

## **P6\_TA(2005)0341**

### **Major and neglected diseases in developing countries**

#### **European Parliament resolution on Major and Neglected Diseases in Developing Countries (2005/2047(INI))**

*The European Parliament,*

- having regard to the hearing organised on 27 April 2004 by its competent committee on Neglected Diseases,
- having regard to the Commission communication of 27 April 2005 entitled "A European Programme for Action to Confront HIV/AIDS, Malaria and Tuberculosis through External Action (2007-2011)" (COM(2005)0179),
- having regard to the Commission communication of 26 October 2004 entitled "A Coherent European Policy Framework for External Action to Confront HIV/AIDS, Malaria and Tuberculosis" (COM(2004)0726),
- having regard to its resolutions on HIV/AIDS, malaria, and tuberculosis, in particular that of 4 October 2001 on accelerated action targeted at major communicable diseases within the context of poverty reduction<sup>1</sup>,
- having regard to its resolution of 30 January 2003 on the proposal for a regulation on aid for poverty diseases (HIV/AIDS, malaria and tuberculosis) in developing countries<sup>2</sup>,
- having regard to the World Health Organization (WHO) Framework Convention on Tobacco Control and the Commission's High-Level Round Table on Tobacco Control and Development Policy held on 3-4 February 2003,
- having regard to its resolution of 4 September 2003 on health and poverty reduction in developing countries<sup>3</sup>,
- having regard to the resolution adopted by the ACP-EU Joint Parliamentary Assembly on 19 February 2004 on poverty-related diseases and reproductive health (ACP-EU 3640/04),
- having regard to the New York Call to Commitment: Linking HIV/AIDS and Sexual and Reproductive Health<sup>4</sup>,
- having regard to its resolution of 10 March 2005 on science and technology – Guidelines for future European Union policy to support research<sup>5</sup>,

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<sup>1</sup> OJ C 87 E, 11.04.2002, p. 244.

<sup>2</sup> OJ C 39 E, 13.2.2004, p. 58.

<sup>3</sup> OJ C 76 E, 25.03.2004, p. 441.

<sup>4</sup> Call to Commitment published at high level meeting organized by UNFPA, UNAIDS and Family Care International, New York 7 June 2004

<sup>5</sup> Texts Adopted, P6\_TA(2005)0077.

- having regard to the European and Developing Countries Clinical Trials Partnership (EDCTP), Special Programme for Research and Training in Tropical Diseases (TDR), Global Alliance for TB Drug Development (TB Alliance), International AIDS Vaccine Initiative (IAVI), International Partnership for Microbicides (IPM), European Malaria Vaccine Initiative (EMVI), Global Alliance for Vaccines and Immunization (GAVI)/The Vaccine Fund, Medicines for Malaria Venture (MMV), Roll Back Malaria (RBM) Partnership and the Drugs for Neglected Diseases Initiative (DNDi) and others who are working to research and develop drugs for neglected diseases,
  - having regard to its resolution of 12 April 2005 on the role of the European Union in the achievement of the Millennium Development Goals (MDGs)<sup>6</sup>,
  - having regard to the report of the UN Millennium Project Task Force on HIV/AIDS, Malaria, TB, and Access to Essential Medicines, “Prescription for Healthy Development: Increasing Access to Medicines”, 2005,
  - having regard to the WHO Paper on A Needs-Based Pharmaceutical R&D Agenda for Neglected Diseases, October 2004, and the WHO paper on the Intensified Control of Tropical Diseases presented at the WHO Strategic and Technical Meeting in Berlin, 18-20 April 2005,
  - having regard to Rule 45 of its Rules of Procedure,
  - having regard to the report of the Committee on Development (A6-0215/2005),
- A. whereas the interconnection of the world, global warming and emerging health threats such as avian flu, Ebola and Marburg, the resurgence of old infectious diseases such as TB, the increased prevalence of vaccine-preventable diseases in developed countries and the growing problem of multi-drug resistance all show the need for a comprehensive approach to be taken to all diseases,
  - B. whereas as there is a lack of sense of urgency in the European Union (EU), as migration and the increase in travel represent a growing risk of spreading these diseases,
  - C. whereas the Global Fund to Fight AIDS, Tuberculosis and Malaria aims to reduce the burden of disease and poverty, and coordination between projects and players is crucial, including the procurement, distribution and evaluation of medicines and coherence with national protocols,
  - D. whereas HIV/AIDS cases continue to grow globally, with women and children particularly affected, and with more new infections in 2004 than in any previous year; and whereas antiretroviral (ARV) prices are an “increasingly serious public health hazard”<sup>7</sup> with second-line medicines up to twelve times more expensive than the most affordable first-line generics,
  - E. whereas both HIV/AIDS and maternal and reproductive ill-health are driven by many common root causes, including gender inequality, poverty and social marginalisation, and whereas the presence of sexually transmitted diseases dramatically increases vulnerability

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<sup>6</sup> Texts Adopted, P6\_TA(2005)0115.

<sup>7</sup> WHO and UNAIDS "3 by 5" progress report, December 2004.

- to HIV infection, yet separate donor policy translates into divided programme delivery,
- F. whereas prevention is the most effective way to fight sexually transmitted diseases (STDs), including HIV/AIDS, and there is a clear link between sexual and reproductive health and the fight against HIV/AIDS,
  - G. whereas access to maternal and reproductive health information and services plays an important role in poverty reduction and should be integral to the fight against HIV/AIDS,
  - H. whereas the prevention of malaria requires the use of insecticide-treated mosquito nets (especially by young children, pregnant women and those living with HIV/AIDS), anti-malarial drugs for pregnant women and indoor residual spraying,
  - I. whereas TB affects one-third of the world's people, and in 2002 caused some two million deaths, many linked to HIV/AIDS, and new diagnostic tests and drugs could tackle this enormous global scourge,
  - J. whereas schistosomiasis can be treated by the drug praziquantel, but the associated cost of chemotherapy is an additional burden on health systems and there are concerns about the emergence of drug-resistant parasites, so there is a need to develop other effective remedies,
  - K. whereas severe visceral leishmaniasis and AIDS reinforce one another but the treatment pentavalent antimony has serious side effects, requires a lengthy treatment and is losing efficacy due to parasite resistance,
  - L. whereas the diagnosis and treatment of human African trypanosomiasis (HAT) or sleeping sickness is difficult,
  - M. whereas the acute phase of Chagas' disease can be treated by only two drugs, nifurtimox and benznidazole, while for the chronic phase there is no treatment,
  - N. whereas dengue is a global health concern and *Aedes albopictus*, a secondary dengue vector in Asia, is now established in Europe and other regions, due to the international used tyre trade; and there is no specific treatment but progress is being made in integrated vector management while the development of vaccines is slow,
  - O. whereas Buruli ulcer is an emerging health threat and can only be treated by surgery to remove the lesion, causing loss of tissue or permanent disability,
  - P. whereas the burden of mental illnesses and epilepsy is growing and neglected,
  - Q. whereas there is a grave shortage of health workers in many parts of the developing world, with migration both from and within poorer regions,
  - R. whereas re-used medical devices led to an estimated 260,000 new cases of HIV/AIDS, 2 million hepatitis C infections and 21 million hepatitis B infections in 2000,
  - S. whereas 5 million deaths worldwide are caused annually by tobacco use and this could double by 2020, with the majority occurring in developing countries,
  - T. whereas there is a chronic lack of investment in international and regional research in

drugs for poverty-related diseases,

- U. whereas it is estimated that less than 10% of the world's biomedical research funds are dedicated to addressing problems that are responsible for 90% of the world's burden of disease and that, of all drugs in development for all neglected diseases in 1999-2000, 18 R&D projects were in clinical development, compared with 2,100 compounds for all other diseases, and the mean time for clinical development for neglected diseases is about three and a half years more than for other conditions,
  - V. whereas scientific advances have been made, including the genome sequencing of parasites causing malaria, leishmaniasis and HAT, but these are not being translated into new products,
  - W. whereas the WHO Prequalification Project is an important network for assessing and procuring new essential medicines,
  - X. whereas yearly an estimated one and a half million children under five die from vaccine-preventable diseases,
  - Y. whereas only one pharmaceutical company has registered medicines available at reduced prices under Council Regulation (EC) No 953/2003 of 26 May 2003 to avoid trade diversion into the EU of certain key medicines<sup>8</sup>; whereas new medicines necessary today, but available only at high prices, are not included in this list,
  - Z. whereas all World Trade Organization (WTO) Member States should have integrated the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement into their national legislation, particularly States which produce generic medicines,
1. Welcomes the Commission's above-mentioned communications, but calls for its approach to be broadened to include other neglected diseases; highlights the fact that the Commission's actions can all be applied to other diseases beyond HIV/AIDS, malaria and TB;
  2. Urges the Commission to translate the policy proposals of the new Programme for Action to confront HIV/AIDS, TB and Malaria into concrete action by ensuring appropriate programming decisions and sufficient budget allocations;
  3. Stresses the critical importance of securing increased and adequate financial resources from Member States and in the funding of the EU's External Actions and development aid given that the resource gap for HIV/AIDS, malaria and TB alone is projected to reach EUR 11 500 million by 2007;
  4. Calls on the Commission to address HIV/AIDS, TB, malaria and other diseases as cross-cutting issues in the external assistance instruments of the next financial perspectives;
  5. Supports the establishment of the European Union Solidarity Fund (COM(2005)0108) in order to provide a common response to emergency situations of different origin in an

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<sup>8</sup> OJ L 135, 3.6.2003, p. 5. Regulation as amended by Commission Regulation (EC) No 1876/2004 (OJ L 326, 29.10.2004, p. 22).

efficient and coordinated way;

6. Recalls that health services in the ACP countries suffered greatly in the 1990s, particularly as a result of the emphasis placed on macro-economic reforms which led to drastic budget cuts in social sectors such as health;
7. Recalls also that repayment and servicing of the debt accounts for almost 40% of GDP per annum in the least developed countries, while education and health budgets are still derisory;
8. Urges ACP countries to meet Parliament's target of allocating 20% to health;
9. Believes that Poverty Reduction Strategy Papers must ensure that the poverty analysis that informs them influence the focus of work in the health sector and provide the opportunity to reorientate health plans and strategies to those health actions most likely to impact on poverty;
10. Stresses that access to drinking water and food is an essential condition for healthy populations; insists therefore on the cross dimension of health and the improvement of living conditions which contributes to increasing life expectancy;
11. Calls on developing countries to restore their public and basic health care systems and services and for the EU to support this process through aid for the emergence and reinforcement of human and institutional capacities and infrastructures;
12. Believes that investment in water supply, sanitation and infrastructure as well as raising awareness of the links between health, clean water, sanitation and hygiene are critical to combating waterborne diseases (including pneumonia, diarrhoea, malaria) and to the delivery of healthcare systems;
13. Calls for the policy document on human resources provided for in the Commission's Programme for Action also to include proposals for urgent action to reverse the loss of health workers from developing countries, such as better training, career opportunities, remuneration, retention incentives, safe working conditions, cooperation with disease-specific initiatives, twinning arrangements, voluntary support and the spread of best practice and technical support;
14. Stresses the need for coordination within the EU and between the EU and other global and local donors, to pool expertise and share technical assistance in order to improve outcomes;
15. Welcomes the Commission's commitment to strengthening the capacity of developing countries to conduct research, but calls for this to extend beyond clinical trials to a broader concept of research that includes operational and health systems research so important in developing more effective, efficient and sustainable implementation of interventions;
16. Emphasises that best practice in scientific research and implementation are needed to ensure effective interventions, projects and programmes;
17. Notes that care should be taken in the way that medicines are dispensed and used in order

to limit resistance;

18. Notes that, as a result of the Asian tsunami, the interruption of malaria, TB or ARV treatment there could cause many deaths;
19. Welcomes the Eurobarometer results showing that the EU public believes that EU aid can be most effective in the fight against AIDS and other diseases<sup>9</sup>;
20. Stresses the urgency of access to medicines and for pharmaceutical producers to make drugs available and affordable in low income countries;
21. Stresses the importance of country leadership and accountability and calls on the Commission to ensure that affected communities and civil society are meaningfully involved in this process to ensure that Action Frameworks reflect the concerns and experiences of marginalised communities;
22. Calls on the Commission to assess the real impact of the measures implemented under Regulation (EC) No 953/2003 and on the pharmaceutical industry to make products available to the people of developing countries at tiered prices for improving access to essential medicines, and to propose complementary measures to enable access specifically to essential medicines if shortages exist;
23. Calls on the Commission to use the EC Stakeholder Forum as a systematic and regular mechanism of consultation with civil society, people affected by HIV/AIDS, malaria and TB and representatives of community-based organisations from developing countries;
24. Reminds the Commission of the importance of women in primary health care and that women, children and people with disabilities need to be mainstreamed into health policies and related statistics and research;
25. Welcomes the Commission's support in its Programme for Action for comprehensive and evidence-based prevention programmes, and urges the Commission to support HIV/AIDS prevention programmes which include political leadership, education to support behavioural change, harm reduction programmes, commodity distribution, voluntary counselling and testing, secure blood supply, vulnerability reduction measures for groups at higher risk of infection as well as social and behavioural research;
26. Stresses the need for increased investment in R&D into new technologies for HIV prevention such as vaccines and microbicides and calls for the development of adapted and affordable paediatric formulations of ARV for the 2.2 million children living with HIV, alongside diagnostic and monitoring tools suited to their needs and to developing country settings;
27. Urges the Commission to acknowledge that distinct HIV epidemics require distinct approaches, whether this be for countries with generalised or with concentrated epidemics; and that greater attention must be given to understanding transmission patterns in each different context and acting in accordance with this evidence;
28. Calls for older people, orphans and other vulnerable children to be taken into account in

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<sup>9</sup> Special Eurobarometer 222, Attitudes towards Development Aid, February 2005.

policies for poverty reduction and support for families affected by HIV/AIDS and other diseases, and for their involvement and participation in the design and implementation of programmes;

29. Calls for a stronger linkage between sexual and reproductive health and HIV/AIDS programmes, and adequate, accessible and affordable HIV/AIDS and sexual and reproductive health related supplies, including male and female condoms and STD diagnostics and drugs;
30. Is very concerned at reports that some African governments are charging a sales or import tax on ARV and other drugs, which then make the drugs unaffordable to poor communities; urges the Commission to investigate this and to encourage governments to abolish such taxes;
31. Calls for countries affected by malaria to commit to and accelerate the introduction of Artemisinin-based Combination Therapy (ACT), recognised as the most effective treatment, calls on donors to finance ACT and support the purchase, prequalification and manufacture of artemisinin-based drugs;
32. Calls for industry to manufacture insecticide-treated nets (ITNs), especially long lasting insecticidal nets, calls for programmes to rapidly scale up coverage of ITNs, to provide training in malaria symptoms, to remove sources of stagnant water and to equip primary health services with drugs and reliable rapid diagnostic tests, and to strengthen country-led partnerships to coordinate the scale up and to eliminate implementation bottlenecks;
33. Considers that simple effective diagnostic tests are needed for leishmaniasis, suited to conditions in resource-poor countries; notes that R&D of new treatments is under-funded and that alternative drugs exist but are expensive and difficult to administer; calls for the speedy registration of promising drugs such as paromomycin and miltefosine;
34. Notes the work of DNDi and TDR on a treatment for HAT, and stresses the urgent need to assess the safety and efficacy of nifurtimox, and to develop new, easy-to-use and accurate diagnostic tests;
35. Calls for increased efforts in the prevention of Chagas' disease by involving target populations in transmission control, by separating living accommodation of animals and people and by combating vectors with insecticide;
36. Welcomes the WHO Global Programme to identify districts where lymphatic filariasis is endemic and treat the at-risk population with a yearly single-dose treatment, for at least five years;
37. Believes that there are great benefits from delivering safe and effective drugs; that controlling or eliminating infections by annual or biannual administration of donated drug interventions costs approximately EUR 0.20 per person treated;
38. Calls for the implementation of the "Quick Wins" identified in the report of the UN Millennium Project 2005 including regular annual deworming;
39. Calls on the EU to take concrete steps to counter poverty and ensure consistency between its policies in the fields of trade, development cooperation and agriculture, with a view to

preventing any direct or indirect negative impact on the economies of developing countries;

40. Calls for a new emphasis on support for mental and neurological diseases and disorders, especially unipolar depression and epilepsy;
41. Believes that health services able to diagnose, manage and treat conditions such as diabetes would save many lives and reduce disability and amputations; in particular access to insulin and Type 2 drugs needs to be expanded and made affordable;
42. Calls on the Commission to support programmes to prevent and cure obstetric fistula and care for the women and girls affected;
43. Calls for initiatives to provide accelerated local access to appropriate diagnostics and safe blood collection methods, with associated training and infrastructure, to monitor key health parameters, and stresses the importance of ensuring that all immunisation programmes mandate the use of medical technology that prevents re-use;
44. Invites the Commission to provide support for strengthening national and international tobacco control programmes;
45. Believes that public-private partnerships such as the RBM Partnership, TB Alliance, IAVI, IPM, GAVI/The Vaccine Fund, MMV, DNDi and the Institute for One World Health together with TDR are key to innovation and capacity-building;
46. Regrets the lack of R&D into diseases which almost exclusively affect poor people in developing countries, due to a lack of viable markets, and stresses that this must be corrected by international efforts;
47. Calls for the Seventh Framework Programme to include specific reference to and funding for research on illnesses that affect citizens of developing countries;
48. Encourages the Commission to examine as of now ways of implementing the concrete steps to be taken with regard to the flexibility of current and planned thematic budget lines and also to simplify procedures in order to improve the synergy and consistency of Community policies, services and programmes in the fight against the three diseases;
49. Calls on the Commission to work with WHO, including through the TDR and the Initiative for Vaccine Research, to draw up an essential R&D agenda to define needs and priorities for the developing world;
50. Believes that the review and registration of drugs should be relevant to the priorities of disease-endemic countries with specific procedures for better assessment of the risk-benefit ratio of drugs for neglected diseases;
51. Calls for the improvement of working conditions for medical staff practising in developing countries, the provision of suitable medical equipment and transfer of technology; calls for an increase in exchange programmes of doctors from Europe to developing countries and vice versa;
52. Calls on the Commission to support integrated research projects involving the complete process of identification of chemicals through to the most effective being put on the

market;

53. Calls for the activities of the EDCTP to be broadened to include other neglected diseases and other phases of clinical development (Phase I and IV);
54. Demands that international standards for ethical research, such as those set out in the Declaration of Helsinki, be applied in all countries;
55. Calls for collaboration with the pharmaceutical industry on poverty diseases, with a new framework proposal for R&D in such diseases, to provide incentives for investment, including protocol assistance, fee waivers, tax credits, subsidies, innovation prizes, assistance for prequalification, advance purchase commitments and partial transfer of patent rights to drugs; and calls also for a "needs based approach";
56. Stresses that education and family planning are as important as the provision of effective drugs;
57. Calls for an obligation on or incentive to the pharmaceutical industry to reinvest a percentage of profits into neglected disease R&D, either directly or through public programmes;
58. Urges, in the context of the WHO Commission on Intellectual Property, Innovation and Health, a new global medical R&D treaty, including minimum obligations to support R&D, priority setting mechanisms and consideration of a system of tradeable credits for investments in particular projects;
59. Believes that building of local R&D and production capacity through technology transfer and sharing should be promoted through development policies;
60. Welcomes the Commission's support for the WHO Prequalification Project in its Programme for Action and calls on the Commission to work with WHO to strengthen and expand its capacity to fulfil the Project's functions;
61. Calls on the Commission and the Member States to give active support to the implementation of the Doha Declaration and to oppose any action taken by WTO Member States that undermines the unanimous commitments made in the declaration on intellectual property and public health, in particular through the negotiation of 'TRIPS plus' clauses in the framework of regional free trade agreements;
62. Instructs its President to forward this resolution to the Council, the Commission, the World Health Organization and the ACP-EU Joint Parliamentary Assembly.