

# EUROPEAN PARLIAMENT

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*Committee on Development*

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PE 359.943v02-00

## AMENDMENTS 1-73

**Draft report**

**(PE 357.813v01-00)**

**John Bowis**

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

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Amendment by John Bowis

Amendment 1  
Citation 1 a (new)

- *having regard to the Commission Communication of 27 April 2005 (COM(2005)0179),*

Or. en

Amendment by John Bowis

Amendment 2  
Citation 4 a (new)

- *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,*

Or. en

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**EN**

**EN**

Amendment by Glenys Kinnock, María Elena Valenciano Martínez-Orozco, Anne Van Lancker

Amendment 3  
Citation 6 a (new)

- ***having regard to the New York Call to Commitment: Linking HIV/AIDS and Sexual and Reproductive Health<sup>1</sup>***

Or. en

Amendment by Johan Van Hecke

Amendment 4  
Citation 8

- having regard to the European and Developing Countries Clinical Trials Partnership (EDCTP), Global Alliance for TB Drug Development (TB Alliance), International AIDS Vaccine Initiative (IAVI), European Malaria Vaccine Initiative (EMVI), ***GAVI (Global Alliance for Vaccines and Immunization)/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,

Or. en

Amendment by John Bowis

Amendment 5  
Citation 8

- 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), Medicines for Malaria Venture (MMV), Roll Back Malaria and the Drugs for Neglected Diseases Initiative (DNDi) and others who are working to research and develop drugs for neglected diseases,

Or. en

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<sup>1</sup> Call to Commitment published at high level meeting organized by UNFPA, UNAIDS and Family Care International, New York 7 June 2004

Amendment by Marie-Arlette Carlotti

Amendment 6

Citation 8 a (new)

- ***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)),***

Or. fr

Amendment by John Bowis

Amendment 7

Citation 8 b (new)

- ***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,***

Or. en

Amendment by John Bowis

Amendment 8

Citation 9

- 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,

Or. en

Amendment by Johan Van Hecke

Amendment 9

Recital A

- 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,

Or. en

Amendment by Irena Belohorská

Amendment 10  
Recital A a (new)

*Aa. 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,*

Or. en

Amendment by Johan Van Hecke

Amendment 11  
Recital B

B. 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,

Or. en

Amendment by John Bowis

Amendment 12  
Recital C

C. 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” with second-line medicines up to twelve times more expensive than the most affordable first-line generics,

Or. en

Amendment by John Bowis

Amendment 13  
Recital C a (new)

***Ca. 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,***

Or. en

Amendment by Glenys Kinnock, María Elena Valenciano Martínez-Orozco, Anne Van Lancker

Amendment 14  
Recital C b (new)

***Cb. 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 rights (SRHR) and the fight against HIV/AIDS,***

Or. en

Amendment by John Bowis

Amendment 15  
Recital C c (new)

***Cc. 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,***

Or. en

Amendment by Filip Andrzej Kaczmarek

Amendment 16  
Recital E

**E. 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*,**

Or. pl

Amendment by John Bowis

Amendment 17

Recital F

- F. 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,

Or. en

Amendment by John Bowis

Amendment 18

Recital J

- J. 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***,

Or. en

Amendment by Filip Andrzej Kaczmarek

Amendment 19

Recital K

- K. (*does not affect English version*)

Or. pl

Amendment by John Bowis

Amendment 20

Recital L a (new)

- La. whereas there is a grave shortage of health workers in many parts of the developing world, with migration both from and within poorer regions,***

Or. en

Amendment by John Bowis

Amendment 21  
Recital L b (new)

***Lb. 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,***

Or. en

Amendment by John Bowis

Amendment 22  
Recital L c (new)

***Lc. whereas 5 million deaths worldwide are caused annually by tobacco use and this could double by 2020 with the majority occurring in developing countries,***

Or. en

Amendment by John Bowis

Amendment 23  
Recital M a (new)

***Ma. 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,***

Or. en

Amendment by John Bowis

Amendment 24  
Recital N a (new)

***Na. whereas the WHO Prequalification Project is an important network for assessing and procuring new essential medicines,***

Or. en

Amendment by Johan Van Hecke

Amendment 25  
Recital N b (new)

***Nb. whereas yearly an estimated one and a half million children under five die from vaccine preventable diseases,***

Or. en

Amendment by Marie-Arlette Carlotti

Amendment 26  
Recital N c (new)

***Nc. 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 medicines<sup>1</sup>; whereas new medicines necessary today, but available only at high prices, are not included in this list,***

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<sup>1</sup> OJ L 135, 3.6.2003, p. 5. Amended by Commission Regulation (EC) No 1876/2004 (OJ L 326, 29.10.2004, p. 22).

Or. fr

Amendment by Marie-Arlette Carlotti

Amendment 27  
Recital N d (new)

***Nd. 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, such as India, and whereas many people in civil society have expressed concern regarding the consequences of access on a global scale to medicines with a high level of intellectual property protection,***

Or. fr



Amendment by John Bowis

Amendment 28  
Paragraph 1 a (new)

**1a. 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,**

Or. en

Amendment by John Bowis

Amendment 29  
Paragraph 2 a (new)

**2a. 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,**

Or. en

Amendment by Irena Belohorská

Amendment 30  
Paragraph 2 b (new)

**2b. Supports the establishment of the European Union Solidarity Fund<sup>1</sup> in order to provide a common response to emergency situations of different origin in an efficient and coordinated way;**

Or. en

Amendment by Marie-Hélène Aubert

Amendment 31  
Paragraph 2 c (new)

**2c. 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;**

Or. fr

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<sup>1</sup> 2005/0033 (COD)

Amendment by Marie-Hélène Aubert

Amendment 32  
Paragraph 2 d (new)

- 2d. *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;***

Or. fr

Amendment by Marie-Hélène Aubert

Amendment 33  
Paragraph 4 a (new)

- 4a. *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;***

Or. fr

Amendment by Irena Belohorská

Amendment 34  
Paragraph 5

- 5. *Calls on developing countries to reinforce basic health services and for EU aid to support their efforts to strengthen human, institutional and infrastructural resources, in particular to facilitate the provision of safe drinking water and adequate sanitation, as well as raising awareness of the links between health, clean water, sanitation and hygiene;***

Or. en

Amendment by Marie-Hélène Aubert

Amendment 35  
Paragraph 5 a (new)

- 5a. *Calls on developing countries to restore their public services and basic health-care systems and considers that EU aid should consist above all of support for this process through aid for the emergence and reinforcement of human and institutional capacities and infrastructures;***

Amendment by John Bowis

Amendment 36  
Paragraph 5 b (new)

**5b. *Believes that investment in water supply, sanitation and infrastructure is critical to combating waterborne diseases (including pneumonia, diarrhoea, malaria) and to the delivery of healthcare systems;***

Or. en

Amendment by John Bowis

Amendment 37  
Paragraph 5 c (new)

**5c. *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;***

Or. en

Amendment by John Bowis

Amendment 38  
Paragraph 6

**6. *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;***

Or. en

Amendment by John Bowis

Amendment 39  
Paragraph 6 a (new)

**6a. Welcomes the Commission's commitment to strengthen 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 to developing more effective, efficient and sustainable implementation of interventions;**

Or. en

Amendment by John Bowis

Amendment 40  
Paragraph 7 a (new)

**7a. Notes that care should be taken in the way that medicines are dispensed and used in order to limit resistance;**

Or. en

Amendment by Johan Van Hecke

Amendment 41  
Paragraph 8

**8. notes (*deletion*) that, as a result of the Asian tsunami, (*deletion*) the interruption of *malaria*, TB or ARV treatment there could cause many deaths;**

Or. en

Amendment by John Bowis

Amendment 42  
Paragraph 10 a (new)

**10a. 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;**

Or. en

Amendment by Marie-Arlette Carlotti

Amendment 43  
Paragraph 10 b (new)

**10b. *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 medicines<sup>1</sup> and for the pharmaceutical industry to make products available to the people of developing countries at a price differentiated on the improvement of access to essential medicines, and to propose complementary measures to enable access specifically to essential medicines if shortages are found;***

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<sup>1</sup> OJ L 135, 3.6.2003, p. 5. Amended by Commission regulation (EC) No 1876/2004 (OJ L 326, 29.10.2004, p. 22).

Or. fr

Amendment by John Bowis

Amendment 44  
Paragraph 10 c (new)

**10c. *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;***

Or. en

Amendment by John Bowis

Amendment 45  
Paragraph 11 a (new)

**11a. *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;***

Or. en

Amendment by John Bowis

Amendment 46  
Paragraph 11 b (new)

**11b. 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;**

Or. en

Amendment by John Bowis

Amendment 47  
Paragraph 11 c (new)

**11c. 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;**

Or. en

Amendment by Irena Belohorská

Amendment 48  
Paragraph 12

12. 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 **life-threatening** diseases, and for their involvement and participation in the design and implementation of programmes;

Or. en

Amendment by Glenys Kinnock, María Elena Valenciano Martínez-Orozco, Anne Van

Lancker

Amendment 49  
Paragraph 12 a (new)

**12a. 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;**

Or. en

Amendment by John Bowis

Amendment 50  
Paragraph 12 b (new)

**12b. 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;**

Or. en

Amendment by Johan Van Hecke

Amendment 51  
Paragraph 13

**13. 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*;**

Or. en

Amendment by Johan Van Hecke

Amendment 52  
Paragraph 14

**14. 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, (*deletion*) 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;*

Or. en

Amendment by John Bowis

Amendment 53  
Paragraph 16

16. 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;

Or. en

Amendment by John Bowis

Amendment 54  
Paragraph 18

18. 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;*

Or. en

Amendment by John Bowis

Amendment 55  
Paragraph 20

20. Calls for the implementation of the “Quick Wins” identified in the report of the UN Millennium Project 2005 including regular annual deworming (*deletion*);

Or. en

Amendment by Marie-Hélène Aubert

Amendment 56  
Paragraph 20 a (new)

- 20a. 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;*

Or. fr

Amendment by John Bowis

Amendment 57  
Paragraph 21 a (new)

**21a. *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;***

Or. en

Amendment by John Bowis

Amendment 58  
Paragraph 21 b (new)

**21b. *Calls on the Commission to support programmes to prevent and cure obstetric fistula and care for the women and girls affected;***

Or. en

Amendment by John Bowis

Amendment 59  
Paragraph 21 c (new)

**21c. *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;***

Or. en

Amendment by John Bowis

Amendment 60  
Paragraph 21 d (new)

**21d. *Invites the Commission to provide support for strengthening national and***

*international tobacco control programmes;*

Or. en

Amendment by Johan Van Hecke

Amendment 61  
Paragraph 22

22. believes that public-private partnerships such as the **RBM Partnership**, TB Alliance, IAVI, **GAVI/The Vaccine Fund**, MMV, DNDi and the Institute for One World Health are key to innovation and capacity-building;

Or. en

Amendment by John Bowis

Amendment 62  
Paragraph 22

22. Believes that public-private partnerships such as the TB Alliance, IAVI, **IPM**, MMV, DNDi and the Institute for One World Health **together with TDR** are key to innovation and capacity-building;

Or. en

Amendment by María Elena Valenciano Martínez-Orozco

Amendment 63  
Paragraph 24 a (new)

- 24a. *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;*

Or. fr

Amendment by John Bowis

Amendment 64  
Paragraph 25

25. 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;

Or. en

Amendment by John Bowis

Amendment 65  
Paragraph 25 a (new)

- 25a. ***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;***

Or. en

Amendment by Irena Belohorská

Amendment 66  
Paragraph 25 (new)

25. ***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;***

Or. en

Amendment by John Bowis

Amendment 67  
Paragraph 27 a (new)

- 27a. ***Demands that international standards for ethical research, such as those elaborated by the Declaration of Helsinki, are applied in all countries;***

Or. en

Amendment by Irena Belohorská

Amendment 68  
Paragraph 28

28. 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, advance purchase commitments and partial transfer of patent rights to drugs, ***calls for a "needs based approach" rather than "profit based approach"***;

Or. en

Amendment by Johan Van Hecke

Amendment 69  
Paragraph 28

28. 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;

Or. en

Amendment by Irena Belohorská

Amendment 70  
Paragraph 28 a (new)

- 28a. Stresses that education and family planning are as important as the provision of effective drugs;***

Or. en

Amendment by John Bowis

Amendment 71  
Paragraph 30

30. 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;

Or. en

Amendment by John Bowis

Amendment 72  
Paragraph 31 a (new)

**31a. 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;**

Or. en

Amendment by Marie-Arlette Carlotti

Amendment 73  
Paragraph 31 b (new)

**31b. 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;**

Or. fr