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REPORT

on on access to healthcare and medicines, with a particular focus on neglected diseases

Committee on Social Affairs and the Environment

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PART B: EXPLANATORY STATEMENT

EXPLANATORY STATEMENT

"We must not become immobilised by what we think of as the "hugeness" of our problems. Let us consider what can be done, and start finding practical ways of doing things." (Nelson Mandela).

Time and again we rehearse the bleak figures which show the global burden of disease. Time and again we are able to demonstrate that investments in good health pay economic and social dividends by reducing mortality, morbidity and disability. We now have the chance to provide the political backing and financial support to improve access to healthcare and medicines and tackle the neglected diseases of the developing world.

We know that the Big Three killer diseases: AIDS, Malaria and Tuberculosis claim 6 million lives a year and are still in desperate need of control. But we must recognise that 1 billion people, a sixth of the world's population, are affected by diseases the world neglects. Diarrhoea, for instance, causes 2.2 million fatalities a year (more than the death toll of TB). Waterborne diseases, malnutrition (especially at birth and in infancy), parasitic worms and vectors all impact on people in developing countries. The *Onchocerca volvulus* worm, for example, causes blindness, visual impairment and skin disease, infecting 37 million people; 95% of whom are in West and Central Africa. The current treatment, ivermectin, is limited as it only kills larvae (not adult worms), resistance is growing and some patients experience a severe adverse reaction.

Many of these neglected diseases may not have high levels of mortality but can be called poverty diseases because of they cause chronic illness, disability and deformity - making it difficult or impossible to work and contribute to the family and economy. As the WHO says: "Their impact is in the impaired growth and development of children, complications during pregnancy, disabling disfigurement, blindness, social stigma and reduced economic productivity and household incomes". And then there are new threats and challenges such as multi-drug resistant strains of diseases such as TB.

It is important to acknowledge the successes: We have developed better bed nets for malaria prevention; we have found combination therapies which are much more effective in treating malaria; we have targeted treatment of children for schistosomiasis; we have established simplified control strategies with inexpensive, safe and effective drugs for parasitical worm infections, costing as little as €0.50 per person per year; we have ivermectin to treat onchocerciasis (though it has limitations noted above); we have started to forge the equitable North/South and Public/Private partnerships we need in science, clinical practice and trials with initiatives such as the European and Developing Countries Clinical Trials Partnership (EDCTP). EU-funded neglected disease research programmes, recognised as among the most effective devised by any international agency, has contributed to many of these successes.

Even since the European Parliament Report on Major and Neglected Diseases (Bowis Report P6_TA(2005)0341) in 2005, we have seen some remarkable welcome developments.

The World Health Assembly agreed in May 2006 on setting up an intergovernmental working group to negotiate an action plan on research and development with a view to "securing an

enhanced and sustainable basis for needs-driven, essential health R&D." The WHO and twenty-five partner organisations announced a new coordinated approach on neglected tropical diseases, including its Preventative Chemotherapy Strategy for parasitic worm infections. There is specific mention for neglected diseases in the European Union's Seventh Framework Programme for Research (FP7), adopted in December 2006, with €6 billion over seven years for Specific International Cooperation Actions (SICAs).

Most of all we appear to have renewed political acceptance to do something about the neglected diseases of the developing world.

So, how do we turn this hope and expectation into results? In short, we must step up the research and development efforts, but at the same time address the other neglected area: strong health systems delivery.

This report sets out the range of responses to improve access to healthcare and medicines by:

- ensuring national budgets and international aid focus on health;
- promoting all the prevention tools at our disposal and developing new ones;
- building the capacity and infrastructure of health systems;
- advancing the research and development into new diagnostics, drugs and vaccines.

RESEARCH & DEVELOPMENT

Starting with the latter point, we need to stress the "D" in the "R&D" so that we can take the wealth of basic research and translate it into innovate treatments and new, easy-to-use, accurate and rapid diagnostic tests and monitoring tools - suited to the local needs and conditions of resource-poor countries. Integrated projects from identification of chemicals through the development phases of clinical trials to registration and manufacture of new products have sadly been lacking in the past. There has been an over-reliance on existing technologies and interventions. Patients suffering from neglected diseases are still too often given archaic drugs, some of which are highly toxic, ineffective or difficult to administer.

Because there are limited viable markets for drugs for diseases that affect the poorest people in the world, the public private partnership model can harness the best of the public sector (in the "R") with the best of the private sector (in the "D").

The first of these partnerships - the Special Programme for Research and Training in Tropical Diseases (TDR) - was established in 1975, co-sponsored by UNICEF, UNDP, WHO and the World Bank, and funded by a wide range of agencies, governments (including EU Member States), foundations, NGOs and companies. It aims to help coordinate, support and influence global efforts to combat a range of major poverty diseases.

The TDR has been up and running for over 30 years. Yet of the 1,393 new drugs that reached the market between 1975 and 1999, only 13 were approved for tropical diseases. Of these 13, six were developed with TDR support. Less than 1% of new drugs placed on the market were developed for infectious tropical diseases.

In recent years we have seen more progress thanks to the establishment of more public development partnerships (PDPs) such as the Drugs for Neglected Diseases Initiative (DNDi),

GAVI Alliance, Global Alliance for TB Drug Development (TB Alliance), Institute for One World Health, International AIDS Vaccine Initiative (IAVI), International Partnership for Microbicides (IPM), European Malaria Vaccine Initiative (EMVI), Medicines for Malaria Venture (MMV), Roll Back Malaria (RBM) Partnership and others. Numerous drug research projects are now underway: The DNDi alone has twenty projects including drugs in clinical development for African trypanosomiasis, Leishmaniasis, Chagas' disease and Malaria, and there is significant progress on vaccines in Edinburgh, Oxford and elsewhere.

We need a new sense of urgency to build on this work, to use this public-private model, support drug candidates through the development pipeline not only the initial research, and to expand the work to a broad range of diseases.

CAPACITY & INFRASTRUCTURE

We cannot stop, however, at the funding and delivery of research and development. It is no use having new drugs, vaccines and equipment if there is no system for their delivery, administration and use on the ground. Half of all of medical equipment in developing countries is not in use. Health system infrastructure, including both human and institutional capacity, is absolutely critical to improving healthcare. In addition to the lack of diagnostic tools and drugs, the fight against disease and ill health is impeded by weak health systems, a crisis in health workforce numbers, and ineffective aid.

Some diseases are neglected, not in the sense of being developing country diseases, but because drugs and specialist treatment and care - to which the developed world has access - are out of the reach in low income countries. For example, whilst diabetes patients in the EU can expect free services and eye and blood tests to keep their condition under control, too many diabetics in developing countries lose limbs and sight and suffer failing livers and early death because the cost of insulin is too high a proportion of the average family budget. For these diseases we need to find ways of ensuring low cost access in such countries. Nor should we forget the millions of people throughout the world who suffer from mental illnesses and neurological disorders and injuries. Although effective treatments exist for many of these conditions, most of the middle and low-income countries devote less than 1% of their health expenditure to mental and neurological health.

Health systems in many countries are starved of resources. The countries themselves will need to invest more from national budgets and spending on health should be recognised as part of good governance measures. In 2003 the United Kingdom spent 15.8% of general government expenditure on health; Germany spent 17.5%; the United States of America spent 18.5%. Yet, the vast majority of ACP governments spend much less than the 15% Abuja target; they are spending a smaller percentage from smaller budgets (see Annex). The time has come to stop this scandal.

The international community will need to complement country-level investments with secure, long-term financial support and technical support, including training of health workers at the local level. The World Health Report 2006 recommends that half of international assistance should be spent on health systems with half of this funding dedicated to strengthening workforces. Health needs to be at the heart of Country Strategy Papers, Poverty Reduction Strategy Papers and Medium Term Financial Frameworks, with actions focused on delivering the most effective health and poverty-reduction outcomes. Drafts of Country Strategy Papers

should be available for scrutiny by Members from the ACP and European Parliament. Aid commitments need to reflect the overall health status and disease burden in countries, not only the HIV/AIDS, TB and Malaria situation. In fact, both poor surveillance of disease (in over sixty countries less than a quarter of deaths are recorded by registration systems) and a lack of indicators to measure global aid on healthcare and social services have limited the effectiveness of aid to date.

PREVENTION

Prevention is of course better than cure; access to preventative measures and education about prevention must therefore form a central plank of health policies. Access to clean water and sanitation is the most effective way to deal with the menace of waterborne diseases. Routine immunisation should be the cornerstone of public health strategies to end the existing situation whereby more than 28 million children miss out on immunisation during their first year - leaving them vulnerable to infectious diseases such as measles and tetanus. Education about hygiene, safe sex and healthy lifestyles - including the risks of tobacco - are all very important. Given the huge numbers of deaths and injuries on roads and the prospect of more roads being built in developing countries, road safety education must also be improved.

The dangers of a lack of education and misleading information are all too apparent when some denunciations of polio vaccinations have resulted in an increase in polio cases. Education is needed to overcome these types of myths, as well as the ignorance and stigma that surround HIV/AIDS and mental ill-health.

ACCESS

Clearly, the reasons for inadequate access to healthcare and medicines are complex. There are issues about health systems capacity and spending, the effectiveness of aid, access to prevention and education and the discovery of new treatments. There are also the effects of international and national pricing policies, tariffs, taxation and the implementation of intellectual property rights agreements.

Invention and creativity themselves provide social and technological benefits and thus intellectual property protection encourages the discovery of new drugs, whose development costs can sometimes be extremely high. The provisions of the Agreement on TRIPS therefore recognise this. Governments and pharmaceutical companies should negotiate a partnership approach which respects patent protection for developed markets, which may involve voluntary licensing agreements, support for health programmes, technology transfer and an increase in local capacity for production, and which reduces prices (through tiered or differential pricing) for low income countries. If the protection of public health cannot be achieved through these measures, then governments also have the right to use other flexibilities under TRIPS including compulsory licensing where necessary. Just the threat of this could increase pressure on pharmaceutical companies to reduce prices - prices that for some second-line anti-retrovirals are up to twelve times more expensive than first-line generics and described in a 2004 WHO report as an “increasingly serious public health hazard”.

In conclusion, we need vigilance, prevention, diagnosis, control, treatment and care, together with research and development. We need to motivate political leaders and ministries of health,

development agencies and banks, public institutes and foundations, charities and philanthropic organisations, scientists and pharmaceutical companies to form an alliance for health.