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REPORT

on the Commission communication on the update of the EC Programme for Action: accelerated action on HIV/AIDS, malaria and tuberculosis in the context of poverty reduction; outstanding policy issues and future challenges (COM(2003) 93 - 2003/2146(INI))

Committee on Development and Cooperation

Rapporteur: Ulla Margrethe Sandbæk

CONTENTS

	Page
PROCEDURAL PAGE	4
MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION.....	5
EXPLANATORY STATEMENT	14
OPINION OF THE COMMITTEE ON INDUSTRY, EXTERNAL TRADE, RESEARCH AND ENERGY	18
OPINION OF THE COMMITTEE ON WOMEN'S RIGHTS AND EQUAL OPPORTUNITIES.....	20

PROCEDURAL PAGE

By letter of 26 February 2003 the Commission forwarded to Parliament its communication on the update of the EC Programme for Action: accelerated action on HIV/AIDS, malaria and tuberculosis in the context of poverty reduction; outstanding policy issues and future challenges (COM(2003) 93), which had been referred to the Committee on Development and Cooperation for information.

At the sitting of 4 September 2003 the President of Parliament announced that the Committee on Development and Cooperation had been authorised to draw up an own-initiative report on the subject under Rules 47(2) and 163 and the Committee on Industry, External Trade, Research and Energy, the Committee on the Environment, Public Health and Consumer Policy and the Committee on Women's Rights and Equal Opportunities had been asked for their opinions.

The Committee on Development and Cooperation had appointed Ulla Margrethe Sandbæk rapporteur at its meeting of 9 July 2003.

The committee considered the draft report at its meetings of 10 September 2003, 1 October 2003, 1 and 2 December 2003.

At the last meeting it adopted the draft resolution unanimously.

The following were present for the vote: Margrietus J. van den Berg (acting chairman), Marieke Sanders-ten Holte (vice-chairwoman), Ulla Margrethe Sandbæk (rapporteur), Marie-Arlette Carlotti, John Alexander Corrie, Nirj Deva, Giovanni Claudio Fava (for Maria Carrilho), Fernando Fernández Martín, Bashir Khanbhai (for Luigi Cesaro), Glenys Kinnock, Maria Martens (for Anders Wijkman), Miguel Angel Martínez Martínez, Didier Rod, Francisca Sauquillo Pérez del Arco, Michel-Ange Scarbonchi (for Yasmine Boudjenah), Maj Britt Theorin.

The opinions of the Committee on Industry, External Trade, Research and Energy and the Committee on Women's Rights and Equal Opportunities are attached. The Committee on the Environment, Public Health and Consumer Policy decided on 11 June 2003 not to deliver an opinion.

The report was tabled on 10 December 2003.

MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION

**on the Commission communication on the update of the EC Programme for Action: accelerated action on HIV/AIDS, malaria and tuberculosis in the context of poverty reduction; outstanding policy issues and future challenges
(COM(2003) 93 - 2003/2146(INI))**

The European Parliament,

- having regard to the Commission communication (COM(2003) 93),
- having regard to the Commission communication on accelerated action targeted at major communicable diseases within the context of poverty reduction (COM(2000) 585) and the Commission communication on a Programme for Action: Accelerated action on HIV/AIDS, malaria and tuberculosis in the context of poverty reduction (COM(2001) 96),
- having regard to the General Affairs Council of May 14 and 15, 2001 on the Programme for Action (PfA),
- having regard to its resolution of 4 October 2001 on reducing poverty (fight against main transmissible diseases)¹ covering the last two Commission communications,
- having regard to the ACP-EU Joint Parliamentary Assembly resolution of 1 November 2001 on HIV/AIDS²,
- having regard to the EU participation in the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), in the Council and the European Parliament's joint decision n° 36/2002, of 19 November 2001³,
- having regard to the ACP-EU Joint Parliamentary Assembly resolution of 21 March 2002⁴ that calls on the Council of the European Union and the European Commission to ensure the impact of HIV/AIDS on older people and their role as carers and educators is acknowledged and supported through the provision of health information, training and access to medicines,
- having regard to the Council Regulation (CE) n° 953/2003, of 26 May 2003 to avoid trade diversion into the European Union of certain key medicines⁵,
- having regard to the Commission communication on Health and Poverty Reduction in Developing Countries (COM(2002) 129),
- having regard to the subsequent Council resolution of 30 May 2002⁶,
- having regard to its resolution of 4 September 2003 on the Commission communication on Health and Poverty Reduction in Developing Countries⁷,

¹ OJ C 87E, 11.4.2002, p. 244.

² OJ C 78, 2.4.2002, p. 12.

³ OJ L 7, 11.1.2002, p. 1.

⁴ (ACP-EU 3398/02/fin).

⁵ OJ L 135, 3.6.2003, p. 5.

⁶ Not yet published in OJ.

⁷ Adopted texts of this date, P5_TA(2003)0379.

- having regard to its resolution of 4 September 2003 on untying aid¹,
- having regard to the UN Millennium Development Goals (MDG),
- having regard to the Articles 65-67-68 of the Declaration of UNGASS of 2001 on HIV/AIDS, referring to orphans, vulnerable children and older people,
- having regard to the Convention on the Rights of the child and articles 45,46 and 47 of "A World Fit For Children", the outcome document of the 2002 United Nations Special Session on Children, specifically the aims for strategies on children affected by HIV/AIDS,
- having regard to the Doha 2001 Declaration on relations between the TRIP's Agreement and Public Health,
- having regard to the establishment of the new European and Developing countries Clinical Trials Partnership (EDCTP) initiative,
- having regard to its resolution on authorisation of generic medicines at WTO level² (Feb. 2003),
- having regard to the ACP-EU Joint Parliamentary Assembly resolution on WTO negotiations on health issues³,
- having regard to the Communication from the EU to the TRIPS Council of June 4th and 5th, 2003,
- having regard to the decisions of the G8 Evian summit on Enhancing Sustainable Development,
- having regard to the International meeting to support the Global Fund to fight AIDS, Tuberculosis and Malaria in Paris, July 16th, 2003,
- having regard to Rules 47(2) and 163 of its Rules of Procedure,
- having regard to the report of the Committee on Development and Cooperation and the opinions of the Committee on Industry, External Trade, Research and Energy and Committee on Women's Rights and Equal Opportunities (A5-0474/2003),

- A. whereas millions of people in developing countries continue to die each year from infectious diseases, most of which can be prevented and cured by medicine,
- B. whereas these three communicable diseases continue to represent the major burden of diseases affecting the poorest people, especially women and children, in developing countries causing the deaths of almost 20 thousand people a day and the infection of many more, leaving behind 13 million orphans to date. The figure is expected to rise to 25 million by 2010,
- C. whereas the health services in most developing countries are to a great extent unable to cope with the needs of their populations and the structural adjustment programmes of the

¹ Adopted texts of this date, P5_TA(2003)0387.

² Adopted texts of this date, P5_TA(2003)0052.

³ (ACP-EU 3565/03/April 2003).

1990s have contributed to the worsening situation, giving rise to drastic budget cutbacks in social sectors,

- D. whereas the three diseases demand a national and global response and are an increasing threat to social and economic development of people living in developing countries,
- E. whereas the spread of HIV/AIDS in particular results to some extent in a drastic fall in life expectancy and a haemorrhaging of manpower, which reduces agricultural and industrial production and restricts educational capacity,
- F. whereas malaria frequently results in death, especially in children; whereas HIV/AIDS primarily affects adults of working age and whereas tuberculosis is often a consequence of HIV/AIDS infections,
- G. whereas tuberculosis is one of the leading causes of death among women of reproductive age and is believed to rank above death in childbirth. Women are less likely than men to be tested and treated for TB,
- H. whereas poverty, inadequate health services, nutritional deficiencies and unsuitable living conditions are instrumental in the propagation of TB. In turn, sickness and death from TB spreads greater poverty in many communities,
- I. whereas over 41% of the world's population is at risk of contracting malaria and this percentage is growing every year owing to deteriorating health systems, increased resistance to medicines and insecticides, climate change and war,
- J. whereas all the data demonstrate that the number of women infected with HIV/AIDS is very high, and is rising. Infection has an impact not only on the women themselves, but also on their pregnancies and children, whence the crucial need for appropriate sexual and reproductive health information and services to be made available so as to enable people in this category to protect themselves against unwanted pregnancies and sexually transmitted diseases, including HIV/AIDS,
- K. whereas the number of rapes of both girls and women in HIV/AIDS-affected countries is extremely high, leading to infection of the victims. Programmes must be set up to offer aid to victims and punish perpetrators,
- L. whereas the sexual and economic subordination of women is a driving force behind the spread of the HIV/AIDS pandemic. The social vulnerability of women must be reduced by improving their health, education and legal and economic status. In order for prevention to be effective, the programmes must take account of the needs of women infected with HIV/AIDS and prevention must become a structural part of national life, in every community and in every family; this must extend to women working as prostitutes,
- M. whereas information, prevention and treatment in relation to malaria, tuberculosis and HIV/AIDS call for different approaches for which appropriate strategies should be developed,

- N. whereas recent developments at UN and international levels pointed out new ways to access treatment and care for people living with, and affected by HIV/AIDS, mainly through the access to antiretroviral medicines, an essential element in the response the epidemic,
- O. whereas no research is currently being carried out into the most neglected diseases which affect developing countries only (e.g. sleeping sickness, Chagas' disease and leishmaniasis),
- P. whereas there is a chronic shortage of investment in research and development in poverty-related diseases and in R&D in the developing countries themselves to obtain the medicines which meet the needs of those countries,
- Q. whereas in spite of an international mobilisation, the existing efforts aren't enough and the international community needs to search for innovative and effective solutions to invert the growing figures of mortality and infected people, solutions not only of financial order,
- R. whereas research and development for poverty diseases, although recently increased, is still insufficient and requires global efforts and support from all actors, governments, industry, NGOs and civil society,
- S. whereas at the WTO Ministerial conference in Doha increased affordability of pharmaceutical products and the interpretation of intellectual property rights were intensely discussed, and a declaration on relations between TRIPs Agreement and Public Health was adopted,
- T. whereas an agreement was adopted by the members of the WTO on 30 August 2003 providing a solution to the problem faced by those countries which do not have sufficient manufacturing capacity in the pharmaceutical sector,
- U. whereas to prevent trade diversion into EU market of pharmaceuticals sold at tiered prices in developing countries, the Council adopted an innovative legal instrument to incentivise the pharmaceutical industry to sign up to "tiered pricing",
- V. whereas incentives for investment in R&D on poverty diseases must guarantee the best use of public money, and must be based on real costs whether offered to the public or private sectors,
- W. whereas prevention and treatment of communicable diseases must be regarded as indispensable for the world community, and thus considered a "global public good",
- 1. Welcomes the Commission Communication evaluating the Action Programme first two years of implementation;
- 2. Stresses its preoccupation with the increasing figures of people affected and the high mortality resulting from HIV/AIDS, malaria and tuberculosis;

3. Considers that the lack of access to health is the result of both a problem of access to care (owing to a shortage of facilities and health workers but also to the lack of public healthcare systems) and access to treatment;
4. Draws the Commission's attention to the fact that it should highlight the important role played by women as the main health promoters and the need for gender mainstreaming in health policies;
5. Recognises lack of data precludes early assessments of the progress towards the attainment of MDG 6 (to halve the number of new cases of HIV/AIDS infection by 2015) and emphasises the need for investments in monitoring and evaluation, including monitoring of national budget allocations and health outcomes as part of the Poverty Reduction Strategy Paper process;
6. Urges the Commission to facilitate the compilation of data on the impact these three diseases have on women and girls, with specific reference to the number of children orphaned and of years of life and schooling lost, the degree to which women's working lives are affected, access to health services and access to treatment (comparison men/women and percentage of sufferers), in addition to epidemiological data.
7. Welcomes the WTO agreement obtained in Geneva on access to medicines; notes, however, that concern was voiced about the rules designed to prevent abuse which might, in practice, encumber the operation of the agreement; calls on the Member States to give a clear commitment to prompt authorisation for requested licences;
8. Calls on the EU and the Member States to take every possible measure to ensure swift and practical implementation of this agreement; calls on them, in particular, to amend European laws on patents and all other relevant legislation to enable medicines to be manufactured in Europe under compulsory licence for export to developing countries; stresses that such a revision must fully respect the Doha declaration on access to medicines;
9. Emphasises the need for a special co-operation with the WHO in the fight against poverty diseases. Specifically requests that the Commission and Member States encourage a broader discussion on the effects of the TRIPS agreement on the availability of affordable generic medicines and actively support the work ongoing presently at the WHO on analysing Intellectual Property Rights, Innovation and Public Health;
10. Encourages the Commission in its collaboration with Roll Back Malaria and the ACP countries on the implementation of Artemisinin combination treatments for malaria; Calls on the Commission to ensure that the support of the EU for the change of national protocols and introduction of treatment combination be formally and internationally known;
11. Notes the dramatic improvements that can take place when immunisation programmes have focused on comprehensive local implementation, and calls for support to initiatives such as Stop TB, Roll Back Malaria, the International AIDS Vaccine Initiative, the International Partnership for Microbicides and the national multi-year immunisation plans

funded and supported by the Global Alliance for Vaccines and Immunisation (GAVI) and the Vaccine Fund;

12. Calls on the EC to support efforts to develop new diagnostic tools to detect active tuberculosis cases more quickly, easily and accurately and use new medicines for treatment; Fixed dose combinations should urgently be developed for use in the meantime;
13. Stresses that access to drinking water and a balanced diet is an essential condition of good public health; stresses the need to take a global approach to health and to improve living conditions which will help to increase life expectancy and combat poverty;
14. Believes that access to basic health and sanitation services must be a governmental priority - and as such reflected in the Country Strategy Papers (CSPs) - with increased annual funding on the part of both the EU and international community and developing countries' own governments;
15. Calls on the developing countries to restore basic public health services and systems and considers that European aid should above all support the developing countries' internal efforts to strengthen their human, institutional and infrastructural resources;
16. Agrees with the Commission Communication "A Stronger European-based Pharmaceutical Industry for the Benefit of the Patient – A Call for Action" that the competitiveness of European industry is declining, but regrets that poverty-linked diseases are not tackled; calls on the European institutions and interested stakeholders to see investments in such diseases as one way of remedying the lack of innovation in the European pharmaceutical industry;
17. Welcomes the new Council regulation (EC) n° 953/2003 concerning the prevention of trade diversion into the EU market of pharmaceuticals sold at tiered prices in developing countries; Regrets the limitations (prices and countries) of the regulation and is looking forward to the evaluation of the results obtained which should be the base for further improvements;
18. Stresses that a system for tiered pricing is only one of the strategies needed for obtaining affordable medical products in a sustainable way and calls upon the Commission, Member States and Developing countries to explore further possibilities - among them global/ regional procurements - that would increase affordability of medical products for countries in need. The human, social and economical impact of poverty diseases cannot be addressed without a whole range of complementary policies and strategies;
19. Calls on the Commission, in the context of its dialogue and price negotiations with the developing countries, to help to reduce the customs duties and levies in those countries which make medicines more expensive, and to promote measures aimed at preventing the price of generic medicines from rising and removing barriers to their production over the medium and long term;

20. Calls upon the Commission and Member States to respect, promote and support the implementation of the Doha Declaration on TRIPS and Public Health; this declaration should form the basis of all bilateral or regional trade agreements concerning intellectual property and public health;
21. Calls on the Commission and the Member States to apply in full the WTO's decision of 30 August 2003 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS agreement and public health designed to deal with the problem of countries which do not have sufficient manufacturing capacity in the pharmaceutical sector; stresses the need to amend Directive 2001/83/EC in order to authorise the production of pharmaceuticals intended for export to a country which does not have sufficient manufacturing capacities for generic pharmaceuticals and where a patent is not in force; stresses that implementation of this WTO decision must fully respect the spirit of the Doha Declaration on the TRIPS agreement and public health;
22. Considers that the complex arrangements under the agreement on TRIPS and public health adopted prior to the WTO Ministerial Conference in Cancun may in fact obstruct access to medicines;
23. Calls on the Commission to provide support for technology transfer and the establishment of local pharmaceutical and other production capacities, particularly in relation to clinical trial programmes in developing countries;
24. Asks the Commission to increase the EU financial participation in the Global Fund to Fight AIDS, Malaria and Tuberculosis, and to ensure that the European Union contributes at least a billion Euro a year on a sustained basis;
25. Calls on the European Commission, as a member of the Board of the GFATM, to ensure that the policies agreed in the PfA, such as ownership of developing countries, transparency in decision making, promotion of generic medicines are implemented by the GFATM and that the needs of orphans and vulnerable children are being adequately supported;
26. Also recalls that debt repayment and servicing accounts each year for almost 40% of the least developed countries' GDP while the budget for education and health remains derisory; considers that the serious problems of indebtedness call for a global solution based on international and national action;
27. Recognises that the involvement of civil society is critical to the global AIDS response and that civil society organisations have acquired significant technical and organisational capacity and requests the Commission to support an enhanced role for NGOs and CBOs in the implementation of the Commission's programme for Action.
28. Therefore welcomes the proposal for the creation of a Stakeholders Forum on Communicable Diseases in the Context of Poverty Reduction, with the participation of representatives from developing countries and civil society;
29. Calls on the EC to recognise and respond to the fact that some groups are more

vulnerable to infection with HIV/AIDS, TB and Malaria and ask the Commission to acknowledge the special consequences the diseases have on children and women;

30. Calls on the EU to develop policies and programmes and to ensure increased resources are made available within its Financial Perspectives 2006-2011 to support a significant scaled-up response to the three diseases; to specifically address the needs of orphans and vulnerable children affected by HIV/AIDS who are most at risk of infection, suffering from stigma and discrimination, psycho-social trauma, child labour, sexual exploitation, and trafficking as well as of being denied access to health, education and legal rights; to also address the specific needs and contributions of older people as carers and educators of orphans and vulnerable children;
31. Believes that palliative care, such as community non-hospice care, can provide a relatively low cost means of relief for those with life-limiting diseases such as HIV/AIDS, TB and Malaria, and should be a part of health strategies;
32. Welcomes the establishment of the European and Developing Countries Clinical Trials Partnership (EDCTP) initiative as an important contribution to international research efforts and calls for the Commission to increase its budgeted funds for R&D for neglected and poverty diseases;
33. Recalls that one of the objectives of the EDCTP Programme is to encourage the participation of the private sector; calls on the Commission to identify, in cooperation with developing countries, industry, NGOs and other stakeholders, the knowledge gaps in R&D in drugs against AIDS, malaria and tuberculosis and provide incentives for industry and public research institutes to undertake commitments to deal with specific problems on the list;
34. Calls on the Commission to ensure the necessary coordination between the Directorates General for Research and Development that will ensure that the latter will finance the development/adjustment of any infrastructures in developing countries that are indispensable for carrying out research activities financed by the Community, as long as the necessary funding is not available locally and exceeds the remit of research projects;
35. Stresses the urgent need to involve the European pharmaceutical industry in the fight against poverty-linked diseases; believes that this could be helped by a new legislative proposal for a framework regulation for R&D in such diseases, which will provide concrete incentives for investment, including simple measures such as protocol assistance, waiving of fees and direct or indirect subsidies, but also advanced incentives such as partial transfer of patent rights to drugs not addressing poverty-linked diseases;
36. Welcomes therefore the Commission's intention to create specific legislative instruments to incentivise R&D for neglected and poverty diseases; calls on the Commission to ensure that the resultant research meets the specific needs of the developing countries and contributes towards a swift improvement in their public health situation;
37. Welcomes the Commission's work on the incentives to promote private sector investment in R&D but calls on the Commission to set up a support programme to encourage public

investment in R&D also, in particular to promote the development of new treatments and diagnostics, including the development of fixed dose combinations; calls on the Commission to carry out a detailed analysis to ensure that the incentives applied guarantee the optimum use of public funds;

38. Urges the European Union to take a leading role in developing effective policy measures and partnerships on R&D of Global Public Goods with a particular focus on therapeutic and preventive technology, such as microbicides and vaccines, that meet the health needs of developing countries;
39. Calls on the Commission to promote an agreement at international level on the R&D needs of the developing countries designed to stimulate investment in medicines which meet the priorities of the developing countries, i.e. to guarantee the effective, appropriate and affordable nature of those medicines;
40. Supports the reprogramming, in partnership with the ACP countries, of unspent EDF funds for use in meeting the health needs of the populations in ACP states;
41. Calls for the nomination of an EU Ambassador to lead the EU's work in this area, promote further policy coherence across member states and enhance the EU's offensive on Health, AIDS and Population policies in the run-up to ICPD +10;
42. Instructs its President to forward this resolution to the Council and Commission, the WTO, WHO, UNAIDS, the ACP/EU Joint Parliamentary Assembly, the African Union, NEPAD, the European Federation of Pharmaceutical Industries and Associations and relevant NGOs.

EXPLANATORY STATEMENT

The Commission adopted its Programme for Action (PfA), entitled *Accelerated action on HIV/AIDS, malaria and tuberculosis in the context of poverty reduction* in February 2001.

The PfA has been in place for two years and the Commission submits now to the European Parliament the evaluation of its implementation, connected political questions and future challenges.

The PfA was based on three approaches: increase impact, affordability and R&D (Research and Development).

HIV/AIDS kills 8000 people a day, and five million more were infected by the virus in 2002. It is the leading cause of death in Africa.

HIV/AIDS is striking at the heart of family and community support structures for the old and young, and is leaving a whole generation of children to be brought up by their grandparents. Current global figures estimate that 13 million children under 15 have already lost either one or both parents to HIV/AIDS, and that another 40 million children will lose their parents within the next 10 years.

Poor women are especially vulnerable to HIV because of their low nutritional status, limited education and employment opportunities and low social status and consequent inability to negotiate safe sex. Once infected, women are more likely to avoid or postpone seeking care because of gender constraints, such as domestic responsibilities and the costs of travel and treatment. In Southern Africa young women are 4 to 6 times more likely to be HIV positive than men of the same age group.

It is estimated that a total of US 7-10 billion dollars a year is needed to address the HIV/AIDS epidemic in low and middle-income countries.

Increased access to comprehensive HIV care and support, including antiretroviral medicines and treatment for HIV-related opportunistic infections, is a global priority.

In addition to advocating for pricing of HIV medicines in line with the purchasing power of countries, other avenues are being pursued to make HIV medicines more affordable. They include encouraging patent-holder companies to grant voluntary licences that allow other manufacturers to produce their products at lower cost; using safeguards in international trade agreements that can help governments expand access to medicines and protect public health; and promoting South-South and North-South cooperation.

In Africa, where two-thirds of the world's HIV-positive people live, health-care systems were already weak and under-financed before the advent of AIDS. They are now buckling under the added strain of millions of new patients. In many places, facilities for diagnosis are inadequate and drug supplies are erratic, even for HIV-related conditions that are easy to diagnose and inexpensive to treat.

The role of communities and community organisations-especially those involving people living with HIV/AIDS-is especially important. Their work promotes social solidarity with

HIV-affected individuals and their families, provides them with emotional support, and helps protect people living with HIV/AIDS against discrimination and the violations of their rights. Often, it is community activism that helps prompt governments to devote more resources to the AIDS response and spurs companies to lower drug prices.

Domestic spending on HIV/AIDS has increased significantly in many countries, including some of the poorest. In 2001, the Abuja Declaration included a pledge by African countries to earmark 15% of their national budgets to health spending.

Tuberculosis (TB) kills about two million people each year, one of the world's leading infectious causes of death among young people and adults. Due to a combination of economic decline, the breakdown of health systems, the spread of HIV/AIDS, the difficulties of DOTS (directly observed therapy short course) and the emergence of multi-drug resistant TB, TB is on the rise in many developing and transitional economies.

HIV/AIDS and TB form a lethal combination, each speeding the other's progress. TB is leading killer of people living with HIV/AIDS.

R&D in new, easier, efficient and affordable drugs and diagnostic tools are urgently needed. The funding gap is US 300 million a year to address the epidemic in low and middle-income countries.

Malaria causes each year one to two millions deaths (90% in Sub-Saharan Africa) and an additional 300 to 500 million clinical cases, the majority of which occur in the world poorest countries.

Prompt and effective treatment of malaria which can reduce death rates by 50% needs to be included in routine child and maternal health care. The main challenge presently in effective treatment is to overcome the resistance to the most commonly used drugs. Developing countries need to be supported in paying for the cost of changing their national protocol and buying efficient combination treatment.

To achieve the goal of halving the burden of malaria by 2010, US2billion dollars need to be spent each year (currently only US 600 million dollars spent)

Both tuberculosis and malaria are contributing factors in another two to four million deaths annually.

Political Initiatives

Combating AIDS malaria and other diseases is the sixth of the eight Millennium Development Goals. Members of the international community want to take steps to halt and begin to reverse the spread of HIV and the incidence of malaria and other diseases by 2015.

The improvement in basic health and sanitation services is fostered at national, regional and international levels, although a lack of financial resources is evident if we want to reach the objective of covering the populations and indirectly to help in the combat to the three and other diseases.

The Declaration of Commitment, adopted at the United Nations General Assembly Special Session on HIV/AIDS in June 2001, highlights treatment and care, including access to antiretroviral medicines, as an essential element in the response to the epidemic. As drug prices drop and health systems improve, significant progress is being made in these areas. But treatment and care are not yet reaching the vast majority of people in need.

At the WTO Ministerial Conference in Doha increased affordability of pharmaceutical products and the interpretation of intellectual property rights were intensely discussed. A Declaration on relations between the TRIPs Agreement and Public Health was adopted. This declaration provides a roadmap on the use of the TRIPs safeguards to increase access to medicines and has clarified the right for countries to give priority to public health over commercial interests.

Trying to prevent trade diversion into the EU market of pharmaceuticals sold at tiered prices in developing countries, the Council adopted Regulation (EC) n° 953/2003. This regulation also includes the criteria to define tiered price products. However, the maximum prices set by the regulation are still quite high (the Commission has proposed lower maximum prices, but the Council raised the maximum) and not all countries are on the list of countries that can benefit from the regulation

Awareness of the lack of R&D for poverty diseases has increased tremendously recently. Incentives for the private industry may be pertinent, in some aspects, but incentives for the public R&D is as crucial. Firstly a needs-driven international R&D priority agenda which will gear the investments towards obtaining medical products that will correspond to the needs of the Developing countries must be defined.

NGOs and others actors have been suggesting that an international convention could be a proper answer to this issue. Such convention would outline an agreement and clear rationale for sharing the burden of the cost of this R&D and define appropriate funding and incentive mechanisms for governments to fulfil their commitments to public sector involvement in R&D.

Evaluation by the Commission

The Programme for Action remains a comprehensive, forward-looking and coherent EU policy framework, contributing to national, regional and international fight against the three diseases.

The Commission identifies areas that need strengthening:

- partnership actions with other international, regional and national actors;
- a flexible involvement of civil society,
- continuous search for more financial resources to carry out a wider partnership action in areas like local production capacity, technology transfer, incentives for innovative

- research and development by the private sector;
- public opinion mobilisation campaigns, especially education and information campaigns to population in risk.

To be efficient and speak in one voice, the Commission has created internally, in November 2002, an EC Programme for Action Interservice Group, and a Task Force to work on a detailed Harmonisation Action Plan for health, HIV/AIDS and education.

In its conclusions, the Commission clearly states the "urgent need for large scale collective action". Therefore it proposes the creation of a Stakeholders Forum on Communicable Diseases in the Context of Poverty Reduction.

The Commission is considering the creation of a specific legislative instrument to incentivise R&D for neglected and poverty diseases, along the lines of the EU Orphan Drug Regulation.

Conclusion

The EP Committee on Development and Cooperation has paid particular attention to the increasingly alarming situation by approving successive reports, both on the PfA or on related areas.

The extent of the problems caused by poverty-related diseases can not be addressed without a whole range of complementary policies and strategies. The EU must contribute by all available means. The unspent EDF funds should, in partnership with ACP countries, be urgently reprogrammed for support in the health sector, specifically for action on HIV/AIDS, malaria and tuberculosis.

The European Union needs to take a leading role in developing effective policy measures and partnerships to ensure the accelerated development, production and effective use of Global Public Goods, with a particular focus on therapeutic and preventive technologies, such as microbicides and vaccines, that meet the health needs of developing countries.

6 November 2003

OPINION OF THE COMMITTEE ON INDUSTRY, EXTERNAL TRADE, RESEARCH AND ENERGY

for the Committee on Development and Cooperation

on the Commission communication on the update of the EC Programme for Action:
accelerated action on HIV/AIDS, malaria and tuberculosis in the context of poverty reduction;
outstanding policy issues and future challenges
(COM(2003) 93 – C5-0384/2003 – 2003/2146(INI))

Draftsman: Dorette Corbey

PROCEDURE

The Committee on Industry, External Trade, Research and Energy appointed Dorette Corbey draftsman at its meeting of 11 June 2003.

It considered the draft opinion at its meetings of 8 September, 6 October and 4 November 2003.

At the last meeting it adopted the following suggestions unanimously.

The following were present for the vote: Luis Berenguer Fuster (chairman), Yves Piétrasanta and Jaime Valdivielso de Cué (vice-chairmen), Dorette Corbey (rapporteur), Nuala Ahern, Konstantinos Alyssandrakis, Per-Arne Arvidsson (for Guido Bodrato), Sir Robert Atkins, Ward Beysen (for Marco Cappato), Gérard Caudron, Giles Bryan Chichester, Nicholas Clegg, Willy C.E.H. De Clercq, Concepció Ferrer, Francesco Fiori (for Umberto Scapagnini), Neena Gill (for Massimo Carraro), Norbert Glante, Michel Hansenne, Malcolm Harbour (for W.G. van Velzen), Hans Karlsson, Bashir Khanbhai, Rolf Linkohr, Caroline Lucas, Erika Mann, Eryl Margaret McNally, Marjo Matikainen-Kallström, Ana Clara Maria Miranda de Lage, Elizabeth Montfort, Angelika Niebler, Giuseppe Nisticò, Seán Ó Neachtain, Reino Paasilinna, Paolo Pastorelli, John Purvis, Godelieve Quisthoudt-Rowohl, Imelda Mary Read, Mechtild Rothe, Christian Foldberg Røvsing, Paul Rübig, Konrad K. Schwaiger, Esko Olavi Seppänen, Claude Turmes and Olga Zrihen Zaari.

CONCLUSIONS

The Committee on Industry, External Trade, Research and Energy calls on the Committee on Development and Cooperation, as the committee responsible, to incorporate the following points in its motion for a resolution:

1. Agrees with the Commission Communication "A Stronger European-based Pharmaceutical Industry for the Benefit of the Patient – A Call for Action" that the competitiveness of European industry is declining, but regrets that poverty-linked diseases are not tackled; calls on the European institutions and interested stakeholders to see investments in such diseases as one way of remedying the lack of innovation in the European pharmaceutical industry;
2. Stresses the urgent need to involve the European pharmaceutical industry in the fight against poverty-linked diseases; believes that this could be helped by a new legislative proposal for a framework regulation for R&D in such diseases, which will provide concrete incentives for investment, including simple measures such as protocol assistance, waiving of fees and direct or indirect subsidies, but also advanced incentives such as partial transfer of patent rights to drugs not addressing poverty-linked diseases;
3. Recalls that one of the objectives of the EDCTP Programme is to encourage the participation of the private sector; calls on the Commission to identify, in cooperation with developing countries, industry, NGOs and other stakeholders, the knowledge gaps in R&D in drugs against AIDS, malaria and tuberculosis and provide incentives for industry and public research institutes to undertake commitments to deal with specific problems on the list;
4. Calls on the Commission to ensure the necessary coordination between the Directorates General for Research and Development that will ensure that the latter will finance the development/adjustment of any infrastructures in developing countries that are indispensable for carrying out research activities financed by the Community, as long as the necessary funding is not available locally and exceeds the remit of research projects;
5. Welcomes the agreement reached within the WTO enabling the export of generic medicines to countries with insufficient manufacturing capacity; calls on the Commission to insist on amending Article 31 of the TRIPS Agreement; stresses the need to amend Directive 2001/83/EC so as to allow manufacturing if a medicinal product is intended for export to a developing country that lacks the capacity to produce generic medicines and where a patent is not in force, and if there is a request to that effect of the competent authorities of that country;
6. Welcomes the acceptance of tiered pricing as a means of improving the supply of essential pharmaceuticals especially to least developed countries; calls on the Commission to pursue a broad strategy for improving affordability of such products, which should include inter alia promotion of tariff cuts on imported pharmaceuticals and effective use of compulsory licences, technical assistance to boost developing countries' involvement in trade negotiations and provision by businesses of treatments to affected employees.

4 November 2003

OPINION OF THE COMMITTEE ON WOMEN'S RIGHTS AND EQUAL OPPORTUNITIES

for the Committee on Development and Cooperation

on the Commission communication on the update of the EC Programme for Action: accelerated action on HIV/AIDS, malaria and tuberculosis in the context of poverty reduction; outstanding policy issues and future challenges
(COM(2003) 93 – C5-0384/2003 – 2003/2146(INI))

Draftswoman: Elena Valenciano Martínez-Orozco

PROCEDURE

The Committee on Women's Rights and Equal Opportunities appointed Elena Valenciano Martínez-Orozco draftswoman at its meeting of 11 June 2003.

It considered the draft opinion at its meetings 1 and 2 October and 3 and 4 November 2003.

At the latter meeting it adopted the following conclusions unanimously.

The following were present for the vote: Marianne Eriksson, first vice-chairwoman; Olga Zrihen Zaari, second vice-chairwoman; Jillian Evans, third vice-chairwoman; Elena Valenciano Martínez-Orozco, draftswoman; Johanna L.A. Boogerd-Quaak, Armonia Bordes, Chantal Cauquil (for Geneviève Fraisse), Christos Folias (for Thomas Mann), Lissy Gröner, Rodi Kratsa-Tsagaropoulou, Astrid Lulling, Maria Martens, Elena Ornella Paciotti, Christa Prets, James L.C. Provan, Amalia Sartori, Miet Smet and Joke Swiebel.

CONCLUSIONS

The Committee on Women's Rights and Equal Opportunities calls on the Committee on Development and Cooperation, as the committee responsible, to incorporate the following points in its motion for a resolution:

1. Draws the Commission's attention to the fact that it should highlight the important role played by women as the main health promoters and the need for gender mainstreaming in health policies;
2. Tuberculosis is one of the leading causes of death among women of reproductive age and is believed to rank above death in childbirth. Women are less likely than men to be tested and treated for TB;
3. Poverty, inadequate health services, nutritional deficiencies and unsuitable living conditions are instrumental in the propagation of TB. In turn, sickness and death from TB spreads greater poverty in many communities;
4. Over 41% of the world's population is at risk of contracting malaria and this percentage is growing every year owing to deteriorating health systems, increased resistance to medicines and insecticides, climate change and war;
5. All the data demonstrate that the number of women infected with HIV/AIDS is very high, and is rising. Infection has an impact not only on the women themselves, but also on their pregnancies and children, whence the crucial need for appropriate sexual and reproductive health information and services to be made available so as to enable people in this category to protect themselves against unwanted pregnancies and sexually transmitted diseases, including HIV/AIDS;
6. The number of rapes of both girls and women in HIV/AIDS-affected countries is extremely high, leading to infection of the victims. Programmes must be set up to offer aid to victims and punish perpetrators;
7. The sexual and economic subordination of women is a driving force behind the spread of the HIV/AIDS pandemic. The social vulnerability of women must be reduced by improving their health, education and legal and economic status. In order for prevention to be effective, the programmes must take account of the needs of women infected with HIV/AIDS and prevention must become a structural part of national life, in every community and in every family; this must extend to women working as prostitutes;
8. Calls on the Commission, in the context of its dialogue and price negotiations with the developing countries, to help to reduce the customs duties and levies in those countries which make medicines more expensive, and to promote measures aimed at preventing the price of generic medicines from rising and removing barriers to their production over the medium and long term;
9. Urges the Commission to facilitate the compilation of data on the impact these three diseases have on women and girls, with specific reference to the number of children

orphaned and of years of life and schooling lost, the degree to which women's working lives are affected, access to health services and access to treatment (comparison men/women and percentage of sufferers), in addition to epidemiological data.