Section 3.3. in line with the objectives of the European Research Area.

The European Clinical Trials Platform (see Section 3.3.1) will seek to use, in addition to research funds and where eligible, financial resources from Community development funds, public-private partnerships and others, necessary to carry out large-scale population trials.

4.2. Partnership, ownership and monitoring of an effective European Community response

It must be noted that most of these development instruments and resources only become **'activated' following the request** of developing country partners or international development partners. Many international and developing country partners have expressed an interest in the actions envisaged under this Programme for Action. **This interest in collaborating with the European Community is accompanied by a clear call for 'user-friendly', 'action-oriented' instruments and partnership arrangements**. In order to ensure full **ownership** at country level it is crucial that developing country partners continue to be involved in the further identification of specific actions.

To date the Commission has not been successful in developing efficient **financial instruments for investing in global initiatives**. The use of small-scale thematic budget lines has only partially allowed this gap to be addressed. Global mechanisms might well allow the Commission to increase development spending and lower transaction costs in co-operation with Member States' activities.

In addition to 'responsive' financing instruments a substantial amount of work needs to be done in terms of **'policy dialogue'** and the use of instruments for policy development and dialogue. Appropriate institutional arrangements and resources will be at the core of the implementation and monitoring of this Programme for Action.

[22] E.g. through the EBAS programme.

5. CONCLUSION

Successful implementation of this Programme of Action over the next five years (2002-2006) will make a major contribution to global efforts to address the development crisis presented by HIV/AIDS, malaria and tuberculosis. The Commission proposes a coherent policy framework to guide accelerated Community action and has taken a lead in efforts to co-ordinate a more effective response by countries and the international community. Developing countries and the poorest populations bearing the greatest burden require co-ordinated support on an unprecedented scale. This will require a strong commitment from countries, Member States, multilateral and bilateral donors.

Annex 1: Programme for Action – Matrix

IMPACT (1 of 2)

ACTIVITIES	GEOGRAPHICAL FOCUS	TIMELINE	PARTNERSHIPS	MONITORING/OUTCOMES
III 1.1 – Optimising impact of HAP interventions targeted at major communicable diseases and poverty reduction. Rapid disbursement. Commission to identify opportunities to direct unspent resources to address the three communicable diseases.				
1. Commission services will provide specific guidance to EC Delegations. Partner countries will be encouraged to address the communicable diseases within the framework for gender sensitive and pro-poor Country Strategy Papers.	1) All developing countries.	1) March 2001-December 2001.	1) All developing countries.	1.1 HAP disbursement portfolio increased by 50% by end 2001. 1.2 Dormant programmes (20) closed or re-oriented by end 2001.
2. The Commission will establish co-operative arrangements for programming.	2) All developing countries.	2) March 2001.	2) All developing countries, other donors.	2.1 Programming guidelines established and used. 2.2. Number of gender sensitive and pro-poor CSPs including HAP interventions increased. 2.3. Delegations staff reinforced and trained.
3. The Commission will facilitate resources for innovative partnerships.	3) All developing countries.	3) February 2001 – July 2001.	3) WHO-UNAIDS - Member States.	3) Partnership and/or Financing Agreements established.
4. The Commission will prioritise HAP interventions within overall development aid.	4) Mainly in Sub-Saharan Africa and South Asia	4) Continuous from March 2001.	4) Civil society, private sector, UN agencies.	4) Resources programmed, partners identified.
5. The European Community will pursue greater articulation between existing global mechanisms and partner countries efforts.	5) All developing countries See 3.4.	5) March 2001-2006. See 3.4.	5) All developing countries, other donors. See 3.4.	5) Increased HAP allocation from current 8% in accordance with improved delivery capacity. See 3.4.

Programme for Action – IMPACT (2 of 2)

ACTIVITIES	GEOGRAPHICAL FOCUS	TIMELINE	PARTNERSHIPS EC, developing countries	MONITORING/OUTCOMES
III.1.2 Strengthening of pharmaceutical policies.				
1. Regional co-operation, capacity building, financial and technical assistance. 2. Enhanced and improved essential drug policy and regulatory schemes. 3. Refine global essential drug policy in favour of the poorest developing countries. 4. Developing systems to prevent diversion of tiered priced products.	Actions will primarily take place at regional level and, due to the devastating effect of the three diseases and the poverty factors in the two regions, be targeted at Africa and South Asia. See 3.2.3.	June 2001-June 2002. See 3.2.3.	For all actions: WHO UNICEF, UNAIDS, Industry. See 3.2.3.	1. Partnerships established. 2.1. Agreement with WHO established. 2.2. Revision of EDL by WHO by end of 2002. 3. Partnership with UNICEF, UNAIDS, Industry identified. 4. See 3.2.3.
III.1.3 Developing local production capacity				
1. Support to sector and market analyses; dialogue, identification of existing business opportunities. 2. Support to the development of sound business plans. 3. Promote licensing agreements and business joint ventures through appropriate incentives.	Actions will take place at regional level with a specific geographical focus on countries with pre-existing local production capacity (in either private or public sector).	For all actions: March 2002 to January 2006.	Partnership will simultaneously involve EU and non-EU generic and research-based industries and relevant regional bodies, the Commission, the EU Member States, the European Investment Bank (EIB) and other financing institutions. Industrial partners.	1. Pre-feasibility studies completed. 2.1 Countries identified for business plans. 2.2 Business plans agreed. 3. Licensing agreements and joint ventures promoted.

Programme for Action – AFFORDABILITY (1 of 1)

ACTIVITIES	GEOGRAPHICAL FOCUS	TIMELINE	PARTNERSHIPS	MONITORING/ OUTCOMES
III.2.1 Tiered pricing	Actions at global level for the developing countries			
1. Lead international efforts to establish a global tiered pricing system.	1. EU, OECD and G8 countries.	1. Initiated in September 2000, ongoing. 2. From March 2001 .	1. EU, generic and research-based industry, G8, OECD and developing countries	1. Commitments from the industry players and developing countries authorities.
2. Set up effective safeguards against product diversion.	2. Importing and exporting countries.		2. EU, industry, OECD, G8 and developing countries	
III.2.2 Tariffs and taxes Impact analysis.		From March 2001.		
III.2.3 Intellectual property legislation	Developing countries.		EU, International organisations, developing countries	Lower consumer prices.
1. Support for TRIPs implementation.		From March 2001.		
2. Discussion of links between TRIPs agreement & public health protection.		From November 2001.	WTO, WIPO and developing countries. Fourth WTO ministerial, WHO, WIPO, Civil Society, Industry players, EU.	Provision of technical assistance where required.

Programme for Action – RESEARCH and DEVELOPMENT (1 of 2)

ACTIVITIES	GEOGRAPHICAL FOCUS	TIMELINE	PARTNERSHIPS	MONITORING/ OUTCOMES
III.3.1 – Strengthening support for Research and Development	All actions will benefit all populations and in particular those in the poorest developing countries.	Ongoing and to be continued up to March 2001 – March 2003.	EU Member States, European Community , G8, developing countries, WHO, UNAIDS, in line with the objectives of the European Research Area..	All R & D activities will be externally reviewed according to pre-determined criteria.
1. Increased support for basic and strategic research.				
2. Creation of a European Clinical Trials Platform.				
III.3.2 – Capacity building in Developing Countries				
1. Support to gender sensitive and pro-poor research activities.				
2. Capacity building (equal opportunities for women and men).				
III.3.3 – Incentives for the development of specific global public goods				
1. EC will examine and develop an incentive package.		1) Preparation as of 2001, incentives in place as of 2002.	1) Partnership with Member States, developing countries, WHO and others	
2. Early dialogue on regulatory aspects.		2) Starting January 2001 - and taking account of February WHO meeting.	2) Various financial partnerships.	
3. Economic research into demand.		3) 1-6 months from February 2001.	3) The UK Prime Minister's office working group and in close consultation with other EU Member States.	
4. Development of joint financing mechanisms.		4) Starting January 2001-and taking account of February WHO meeting.	4) Idem.	
5. The AIDS Vaccine Task Team strengthened.		5) From January 2001.	5) New operational partnership in support of an AIDS vaccine (with UNAIDS and IAVI).	

Programme For Action – GLOBAL MECHANISMS (1 of 1)

ACTIVITIES	GEOGRAPHICAL FOCUS	TIMELINE	PARTNERSHIPS	MONITORING/ OUTCOMES
III.4. Participation in global partnerships				
1. The EC will promote the reform of the international financial architecture to foster increased availability and development of global public goods.	For all actions. Global actions in favour of the poorest populations most affected by the three major communicable diseases.	1. January 2001 and continued.	1. G8 and European States	1.1 Adequate burden-sharing in place. 1.2 Coherent policy between global partners.
2. The EC will strengthen its partnership with the UN organisations.		2. By July 2001.	2. UN organisations, and in particular with the WHO and UNAIDS.	2. Partnerships with UN established.
3. The EC will continue its co-operation with the US & Japan, in particular on tiered pricing.		3. November 2000 and continued.	3. EU/US and Japan.	3. Joint EU/US/Japan position on tiered pricing in place.

Annex 2: Basic Principles for Health, AIDS and Population support

(1) Build on the development agenda of each country, targeting poverty reduction and equality between men and women, however it is expressed and whether within a Comprehensive Development Framework, a Poverty Reduction Strategy or as a national development plan. The country's stakeholders' ownership is vital.

(2) The approach to effectively address the burden of communicable diseases at country level will be context specific. The 'best fit' for accelerated action will build on what is in place and will employ a range of interventions, funding mechanisms and partners.

(3) Countries where effective policies, institutions and on-or-off budget co-ordination are in place will be supported through the mechanism of choice of the country. In countries without coherent policies and mechanisms and/or where institutions are weak, or in countries in crisis, support will be facilitated through partnerships with NGOs and/or UN agencies.

(4) The health, AIDS and population policy environment and practice will define potential instruments and channels of support.

(5) Efforts should support actions that strengthen health systems and further build national capacity. Effective support will deliver health outcomes which will be monitored.

(6) Coherent action will support a common framework, in partnership with all stakeholders - governments and non-government actors, the public and private sector, donors and international agencies.

(7) Effective pro-poor support will contribute to other important development outcomes relating to crosscutting concerns such as the promotion of human rights, equality between men and women, children's rights and the environmental dimension.

(8) Partners will need to employ imaginative approaches which can deliver equitable health outcomes, are financially fair and responsive to people's demands and which harness the resources of all potential contributors.

(9) The Commission will invite Member States that are interested in working jointly on short-term deliverables to develop flexible mechanisms to support interested partner countries (co-financing, silent partners, technical assistance, etc.).

Annex 3: Clarification of terminology

a) Global public goods

'Public Goods' are goods which benefit society as a whole. The concept of 'national public goods' such as the maintenance of law and order is not new. But in an increasingly interconnected and interdependent world much more attention is now being paid to 'global public goods'. Examples range from the control of communicable diseases, to the provision of global financial stability, the protection of the environment and the prevention of conflict.[1]

The technical know-how necessary to support 'global public goods' will benefit all populations irrespective of who pays for their development. This creates a 'free-rider' problem, in that individuals and governments will be willing to pay less than the value of the benefits they receive. Specifically with regard to for example HIV/AIDS and malaria vaccines, the private sector is unlikely to recoup research and development costs for health technologies that primarily benefit countries and populations with low ability to pay.

The solution ultimately lies at global level with countries, donors and the private sector taking joint responsibility and sharing the cost related to the development and availability of 'global public goods'. A co-ordinated approach through a shared public facility may therefore be the best answer.

b) Local Production

Local production refers to the manufacture of key pharmaceuticals (including global goods such as new vaccines) in accordance with national legislation and with related international obligations where applicable. It includes local production of patented products under licensing arrangements and joint venture agreements, as well as other activities such as re-labelling and re-packaging.

In the context of this Programme for Action, supporting local production of low-cost key pharmaceuticals means more than simply boosting local manufacturing capacity. It is first and foremost an industrial development issue involving a technology transfer between European and developing country industries, as well as promoting South-South co-operation and helping to integrate developing countries into the world economy. Indeed, those countries, which are relatively advanced in terms of local production capacity and whose companies receive support under this Programme for Action, should be prepared to provide technical assistance and participate in technology transfer ventures for the benefit of poorer countries.

[1] Eliminating World Poverty: Making Globalisation Work for the Poor, White Paper on International Development, UK Government; December 2000.

Annex 4: Acronyms

ACP	Africa, Caribbean and Pacific
AIDS	Acquired Immune Deficiency Syndrome
ALA	Asia and Latin America development co-operation programme
CBO	Community Based Organisation
CSP	Country Strategy Paper
DAC	Development Assistance Committee
DG	Directorate General
EBAS	EU-ACP Business Assistance Scheme
EC	European Community
ECHO	European Community Humanitarian Aid Office
EDF	European Development Fund
EDL	Essential Drugs List
EIB	European Investment Bank
EMEA	European Medicines Evaluation Agency
ESIP	EU SADC Investment Promotion Programme
EU	European Union
FP	Framework Programme
G8	Group of G7 most industrialised countries and Russia
GAVI	Global Alliance for Vaccines and Immunization
HAP	Health, AIDS and Population
HIV	Human Immune Deficiency Virus
IAVI	International AIDS Vaccine Initiative
LDC	Least Developed Countries
MEDA	Mediterranean countries development co-operation programme
NGO	Non-government Organisation
NIP	National Indicative Programme
OECD	Organisation for Economic Cooperation and Development
PRSP	Poverty Reduction Strategy Paper
R&D	Research and Development
REPA	Regional Economic Partnership Agreement
RIP	Regional Indicative Programme
SADC	Southern Africa Development Community
TRIPs	Agreement on Trade Related Aspects of Intellectual Property Rights
UN	United Nations
UNAIDS	United Nations Joint Programme on HIV/AIDS
UNCTAD	United Nations Conference on Trade and Development
UNICEF	United Nations Children's Fund
WHO	World Health Organisation
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation