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REPORT

on Major and Neglected Diseases in Developing Countries
(2005/2047(INI))

Committee on Development

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MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION

on Major and Neglected Diseases in Developing Countries (2005/2047(INI))

The European Parliament,

- having regard to its hearing on Neglected Diseases, 27 April 2004,
- having regard to the Commission communication of 27 April 2005 (COM(2005)0179),
- having regard to the Commission communication of 26 October 2004 (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 reduction¹,
- having regard to its position of 30 January 2003 on the proposal for a regulation on aid for poverty diseases in developing countries²,
- having regard to the 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 countries³,
- 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 Health⁴
- having regard to its resolution of 10 March 2005 on science and technology – Guidelines for future European Union policy to support research⁵,
- 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), GAVI (Global Alliance for Vaccines and Immunization)/The Vaccine Fund, Medicines for Malaria Venture (MMV), Roll Back Malaria (RBM)

¹ OJ C 87E, 11.04.2002, p. 244.

² OJ C 39E, 13.2.2004, p. 58.

³ OJ C 076, 25.03.2004, p. 246.

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

⁵ P6_TA-PROV(2005)0077.

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) (2004/2252(INI))⁶,
 - 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 Disease 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, 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 actors 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”⁷ 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 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

⁶ P6_TA-PROV(2005)0115.

⁷ WHO and UNAIDS “3 by 5” progress report, December 2004.

(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, in 2002 caused some two million deaths, many linked to HIV/AIDS, and new diagnostic tests and drugs could tackle the 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 to 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 cost under Council Regulation (EC) No 953/2003 of 26 May 2003 to avoid trade diversion into the European Union of certain key medicines⁸; whereas new medicines necessary today, but available only at high prices, are not included in this list,
 - Z. whereas all WTO Member States should have integrated the TRIPS agreement on intellectual property rights into their national legislation, particularly States which produce generic medicines,
1. Welcomes the Commission's Communications, but calls for its approach to be broadened to other neglected diseases; highlights the fact that the actions of the Commission 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 €11.5 billion 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;

⁸ OJ L 135, 3.6.2003, p. 5. Amended by Commission Regulation (EC) No 1876/2004 (OJ L 326, 29.10.2004, p. 22).

5. Supports the establishment of the European Union Solidarity Fund⁹ in order to provide a common response to emergency situations of different origin in an efficient and coordinated way;
6. Recalls that health services in the ACP countries suffered greatly in the 90s, 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 the European 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 are essential conditions 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 strengthen the capacity of developing

⁹ 2005/0033 (COD)

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 to 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 that show the EU public believes that EU aid can be most effective in the fight against AIDS and other diseases¹⁰;
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 Council Regulation (EC) No 953/2003 of 26 May 2003 to avoid trade diversion into the European Union of certain key medicines¹¹ and for the pharmaceutical industry to make products available to the people of developing countries at a price differentiated for improving the access to essential medicines, and to propose complementary measures to enable access specifically to essential medicines if shortages are found;
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 organizations 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

¹⁰ Special Eurobarometer 222, Attitudes towards Development Aid, February 2005.

¹¹ OJ L 135, 3.6.2003, p. 5. Amended by Commission regulation (EC) No 1876/2004 (OJ L 326, 29.10.2004, p. 22).

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 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 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 antiretroviral and other drugs, which then make the drugs unaffordable to poor communities; urges the Commission to investigate this and to encourage governments to remove 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 (LLINs), 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 €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 specific 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 European Commission to work with the WHO, including through the Special Programme for Research and Training in Tropical Diseases 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 development¹²;
54. Demands that international standards for ethical research, such as those set out in the Declaration of Helsinki, are 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

¹² (Phase I and IV).

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 the 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.

EXPLANATORY STATEMENT

**"Principiis obstata; sero medicina paratur
Cum mala per longas convaluere moras."**

***(Stop it at the start; it's late for medicine to be prepared when disease has grown strong
through long delays). Ovid***

2005 has seen a new health threat on our agenda: Marburg emerged in Angola. This deadly haemorrhagic disease has a mortality rate of over 90%. ECHO has swiftly supported Médecins Sans Frontières in providing not just powerful antibiotics and intravenous fluids, but water purification systems and disposable protective gear.

Just one example of the need for vigilance, prevention and rapid response, just one reason why we must never cherry pick in our battle against disease. We must continue to tackle the Big Three of AIDS, Malaria and Tuberculosis - which are still not under control and are still spreading to new regions - but as many or more people die, become chronically ill or live with disabilities caused by diseases the world neglects. It is time to end that poverty of fatalism; it is time to bring neglected diseases in from the cold and to bring real hope to those who live with and too often die from them.

There are emerging health threats from new diseases such as Avian Flu and Ebola, which pose a growing risk to EU citizens as a result of the increase in travel and population mobility. It is possible that some of these diseases will increase in frequency in the western world as a result of global warming. Meanwhile, old infectious diseases are resurgent, notably TB, increasingly in multi-drug resistant strains. The fight against disease everywhere is in everybody's health and indeed security interests.

Health research and development (R&D) can yield rapid results. The outbreak of Severe Acute Respiratory Syndrome (SARS) in 2003 led to unprecedented international cooperation to sequence the virus, and through successful public and private cooperation, to develop and deploy a diagnostic kit. SARS also made communicable disease a political priority, leading to the establishment of the European Centre for Disease Prevention and Control. We need the same dynamic approach to deal with other major global diseases.

Only a very few new drugs and vaccines have been developed to deal with the "most neglected diseases" - often parasitic diseases such as Leishmaniasis, Sleeping Sickness or Onchocerciasis, and Dengue, Trachoma and infectious diarrhoeal diseases. Patients suffering from these illnesses are given archaic drugs, some of which are highly toxic, ineffective or difficult to administer.

Urgent action is needed to develop new drugs, tests and vaccines that are adapted to developing countries' needs, and to make them available at affordable prices.

Less than 1% of the 1,393 new drugs placed on the market between 1975 and 1999 were developed for infectious, tropical diseases. Since then the situation has remained virtually unchanged, although a handful of organisations are now working to change it. There already

exists the scientific knowledge that could contribute to the development of new treatments. Because of the lack of a viable commercial market, they need direct support to ensure that the R&D is carried out to find new diagnostic tests and treatments.

To our shame, “Neglected Diseases” have not received the attention they deserve from EU actions. The European Parliament, in its report of 12 July 2001¹³ specifically requested the Commission “to take the initiative for a proposal for neglected diseases (such as trypanosomiasis, filariasis, bilharzia and ebola); this proposal should provide incentive for the development of drugs and vaccines destined to combat poverty-related diseases for which there is a limited market”. Then, its report of 10 December 2003¹⁴ on the update of the EC Programme for Action said “no research is currently being carried out into the most neglected diseases which mainly affect developing countries” and that “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”.

To get drugs for neglected diseases on the market, the Commission should support integrated research projects involving the complete process of identification of likely candidate chemicals through to the most effective and least toxic being put on the market. This will involve screening potential chemicals which are active against these diseases, selection of those with the most potential, carrying out pre-clinical testing on them, and based on these results, developing and carrying out clinical trials on the most promising drugs. The emphasis on “translational research” to bridge the gaps between basic research and useful applications in the Seventh Research Framework Programme is good news - but this should explicitly include neglected diseases most in need of such research. In addition, the activities of the EDCTP should be expanded to include other neglected diseases as well as other phases of clinical development.

DNDi has estimated that over the next ten years a minimum of €250 million will be needed to put on the market six or seven medicines that are effective against Trypanosomiasis, Chagas Disease, and Leishmaniasis, and to have a balanced portfolio for other key medicines at various stages of development.

Health systems in many developing countries are starved of resources. The countries themselves will need to mobilise increased investment for better health outcomes, and initiatives to commit more money from national budgets to health are welcome. Yet the international community will need to complement country level public and private investments with long-term financial support; many countries will require capacity building and technical support, including training of health workers at the local level. To this end, the European Parliament has consistently called for adequate, predictable and additional funding and for 35% of development aid to be allocated to health and education.

Nor should it be forgotten that millions of people throughout the world suffer from mental and neurological disease. Although effective treatments exist for many of these diseases, most of the middle and low-income countries devote less than 1% of their health expenditure to

¹³ (A5-0263/2001).

¹⁴ (A5-0474/2003).

mental and neurological health.

Developing countries have inadequate access to affordable services and drugs. The reasons are complex and include the effects of international and national pricing policies, tariffs, taxation and the implementation of intellectual property rights agreements. Options to further improve access and affordability include the exploration of the use of differential or tiered pricing, voluntary licensing agreements, technology transfer and an increase in local capacity for production.

Diseases which merit attention

Malaria

Globally 2.2 billion people are at risk of Malaria. *Plasmodium falciparum* is the most deadly form of Malaria of which there were over 500 million cases in 2002. Most common in sub-Saharan Africa, it causes extremely high mortality, mostly in children. Pregnant women and unborn children are particularly vulnerable.

Malaria is spreading to new regions of the world and reappearing in areas where it had been eliminated. Imported malaria is now a health issue in Europe. Between 1972 and 2000 the reported number of imported cases increased ten-fold, from 1,500 to over 15,000; more than 700 people in the WHO European Region have died in the last decade.

Malaria is preventable and curable - with more support for programmes to encourage the use and renewal of mosquito nets, to provide training in recognition of symptoms of malaria, to remove sources of stagnant water, and to equip primary health services with treatment drugs.

In the face of drug resistance and ineffective insecticides, the WHO recommends combining two antimalarials, one being a derivative of artemisinin made from the plant *Artemisia annua*. Cultivation of the plant takes at least 6 months and extraction, processing and manufacturing at least 2 to 5 months. Therefore, reliable forecasting of global ACT requirements is essential for securing supplies.

In April 2005, DNDi announced the development of an artesunate and amodiaquine co-formulation in a single tablet, which should become the indispensable treatment for malaria. It will be sold at cost to the countries affected, to international organisations and NGOs. It will be less expensive than all other combinations containing artemisinin derivatives and is not covered by any patent. This development, funded in part by the EU Research budget, illustrates the potential of R&D into other neglected diseases.

HIV/AIDS

An estimated 39.4 million people are living with the HIV virus. Last year AIDS killed 3.1 million people, the majority in sub-Saharan Africa. Only 700,000 of the nearly 6 million people in need of antiretroviral (ARV) treatment against HIV in developing countries have access to it, and since July 2004 only 260,000 new patients have benefited from ARV therapy in developing countries. ARV prices are high and second-line medicines up to twelve times more expensive than the most affordable WHO-recommended first-line generics.

It is estimated that 16 million children under 15 have already lost either one or both parents to HIV/AIDS, leaving the old and young to support

each other in families. The needs of children and older people (often carers) should not be neglected.

A massive effort on all fronts of prevention, treatment, care (including palliative care), microbicides and vaccines is needed to achieve a response on a scale that matches that of the global AIDS epidemic.

TB

An estimated 1.8 million people died of TB in 2002. Southeast Asia accounts for a third of cases globally and Africa accounts for more than a quarter.

TB accounts for about 13% of AIDS deaths worldwide. Drug resistant TB is increasing and strains of TB resistant to all major anti-TB drugs have emerged. Particularly dangerous is MultiDrug-Resistant TB. While drug-resistant TB is generally treatable, it requires up to two years of expensive chemotherapy.

Leishmaniasis

The group of diseases caused by *Leishmania* parasites are transmitted by sandfly bites. The leishmaniasis are endemic in 88 countries and 12 million people are affected. Around 1.5 to 2 million new cases occur annually, and this is rising.

The most life-threatening form is Visceral Leishmaniasis (VL), commonly known as kala-azar, which attacks the immune system and from which the 57,000 deaths reported in 1999 is thought to be significantly below the real number. Pentavalent antimony, the most widely prescribed drug to treat Leishmaniasis, was discovered a century ago, has serious side effects, requires prolonged treatment and is losing efficacy in some regions due to parasite resistance. Although newer treatments exist, they are not optimal due to problems of toxicity, high price or difficulty in administration. Co-infection with HIV poses an additional challenge.

AIDS and VL reinforce one another. VL accelerates the onset of AIDS and shortens the life expectancy of HIV-infected people, whilst HIV spurs the spread of VL. AIDS increases the risk of VL by 100-1000 times in endemic areas. Leishmania/HIV co-infections are considered a real threat, even in south-western Europe.

Schistosomiasis

Schistosomiasis (bilharzia) infects 200 million people globally of which 20 million are thought to suffer severe consequences causing about 20,000 deaths annually. Treatment with praziquantel is available but there is concern over the potential for the emergence of resistant parasites. Again there is a need to develop alternative therapies.

Sleeping Sickness

Human African Trypanosomiasis (HAT), or sleeping sickness, is caused by a species of *Trypanosoma* via the bite of the tsetse fly. The disease ultimately spreads to the central nervous system when the characteristic signs of sleeping sickness appear. HAT is endemic in sub-Saharan Africa with 60 million people at risk. WHO estimates over 300,000 cases of the disease, but most go unreported.

The limited choice of available drugs, their toxicity (causing mortality in 5% of patients), and the disease's growing unresponsiveness to drugs, make it imperative that new treatments are urgently developed.

Chagas Disease

American Trypanosomiasis or Chagas Disease is prevalent in Central and South America where 18 million people are infected with the parasite and an estimated 50,000 deaths occur annually. This amounts to about 25% of the region's population at risk, yet only two drugs, nifurtimox and benznidazole - neither ideal - can treat the acute phase; for chronic Chagas Disease there is no treatment at all.

Dengue

Dengue is a mosquito-borne infection found in tropical and sub-tropical regions, predominantly in urban and semi-urban areas. The global prevalence of Dengue has grown dramatically in recent decades and it is now endemic in more than 100 countries.

Some 2,500 million people - two fifths of the world's population - are now at risk from dengue. WHO currently estimates 50 million cases of infection worldwide every year. Between 1995 and 2001 the number of reported cases more than doubled in the Americas.

In recent years, *Aedes Albopictus*, a secondary Dengue vector in Asia, has spread to parts of Europe, the USA and other countries thought to be a result of the international trade in used tyres.

There is no specific treatment for dengue fever. Vaccine development for Dengue and Dengue Haemorrhagic Fever is difficult but progress is being made.

Ebola Haemorrhagic Fever

Ebola Haemorrhagic Fever has killed over 1,200 since the Ebola virus was discovered. No specific treatment or vaccine is yet available. Several vaccine candidates are being tested but it could be several years before any are available. A new drug therapy has shown early promise in laboratory studies and is being evaluated further. However, this too will take several years.

Lymphatic Filariasis

Over 120 million people are infected by Lymphatic Filariasis, known as Elephantiasis; over 40 million of them are seriously incapacitated and disfigured by the disease which spreads because of rapid urban growth. Lymphatic Filariasis can cause enlargement of limbs, genitalia and breasts and internal damage to the kidneys and lymphatic system. In endemic communities up to 50% of men and 10% of women can be affected. Treatment is by a once-yearly administration of single doses of albendazole plus either diethylcarbamazine or ivermectin carried out for 4-6 years.

Buruli Ulcer

Buruli Ulcer is an emerging health threat; the third most common mycobacterial infection in healthy people after TB and leprosy. It destroys skin and tissues and causes deformities. Lesions occur mainly in the limbs. At present, the only treatment available is surgery to

remove the lesion and a skin graft if necessary. This is both costly and dangerous, with loss of tissues or permanent disability.

Neuropsychiatric Disorders

Mental illnesses are common to all countries and are rapidly increasing. They cause considerable economic and social costs. One in four of us develop one or more such disorders at some stage in life and 450 million people world-wide are affected by mental, neurological or behavioural problems.

Cost-effective treatments exist for most disorders, but mental health legislation, treatment and community care are not given the priority they deserve.

Some 121 million people currently live with depression. Each year 5.8% of men and 9.5% of women will experience a depressive episode and 873,000 people commit suicide each year.

50 million people are affected by Epilepsy; more than 80% of them in the developing world. 70% of people with Epilepsy can be seizure-free if treated with antiepileptic drugs. Although in most countries the cost of treatment can be as low as \$5 per patient per year, the vast majority remain untreated. In Africa, 80% receive no treatment.

24 million people have Schizophrenia; 37 million people live with dementia, mainly Alzheimer's. With ageing populations, this is projected to rise rapidly in coming years.

Child and adolescent disorders are common. 10-20% of children have mental or behavioural problems. The overall prevalence of learning disability is between 1% and 3%. It is more common in developing countries because of higher incidence of injuries and deprivation of oxygen at birth and early childhood brain infections.

PROCEDURE

Title	Major and Neglected Diseases in Developing Countries			
Procedure number	2005/2047(INI)			
Basis in Rules of Procedure	Rule 45			
Committee responsible Date authorisation announced in plenary	DEVE 12.5.2005			
Committee(s) asked for opinion(s) Date announced in plenary	INTA 12.5.2005	BUDG 12.5.2005	ENVI 12.5.2005	FEMM 12.5.2005
Not delivering opinion(s) Date of decision	INTA 12.7.2005	BUDG 9.6.2005	ENVI 14.6.2005	FEMM 21.6.2005
Enhanced cooperation Date announced in plenary				
Motion(s) for resolution(s) included in report				
Rapporteur(s) Date appointed	John Bowis 16.3.2005			
Previous rapporteur(s)				
Discussed in committee	23.5.2005	21.6.2005		
Date adopted	21.6.2005			
Result of final vote	for: 31 against: 0 abstentions: 0			
Members present for the final vote	Margrete Auken, Alessandro Battilocchio, Margrietus van den Berg, Danutė Budreikaitė, Marie-Arlette Carlotti, Thierry Cornillet, Nirj Deva, Koenraad Dillen, Alexandra Dobolyi, Fernando Fernández Martín, Michael Gahler, Hélène Goudin, Jana Hybášková, Filip Andrzej Kaczmarek, Maria Martens, Miguel Angel Martínez Martínez, Luisa Morgantini, Józef Pinior, José Ribeiro e Castro, Toomas Savi, Frithjof Schmidt, Feleknaš Uca, Anna Záborská, Jan Zahradil, Mauro Zani			
Substitutes present for the final vote	John Bowis, Manolis Mavrommatis, Eoin Ryan, Anne Van Lancker, Zbigniew Zaleski, Gabriele Zimmer			
Substitutes under Rule 178(2) present for the final vote				
Date tabled – A6	22.6.2005		A6-0215/2005	