

Germany's Global Responsibility in the Fight against Neglected Diseases –

Promoting Innovation and Ensuring Access to Medicine for All.

That the Bundestag determine:

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[... Here, a part of 4 paragraphs on the description of diseases is left out to make the translation possible before the IGWG session...]

Modern medical and pharmaceutical research, particularly in the private sector, is concentrated substantively largely on product development and therapy strategies for health problems in prosperous countries. With increasing enhancement of the share of commercial research – primarily in the pharmaceutical industry, but also in publicly financed institutes which are increasingly dependent on commercial uses – research and development of effective forms of therapy are being oriented towards economically lucrative "health markets", while the diseases of poor countries and poor people are not profitable for such health research and are therefore neglected.

This also applies to an even greater degree to remedies for disease recognition (diagnostics) and prophylaxis (prevention), such as vaccines.

Moreover, new, effective medicines and procedures are, due to the TRIPS Agreement, subject to virtually a worldwide monopoly of the patent holders so that they have no imitator competition for long periods – the current patent terms are at least twenty years – and are therefore economically prohibitively expensive for needy sick persons and their dependants in many regions of this world, although they could be available and life-saving, on the basis of their production costs at a fraction of their current prices.

But the developing countries, too, bear a responsibility. Insufficient research and development efforts and insufficiencies in public supply are a frequent cause for the fact that access to important medicines in remains limited in developing countries. A World Bank study has pointed to the problems of publicly provided drugs in sub-Saharan Africa. Of every \$100 spent by the public sector on medicines, only \$12 worth of medicines

actually reach the patient. Moreover, corruption also has a negative effect on the supply of medicines in developing countries.

For ethical reasons, too, it is necessary that research efforts and the development of medications by the pharmaceutical industry be determined not only by considerations of prospective sales and market opportunities, but primarily by the physical needs, especially of the neediest segments of the world's population.

For every AIDS patient who can be provided with anti-retroviral therapy, at least five new HIV infections are counted. Therefore it is appropriate to concentrate publicly supported research programmes primarily on the development of preventative measures and vaccines.

In the area of tuberculosis treatment, too, there are still great deficits. The range of available tuberculosis medications has not been expanded over the past twenty years, and is increasingly losing its efficacy due to the development of resistances. Not only clinical trials of known substances, but also basic research for new therapy approaches urgently needs to be undertaken here.

In recent years, financially potent foundations, the joint efforts of governments and international organisations, private companies and organisations of civil society have given rise to numerous initiatives in the area of neglected diseases, with the goal of easing the crisis faced by those affected, and of finding and closing the gaps in global health care.

Donation programmes sponsored by business have had a positive effect on the provision of medicines for AIDS, malaria, tuberculosis and tropical diseases. For example, the British Department for International Development (DFID) has confirmed the uniformly positive results of such donation programmes in the area of tropical poverty diseases, specifically of programmes in Sri Lanka, Uganda and Zambia for the control of leprosy, river blindness and sleeping sickness.

Product-development partnerships (PDPs) such as the Global Alliance for Vaccines and Immunisation (GAVI), the Drugs for Neglected Diseases Initiative (DNDI), the International Partnership for Microbicides (IPM), the Medicines for Malaria Venture (MMV), the TB Alliance and others are working to advance the development of new therapies urgently needed in developing countries. They are helping to mediate between the economic interests of individual pharmaceutical companies and public health interests, and to develop regulatory functions. For example, such cooperative efforts have pushed the therapy costs for a complete malaria treatment with the new artemisin combination of preparations to below one euro in many African countries.

At present, an intensive dialogue about such models of cooperation is taking place in expert circles. At the same time however, we are also experiencing intense conflicts regarding the concrete implementation of

the TRIPS Agreement and the exception regulations confirmed in Doha for the protection of public health which are particularly important for developing countries.

The WTO declaration adopted in Doha in 2001 on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and on Public Health sent an important message that a compromise would have to be sought between the protection of intellectual property on the one hand and the needs of health care in developing countries on the other.

In the autumn of 2007, the Intergovernmental Working Group on Public Health Innovation and Intellectual Property (IGWG), founded in 2006, began, under a mandate from the WHO World Health Conference, to develop proposals for solutions which were to take up the results of a WHO experts' commission on this issue. The continuation of these negotiations is to be provided this spring; a draft resolution is to be presented to the World Health Conference in Geneva in May 2008.

However, the efforts to rein in especially infectious diseases through education, prevention, or vaccines available in quantities appropriate to the need, are still far too modest! In view of the great power of innovation of global business structures, it is now important to provide incentives for development processes such that research into diseases as well as preventative strategies and vaccines so far neglected become a worthwhile project for science.

The Federal Republic of Germany has researchers and research capacities at its disposal which are recognised worldwide and can serve to help people all over the world and enhance the reputation of the Federal Republic. The historical commitment of German researchers, such as Robert Koch, Paul Ehrlich and others, for public health and for the scientific reputation of our country, justify a special international responsibility.

II. The German Bundestag welcomes

- The existing commitment of some pharmaceutical companies, which has contributed to the development of a malaria preparation tailored to the needs of tropical African countries, or which has, for the past two years, used the transfer of technology programmes to share their technical know-how with local companies in developing countries for the production of a HIV medicines free of charge;
- The fact that the Federal Republic of Germany, through its parliament and government, was able, during its EU presidency and as the host of the G8 Summit, to demonstrate that it takes these pressing challenges seriously. At the G8 Parliamentarians' Conference on the Economic Rewards of Investing in HIV/AIDS Prevention and Health in May 2007, over a hundred MPs formulated firm demands on the governments of the G8 countries. The Federal

Republic has also provided important financial aid for treatment and preventive programmes for the three major diseases AIDS, TB and malaria, not least by means of its contribution to the funding of the Global Fund to Fight AIDS, Tuberculosis and Malaria, and by the expansion of relevant bilateral commitments;

- The commitment of the Federal Government for the first European measure under Article 169 of the EC Treaty, the European and Developing Countries Clinical Trials Partnership (EDCTP), in which member countries undertook to jointly promote the development and evaluation of new vaccines, drugs and other measures for preventing and combating HIV/AIDS, malaria and tuberculosis in close partnership between Europe and Africa;
- The efforts of the Federal Government during the IGWG negotiations in favour of a constructive solution and for the achievement of progress for developing countries, jointly with our European partners.

III. The German Bundestag calls on the Federal Government

- To encourage pharmaceutical companies to develop alternative pricing structures which take into account such criteria as large quantities and lower profit margins, and improve access to drugs;
- To take measures to advance research, the expansion of capacities, and regional procurement systems, and to help with registration, so as to facilitate and promote the production of lifesaving drugs by developing countries;
- To promote, in the context of the major developmental policy goal "Health", the application of the following measures:
 - a broad spectrum of platforms, including public-private partnerships, which have the objective of research and development in the area of poverty-related, tropical and neglected diseases, and are prepared to cooperate with corresponding public health initiatives,
 - a simpler and less expensive management of licence agreements for companies which want to produce necessary medicines in developing countries,
 - examination of new research incentives,
 - construction of international research instruments to be maintained on a broad basis through intergovernmental cooperation, and orientation of research and development of new medicines against life-threatening diseases towards real needs; here, the main emphases should be placed

where medical research is the most necessary, and development assistance in the area of the medicinal supply can be structured more economically on a permanent basis,

- at WHO, promotion of the formulation of research priorities on neglected diseases, along with others;
- To support, within the European Union, amplified funding of research and development in the area of the neglected diseases in the research framework programmes,
- To work within the European Union to ensure that EU financial aid in the context of the existing funding be strengthened for those public-private partnerships which are active in the research and development of drugs which are particularly important for developing countries;
- To work within the European Union and worldwide to ensure that free access to publicly financed medical research results be secured for people in the countries of medium and low income;
- To provide support, including political support, to developing countries, as provided under the TRIPS Agreement, and to make use of the so-called flexibilities confirmed in the Doha Declaration in the interests of supply with affordable drugs for life-threatening diseases. Here, the Federal Government should further ensure that the Economic Partnership Agreements not result in any stricter application of TRIPS in the least developed countries: the exception regulations in the area of protection by pharmaceutical patents which were granted to the least developed countries should be extended beyond 1 January 2016;
- To continue to constructively support the success of the IGWG Process in the context of the regular negotiations at the World Health Organisation, and to regularly inform the Bundestag about the progress of these negotiations;
- The objective of the contribution of the Federal Government in this regard should be:
 - to formulate and publicise clear responsibilities and transparent support structures within the Federal Government for the fields of work stated herein,
 - to promote such innovations in the area of health which are relevant for people in the developing countries and have hitherto been too little investigated,
 - to facilitate needs-oriented access to medicine for people in developing countries,

- to establish a priority for research into vaccines and preventative medicines and non-medicinal strategies,
- to examine and/or strengthen effective new instruments for innovation support, along with the incentives provided by the patent system,
- to ensure that commitments which are as clear, effective and binding as possible are made.