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The fight against tropical poverty-related diseases

Policy Paper for the Churches & Pharmaceutical Industry Working Group by Matthias Vennemann

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companies account for about 80 percent of the overall pharmaceutical

The fight against tropical poverty-related diseases

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Members of the Churches &

Pharmaceutical Industry Working Group

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Preface

The "tropical poverty-related diseases" discussed in this policy paper by the German Association of Research-based Pharmaceutical Companies (VFA) and the Joint Conference on Church and Development (GKKE) is not an established term. It refers to widespread diseases which predominantly affect impoverished people living in developing countries. In tropical countries, countless people contract and die from Chagas disease, sleeping sickness or river blindness each year.

One important characteristic these diseases have in common is the lack of attention devoted to them. A number of these health disorders are, therefore, deemed "neglected diseases". This term refers to neglect in multiple respects. First, there is often a lack of appropriate medicines, because insufficient funds are allocated for the necessary research and development; second, the health care services in developing countries barely make an effort to fight these widespread diseases and, finally, overseas development assistance also fails to give priority to these diseases. Overall, it must sadly be noted that the share of health care measures in the overall development aid to developing countries remains at a very low level.

VFA and GKKE, which have long maintained a constructive dialogue on health topics in developing countries within the Churches & Pharmaceutical Industry Working Group, have taken up this issue and commissioned Dr. Matthias Vennemann to conduct this study. Both organizations wish to thank Dr. Vennemann sincerely for his diligent execution of the study, which names the existing deficits with regard to the treatment of these diseases and simultaneously identifies measures which would be required in order to combat the problem. Once again, it shows that pharmaceutical companies as well as churches can make effective contributions and can even increase their efforts when it comes to health in developing countries. The result of the dialogue regarding these issues also demonstrates that they are prepared to assume greater responsibility and to expand their commitment. However, the governments in developing countries must also set corresponding clear priorities in their domestic policies. Additionally, it is time to redefine the status of health-related programs in public development aid.

One of the clear findings of Dr. Vennemann's study is that health care investments are worth the effort. Therefore, VFA and GKKE hope that the study will trigger a broad public discussion and also encourage the development of solutions that will benefit distressed people in southern countries.

Berlin/Bonn, November 30, 2006

1. Why is health so important for development and the fight against poverty?

The significance of health for the individual

At the turn of the millennium, the renowned market research institute Gallup conducted an international survey on behalf of the United Nations – the so-called Millennium Survey. A total of 57,000 people in 60 countries were asked about the most important asset in their lives. As it turned out, everywhere in the world, people assigned great priority to health. In 37 out of the 60 countries, health was the most important asset for people, more important even than a happy family, a job, freedom or peace.¹

If we ask the poor people of the world for their experience with health and disease, as was done by the large-scale "Voices of the Poor" survey by the World Bank, it becomes apparent that the poor regard good health as their most important possession. On the other hand, serious diseases are feared, because they prevent people from finding ways out of destitution and can be the trigger for drifting into abject poverty, especially if they affect men or women who are the family providers.²

For the development economist and Nobel laureate Amartya Sen, health is also an integral component of human development, because – like education and an income – good health "enhances the capability to lead the kind of lives we have reason to value." For Sen, the process of development is about improving the quality of life and increasing people's freedom. In his view, one of the most important freedoms is the "freedom from avoidable ill-health and from escapable mortality".³

Of course, all of this can also be expressed differently: Health has intrinsic value; it is a value in and of itself. Everywhere in the world, people consider it a great good that is particularly worth protecting. Good health increases the individual's opportunities of life and fulfillment. It enhances the chances of men and women alike to participate in life both economically, socially and politically.

In addition, health is a generally acknowledged fundamental right. According to the Constitution of the World Health Organization from the year 1948, "the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition." In the International Covenant on Economic, Social and Cultural Rights from the year 1966, the contracting states have expressly recognized the right "of everyone to the enjoyment of the highest attainable standard of physical and mental health." At the same time, they agreed that they "shall take, individually and through international cooperation, [...] appropriate steps to ensure the realization" of the rights acknowledged by the covenant.

The significance of health for development and the fight against poverty

Apart from its significance for the individual, it is widely accepted today that health is also of outstanding importance in the fight against poverty and for economic development in poor countries.⁶

Not too long ago, many development experts considered the poor state of health of people in developing countries to be a primary consequence of poverty. To improve the state of health sustainably, it was argued, poverty would have to be conquered first. Today, it is generally accepted that the poor state of health of a population is not just the result of poverty and economic underdevelopment but also one of its main causes.⁷

This new perspective was introduced in a series of research papers in the mid-1990s that systematically addressed the relationship between health, development and poverty.⁸ In statistical comparisons between countries and historical analyses, these studies found a systematic link between health and economic development, and demonstrated the channels through which a population's state of health impacts economic development opportunities.

An important historical example was given by East Asia, where the improvement of health in the 1950s and 1960s preceded the economic boom in the following decades. Through a temporary change in age structure and a decrease of the dependency ratio, the demographic transition from high to

low mortality and fertility provided the East Asian countries with opportunities for economic growth.

Various mechanisms plausibly explain the interrelations between health and economic development: 10

- The healthier people are, the greater their labour productivity. Knowledge and health are both forms of human capital. 11
- Healthy children show a better performance at school.
- The willingness of parents to invest in their children's education and professional training increases with the children's probability of reaching adulthood.
- The prospect of a long life increases the inclination to accrue savings. This makes available more local funds for investment.

These findings from the late 1990s provided the empirical basis for a new understanding of health as an important foundation for the sustainable reduction of income poverty in the developing world. This new understanding was most concisely phrased in the communiqué of the 2000 G8 summit in Okinawa:

"Health is key to prosperity. Good health contributes directly to economic growth whilst poor health drives poverty. Infectious and parasitic diseases, most notably HIV/AIDS, TB and malaria, as well as childhood diseases and common infections, threaten to reverse decades of development and to rob an entire generation of hope for a better future. Only through sustained action and coherent international co-operation to fully mobilise new and existing medical, technical and financial resources can we strengthen health delivery systems and reach beyond traditional approaches to break the vicious cycle of disease and poverty."

However, it should be added that international health issues are especially relevant today not just for humanitarian reasons and reasons of development policy. New and old infectious diseases that spread across all borders – AIDS, SARS and avian flu are the most obvious examples - threaten not just the health of poor people, but also represent a threat to global security.^{12, 13}

It is for all of these reasons that health issues are regularly on the agenda of the highest political bodies today. Apart from the responsible UN organizations, the Group of Eight (G8) has also assumed a role in global health governance.¹⁴ The G8 summit in Okinawa in the year 2000 showed not only the priority of health in poverty reduction but – based on its demand for "new global partnerships" – also initiated a development that ultimately resulted in the establishment of the Global Fund to fight AIDS, Tuberculosis and Malaria (GFATM). Since 2000, the G8 summits have regularly addressed global health issues.¹

Health and the Millennium Development Goals

In the United Nations' Millennium Declaration of the year 2000, the people of the world – represented by their heads of state and government – committed to improve sustainably the living conditions for poor people all over the world. Eight Millennium Development Goals are at the heart of the Millennium Declaration ratified by the United Nations in 2000 (see Table 1).

Table 1: The Millennium Development Goals (MDGs) of the United Nations

Goal 1: Eradicate extreme poverty and hunger	Goal 5: Improve maternal health	
Goal 2: Achieve universal primary education	Goal 6: Combat HIV/AIDS, malaria and other diseases	
Goal 3: Promote gender equality and empower women	Goal 7: Ensure environmental sustainability	
Goal 4: Reduce child mortality	Goal 8: Develop a global partnership for development	

Source: United Nations (2001), Road map towards the implementation of the United Nations Millennium Declaration: Report of the Secretary-General

At the G8 summit in Genoa in 2001, the GFATM was established following the recommendations of UNGASS. The summit in Kananaskis (Canada, 2002) addressed the action plan for Africa with an important health component. Under the spell of the SARS outbreak, the G8 summit in Evian in 2003 dealt with approaches for the global control of new infectious diseases and launched a polio initiative – including the mobilization of USD 500 million for the fight against this disease. The G8 summit in Sea Island (USA, 2005) resulted in the foundation of the Global Aids Vaccine Initiative. In 2005, in Gleneagles, the G8 committed to doubling development aid for Africa by the year 2010. Finally, the St. Petersburg summit in July 2006 was concerned with problems in the fight against infectious diseases.

More than half of these goals are directly or indirectly related to health improvement. This fact also expresses the relevance attributed to health with regard to development and poverty reduction today:

- The achievement of the first goal (MDG 1) the elimination of extreme poverty and hunger – refers specifically to the reduction of malnutrition and underweight in children under the age of five years.
- Three goals (MDG 4, 5 and 6) refer directly to coping with specific health problems in developing countries: the reduction of infant mortality, the improvement of mothers' health and the fight against HIV/AIDS, malaria, tuberculosis and "other diseases".
- The safeguarding of ecological sustainability (MDG 7) includes the improvement of access to a sustainable supply of clean drinking water.
- In addition, one of the requirements under MDG 8 (establishment of a development partnership) is directly related to pharmaceuticals and aims at "making affordable, essential pharmaceuticals available in development countries in cooperation with the pharmaceutical companies."

In September 2005, a resolution of the UN General Assembly – the MDG World Summit – impressively confirmed the relevance of the Millennium Declaration, including its health-related objectives. The resolution also acknowledges the progress made in securing development funding, especially based on the Monterrey consensus, the debt relief of the Group of Eight and the efforts in the field of new development funding instruments.¹⁵

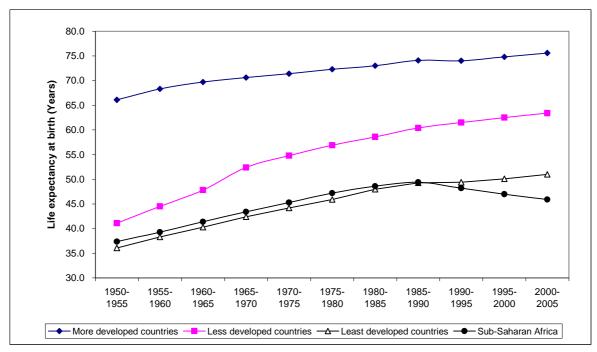
2. How is health 'produced' and what is its value?

Trends in life expectancy during the 20th Century

According to a recent report by the German Federal Statistical Office, life expectancy in Germany has more than doubled in the past 135 years. Based on the new calculations, a boy born today will reach an age of more than 83 years, while a girl born today will likely live to the age of 89. In 1871, the life expectancy of boys in Germany was about 39 years. For girls, it was about 42 years. ¹⁶

However, Germany was not the only scene of a veritable "health revolution" during the 20th Century. Rather, this development took place in all industrial nations and – since the 1950s and 1960s – has also increasingly reached the developing countries.

Figure 1: Trends in life expectancy in more and less developed countries, as well as in sub-Saharan Africa, 1950-2005



Source: United Nations (2005) World Population Prospect: The 2004 Revision Population Database

A look back at the situation around 1950 reveals the dramatic differences in the development of health between the affluent and the poor countries at that time. While life expectancy had reached 65 to 70 years at the start of the 1950s in Western Europe and the United States, it was at a mere 35 to 40 years in large parts of Asia and Africa. As shown in Figure 1, between 1950 and 1990, life expectancy increased from 66.1 to 74 years in the industrial nations, from 41.1 to 63.4 years in the developing countries, and from 36.1 to 49.1 years in the least developed countries.

Therefore, between 1950 and 1990, the gain in life expectancy was 7.9 years (2 years per decade) in the more developed countries, 20.4 years (5.1 years per decade) in the less developed countries, and 13.3 years (3.3 years per decade) in the least developed countries. Finally, in sub-Saharan Africa, it was 10.8 years or 2.7 years per decade.

These differences in the speed of health improvement between poor and rich countries have led to a noticeable reduction in global health inequality. While the gap in life expectancy between the rich and the poor countries was 25 years in 1950, this difference was reduced to 12.5 years in 1990. Over the same period, the difference between the life expectancy of the most affluent and the poorest countries decreased by 20% - from 30 to 24.6 years.

The fact that the inequality between poor and wealthy countries decreased so much between 1950 and 1990 is particularly remarkable, because – based on the unanimous opinion of development experts – no comparable positive economic development was recorded in the poor countries. Differences in life expectancy between poor and affluent countries have reduced between 1950 and 1990, but the gap in national income did not get smaller.¹⁷

Since the start of the 1990s, the speed of convergence with regard to health between the wealthy and the poor countries has also decreased. Today, at the beginning of the 21st Century, life expectancy in the developing countries is increasing only slowly. Due to the AIDS epidemic, the trend has even reversed in sub-Saharan Africa. At the end of the 1980s, the local life expectancy had almost reached 50 years; currently, it is only 46 years. This corresponds to the 1970 level.

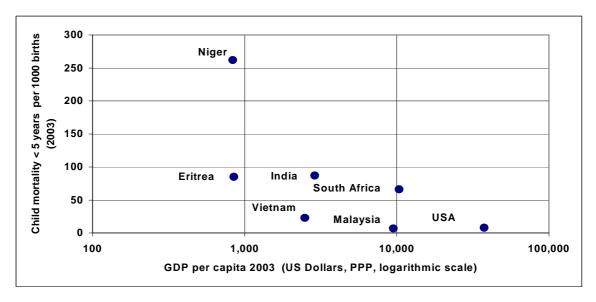
This figure includes a large area of fluctuation. The life expectancy is higher than 65 years in Mauritius and Cape Verde, 55 years in Senegal, and less than 40 years in Zimbabwe, Swaziland and Sierra Leone.

Causes for the decrease of mortality

Among development experts, it was long viewed as almost irrefutable dogma that health in poor countries primarily comes about through the work of the 'invisible hand' of general economic development and an increase in the standard of living. Referring to the 1960s work of British social medicine expert McKeown on health progress in Europe in the late 19th- and early 20th-Century, it was argued that health care services and medical progress had very little impact on health improvement under poverty conditions, if any. However, in light of newer findings, this opinion, which is still held by some health researchers and development experts, has become untenable.

Many different factors influence the state of health of a population. Of course, health is linked to the degree of affluence achieved, to the social and political conditions, to the people's level of education and nutrition (especially of women) and to health care services. But how do these factors act together, and why are there such great differences in the state of health of various nations and in the progress these nations make in improving it? Why have numerous low-income countries (Sri Lanka, Cuba, China and the Indian state of Kerala, to name but a few) made great progress in public health improvement over the past decades despite their low incomes, while other countries with comparable low incomes have not?

Figure 2: Infant mortality (< 5 years) and per-capita income in selected countries



Source: UNDP Human Development Reports Concept: Gapminder (www.gapminder.org)

A look at the differences in child mortality levels in relation to per-capita income for various countries (as shown in Figure 2) clearly marks the problems that need to be better understood.

- Despite comparably low per-capita income (in GDP purchasing power parity, U.S. dollar), the level of child mortality differs strongly between Niger and Eritrea.
- In spite of lower income, child mortality in Eritrea is about as high as in India.
- Despite an almost identical level of income, significantly more children (per 1,000 live births) die in India than in Vietnam.
- At the same time, child mortality in India is about as high as in South Africa, where the per-capita income is much higher.
- Finally, in Malaysia with a per-capita income as high as South Africa child mortality is much lower than in South Africa and reaches the same level as in the United States, even though Americans are almost four times as affluent as Malaysians.

It is obvious that the conventional explanation, which sees the increase of the per-capita income as the first and foremost cause of the improvement of public health, can not account for these differences.¹⁹ What does recent health research say about this?

In April 2006, the Disease Control Priority Project (DCPP) – a joint initiative of the U.S. National Institutes of Health, the World Health Organization and the Gates Foundation, published a large health study in which more than 500 renowned experts collaborated. The actual goal of the DCPP was to identify and describe the most cost-effective strategies for coping with the health problems of countries with low and medium income.

The comprehensive work of the DCPP also includes analyses of the current state of knowledge regarding the causes of public health improvement during the 20th Century. These analyses came to the following conclusions²⁰:

 Technical progress – defined as new knowledge that leads to the development of innovative products and alters human behaviour – has been in the recent past and still is today the fundamental cause of the improvement of public health.

- Ceteris paribus i.e. the state of income, education and nutrition being equal, differences in the state of health of their populations will be determined by the degree to which the countries acquire new health knowledge and participate in medical progress.
- The creation and dissemination of new health knowledge and technologies is therefore of essential and key significance for the improvement of health in poor countries.

Since it would go beyond the scope of this work to describe fully the analyses on which these findings are based, we will only present a few highlights below.

As early as the 1950s, U.S. economist Kingsley Davis²¹ observed that "the reduction of mortality in underdeveloped areas since 1940 has been brought about mainly by the discovery of new methods of disease treatment applicable at reasonable cost and by the diffusion of these new methods... The reduction could be achieved rapidly because it did not depend on general economic development or social modernization ..."

As a matter of fact, the health successes of the 1940s and 1950s are almost forgotten in today's development discussion. Classic public health measures such as the introduction of water supply and sanitary systems; the improvement of individual hygiene – not limited to but especially in infant care; the broad introduction of preventative vaccines; the use of sulfonamides and penicillin for the treatment of previously often-fatal bacterial infections such as pneumonia; the treatment of tuberculosis with streptomycin and isoniazid; malaria control with quinine or chloroquinine and DDT for mosquito control - were applied on a global scale for the first time during that period. Large-scale WHO and UNICEF programs often played an important role in this respect. During the first two decades after World War II, the dissemination of this new health knowledge and the use of new health technologies often led to an unprecedented improvement in public health in many of the countries that were poor at the time. ^{22,23}

As described above, international health development stands apart from the development of per-capita incomes. While the international differences with regard to life expectancy have decreased by and large since 1950, the income disparity between the countries has not decreased but grown even

larger instead.²⁴ Based on an analysis of income and health data for 49 countries from 1965 to 1995, Nobel laureate Gary Becker and his colleagues showed that the health status became more similar during that period, despite the fact that the income differences increased between industrial nations and developing countries.²⁵ In this analysis, the extension of life expectancy in the developing countries between 1965 and 1995 was attributed to a quick reduction of mortality due to respiratory and infectious diseases, as well as diseases of infancy. It became possible, because these countries were able to "absorb" simple, low-cost and long-proven medical technologies from the industrial nations. The analysis of Becker and his colleagues largely attributed health improvements in the affluent countries to the development and use of innovative pharmaceutical products.

The publications of other economists and health researchers have attempted to assess quantitatively the influence of various important factors on public health, such as education, income and the dissemination of health-related knowledge and technologies. In empirical studies by a group of World Bank researchers on the decrease in infant mortality in 115 countries between 1960 and 1990, income increases could explain only 17% of the reduction in mortality among children under the age of five years. Changes in the level of education accounted for 38% of the reduction. On the other hand, the dissemination of new health knowledge and its application explained 45% of the decrease in infant mortality for the specified time period.

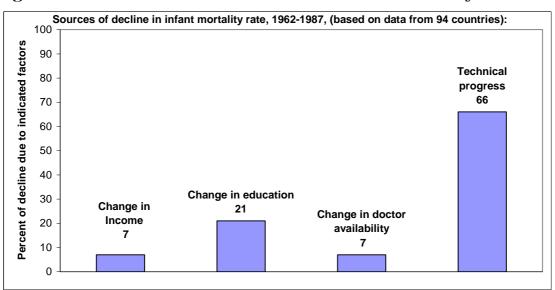


Figure 3: Factors related to the decrease in infant mortality

Source: Jamison, DT; ME Sandbull; L Wang (2004) Why has Infant Mortality Decreased at such Different Rates in Different Countries? Disease Control Priorities Project Working Paper No. 21

Additional studies of these interrelations have also shown that differences in the speed with which new health technologies are implemented could explain differences in mortality reduction between individual countries. In an analysis of data from 94 countries from 1962 to 1987 by Jamison, Sandbu and Wang, the 'rate of technical progress' turned out to be the most important determinant for health improvement. Between 1962 and 1992, infant mortality in the 94 countries from which data were available decreased from 97 infants per 1,000 live births to 44 per 1,000. A total of 66% of this infant mortality reduction was due to differences in the rate of technical progress, 21% to an improvement in the level of education in girls and women, 7% to higher income and another 7% to an increase in the number of practicing physicians (Figure 3).

Empirical studies by U.S. economist Frank Lichtenberg additionally point to a systematic relationship between mortality and morbidity and the introduction of new pharmaceutical technologies. In the United States, for example, a significant correlation exists between the introduction rate of new pharmaceuticals and an increase in the average age of death.²⁷ Whether patients are treated with old or innovative drugs (with a new chemical entity) does not just influence their rate of survival but also the degree of limitation to their physical and social activities.²⁸ Other econometric studies by Lichtenberg show that there is a significant statistical relationship between the number of new market launches of innovative pharmaceuticals and an increase in life expectancy.²⁹ Sure enough, this positive correlation between the introduction of pharmaceutical innovations and the decrease in the burden of disease currently only exists in the more affluent countries. It cannot be ascertained in developing countries. 30 One reason for this lies in the fact that currently only a few genuine pharmaceutical innovations address the particular health problems of poor nations.

New views on the contribution of health to the overall standard of living

In general, national income serves as a measure of prosperity of nations, and development economics uses the growth of the gross domestic product

(GDP) per-capita as a benchmark for economic development. However, national income provides only an incomplete measurement of the status of a country's economic welfare. Everywhere in the world, people consider health "the greatest good." However, its value has not yet been considered in the determination of economic well-being.

It is obvious that the standard of living of various countries can be quite different despite the same income. For example, Botswana and Turkey have a comparable per-capita income – at least if measured in PPP terms. Nevertheless, there is a great difference in the standard of living. Life expectancy in Botswana is a mere 45 years, while it is about 67 years in Turkey.

Economist William D. Nordhaus recently presented a method that allows the value people assign to health to be expressed in monetary terms and added as "health income" to the national welfare estimates that were previously only based on national income.³¹ To estimate the health income, Nordhaus suggests basing it on the amount of consumption the people of a country are willing to sacrifice in order to extend their lives.

The pivotal point for determining the health income is the so-called "value of a statistical life", or VSL. Various methods can be used to calculate the VSL. One can ask people how much money they would be willing to spend to extend their life by one year. However, such surveys usually result in unrealistically high estimates of the VSL. A more objective method determines the VSL from wage differences between jobs with higher and lower health risks. If someone is willing to assume a job with an increased accident risk for a certain hardship allowance, the amount of this allowance represents an estimate of the monetary value he assigns to his life. In contrast to surveys, this approach has the advantage that it is based on real instead of hypothetical decisions. If a worker demands (and receives) e.g. EUR 500 as an annual hardship allowance for a riskier job that is the same in all other respects and the risk of dying on the job is 1:10,000 per year instead of zero, it is concluded that the reduction of the risk of dying on this order of magnitude in society is worth EUR 500. The "value of a statistical

The United Nations Development Programme (UNDP) uses the Human Development Index (HDI) to measure the state of human development. In equal proportions, this index includes per-capita income, level of education and life expectancy. Economists criticize that the weighting of the HDI is arbitrary. (Nordhaus)

life" results from the amount of money determined in this manner that is necessary to accept the higher risk, divided by the magnitude of the risk. In the case described above, the value of the statistical life would be estimated at EUR 5,000,000 (= 500/(1/10,000)). Typically, as was shown by studies for various industrial nations, the "value of a statistical life" determined in this manner is about 100 to 200 times the per-capita gross domestic product of a country. To calculate the "health income" in the United States, Nordhaus estimates the "value of a statistical life" at about USD 3,000,000 and the "value of a life year" at about USD 100,000.

Nordhaus used this approach for determining the health income to estimate the economic value of health improvement in the United States over the course of the 20th Century. Between the year 1900 and the year 2000, the life expectancy in the United States increased from 49 to 78 years. During the same period, consumer spending adjusted for inflation per person and per year grew from USD 3,100 to USD 18,000. According to Nordhaus' calculations, the economic value of the increase in life expectancy during the past century approximately corresponds to the growth value for all non-health-related goods and services. Due to the greater life expectancy, the "overall income" (consisting of the national income and the health income) in the United States during the 20th century therefore grew about twice as strongly as the mere consideration of the gross domestic product would lead us to assume. In other words, the improvement of health in the United States represents half of the actual welfare gain of the past century.

Of course, there are numerous other useful applications for this method of estimating the economic value of health improvements. It is obvious that this perspective results in a new assessment of financial inputs for the health care system. From this point of view, it is not the absolute cost increase of health care services - i.e. in relation to the cost of living - that is key for their assessment but the health and, ultimately, welfare gain achieved by relative additional spending in the health care sector. In this respect, studies prove that the much lamented cost increase in health care services in the industrial nations during the past few decades compares favourably with the welfare gain attained through the improvement of health based on the additional cost. In Germany, a working group of the Institute for the World Economy around economist Michael Stolpe recently pointed out this perspective and its consequences for German health care financing. ³⁵

Furthermore, this approach is appropriate for viewing the costs of research and development (R&D) in the pharmaceutical sector and the additional costs for the application of innovative pharmaceutical products in relation to the monetary value of the health gain facilitated in this manner. Health economist Frank R. Lichtenberg estimated that the costs for extending the duration of life per year that was achieved by the introduction of new specialty pharmaceuticals in OECD countries since the 1980s are many times less than the value expressed in money that is attributed to an additional year of life by society.³⁶

Other applications of health income lead to a reassessment of historical trends in welfare differences between nations. In a seminal study, the two economists François Bourguignon and Christian Morrison examined the trends in international inequality between 1820 and 1990.³⁷ Their long-term study led to initially surprising results. In contrast to frequent assumptions made in the current discussion on the consequences of globalization, global inequality is not a new problem that did not exist in the supposed "golden" days of the past. The opposite is true. The inequality in the international distribution of incomes steadily increased between 1820 and the end of World War II. The income disparity between countries only stabilized since 1950. Nevertheless, there is still no real convergence of the income level between industrial nations and developing countries on a global scale, despite the economic success of some emerging countries. According to Bourguignon's estimates, the differences between the nations with regard to life expectancy have also continuously increased from the early 19th century to the end of World War II. In contrast to the income development, a real convergence in life expectancy was observed during the second half of the 20^{th} century. Despite the continuing large health disparity between the poor and the affluent countries, the absolute differences in life expectancy were significantly smaller around 1990 than during the earlier part of the 20th century. If we include the health gain of the past decades as "health income" in a consideration of the development of economic welfare, it partly makes up for the lack of progress in the creation of greater international income equality.

This assessment is confirmed by the above-mentioned study by Becker, Philipson and Soares on the international income and health development from 1965 to 1995. Based on data for 49 industrial nations and developing

countries, the study examined how the per-capita income and the "health income" resulting from the increase of life expectancy developed. Becker and his colleagues noted that, due to the welfare gain as a result of greater life expectancy, these countries experienced a decreasing difference in economic welfare between 1965 and 1995 despite diverging (!) incomes. During this period, the growth rate of the "overall income" determined by considering the improvement of health in the developing countries was 192%, compared to 140% in the industrialized nations.

The method presumably first described by Nordhaus not only allows the determination of welfare gains based on decreased mortality but also of welfare losses due to increased mortality. Studies by the WHO and the IMF have recently used this approach to identify the welfare effects caused by the increased AIDS-related mortality in Africa. If "health income" is included in determining the state of economic welfare, it becomes apparent that the AIDS epidemic already had a disastrous impact on affected countries in the 1990s. Estimates of welfare losses based on the AIDS-related mortality increase in sub-Saharan Africa overall between 1990 and 2000 are on the order of magnitude of 15% of the total African income. For particularly heavily affected countries such as South Africa or Botswana, the IMF study estimated welfare losses worth 60% to 80% of overall income.

3. The specific problems of poor countries with health care services

Health care systems

Both in developed and in developing countries, the provision of adequate health care for the population is a key government responsibility and part of good governance. This does not mean that the government itself must supply all necessary health care services. It can partially or entirely assign this task to the private sector, as is done in Germany. However, to achieve good governance stewardship, the government must protect its citizens from undue health risks and the negative welfare consequences of serious disease. It must also ensure that the necessary services for the provision and maintenance of health are available to the population, that their fair financing is ensured, and that the health care system addresses the key health problems and concerns of the people. Certain services in the fight against diseases, the provision of which does not offer any incentives for the private sector, must additionally be publicly supplied or at least funded.

Today, there are large differences between developing countries with regard to the degree of implementation of this concept of a health care system, the state of health care services, their efficiency, quality and outcomes. ⁴²

Whether a country has a per-capita income of USD 400 or of USD 4,000, the factors that strongly influence the quality of the health care system are the government's concern for the health of its citizens (and the poor in particular), and how public and private responsibilities in health care services are organized. As a result, generalizations about the state of health care provision in developing countries are neither advisable nor permissible.

Apart from regions in which the government has ceased to exist or where there is war, the largest problems are usually faced by poor countries in which the government neither lives up to its role as a steward for the health care system nor fulfils its core functions in fighting infectious diseases and in regulating the market for medical services and pharmaceuticals. In such conditions, which exist for example in large parts of West Africa, a chaotic medical pluralism has developed.⁴³ Medical services of all kinds and of

varying quality are offered by a great variety of service providers against a fee: from drug sellers around the corner and nurses in the backroom of their apartments to specialized physicians with their own practice.

On the other hand, as part of health care reforms, some African countries have made substantial progress in developing appropriate health care services over the past few years. Ghana is a good example in this respect, where church-sponsored health services have actively participated in these reforms.

In the 2001 report of the Commission on Macroeconomics and Health, the World Health Organization has attempted to describe the situation and especially the performance of health care services in low-income countries. Special attention was devoted to the question as to what extent these countries' health services were able to provide a minimum of preventative and curative health care for their population that – based on today's knowledge – would be necessary to cope with the most important health problems. According to the study:

- Appropriate medical care was received by only two-thirds of all women during their pregnancy and less than half during their delivery.
- Only two-thirds of all children were vaccinated against measles, which is frequently fatal under conditions of poverty, and only about half had access to customary simple standard therapies for life-threatening respiratory infections or diarrhoea.
- In tropical low-income countries, in which malaria is a massive problem for public health, only 2% of the population had access to insecticidetreated mosquito nets for their beds, which can provide effective protection from malaria transmission through mosquitoes. Less than onethird of malaria cases were adequately treated with medication.
- In less than half of all cases, infectious pulmonary tuberculosis was treated with the current standard supervised multi-drug-therapy (DOTS).
- In low-income countries, interventions to prevent sexual transmission of HIV had reached only 10% to 20% of the population. This percentage was significantly lower for other measures to avoid transmission of HIV, i.e. from mother to child or through blood transfusions.
- Only about 5% to 10% of the people suffering from AIDS received relief in the form of palliative treatment for AIDS-related infections.

 The share of AIDS patients with access to modern life-prolonging combination therapy with multiple antiretroviral drugs was below one percent.

The Commission identified low health care spending in the investigated countries as the main cause of this blatant lack of access to essential health intervention. On average, with a per-capita income of little more than USD 400, they spent only about USD 13 on public health care.

However, other studies by the Commission also describe a number of non-finance-related obstacles obstructing the establishment of appropriate and efficient health care. These can affect various levels: from households and communities, local health services, the health care sector and its policies, public administration and the government, to geographical conditions (see Table 2).⁴⁵

Table 2: Obstacles to the introduction of effective health care services

Household and community

Low demand for effective intervention

Social, financial and physical barriers prevent access to health care services

Insufficient number and misaligned distribution of trained personnel

Weak guidelines, problems with program management and supervision

Insufficient infrastructure (including labs and communication)

Insufficient access to health services

Health care sector and health policies:

Weak and simultaneously over-centralized systems for planning and management

Weak drug policies and distribution systems

Insufficient regulation of the private pharmaceutical sector and the private or NGO providers of health services

Weak incentives to use effectively available resources and to respond to consumers (clients)

Lack of cooperation and partnership between the public health administration and civil society

Dependence on donor financing and donor interference

Practices of donors that harm a country's own local policies

Public administration

Insufficient infrastructure – especially with regard to transportation and communications systems

Government

Poor governance, corruption; limited legal and contractual security

Low political priority is attributed to social services

Restricted freedom of the press

Lack of accountability

Geographical conditions

Difficult-to-access terrain

Adapted from: Hanson, K; K. Ranson; V. Oliveira; A. Mills (2001) Constraints to Scaling-Up Health Interventions: A Conceptual Framework and Empirical Analysis, CMH Working Papers Series No. WG 5:14

Medical personnel

One subject that has recently attracted special attention in the discussion of problems of health care services in poor countries is the lack of medical personnel. As stated in the 2006 World Health Report of the WHO, there is currently an acute lack of medical personnel in 57 countries - 36 of them in sub-Saharan Africa. The report concludes that for this reason alone the health-related Millennium Development Goals cannot be achieved. 46 The World Health Organization (WHO) indicated that these countries face a manpower shortage of more than four million in the health care sector. According to the WHO, this serious staff shortage, which equally affects clinical personnel, health management employees and public health workers, requires greater attention in international health cooperation. To remedy the situation, at least half of the additional health care funding component of the general increase in official development aid up to 2015 should be assigned to health system development, and 50% of that amount should be allocated to training medical personnel. As additional measures, the WHO suggests directly supporting training facilities for medical personnel in countries with a particularly severe manpower shortage and to facilitate an increased exchange of educators and students as part of partnerships between medical and nursing schools in poor and affluent countries. Based on the WHO's opinion, the special personnel requirement for coping with acute and foreseeable global health threats - such as a potential influenza pandemic should also be taken into special consideration when planning human resources for the health care systems in poor countries. Furthermore, according to the WHO, future bilateral agreements between affluent and poor countries should regulate personnel recruitment according to ethical principles.

However, the WHO also pointed out that the main causes of the shortage of suitable medical personnel and the migration of qualified workers - the so-called brain drain - lie with the health care services of the poor countries themselves. Often, there are no national strategies for human resources development in the health care sector. Only in combination with unsatisfactory working conditions and poor compensation at home do higher wages in more affluent countries - or active recruitment programs in some Anglo-Saxon countries - materialize into an actual motive for migration. As A. Mejia presented in his classic analysis⁴⁷ of the problem in the 1970s, the most important reason for the migration of medical personnel from poor

countries is the simple fact that some low-income countries produce more medical personnel than they can meaningfully employ and compensate in their health care systems. This particularly applies to highly specialized clinicians who cost a lot of money but can make only a small contribution to public health under the health care conditions of poor countries and in view of the acute health service requirements. Poorly equipped, chaotic health care systems do not just drive well-trained medical personnel out of the country but also into private practice. The uncontrolled and unregulated expansion of private health care services and the resulting so-called "marketization" of the health care sector (see below) currently experienced by many low-income countries are just the other side of the same coin when it comes to migration.

Therefore, it would be a meaningful approach to tackle the problem of brain drain by making jobs in a health care system which is well oriented toward the actual health needs of the people to be more attractive in every respect, and this requires more than just better wages. Another possible way out of the human resources crisis could be the increased training of medical support staff who are specialized for working in the health care services for poor countries and for whom there is no demand overseas as a result.

Looking more intensively into the problem of brain drain in the health care sector raises a number of complex questions. Often, personnel migration is directly blamed for insufficient health care services and consequently the poor state of health of the people in the affected countries. Instead, it may well be that both phenomena – migration of qualified personnel and poor health of the population – have the same fundamental cause: the unsatisfactory state of affairs in the health care services of many poor countries.

The development debate rightfully focuses strongly on improving women's chances of survival and fulfilment. It is also for this reason that one cannot object to the fact that young women in the developing countries in particular orient their career planning toward the needs of a global job market for medical personnel, that they prepare to become doctors, nurses or midwives and use the skills they acquired – often at great financial sacrifice – to escape from local destitution. After all, it is their prerogative. Of course, the departure of these workers is a bitter loss to the health care services of poor countries. At least it would be, if these services were able to offer them

acceptable work conditions. However, under economic considerations, it has not yet been established whether the migration of health workers actually causes such substantial damage overall. Money transfers to the poor home countries from overseas seem to balance a good share of these costs. On the other hand, of course, these transfers do not directly benefit the health care system.

The discussion around the brain drain of health care workers from Africa could gain a lot of substance looking at the experience of the Philippines, where nursing staff have been trained for jobs in affluent countries in a targeted manner for decades. The Philippine health care system certainly has many problems, but the shortage of medical personnel is not one of them. Today, the per-capita number of health care workers in the Philippines is higher than in Great Britain, for example. At the same time, the so-called OFWs (overseas Filipino workers) send about one billion U.S. dollars home every month. This is about as much as foreign investors invest each year (!) in the Philippines.

Therefore, it is probably not very useful to regard the migration of medical personnel from the health care services of the developing countries as a predominantly moral or ethical problem of the affluent countries – or even of the health care migrants themselves – as is done in some analyses. Brain drain is an economic problem first of all, not a moral one. Nevertheless, it is a moral question whether the rich countries make a sufficient contribution toward creating acceptable working conditions for well-trained doctors and nurses from poor countries at home, thereby enabling them to practice their craft to the benefit of the people locally instead of abroad and to contribute to an improvement of public health.

Table 3: The share of the private sector in health care services of developing countries

Region	% of physicians in private practice	% of hospital beds in the private sector		
		Profit-oriented	Non-profit	All
Middle East	35	12	0	12
Asia	60	21	10	31
Latin America / Caribbean	46	n/a	n/a	29
Africa	46	16	18	34
Average	55	21	7	28

Based on data from 35 developing countries

Source: Hanson, K.; P. Berman (1998) Private Health Care Provision in Developing Countries: A Preliminary Analysis of Levels and Composition. Health Policy Plan 13,3: 195-211

Private and church-operated health care services

As in Germany, private organisations play an important role in the provision of health care for the population in developing countries. The common definition of the private health care sector in developing countries includes all providers of health care services who offer their services outside the public health care sector - regardless of whether they do this for commercial or philanthropic reasons. As a result, the private health care sector includes drug hawkers, as well as office-based physicians, church-operated community clinics or NGO hospitals. A midwife employed in public service who performs private freelance midwifery in the evenings would also be considered part of the private sector. The health care services offered by the private sector in developing countries are diverse and range from acute hospital care and outpatient care through physicians and nursing staff in clinics to privately operated laboratory institutions as well as wholesale and retail pharmaceutical trade.

According to one of the few sound empirical studies on the contribution of the private sector to health care, about half of the practicing physicians in the developing countries overall offer their services in private practice.⁵⁰ Approximately 30% of all hospital beds are provided by hospitals with private sponsorship, but there may be large differences between individual countries and continents. As indicated by the data, the majority of privately sponsored

health care in developing countries is supplied by private profit-oriented providers of health care services. Only in Africa is the contribution of non-profit sponsors (predominantly churches) in health care usually higher than that of profit-oriented services.

In many African countries, church-sponsored health care goes back to the missionary roots of the churches. Apart from the foundation of Christian communities and the construction of churches, the establishment of schools and infirmaries was frequently an integral component of missionary work. In many regions of Africa, church-operated health care services introduced modern hygiene and nutritional knowledge, and provided people with access to the achievements of medical progress.

Today, in many low-income countries, and especially in Africa and Southern Asia, networks of church-related health care institutions exist that offer health care services for the population in hospitals, dispensaries and clinics, as well as in community-oriented primary health care projects. The conditions under which church-based health services work in low-income nations differ from country to country. While they are officially acknowledged and receive public funding in some countries, as in Germany, they must do without any subsidies in others and have to finance themselves from fees and the sale of pharmaceuticals.

It is difficult to determine the extent of this church network of health care providers in poor countries in terms of numbers and size. If there are any data, they are only available at the national level for most countries and in the so-called "grey literature." Table 4 summarizes the estimated share of church-sponsored health care services in inpatient medical care for a few selected low-income countries. To obtain more detailed, objective data on the overall contribution of the churches to health maintenance in poor countries, a separate research project would be necessary. Little is also known about the objective health effects of church-run health care services in poor countries, i.e. on its actual contribution to the maintenance and improvement of public health. In this respect, the churches' health services show the same evaluation gap as the public ones. On the other hand, experts agree that the church-sponsored health services networks in poor countries harbour enormous potential for the improvement of public health.

Table 4: Church-sponsored health care institutions and their estimated share in medical care in some selected low-income countries

Countries	Number of church-sponsored health institutions	Estimated share in medical care
Cameroon	301	20%
Ghana	138	35%
Kenya*	880	40%
Lesotho	83	40%
Malawi	153	37%
Nigeria	354	n/a
Tanzania	151	48%
Uganda	391	53%
Zambia	100	30%
Zimbabwe	90	30%
India	3,339	12%

^{*} Except for Kenya, only institutions for inpatient medical care

Sources: Cameroon: Joseph Ntangsi: An Analysis of Health Sector Expenditures in Cameroon Using a National Health Accounts Framework.

http://www.hsph.harvard.edu/takemi/rp141.pdf. Kenya: Samuel Mwenda: Healing Ministry in Church hospitals in Africa; the role of CHAK. Presentation at Ecumenical Study Consultation, Breklum, 2005. Ghana, Lesotho, Malawi, Tanzania, Uganda, Zambia and Zimbabwe: Frank Dimmock: Christian Health Associations In Africa Presentation at CCIH Annual Conference May 29, 2005 www.ccih.org/conferences/presentations/2005/CHAs-dimmock.ppt. Nigeria: George Larbi et. al. Nigeria: Study Of Non-State Providers Of Basic Services. www.eldis.org/static/DOC18182.htm. India: Madhurima Nundy: The not-for-profit sector in medical care. NCMH Background Papers: Financing and Delivery of Health Care Services in India. August 2005

www.who.int/entity/macrohealth/action/Background%20Papers%20report.pdf

Positive developments and experiences

When taking a look at the numerous obstacles standing in the way of creating effective health services in low-income countries, it might appear that any attempts to change the situation must be doomed to fail from the outset. That is not the case.

Total international development funding in the health care sector has increased in the four years since 2002. The establishment of the Global Fund to fight AIDS, Tuberculosis and Malaria as well as stronger U.S. efforts in the

fight against AIDS have made an important contribution in this respect. It is due to these developments that the number of AIDS patients treated with antiretroviral drugs (ARVs) in developing countries has grown dramatically. According to 2006 WHO reports, 810,000 AIDS patients in Africa are being provided with antiretroviral therapy – eight times more than two years ago. The share of patients in need of treatment that actually receive such therapy increased from 2% to 17%. The WHO estimated that, in 2005, of the 1.3 million people being treated with ARV in countries with a low or medium income, about 716,000 (55%) were obtaining one or several drugs through the Accelerated Access Initiative of the research-based pharmaceutical industry.⁵¹

Published in 2004, the "Millions Saved Project" carried out a rigorous empirical evaluation of 17 health programs supported with private and public development funds in various areas and geographic regions: from the reduction of river blindness, Guinea worm infection control in sub-Saharan Africa, the fight against tuberculosis in China, the improvement of mothers' health in Sri Lanka and trachoma reduction in Morocco, to the control of diarrhoea in Egypt and Chagas disease in the south of Latin America. Objectively verifiable improvements of the health situation were found for all programs.

According to the assessment of the authors, these results show:

- Even in the poorest countries with weak health care systems, it is possible to achieve health improvements based on targeted intervention.
- The health programs were successful because they received outside help in the form of allocations, loans, technical support and donations.
- The necessary investment to achieve some health improvement was low compared to its social and economic benefit.
- The success was made possible through the cooperation of a great variety of partners: national governments, private companies, church groups and non-government organizations.
- The public health care sector was always involved in successful programs and sometimes played a key role.
- It is possible to educate people to healthier behaviour
- Specific program elements can contribute to strengthen health care systems.

Experiences of church-sponsored health care services in Asia, Latin America and Africa as well as their overseas partners also show that it is possible even under the most difficult conditions to positively contribute to improving and maintaining public health in poor countries.

Supply and distribution of pharmaceuticals

A comprehensive analysis of the pharmaceutical sector in low-income countries would go beyond the scope of this study. As a result, this part of the paper only takes a brief look at the pharmaceutical situation in low-income countries, addressing the subject areas mentioned in the reference frame.

Supply of essential drugs

It is one of the targets for the Millennium Development Goals to make essential, affordable drugs available in the developing countries in cooperation with pharmaceutical companies. During the past few decades, great progress was made in the supply of essential pharmaceuticals on a global scale. According to information from the WHO, only about half of the world population had access to essential drugs in 1977. By 1997, this share had increased to two-thirds of the global population. One-third of humanity remains without access to essential drugs today. In parts of sub-Saharan Africa and Southern Asia as well as countries such as Brazil and India, the share of the population without access to pharmaceutical care with the most important drugs is more than 50%. More recent data on the share of the population that actually has access to pharmaceuticals today are currently unavailable.

Low health care spending as a cause of insufficient access to pharmaceuticals

The main reason for the lack of access to pharmaceuticals in low-income countries is low health care spending. The amount of health expenditures depends mainly on the level of national income. ⁵³ In low-income countries (less than USD 1,000 per person per year), an average of USD 13 is available for health care per person each year. In countries with a high per-capita income (more than USD 7,000 per person per year), the equivalent sum

The UN has developed a monitoring system for the MDGs. The data can be viewed at http://unstats.un.org/unsd/mi/mi coverfinal.htm. Currently, no information is available on Goal 17.

amounts to USD 2,043. There is a direct relationship between the national income, the overall amount of health care spending and the funds that can be spent on pharmaceuticals. Health care spending increases with national income; its income elasticity is about 1.2. This means that health care spending goes up by about 1.2% on average for each percentage point the national income increases. In absolute terms, pharmaceutical spending also rises along with health care spending. In developing countries, the share of health expenditures made for pharmaceuticals is higher than in the industrial nations. It constitutes about 10% to 40% of public and 20% to 50% of private health care spending, while the OECD average is about 12%.⁵⁴ Based on WHO estimates, per-capita pharmaceutical expenditures in low-income countries were approximately USD 4 in the year 2000.

Inefficiencies in public pharmaceutical care

Inefficiencies in public health care are frequently the cause of ongoing restrictions to access to essential drugs in low-income countries.

Supplying a population with essential drugs requires a sophisticated and complex system. ⁵⁵ Drugs must be approved, selected, procured, distributed and prescribed. "Better Health in Africa" – a study by the World Bank in the 1990s – has impressively pointed out the problems of publicly run pharmaceutical supply systems in sub-Saharan Africa. ⁵⁶ Of each USD 100 spent by the state on drugs, only USD 12-worth of drugs actually reach the patients. The reasons for these losses are inefficiency and waste at all levels: in procurement, in the assessment of required quantities, in stockpiling and distribution and in prescription by the health care services (Figure 4).

Budget Value received by allocation for consumer drugs \$100 \$50 \$100 \$90 \$76 \$49 \$30 \$15 \$12 Inatequate buying practices Quantification problems Inefficient procurement Non-compliance by patients Inefficient distribution Irrational prescription

Figure 4: Inefficiency and waste in public pharmaceutical supply systems in Africa

Source: World Bank (1994) Better Health in Africa: Experiences and Lessons Learned

■ Cumulative losses

□ Remaining value

Like the health care sector itself, the supply system for pharmaceuticals is quite susceptible to corruption everywhere in the world. This finding is not restricted to countries with poorly developed legal institutions, low wages and insufficient control systems for goods and finances, but it applies to them in particular. After expenses for human resources, pharmaceuticals constitute the largest part of public health care spending in developing countries. There are opportunities for corruption and individual profit everywhere - whether it is about the approval of a certain drug or about the source that it is supplied from what quantity, where it is distributed and how frequently it is prescribed.

The contribution of the private sector to pharmaceutical care

In many cases, private pharmacies, pharmaceutical sellers and health institutions make an important contribution to supplying the population with medicines. Overall, these private business activities have a more positive impact on the availability of pharmaceuticals. Especially in rural regions, it is frequently private traders that provide the population with medication. One example particularly worth mentioning in this respect is the supply of drugs for malaria treatment in Africa. The largest share of malaria drugs is imported and distributed by private citizens and subsequently sold locally by small

retailers.⁵⁸ The network of small retailers is often better developed than that of public health care services.

Church-supported drug distribution organizations in sub-Saharan Africa

As described above, church-supported health care services provide an important contribution to health care services, especially in Africa. A joint evaluation study of the WHO and the Ecumenical Pharmaceutical Networks Kenya has recently analyzed the work of 16 church-based drug supply organizations (DSOs) in 10 African countries (Cameroon, Ghana, Kenya, Congo, Malawi, Nigeria, Rwanda, Zambia, Tanzania, Uganda). The services of the DSOs focus on the areas of procurement and distribution of pharmaceuticals and the implementation of training measures. In 2002, the annual sales of 10 of the 16 supply organizations reporting sales figures was about USD 21 million. Eleven of the 16 DSOs were supported by various private, church-run and/or public donor organizations. Quality assurance for the drugs distributed by them represents the greatest challenge for the DSOs. Church-operated distribution organizations for pharmaceuticals in part make up for public supply deficits by facilitating access to essential drugs for people even in remote and rural areas.

Quality problems with pharmaceuticals in local markets

An uncontrolled private commitment in the pharmaceutical sector is not without problems, which is why local markets for pharmaceutical products require government regulation. As for other medical services, there is an information asymmetry between buyers and sellers of pharmaceuticals. Consumers usually cannot assess the quality of the offered products. As a result, consumers easily become victims of medical practitioners or dealers of medical products (moral hazard) who force inappropriate, unnecessary or maybe even dangerous or counterfeit drugs on them at exorbitant prices. Vector Poor-quality or even counterfeit drugs represent a large share of the pharmaceutical products traded in the markets of low-income countries. In recently conducted surveys of the WHO in Africa, 50 to 90% of the examined malaria drugs and more than 50% of the tested antiretroviral drugs were of

In collaboration with the Pharmaceutical Institute, Bonn, and Missionsärztliches Institut, Würzburg, the German Pharma Health Fund (GPHF) has developed a so-called "Minilab" for the testing of pharmaceuticals under simple conditions. The use of the GPHF Minilab® allows the quick, handy and cost-effective identification of counterfeit drugs, thereby contributing to the assurance of pharmaceutical quality standards even in peripheral health institutions in poor countries. (See: http://www.gphf.org/web/projekte/minilab/index.htm)

inferior or unacceptable quality.⁵⁹ A study in Southeast Asia found the labelled active ingredient artesunate in only 38% of 104 anti-malaria drugs purchased in the open market.⁶⁰ With the support of WHO and IFPMA, an international conference in 2006 addressed the issue of counterfeit drugs and potential countermeasures.⁶¹

Donation programs of the research-based pharmaceutical industry

Donation programs by the research-based pharmaceutical industry have a positive impact on drug research for AIDS, malaria, tuberculosis and tropical diseases. A study by the IFPMA at the end of 2005 estimated the contribution of the research-based pharmaceutical industry to pharmaceutical care in developing countries for AIDS, tuberculosis, malaria and tropical povertyrelated diseases since 2000 at USD 4.4 billion.⁶² In the meantime, a validation of this study by the London School of Economics has confirmed this estimate. 63 An independent evaluation conducted by DFID confirmed the entirely positive effects of donor programs in the field of tropical povertyrelated diseases based on an assessment of activities in Sri Lanka, Uganda and Zambia for the control of leprosy, lymphatic filariasis, river blindness and sleeping sickness. Primarily in the public health care sector, the programs facilitated better access to high-quality drugs for neglected diseases that the governments would have been unable to finance. Acceptance of the programs by the supported countries was high and the programs were implemented under the direction of the responsible institutions. Especially for poor people, the programs resulted in verifiable improvements of health.

Challenges for the governments and health care systems of poor countries

The MDGs pose significant challenges for the low-income countries. To achieve these goals, they have to ensure that their populations have access to essential health care services. In addition, the people must be protected from the economic consequences of serious illness, thereby contributing to the reduction of income poverty. Both tasks are challenges for good governance.

The provision of essential health care services to the population- which is indispensable for achieving the health-related MDGs - requires a massive mobilization of local financial resources for the health care sector. The

governments of low-income countries are obviously aware of this necessity. In the 2001 Abuja Declaration on AIDS, malaria and tuberculosis, the heads of government of the African countries committed to spend 15% of their public budgets on health care. As shown by an analysis on the occasion of the summit of the African heads of state in Abuja in May 2006, only one African country (Botswana) has so far met this target. Among those African countries with the lowest share of health care spending in public expenditures (< 5%) are the most populous countries of the continent – Ethiopia, Nigeria and the Democratic Republic of Congo. The African heads of government have repeated their voluntary commitment in a renewed declaration in 2006. If more African countries were to meet this financing requirement, it would represent an important expression of political intention to improve the health situation on the continent. Of course, the increase of public health care spending would not solve the African health care services' financing problem, as is shown by the following consideration:

According to the latest World Bank information, a typical low-income country in 2002 had a national per-capita income of USD 410 of which about 20% - i.e. approximately USD 82 - was available for public spending. ⁶⁵ If such a country spends 15% of its government budget for public health care, this results in public health care spending on the order of USD 12.30. This sum covers only about one-third of the amount necessary (USD 35 to 40) for publicly financing a minimum of essential preventive and curative services.

In view of the shortage of funds, it is particularly important that poor countries use their health care resources as efficiently as possible. They should therefore design their health care systems in such a manner as to achieve maximum health effects with the use of their limited available means. This is best done by selecting a publicly financed basic package of the most cost-effective preventative and curative health intervention measures which is accessible for all and especially takes into account the main health problems of the population and the targets of the MDGs. It is recommended that private and, if available, church-based health care services cooperate in the introduction of such a package.

Apart from financing issues in the health policy of poor countries, those institutional factors that are currently preventing efficient, fairly financed health care services that are oriented toward the needs of the population also deserve special consideration. Especially weaknesses in the following areas are particularly worth mentioning⁶⁶:

- The government's stewardship of the health care system and regulation of the market for medical services and pharmaceuticals;
- The organizational structure of the health care system, especially with regard to the division of public and private tasks and functions;
- The staffing of the health care services with medical personnel; and
- The allocation of health care resources based on fair social criteria.

Currently, the main source of finance for health care services in poor countries is the citizens themselves. The health care services directly charge patients and their dependents for medical services and drugs received. 2006 World Bank data show that about 70% of all health care spending in low-income countries is private expenditure, more than 90% of which is paid to the health care services directly out of pocket. In the case of severe illness, these costs represent a potential cause of absolute impoverishment for individuals and their families. Improved protection of the population against the economic consequences of serious illness can only be achieved through the increased use of public funds in health care financing or through the introduction of insurance systems.

Due to the significance of public health for poverty reduction and the economic development of poor countries, health care problems deserve special consideration in designing poverty reduction strategies.

Pharmaceutical sector

Special challenges for the poor countries also apply to the pharmaceutical sector. The achievement of the health-related MDGs critically depends on an adequate supply of pharmaceuticals (Table 5). Health improvement for children and infants is unthinkable without vaccines and antibiotics. The reduction of maternal mortality is based on better prenatal care and obstetric services, and requires access to vaccines, drugs, medical supplies and medical technology. The fight against malaria, tuberculosis and AIDS cannot succeed without testing facilities and access to combination therapies to treat these diseases.

Table 5: Health-related MDGs and pharmaceutical products

Lloolth problem	Doguirod phormocoutical products (everence)	
Health problem	Required pharmaceutical products (examples)	
Contagious childhood diseases	Vaccines and antibiotics	
Health of pregnant women and mothers	Vaccines, malaria prophylaxis, diagnostic tests (HIV, syphilis, etc.), trace elements and minerals for prenatal care; treatment of obstetric problems, anaesthetics for surgery, blood products	
HIV/AIDS	HIV tests, drugs for the therapy of opportunistic infections, antiretroviral medication	
Malaria	Diagnostics and medication for combination therapy; Pharmaceutical prophylaxis for children and pregnant women	
Tuberculosis	Diagnostics and pharmaceuticals for multi-drug- therapy	

Source: Author

The WHO advises its member countries to introduce concise national drug policies to provide access to essential drugs for their population, to assure the quality and safety of pharmaceuticals and to ensure their rational use.

4. Ways to provide the developing countries with innovative pharmaceuticals

The dissemination of new knowledge and the usage of innovative pharmaceutical products played a key role in improving the global health situation and facilitating the resulting welfare gain during the past few decades. The experience of the AIDS epidemic in particular shows how much global health depends on the ability to develop quickly new knowledge and new technology in diagnostics, prevention and therapy. The knowledge of how AIDS spreads and how to avoid infection, the ability to diagnose HIV infections without doubt and the development of effective medication for treatment have paved the way for coping with the epidemic.

However, the experience with AIDS has also shown that incentive mechanisms that are indispensable for the research and development of new chemical entities can come in conflict with the right of people with life-threatening diseases to receive appropriate treatment.⁶⁷ Therefore, it is an important challenge for our time to find solutions for this conflict that facilitate both continuous pharmaceutical innovation and access to available innovative drugs for people in poor countries as well.

Many discussions about this subject – as in this paper – refer almost exclusively to the "classic" health problems of poor countries. In some regions of the world, it is true that the health situation continues to be determined primarily by infectious diseases and by the health problems of infants and mothers that have long been solved in other areas. Changing this situation is not just a local but a global responsibility. It is also for this reason that poverty-related diseases rightly represent one focus of global health policy.

The necessity of building this global focus should not obscure the fact, however, that, from an epidemiological point of view, the rich and poor countries today have more common features than distinguishing ones. The diseases of the so-called First World have long become problems in the Third World as well. In all regions of the world – with the exception of Africa and parts of South Asia – the main burden of disease is caused by non-contagious diseases. Therefore, solutions are required to facilitate access to innovative

pharmaceuticals to treat chronic diseases in those areas in which the people's income situation does not allow them to pay rich world prices. In the medium term, this will be about finding solutions that go beyond the conventional individual measures for infectious diseases, such as price discounts for certain drugs and pharmaceutical donations.

In the international debate, different approaches are being discussed for a differentiated pricing system that leaves the proven incentive mechanisms for innovation intact, yet provides access to innovative pharmaceuticals for more people in low- and medium-income countries. Basically, a segmentation of the pharmaceutical markets into two or more price zones represents one of the possible options.⁶⁸ Today, research-based pharmaceutical companies already have differentiated pricing for innovative drugs and take into account the differences in financial resources of health care services and in the purchasing power of countries with higher and lower incomes. In fact, for vaccines and contraceptives, there has been a separation of markets for years. The economic, legal and practical problems that stand in the way of introducing a market segmentation system are complex. The discussion focuses on the following questions: According to which criteria should pricing be implemented and how can all countries assume a fair share of the cost of innovation in such a system? How can an effective separation between zones with low and high prices be successfully implemented and how can re-export from low to high price markets be avoided? How can it be ensured in a legally binding manner that a market segmentation system for patented, innovative pharmaceuticals will not lead to a situation in which low prices for innovative products in low-price countries are used by rich country governments as a benchmark for setting reference prices?⁶⁹ While all of these are certainly difficult questions, they should be solved in the interest of the people.

5. The Millennium Development Goals for health and tropical poverty-related diseases

With regard to improving health in poor countries, the MDGs attach great importance to the reduction of mortality in children and women and to the fight against AIDS, malaria and tuberculosis. This focus is the subject of a quite controversial development and health policy discussion. Some critics believe the MDGs must refer more explicitly and specifically to reproductive health and name separate targets in this area. VI Others see an inexcusable neglect in the fact that chronic diseases are not mentioned in the MDGs, although they are on the rise in many developing countries. According to yet another set of critics, the same applies to mental disorders, which cause much individual suffering and a great burden of disease worldwide.

However, from a health and development policy perspective, much speaks in favour of the current focus of the health-related MDGs as far as the poorest countries are concerned. The poor state of health of women and children, as well as the three large infectious diseases, are the main causes of "premodern" rates of mortality and morbidity, as they still exist in many low income countries. The excessive mortality these diseases cause in poor countries contributes substantially to the continued – and partly even increasing – health inequality between low- and high-income countries. In addition, proven effective and affordable health technologies for prevention and therapy are available for coping with these health problems.

A meeting held by international health experts in early 2006 at the renowned Karolinska Institute in Stockholm pointed to yet another gap in the health-related MDGs. Millennium Development Goal 6 exclusively addresses the fight against the three large infectious diseases (AIDS, malaria, tuberculosis) but leaves out other significant infectious diseases in poor countries. These include the so-called "neglected tropical diseases," which are spread endemically in large parts of Africa, Asia and Latin America and have disastrous impacts on the people's health. Therefore, the expert conference

The so-called MDG Summit of the UN in September 2005 specially emphasized the importance of reproductive health. Three of the MDGs are directly relevant for reproductive health: the goal of gender equality, the prevention of sexual transmission of the HI virus, and the improvement of maternal health. (See: Messages from the UN Millennium Project Reports: Population, Reproductive Health and the Millennium Development Goals. June 2005.)

in Sweden suggested incorporating the fight against these diseases in the canon of health-related MDGs and to take specific measures in this respect.

Initially, this concerns 13 frequent diseases in tropical and subtropical areas, as presented by tropical medicine experts Hotez, Molyneux and other authors in a publication in PLoS Medicine in May 2006 (Table 6):

Table 6: Examples of tropical poverty-related diseases

Diseases caused by protozoa

Kala-azar (visceral leishmaniasis)

Sleeping sickness (African trypanosomiasis)

Chagas disease (American trypanosomiasis)

Worm infestations (helminthiasis)

Schistosomiasis (bilharzia)

Lymphatic filariasis (elephantiasis)

Onchocerciasis (river blindness)

Dracunculiasis (Guinea worm)

Ascariasis (roundworm)

Trichuriasis (whipworm)

Hookworm

Bacterial diseases

Buruli ulcer

Leprosy

Trachoma

According to: Hotez PJ, Molyneux DH, Fenwick A, Ottesen E, Ehrlich Sachs S, et al. (2006) Incorporating a Rapid-Impact Package for Neglected Tropical Diseases with Programs for HIV/AIDS, Tuberculosis, and Malaria. PLoS Med 3(5): e102

Three of these diseases are caused by protozoa (kala-azar, sleeping sickness, Chagas disease), seven by worms (bilharzia, lymphatic filariasis, onchocerciasis, dracunculiasis, ascariasis, trichuriasis, hookworm), and three others are bacterial diseases (Buruli ulcer, leprosy and trachoma).

There are weighty arguments that advocate in favour of including the reduction of the burden of these diseases as another global development objective and combining their control with the fight against the three large infectious diseases.

Kala-azar and sleeping sickness, bilharzia and filariasis, ascariasis and whipworm, trachoma and Buruli ulcer as well as the other mentioned diseases affect almost exclusively poor people in rural areas and in the city slums of warm countries in Africa, Asia or Latin America. There, they frequently cause chronic suffering and lasting disability, thereby contributing to keeping people trapped in poverty. As a result, this category of diseases could also rightly be called the actual tropical poverty-related diseases (see Box 1).

Box 1: What are "neglected diseases" and "tropical poverty-related diseases"?

The term "neglected disease" came up after a 2001 publication of an MSF working group in the journal "Tropical Medicine and International Health." A publication of the same authors in part in "The Lancet" later contributed to its further dissemination in expert circles and in the development policy debate. In these papers, diseases for which no effective, affordable or simply administered remedies exist are implicitly deemed "neglected."

Currently, there is no standard definition for the term "neglected diseases" and various expert working groups have published lists of "neglected diseases" or "neglected tropical diseases" that may differ substantially:

The Pan American Health Organization calls all tropical diseases occurring on the American continent "parasitic and neglected tropical diseases."

The publications by Trouiller and his colleagues mention the following diseases: Ascariasis (roundworm), Chagas disease (American trypanosomiasis), diarrhea, hookworm, kala-azar (visceral leishmaniasis), leprosy, lymphatic filariasis (elephantiasis), malaria, onchocerciasis (river blindness), schistosomiasis (bilharzia), sleeping sickness (African trypanosomiasis), trachoma, trichuriasis (whipworm) and tuberculosis.

Three of these diseases are also deemed the "most neglected diseases": Chagas disease, kala-azar and sleeping sickness. ^E

The report on the evaluation of the PPPs for product development by the London School of Economics dealt with the progress in research and development with regard to the following "neglected diseases":

Chagas disease, dengue fever and dengue hemorrhagic fever; kalaazar, leprosy, lymphatic filariasis; malaria; onchocerciasis, schistosomiasis; sleeping sickness and tuberculosis.

The World Health Organization runs its own department dealing with the "neglected tropical diseases" (NTDs). According to the understanding of this WHO working group, NTDs in the true sense include the following diseases: Ascariasis; Buruli ulcer; cholera; dengue fever and dengue hemorrhagic fever; dracunculiasis; hookworm; kala-azar; leprosy; lymphatic filariasis; onchocerciasis; schistosomiasis; sleeping sickness and trichuriasis.

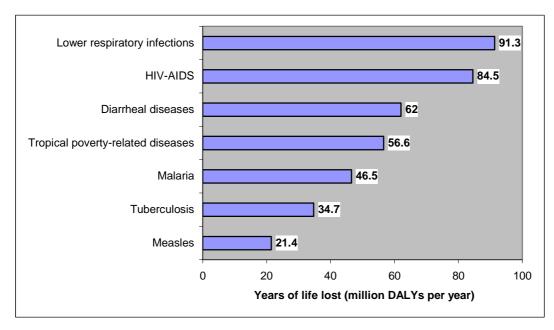
Finally, a working group around tropical medicine experts Hotez and Molyneux in collaboration with the Columbia Earth Institute defines "tropical neglected diseases" as three bacterial diseases (Buruli ulcer, leprosy and trachoma), three diseases caused by protozoa (Chagas disease, kala-azar and sleeping sickness) and seven worm infestations (ascariasis, dracunculiasis, hookworm, lymphatic filariasis, onchocerciasis, schistosomiasis, and trichuriasis).

This policy paper for the Working Group of Churches and the research-based pharmaceutical industry means exactly these diseases when it speaks of "tropical poverty-related diseases."

Literature on "neglected diseases":

- A) Trouiller P, Torreele E, Olliaro P, White N, Foster S, Wirth D, Pecoul B: Drugs for neglected diseases: a failure of the market and a public health failure? Trop Med Int Health. 2001 Nov; 6(11):945-51
- B) Trouiller P, Olliaro P, Torreele E, Orbinski J, Laing R, Ford N: Drug development for neglected diseases: a deficient market and a publichealth policy failure. Lancet. 2002 Jun 22; 359(9324): 2188-94.
- C) Yamey G.: Public sector must develop drugs for neglected diseases. BMJ. 2002 Mar 23; 324(7339):698.
- D) See: http://www.paho.org/english/ad/dpc/cd/neglected-diseases.htm

Figure 5: A comparison of years of life lost in 2001 due to infectious diseases



Data source: Hotez, PJ; Molyneux, DH; Fenwick A; Ottesen, E; Ehrlich-Sachs, S et al. (2006) Incorporating a Rapid-Impact Package for Neglected Tropical Diseases with Programs for HIV/AIDS, Tuberculosis and Malaria. PLoS Med 3(5): e102

Apparently, experts previously underestimated the extent to which these tropical poverty-related diseases contribute to premature death and unnecessary disability. Based on recently published data, more than 500,000 deaths per year caused by these diseases must be assumed in the warm regions of the world. Measured in DALYs, today's customary measure for the burden of disease of a population, the tropical poverty-related diseases cause a loss of more than 56 million DALYs per year. This number means that despite their limited geographic spread, the tropical poverty-related diseases cause suffering on a scale that is comparable to that of other significant infectious diseases. Figure 5 shows a comparison of the global "DALY losses" due to the most important infectious diseases.

Measures to combat tropical poverty-related diseases can easily be combined with health interventions for other diseases, especially malaria. Today, the essential basics of malaria control include health education, the distribution of treated mosquito nets, the spreading of insecticides, the preventative

Note that this figure excludes malaria. Based on conservative estimates, it claims about one million additional victims per year.

administration of medication and standardized therapy. The control of tropical poverty-related diseases is based on comparable elements. As a result, integrated control measures would be appropriate. Under feasibility aspects, the option to combine measures to control tropical diseases is of key importance. Currently, six separately acting public-private partnerships combat individual tropical diseases in various African countries. The health care services of many poor countries now also suffer from the great variety of different public and private initiatives that each pursue meaningful goals but too often do so in a minimally coordinated manner. At the same time, the number of health staff who can plan and implement such measures in the periphery – at the events site – is extremely limited especially in the poorest countries.

Another argument in favour of incorporating the integrated fight against tropical poverty-related diseases into existing efforts to achieve the Millennium Development Goals are the expected synergies. Anaemia and malnutrition caused by worm infestations in children represent significant obstacles for child development and education. Anaemia during pregnancy jeopardizes the health of both women and children. Furthermore, recent research papers increasingly point to the fact that appropriate therapy of chronic tropical infections can positively impact the clinical course of malaria, tuberculosis and AIDS.

The targeted use of scientifically sound preventive and curative health interventions in the fight against tropical poverty-related diseases leads to verifiable health improvements, as was shown by several independent evaluations. Furthermore, measures for combating tropical poverty-related diseases are among the most cost-effective ones available for disease control in developing countries. Even according to cost-benefit (!) considerations, the results are impressive. Programs for onchocerciasis and filariasis control generate not just health gains but additional benefits in the form of economic productivity. Their "return on investment" usually exceeds 15% to 30%. Very few programs for health improvement in the developing countries can make similar claims.

Realistic estimates for an integrated package to control seven of the mentioned tropical poverty-related diseases in Africa (ascariasis, hookworm, trichuriasis, lymphatic filariasis, onchocerciasis, bilharzia and trachoma) with

a total of four proven pharmaceuticals are already available. At a cost of less than one U.S. dollar per treatment, a package of coordinated measures for Africa would cost about USD 200 million per year.⁷³

One political argument can be added to the numerous arguments in favour of incorporating the tropical poverty-related diseases in the Millennium Development Goals: Civil society groups have long been demanding a greater consideration of "neglected tropical diseases" in international cooperation.

In the meantime, the above-mentioned contribution by Hotez, Molyneux and others has led to a lively discussion on the priorities in the fight against tropical diseases. On the one side of this debate are the health experts of DNDi/MSF, who see the highest international priority and biggest necessity for pharmaceutical research and development in combating "neglected tropical diseases." On the other side are the tropical medicine experts of the World Health Organization, who are in charge of the global control of these diseases. They currently see the main problem in the failure of the international community and the national governments to use the available intervention measures for the fight against tropical poverty-related diseases on a large scale for the benefit of the people. The WHO experts fear that an excessive focus on R&D for tropical diseases could lead to a situation in which the urgency of concrete measures to reduce the resulting mortality, morbidity and disability may be neglected. To

A review of the arsenal available today for the fight against "neglected tropical diseases" fully confirms the assessment of the WHO experts. From the perspective of the technologies available for their control, the "neglected tropical diseases" can be divided into three groups, as is also done by the WHO.

- The first group includes diseases for which strategies and control technologies are available in the form of safe and effective drugs that facilitate preventative chemotherapy to be implemented on a large scale. This applies e.g. to lymphatic filariasis, onchocerciasis, schistosomiasis and geohelminths.
- The second group includes tropical poverty-related diseases that are difficult to control on a large scale with available technologies and whose

control is based on case finding and individual chemotherapy. This group features e.g. the Buruli ulcer, sleeping sickness and the leishmaniases.

• For diseases in which a vector is responsible for transmission, e.g. Chagas disease, sleeping sickness, the leishmaniases, river blindness or lymphatic filariasis, vector control measures represent another control approach.

Table 7 lists the means available to fight tropical poverty-related diseases today, describes technical problems and challenges encountered during their control and outlines priorities in research and development following the recommendations of the DCPP and the priorities of the WHO.⁷⁶

Table 7: Tropical poverty-related diseases, control strategies and R&D priorities

Name	Control strategies	Special problems	R&D
Leishmaniasis	Treated mosquito nets Vector control Case finding and treatment	No rapid diagnosis available Broad introduction of orally administered, non-toxic drugs Vaccine development	Kits for diagnostics in resource poor environments Effective and safe oral combination treatment Vaccine development
Sleeping sickness	Case finding and early treatment Vector control	Quick diagnosis Safe and simple drug treatment Simpler vector control	Kits for diagnostics in resource poor environments (including staging of the acute disease phase) Effective and safe oral combination treatment (especially for the late stages of the disease)
Chagas disease	Prevention of transmission through vector control and examination of blood transfusions	Control of "wild" vectors Causal treatment of infected and sick people	Better diagnostics Medication for the causal therapy of infected and sick people

Lymphatic filariasis	Interruption of the transmission based on regular mass chemotherapy	Sustainable coverage with mass therapy Limitations of drugs available today (adult worms)	Drugs that eradicate or sterilize adult worms
Onchocerciasis	Regular mass therapy	Sustainable coverage with mass therapy Limitations of drugs available today (adult worms)	Drugs that eradicate or sterilize adult worms
Geohelminths (roundworms, whipworms and hookworms)	Periodic mass treatment Deworming of school children Hygienic measures	Risk of developing resistance to vermicides	Innovative drugs Vaccines
Schistosomiasis	Periodic mass therapy (with Praziquantel) Hygienic measures	Risk of developing resistance to Praziquantel	Innovative drugs Vaccines
Trachoma	Surgical intervention Antibiotics Hygiene (individual and public water supply/sewage)	Effective control requires combined measures	Development of a vaccine
Buruli ulcer	BCG vaccination Case finding and therapy Treatment with antibiotics, surgery and prevention of disabilities	Complicated diagnostics Vaccines and antibiotic therapy have only limited effectiveness	Development of diagnostic drugs, vaccine and improved drug therapy
Leprosy	Case finding and treatment with MDT Prevention of disabilities in sick individuals	Diagnosis of infections Prevention of leprosy-related disabilities	Improved diagnostics Simpler and quicker treatment Means for the prevention and treatment of neurological damage
Dracunculiasis (Guinea worm)	Water filters Symptomatic therapy	None, dracun- culiasis is about to be eradicated	Currently no particular R&D requirements

Sources: WHO, Disease Control Priority Project and author

When taking a look at the research priorities for tropical poverty-related diseases listed in Table 7, it should be noted that the need for additional research is not limited to the development of new pharmaceutical technologies. When it comes to these diseases, significant knowledge gaps also exist with regard to biology, epidemiology, social science and economics.

As concerns the concrete need of additional research and development, the following has to be stressed:

For Chagas disease, there is neither a vaccine nor causal therapy available, and control measures are therefore restricted to the control of the vectors transmitting the disease. Causal therapies available today for the leishmaniases and sleeping sickness mostly are impractical and toxic. Therefore, they cannot simply be applied on a large scale. As a result, there is a special need for R&D with regard to these diseases.

However, for all of the other listed diseases, effective preventative and/or curative interventions are readily available today. Nevertheless, even in this area, there is still much room for incremental improvements in prevention, diagnostics and therapy.

6. Research and development for pharmaceutical products in the area of poverty-related and infectious diseases

The fact that there is an overall lack of innovative health intervention and pharmaceutical products for tropical diseases and other health problems in low-income countries is not a new discovery. As early as 1975, a special program of the World Health Organization was established to address this issue: the WHO/Special Programme for Research and Training in Tropical Diseases (TDR). Based on public funding through international organizations, the TDR was meant to help eliminate the deficit. The first public-private partnerships (PPPs) for product development in the field of what was then still called "tropical orphan diseases" were established as early as in the 1990s for the same purpose. The same purpose.

An analysis in the medical journal "The Lancet" of June 2002 shows how necessary new initiatives were in this area. A group of health experts reported about the results of a quantitative survey which looked at the priorities in research and development of pharmaceuticals. According to the result of this survey, out of the total number of 1,393 innovative specialty pharmaceuticals launched between 1975 and 1999, only 13 served the purpose of treating what was apparently called "neglected infectious diseases" for the first time. Furthermore, only a few ongoing development projects addressed infectious diseases in 2002. The authors of the survey interpreted this result as a system-related failure of public and private pharmaceutical research.

Partnerships for product development

Today, just four years later, the situation presents itself completely differently. A survey conducted in 2005 by the London School of Economics (LSE) and the Wellcome Trust closely examined the current R&D activities of

These PPPs for product development for "neglected diseases" are non-profit organizations that collaborate with pharmaceutical companies and research firms in their R&D activities.

^{IX} Apart from these product development partnerships, there are numerous other partnerships with the objective of fighting tropical poverty-related diseases.

the research-based pharmaceutical industry, the product development $\mbox{PPP}^{\mbox{\scriptsize X}}$ and the TDR coordinated by the WHO. 80

It found that 63 new pharmaceuticals in the field of "neglected diseases" were in various phases of research. Two of them were being examined for marketing authorization, and another 18 were undergoing clinical trials. The research-based pharmaceutical industry was conducting a quarter (16) of these 63 development projects independently – partly in specially established research institutes. In a further 16 projects, large research-based companies were collaborating with PPPs. Twenty-nine projects were implemented by the PPPs in collaboration with small and medium-sized pharmaceutical companies. The TDR is working on six development projects. If funding of the PPPs remains secure and the normal attrition rates in drug development are assumed, the authors of the LSE evaluation expect nine or 10 newly approved pharmaceuticals for the treatment of tropical poverty-related diseases by the year 2010.

The activities of the product development PPPs were primarily facilitated through the financial support of philanthropic organizations (first and foremost the Gates Foundation), which contributed the lion's share (78.5%) of the total costs so far of USD 255 million. Overall, only little more than 16 percent of the expenditures of the PPPs came from public sources – predominantly from contributions of the United States (5.9%) and the United Kingdom (4.1%). The order of magnitude of support by the research-based pharmaceutical industry is currently unknown. It is difficult to validate, because it is composed of direct and indirect allocations: Apart from donations, the pharmaceutical companies provide contributions in kind or the work time of its key executives and employees in PPP-related activities.

These developments give rise to guarded optimism. PPPs for product development seem to be an effective means for overcoming the bottleneck regarding new pharmaceuticals for the treatment of the most important tropical diseases. However, it will take years before the drugs that are currently in the research pipeline will reach market maturity.

Medicines for Malaria Venture (established in 1999); TB Alliance (established in 2000); Institute for OneWorld Health (established in 2000); Drugs for Neglected Diseases Initiative (established in 2003)

The LSE evaluation referred to the following diseases that are considered "neglected diseases": sleeping sickness, Chagas disease, dengue fever, leishmaniasis, leprosy, lymphatic filariasis, malaria, onchocerciasis, bilharzia and tuberculosis.

To ensure this succeeds at all, the authors of the LSE study warned that the very high costs for clinical trials, which will be incurred soon, would have to be paid by public institutions. This places demands in particular on the governments of the affluent countries that have previously held back strongly when it came to supporting this innovative approach for the development of new pharmaceuticals. As is shown by the example of tuberculosis, the scale of necessary public support for the development of these products is considerable. The Global TB Alliance - one of the PPPs evaluated - indicates USD 120 to 240 million in expected costs for the development of a new TB drug. Cumulatively, however, the Global TB Alliance only has USD 36 million available in development funds until 2007. At USD 100 to 400 million, a socalled portfolio analysis published in "Science" magazine made an even higher estimate of the funding requirement for the development of a single innovative pharmaceutical for the treatment of tuberculosis.81 In 2004, the Priority Medicine Project estimated the additional financing needs of the PPPs for ongoing pharmaceutical projects in the field of "neglected diseases," which were evaluated in the LSE study, at EUR 1.4 billion in total.⁸² So far, it is completely unclear where public funds on this scale can be raised.

Gaps in research and development

In recent international discussions, gaps in research and development have always been linked very closely to the problem of tropical diseases. However, other data in the above-mentioned study point to a much larger and more fundamental problem. There is not simply a lack of new pharmaceutical products for the control of "neglected tropical diseases" that affect the world's poorest populations. This deficit exists also for infectious diseases as a whole. From 1975 to 1999, 16% (one-sixth) of innovative pharmaceuticals were for infectious diseases. However, during the same period, about one-third of the global burden of diseases was due to infectious diseases. In contrast to the tropical poverty-related diseases, there is no prospect to solve this problem yet. According to the latest estimates, about 20% of the global burden of disease continues to be caused by infectious diseases.⁸³ But according to information from the VFA, only 13% of the 316 pharmaceutical projects of the VFA member companies are for infectious diseases.⁸⁴ In times when bacterial infections that were previously considered trivial develop into a global public health problem due to the development of resistance, when there is a blatant lack of new vaccines for infectious diseases and when there are no real remedies available for most viral diseases including AIDS, such an imbalance is worrisome. According to the opinion of experts, the outbreak of a new influenza pandemic is just a question of time.

In addition, from a public health perspective, the gaps in research and development for new pharmaceutical products are not limited to infectious diseases when it comes to the health problems of the poor countries. The "Priority Medicine Project," a study published on behalf of the Dutch government and the World Health Organization in 2004, pointed out a significant deficit of innovative pharmaceutical products in various areas.85 This analysis takes into account the fact that the epidemiological profiles of the industry and the developing countries (with the exception of sub-Saharan Africa) are increasingly approaching each other today. As a result, the list of gaps in the worldwide range of pharmaceutical products identified by the study ranges from infectious diseases and simple-to-use medication in the secondary prevention of cardiovascular diseases (the so-called poly-pill) and stroke therapy to the drug treatment of chronic-obstructive pulmonary disease and alcohol-related liver diseases. However, the study of the Priority Medicine Project also shows that it is difficult to set generally applicable "evidence-based" priorities in pharmaceutical research. The results differ depending on whether priorities in research and development are set based on considerations of today's global burden of disease, scientific feasibility, with the inclusion of global social responsibility criteria or taking into account alarming scenarios such as an influenza pandemic or bioterrorism.

Causes for gaps in the development of pharmaceuticals

In part, the lack of new pharmaceutical products to cope with the most pressing health problems in poor countries and infectious diseases may also be due to the fact that today's knowledge and technologies are reaching their limits. This certainly is the case for AIDS and malaria, where vaccine research operates at the frontier of technologies available today.

The basic problem, however, seems to lie elsewhere: in economics. The incentive mechanisms for research and development projects regarding infectious diseases for the private sector are inefficient and public funding of research and development projects is insufficient.

The priorities of the affluent countries in public research funding in the health care sector are primarily determined by the health problems of its own populations. As a result, the focus is on chronic and not on infectious diseases. One example in this respect is the Health Research 2000 program of the German government.86 From 2000 to 2004, only between 8% and 13% of project funding - about EUR 25 million per year on average - was for infectious diseases. Another example comes from the U.S. National Institutes of Health (NIH). The NIH is the largest public funding institution for public health research projects in the world with a budget worth USD 28 billion in 2005. Between 2000 and 2005, about 13% of NIH spending was used for the research of infectious diseases.⁸⁷ The European Union's Sixth Framework Programme for research support had an overall health care budget of EUR 2.2 billion for the years 2002 to 2006, but it is unclear what share was allocated to infectious diseases and other health problems in poor countries.88 For legal reasons, no funds were available for translational research in the pharmaceutical sector. A stronger focus on the health problems of developing countries - including the funding of R&D in the pharmaceutical sector - is only planned for the Seventh Framework Programme of the European Union from 2007 to 2013. In contrast to the previous Framework Programmes, funding is also meant to include translational research. These examples show that current public funding of research projects for infectious diseases by the industrial nations hardly matches the global magnitude of the problem.

Lack of incentives for research and development

It is a well-substantiated fact that research and development in the pharmaceutical sector is a lengthy and expensive matter that involves considerable risk. The development of a new drug takes years, most of the substances tested fail the test, and development costs for a new pharmaceutical up to marketing authorization are in the order of several hundred million Euros.

As recently described by the Pharmaceutical Shareholders Group, today's model for research and development in the pharmaceutical sector is ultimately based on a "social contract" between society and the research-based pharmaceutical industry. ⁸⁹ In exchange for high-risk investments, the government grants the industry patent rights allowing it – for a limited time period – to market on a monopoly basis innovative pharmaceutical products that benefit public health and are the fruit the industry's research and

development work. XII However, this contract, upon which research and development in the pharmaceutical sector is based, can only work if there actually is an incentive for the newly developed products due to cash-value demand in the market. Diseases that frequently occur in affluent countries create such an incentive, which is why a steady stream of pharmaceutical innovations is created for the diagnosis, prevention and therapy of frequently occurring diseases in wealthy countries.

Nevertheless, there are also diseases in the industrial nations for which this system does not simply lead to the desired pharmaceutical innovations. For rare diseases that only affect a small number of people in the more affluent countries, the conventional incentive mechanisms do not work so easily. To promote R&D for rare diseases, the legislature in the United States created additional research incentives in the early 1980s with the so-called Orphan Drug Act, which included the introduction of more extended patent protection, tax relief, a simplified marketing authorization procedure and appropriations for clinical trials for companies active in this research area.

Since 1983, these measures have resulted in the marketing authorization of a variety of drugs for the treatment or rare diseases in the United States. 90 In 2000, the EU introduced a comparable regulation for orphan drugs. One conclusion to be drawn from this experience is that the right incentive mechanisms will lead to research and development even in neglected fields.

The situation of health problems that occur exclusively in poor countries is the same as for the so-called "orphan diseases" in the 1980s. There is a lack of incentives for research and development. According to WHO estimates, about USD 440 billion was globally spent on pharmaceuticals in 2000. Pharmaceuticals in 2000.

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The patent issue is not the subject of this paper. However, in the words of former UN High Commissioner for Human Rights, Mary Robinson, there are "potential conflicts between the intellectual property rights of pharmaceutical companies, which are vital for innovation and research, and the rights of people facing life-threatening disease to adequate health care. [...] The World Trade Organization's Declaration on the Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement) and Public Health adopted in Doha in 2001 sent an important signal regarding the need to balance intellectual property rights against public health priorities for developing countries." See: Mary Robinson: Ethics, Human Rights and Globalization. Second Global Ethic Lecture of the Global Ethic Foundation. Tübingen 2002

"Push and Pull": Approaches in supporting R&D

How to best promote increased research and development activities for pharmaceuticals for neglected health problems in poor countries is currently the subject of international debate. People agree that solving the problem would require a greater public commitment regarding the direct funding of public and private research projects.

- o Another focus in the discussion is the creation of incentives for private investments - in this context, we also speak of so-called "pull mechanisms."92 Two of these approaches appear particularly realistic: The lack of cash-value demand for new pharmaceuticals or vaccines could be compensated with public funds through so-called advance market commitments. 93 For example, if the international community or a group of wealthy countries would legally commit to purchase a certain quantity of malaria vaccine in the future at predefined terms, it would be a normal business decision for a company conducting research in this area to invest in the development of such a vaccine. In this approach, the government would more or less assume the role of the market via advance purchase commitments, thereby creating incentives for R&D. According to estimates by the "Center for Global Development", to develop a malaria vaccine, an advance purchase commitment worth USD 3 billion for buying 250 million doses of a malaria vaccine at a price of USD 15 per dose would be a realistic incentive. This sum would only be payable after one or several companies succeeded in actually developing a vaccine up to marketing authorization. Discussions regarding advance market commitments as an instrument for promoting vaccine research have progressed far and are also occupying G8 summits, including the one in St. Petersburg. 94
- O Another realistic incentive mechanism, currently being discussed in the United States and specific to American circumstances, is transferable rights for prioritized treatment in the marketing authorization of new pharmaceuticals through the U.S. Food and Drug Administration (FDA). Put simply, a company that has developed an innovative pharmaceutical with special relevance in impoverished countries would receive a voucher for an accelerated marketing authorization procedure with the FDA. Other companies striving for approval of a product with marketing opportunities in the United States could purchase this voucher, thereby achieving

accelerated marketing authorization from the FDA and a quicker launch of their product. 95

Other incentive mechanisms are concerned with the reduction of development costs based on the simplification of the current clinical trials for pharmaceuticals and the streamlining of the marketing authorization procedure for innovative drugs.

While the pros and cons of the various approaches require additional discussion, one thing is already clear: Various mechanisms will be required to overcome the bottleneck in the development of pharmaceuticals for the prevention and treatment of poverty-related diseases: more public funds, incentives for private investments and public-private partnerships.

7. Conclusions

The reference frame of this paper, which was broadly designed at the request of the client institutions, required a tour de force through a wide variety of international health issues. As a result, the paper could only highlight some of the subjects. How can the numerous described findings and experiences be summarized? And what requirements do they pose for the various players in the political arena, in (religious) civil society and the private sector?

As part of international poverty reduction efforts, the greatest importance is assigned to improving the health situation in low-income countries today. Three of the eight Millennium Development Goals are directly aimed at health improvement. This is a good thing. Health is a value in and of itself. In addition, better health can help the people in poor countries find ways out of destitution and increase opportunities for economic development. Therefore, it is a cornerstone of prosperity.

Newer health science research by leading experts shows that the generation and worldwide dissemination of knowledge and technologies – including pharmaceutical products – played an important part in the improvement of the global health situation during the second half of the 20th century.

New methods in economics allow us to determine the effects of health improvements on economic welfare. Studies by globally leading economists show that greater life expectancy and the increased quality of life as a result of health improvements during the 20th century have led to great welfare gains everywhere in the world. Conversely, the deterioration of the health situation due to the AIDS epidemic in particularly affected countries has resulted in dramatic welfare losses since the 1990s.

At the beginning of the 21st Century, today's health knowledge and available health care technologies make better health a realistic future prospect even in low-income countries. Poor countries do not need to become rich before their populations can become healthier.

In the poorest countries in Africa and Asia, the financial means to introduce the health intervention measures on a broad scale that are necessary to improve the health of the population are unavailable. Therefore, they increasingly need external aid. Of course, the missing funds and the lack of other resources are not the only obstacle standing in the way of establishing appropriate health care services and an adequate supply of pharmaceuticals. These problems notwithstanding, the results of reliable evaluation studies convincingly show that well-organized health programs result in objectively verifiable health improvements under the most difficult conditions and in the poorest countries.

The objectives of the health-related MDGs currently include health improvements for women and children and the reduction of the burden of disease caused by the three large infectious diseases – AIDS, malaria and tuberculosis. This focus is appropriate. It is exactly these problems that, – despite all progress, continue to be primarily responsible for the high mortality and morbidity in the poorest regions of the world and are the main cause for global health inequalities.

However, this can also be said about tropical poverty-related diseases, which have not been taken into consideration by the MDGs so far. As a result, it appears appropriate and necessary to add them as a focus to the international agenda of poverty reduction efforts. Tropical poverty-related diseases predominantly affect the populations of poor rural areas and the city slums in the warm regions of Africa, Asia and Latin America. To a large extent, they are the consequence of and cause of poverty. Their contribution to the already high burden of disease in the affected countries was previously underestimated. Most of these diseases can be effectively controlled with the existing arsenal of preventive and curative health interventions. Their control offers a particularly favourable cost-benefit ratio.

In view of the important role that health technologies have been proven to play in producing and maintaining health, the generally acknowledged lack of innovative pharmaceutical products for the prevention and treatment of infectious diseases and for coping with other health problems in poor countries is particularly significant. To overcome this deficit, greater government funding of public and private research projects and for creating incentives for research and development will be required. In this respect, special note should be taken of advance market commitments and the PPPs for product development.

Civil society initiatives, private foundations, public institutions and the research-based pharmaceutical industry collaborate in PPPs for product development. The increased effort put into the research and development of new products for the prevention and treatment of so-called "neglected diseases," which expresses itself via the establishment of these PPPs, is beginning to show success. The PPPs are reporting an encouraging number of new products that are currently undergoing various phases of development. Now, the PPPs for product development require sustained private commitment and increased financial support from the governments of the affluent countries to be able to continue and successfully conclude the development of new pharmaceuticals for the prevention and treatment of frequent infectious diseases in poor regions of the world.

8. Courses of action recommended by the Working Group

Development cooperation by the churches

For the Christian churches in developing countries that are immediately faced with the illness and poverty of countless individuals, the question of healing is not just a medical problem but also a pastoral challenge. Their responsibility exceeds by far the aspect of development when they consider that the gospels especially emphasize the particular care of Jesus Christ for the sick. From their point of view, the elimination of disease is more than just the physical restoration of the sick individual. It is also a sign of the Kingdom of Heaven beginning with the coming of Jesus. The connection of salvation and healing is an essential constituent of church services for sick individuals.

The many different church-based health care services that were often established by missionaries and are sponsored by the local churches today should therefore not be viewed as a traditional burden but instead as a living treasure with great potential. The "option for the poor" as a guideline of church development cooperation should be implemented especially in this area, because health is a prerequisite for achieving an independent life under conditions that are appropriate for human beings.

The churches in southern countries should continue to care for people in rural regions and urban areas of poverty who barely have access to health care services. Various tasks will arise in this respect.

To counter health risks, the churches must increase their preventative help in health education and vaccinations. In the curative sector, they will also have to expand their services, especially for the care of mothers and children. As an underprivileged segment of society, women and children suffer from tropical poverty-related diseases particularly frequently.

Since domestic health care workers have largely replaced foreign experts in all areas today, they must be given special attention. Prerequisites for better quality in medical care can be created, based on on-site professional training and by improving their personal living conditions. In hospitals and health care facilities, special care must be taken to ensure

efficient management and administrative structures. Networks in which church institutions can prove that they are responsible partners for the public health care sector are important as well. Health services can only be ensured for a large number of people if it is subject to a government guarantee. Health insurance systems have an important role in this respect, and their continued establishment should be supported by the churches. An increased exchange on viable models would be desirable.

Based on increased financial and technical collaboration, church-based development cooperation efforts should support overseas partners in tapping their full potential regarding the health improvement of poor people while placing a special emphasis on the control of infectious and tropical diseases. They should aim at model collaborations with other development cooperation sponsors; in doing so, new forms of collaboration with the pharmaceutical industry as part of a public-private partnership will become more important.

Furthermore, the churches should intensify their dialog with politicians and society and work towards obtaining greater public support for the promotion of public health as a key area in the development partnership of North and South. This dialogue should take place with a view towards implementing the Millennium Development Goals and underscore the responsibility of all parties involved in contributing to structurally sustainable solutions.

Research-based pharmaceutical industry

The research-based pharmaceutical industry is asked to intensify further its own product development activities in the field of infectious/tropical diseases and to increasingly collaborate in product development PPPs. It should expand its commitments (e.g. rebates, pharmaceutical donations, training of specialized personnel and participation in on-site aid programs) in support of health-related activities in poor countries. This also applies in particular to the future expansion of measures regarding the control of tropical diseases. At the same time, the industry should constructively participate in all efforts concerned with finding a basic and fair solution for the accelerated distribution of innovative patented pharmaceuticals. Positive examples already exist, such as voluntary licensing to local manufacturers or the cooperation with the WHO, e.g. in malaria control.

The fairness requirement equally applies to the manufacturers of copy products (generic drugs) – they should not undermine aid offers by the research-based pharmaceutical industry. It should also go without saying that the diversion of pharmaceuticals that were supplied to developing countries at reduced prices must be effectively prevented.

An active involvement of pharmaceutical companies in planning activities at the earliest possible date would be of key significance for the success of the contribution of the pharmaceutical industry in the respective aid programs initiated by international institutions. Approval processes and lead times require considerable time, and there is a substantial need for information and communication.

Industry organizations such as the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) in Geneva should make themselves available as contacts. They could assume a consulting and coordinating role, thereby making an effective contribution to a working cooperation. Both companies and associations should be open to such cooperation requests and view it as their duty to collaborate.

Many research-based pharmaceutical companies already have significant experience in implementing aid programmes in developing countries. This could be very useful for development cooperation institutions and sponsors, and they should actively be provided with access to this wealth of experience. This could strongly improve the coordination of the cooperation with governments and aid organizations in particular.

As part of public-private partnerships for the control of infectious/tropical diseases, the research-based pharmaceutical industry is indispensable. All companies should acknowledge their responsibility and participate in the reduction of tropical poverty-related diseases.

Low-income countries

Due to the importance of health in poverty reduction and the economic development of poor countries, health care problems deserve special consideration in the design of the countries' own poverty reduction strategies.

One of the main challenges for poor countries is the funding of the health care services required to achieve the health-related MDGs. Overall, the needed funding exceeds the means of low-income countries, thereby requiring donor support in the medium term. Nevertheless, the capacity of public budgets for health care funding is not fully used in many low-income countries.

In view of the funding shortage, it is indispensable that poor countries use their health care resources as efficiently as possible. Therefore, they should orientate their health care systems in such a manner as to achieve maximum health effects with the use of their limited available means. This is best done by selecting a basic package of the most cost-effective preventative and curative health interventions that is largely financed with public funds and accessible for everybody. These health interventions should specially address the most important health problems of the population and the targets of the MDGs. During the introduction of such a package, it is recommended that the countries cooperate with private and church-based health services in particular.

Especially those institutional and organizational factors in the health policies of poor countries deserve special consideration, which in many cases currently prevent efficient and fairly financed health care services that are oriented on the needs of the population.

In particular, weaknesses in the following areas should be mentioned:

- The government's stewardship of the health care system and regulation of the market for medical services and pharmaceuticals;
- The organizational structures of the health care system, especially with regard to the distribution of public and private duties and functions;
- The staffing of health care services with medical personnel; and
- The allocation of health resources based on socially fair criteria.

Improved protection of the population against the economic consequences of serious illness is another important challenge for the health or social policies of low-income countries. It can only be achieved through the increased use of public means for health care funding or the introduction of insurance systems.

Following the WHO recommendations, one important task in the health policy of poor countries with regard to the pharmaceutical sector is ensuring the population's access to high-quality essential drugs and to safeguard their rational use.

German development policy

The German development policy sector is asked to find a coherent answer to the health development problems in poor countries, taking into account the key significance of health for poverty reduction and economic development. The health problems of poor countries should be more strongly considered in the development budget increases planned by 2015.

In particular, the following key measures should be considered:

- Support for international efforts to place a focus on neglected tropical poverty-related diseases within the international aid context;
- Political support of initiatives for the creation of research and development incentives in the field of infectious/tropical diseases;
- Elimination of legal problems that prevent the sale of patented pharmaceuticals by the research-based pharmaceutical industry to poor countries at affordable prices;
- Increased funding of multi- and bilateral programs in the health care sector with special attention to tropical poverty-related diseases and collaboration with the private health care sector in developing countries;
- Financial participation in PPPs for product development and in initiatives to create advance market commitments for the development of vaccines;
- Increased and targeted support for health research in Germany focused on the health problems of poor people and tropical poverty-related diseases, including the funding of both implementation-related and basic research;
- Capacity expansion in technical support for programs to reducetropical poverty-related diseases, in cooperation with German expert institutions;
- Technical and financial support for relevant research institutions in developing countries, as well as promotion of collaboration with them.

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Appendix

Abbreviations

AIDS Acquired Immune Deficiency Syndrome

ART Antiretroviral Therapy

ARV Antiretroviral Drug

GDP Gross Domestic Product

DALY Disability Adjusted Life Year

DCPP Disease Control Priority Project

DDT Dichloro-Diphenyl-Trichloroethane

DFID UK Department For International Development

DNDi Drugs for Neglected Diseases Initiative

DSO Drug Supply Organization

EU European Union

G8 Group of Eight (Heads of State and Government of

the eight leading industrial nations)

GFATM Global Fund against Aids, Tuberculosis and Malaria

HIV Human Immunodeficiency Virus

IFPMA International Federation of Pharmaceutical

Manufacturers and Associations

LSE London School of Economics & Political Science

MDGs Millennium Development Goals

NGO Non-Governmental Organization

MSF Médecins Sans Frontières (doctors without borders)

NCEs New Chemical Entities

NTD Neglected Tropical Disease

OECD Organization for Economic Cooperation and Development

PPP US\$ Purchasing Power Parity US-Dollar

PPP Public-Private Partnership

R&D Research and Development

SARS Severe Acute Respiratory Syndrome

TB Tuberculosis

TDR Tropical Disease Research (unit at WHO)

TRIPS Trade Related Aspects of Intellectual Property Rights

UN United Nations

UNAIDS United Nations Special Program on HIV/Aids

UNDP United Nations Development Program

UNFPA United Nations Population Fund (formerly United

Nations Fund for Population Activities)

UNGASS United Nations General Assembly Special Session

UNICEF United Nations Children's Fund (formerly United Nations

International Children's Emergency Fund

VFA Verband Forschender Arzneimittelhersteller e.V.

(German Association of Research-Based Pharmaceutical Companies)

WHO World Health Organization

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