Chapter 10

Access to Essential Medicines: Global Justice beyond Equality

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Introduction

Millions of people in low-income countries have little or no access to safe and high quality medicines. They suffer and die from medical conditions that can be treated in other parts of the world. Effective drug treatment now exists for many infectious diseases that are among the leading causes of death in poor countries: About 10 million people die each year from acute respiratory disease, diarrhoea, tuberculosis or malaria. Most disastrous for the people in low-income countries is certainly the HIV/AIDS pandemic. Forty million people have been infected with HIV at the end of 2005, with the majority (25.8 million) living in sub-Saharan Africa. Out of the five million new HIV infections worldwide in 2005, more than 3 million occurred in this region. Although the national HIV prevalence rates in sub-Saharan countries recently showed a more variable pattern (e.g. declining rates in Kenya, Uganda, Zimbabwe, but rising in Mozambique and Swaziland) – making it inaccurate to speak of single 'sub-Saharan AIDS epidemic' – it remains by far the most affected region of the world.[1] While there is still no cure for HIV, antiretroviral drugs can significantly improve the course of the illness and increase life expectancy.[2] Some drugs have proven to reduce the mother-to-child transmission of HIV (Brocklehurst et al., 2002; Jackson et al., 2003). In sub-Saharan Africa, however, less than half a million people – i.e. only one in 50 persons with advanced disease – have access to effective antiretroviral drugs and basic medications against HIV-related disease.[3] As a consequence, about 11 million children have lost one or two of their parents due to AIDS and grow up in societies in which most of the adult authority figures are

1 *Joint United Nations Program on HIV/AIDS (2005): AIDS Epidemic Update* (2005), Geneva: UNAIDS; Available at: www.unaids.org (Accessed on 12 February 2006).

2 As mathematical models of HIV infections and fatality rates in Sub-Saharan Africa show, treatment measures lead to an impressive benefit especially if they are combined with preventive interventions (Salomon et al. 2005). With respect to the ethics of allocating scarce resources, it might be even more interesting that increased spending on prevention will not only reduce the number of new infections by half, but also result in net financial savings, as future costs for treatment and care are averted (Stover *et al.*, 2006).

3 World Health Organisation (2004) The world health report 2004: Changing History. Geneva: World Health Organization. Available at www.who.int/whr/2004/en (accessed February 12, 2006).

dead.[4] In 2005, more Africans died of AIDS than in any other year so far – about 2.4 million people.

Lack of access to essential medicines not only inflicts tremendous suffering on poor populations, but also keeps them in the poverty trap. Serious illness is one of the major reasons for declining economic productivity and stagnating development. Poverty is both cause and effect of the high burden of disease.[5] Hence, for people living in low-income countries it is virtually impossible to escape from this vicious circle of poverty and illness. Even if drugs are available in these countries, they are often unsafe, not distributed properly in a deficient health care system or not used appropriately (Pecoul et al., 1999; Henry et al., 2002; Quick, 2003). Other non-medical factors further aggravate this fatal situation: Many people are undernourished; they lack access to safe water and basic sanitations and have no adequate shelter.

There have been several initiatives to alleviate this disastrous situation. Among the first was the Model List of Essential Medicines launched by the WHO in 1977 to help countries to select, distribute and use essential drugs that satisfy priority health needs.[6] This list has since then been revised every 2 years and can be seen as a breakthrough in international public health that is even discussed as a model for health care planning in high-income countries (Hogerzeil, 2004). Another recent WHO activity was the '3 by 5' initiative, launched to provide 3 million people with HIV/AIDS in low- and middle-income countries with life-prolonging antiretroviral drugs by the end of 2005.[7] Some pharmaceutical companies have lowered prices for patent protected drugs or offered medications for free (Cochrane, 2000). Other organisations and private persons have donated funds to low-income countries (e.g. the Gates Foundation). Yet, these efforts have not been very successful so far: There is still a huge gap between the potential to save millions of lives with safe and cost-effective drugs and the sad reality of extremely high morbidity and mortality in most low-income countries of the world. There is little controversy on that this situation is morally unacceptable and that something should be done to improve access to essential drugs for these deprived populations. So, one might ask, is the lack of access to essential medicines really a genuinely *ethical* problem in the sense that we do not know what is morally right or wrong? The moral imperative seems to be as clear as it could be: We should ensure access to essential drugs for all people in the world!

However, while there is little disagreement *that* something should be done, there is considerable disagreement *what* should be done: What are the most effective strategies to change this obviously unacceptable situation? On the face of it, this

4 This fact is very impressively illustrated by the projected population structure in Botswana with and without the AIDS epidemic (Attaran, 2004).

5 For further analysis of the impact of improved access to essential drugs on reducing severe poverty see, e.g. Pogge (2005). For the effects of poverty on impairing access to essential drugs see, e.g. Attaran (2004).

6 For the latest version, the 'WHO's Thirteenth Model List of Essential Medicines', see: www.who.int/medicines/organization/publications/essentialmeds_committeereports/en/index.html.

7 World Health Organization, − The 3 by 5 Initiative. Available at: www.who.int/3by5/en (Accessed on 12 February 2006).

again does not seem to be a real *ethical* problem: Is it not rather a question of instrumental reasoning if we try to find the most effective means to achieve a – more or less – uncontroversial goal?

This first impression certainly has some plausibility: There are several different approaches that could contribute to alleviate the access problem: Some have suggested price reductions on behalf of the pharmaceutical industry. Following the concept of 'differential pricing', the companies should sell their drugs to low-income countries at prices near the marginal cost of production, while regaining the investment for research and development (R&D) through maintaining high profit margins in high-income countries.[8] Others have called for increased donor funding for the purchase of essential drugs. Bulk purchasing arrangements, as performed by the Delhi Society for Promotion of Rational Use of Drugs, have been proposed to achieve significantly lower prices on the market (Ahmad, 2002). Still others have suggested compulsory licensing of patent protected drugs to allow the production of cheaper generic equivalents (e.g. Schüklenk, 2002). And the WHO Commission on Macroeconomics and Health (2001) has favoured a voluntary arrangement by the pharmaceutical industry for pricing and licensing of production in low-income markets.[9] Which of these different approaches we favour certainly depends on instrumental judgements about which strategy will be most effective to improve access to essential drugs in low-income countries.

However, below the surface of these instrumental considerations there is a truly *ethical* issue that represents a major obstacle to straightforward solutions of the access problem: '*Who* should do *what* for *whom*?' (O'Neill, 2002, p.42). While there is wide agreement that we have *some* obligation towards people who lack access to essential medicines, there is considerable disagreement about *how* this obligation should be allocated: *Who* is obliged to help the people in low-income countries to get access to essential drugs? And *what* concrete actions do these obligations require? And *who* are the appropriate recipients of the required actions? In our opinion, this 'allocation of obligations' represents the biggest ethical challenge in improving access to essential drugs in low-income countries. What we need is an ethical justification of how we should allocate responsibilities among the different agents and agencies that could contribute to alleviate the access problem.

Why does this 'allocation of obligations' pose such a hard problem for ethical analysis? The reason is the *global* scale of the issue: Access to essential drugs is impeded by a web of causations that include local as well as global factors, involving many different agents and institutions (Pecoul et al., 1999; Quick, 2003; Attaran, 2004; Barton, 2004). How can we identify and ethically justify obligations to improve the

8 The World Trade Organization ministerial Conference in Doha and the joint Global Health Council/World Trade Organization/WHO workshop emphasised the need for differential pricing to minimise the adverse effects of patent protection; Available at: www.who.int/medicines/library/en/ (Accessed on 12 February 2006). A method to derive differential prices for essential drugs in countries of variable national wealth has been proposed by Lopert et al. (2002).

9 Report of the WHO Commission on Macroeconomics and Health 'Macroeconomics and Health: Investing in Health for Economic development' (2001), 86−103 (www.cmhealth.org).

access problem within this global web of causations? Do these obligations transcend national borders? To what extent are people in high-income countries responsible for the situation of people in low-income countries? There are two common strategies to ethically justify access to essential medicines: a distributive justice and a rights-based approach. In the following we would like to show that neither of the two approaches is able to give a sufficient justification for the allocation of responsibilities. Rather, one should start with a systematic account of *obligations*, because it makes more explicit what action is required by whom to improve access to essential drugs (O'Neill, 2002). This will narrow the gap between the rather abstract considerations of distributive justice and concrete action to improve access to essential drugs.

Distributive Justice Beyond Equality

Due to its global scale, the access problem presents a big challenge for traditional theories of distributive justice that usually focus on the distribution of goods within states or bounded societies.[10] During the last 10 years, several authors have tried to extend these theories of distributive justice to a global scale. It would be far beyond the scope of this paper to give a detailed account of the different approaches that have been proposed so far.[11] Therefore, we limit ourselves to some general considerations. Without doubt, there is enormous *inequality* between high-income and low-income countries in the world. Though constituting 44% of the world's population, the 2.7 billion people who – according to estimates of the World Bank – live below the poverty line of $2 per day account only for approximately 1.3% of the global social product. They would need an increase of just another 1% to escape the so defined poverty. The consumption of high-income countries (955 million citizens), by contrast, amounts to 81% of the global social product with an average *per capita* income that is almost 180 times greater than that of the poor (Pogge, 2005). As poverty is one of the main causes of ill health, these economic inequalities also contribute to large inequalities in health status. And the income gaps are greater today than 50 years ago and most likely will continue to grow. The large discrepancies in life expectancy between low-income and high-income countries – for example 26.5 years in Sierra Leone *vs.* 73.6 years in Japan[12] – are a clear indicator of these tremendous global inequalities. Theories of global distributive justice now have to show that these inequalities are morally unacceptable.

Drawing on the work of the political philosopher Charles R. Beitz, we distinguish *direct* from *indirect* reasons why social inequalities are objectionable (Beitz, 2001). *Direct* reasons are based on the assumption that distributional inequality is a morally bad thing in itself. These reasons are usually derived from an egalitarian account of distributive justice, which is probably the most common approach. *Indirect* or *derivative* reasons, by contrast, show that social inequality is a morally bad thing by reference to other values than equality. In our opinion, these derivative reasons

10 E.g. Rawls' "Theory of justice" (Rawls, 1971).

11 For a selection of recent papers see Pogge (2001).

12 Healthy life expectancy at birth (HALE), The World Health Report (2001) (http://www3.who.int/whosis).

provide a philosophically less ambiguous and practically more promising approach to global inequalities.

There are several derivative reasons why global inequality matters (Beitz, 2001). First of all, social inequality is usually associated with *material deprivation*: the worst off live in terrible conditions, suffering from severe poverty, hunger and ill health. Here, not inequality *per se* is morally compelling, but the concern with the tremendous suffering of the poor that could be relieved by a comparably small sacrifice of the rich. *Prima facie*, this constellation is a strong moral reason that calls for improving the living standard of disadvantaged populations. A second derivative reason is that large inequalities of resources significantly restrict a person's capacity to determine the course of her life (Daniels, 1985). By use of their political or economic power, the better off can exercise a considerable degree of *control* that limits the range of opportunities open to the worse off. Like the material deprivation, these restricted choices are reasons that apply both to domestic and global inequality because they refer to *basic human needs* that show little variability across different cultures and societies.[13] Any human being has the need for decent basic living conditions and a reasonable freedom of choice. We set aside for now the deeper philosophical question of exactly defining 'decent' living conditions and a 'reasonable' degree of freedom of choice. A third derivative reason that makes inequality unacceptable is *procedural unfairness*. Global inequality often is associated with asymmetric decision procedures that are dominated by the rich and sometimes even exclude the poor. One example is the UN Security Council that grants a veto to the five permanent members but not to representatives of those states that are the potential recipients of humanitarian interventions.[14] Again, it is not inequality *per se* that matters but the distorting impact on the process of decision making that puts the interests of the poor at a disadvantage.

Compared to the *direct* equality-based reasons, these *derivative* reasons have several advantages. They do not depend on some theoretical ideal of a global egalitarian distribution of goods which is deeply rooted in the Western culture of social democracy and which appears to be too abstract and formal to give concrete guidance on how we can improve the extreme deprivation of the people in low-income countries. In addition, egalitarian accounts of distributive justice are philosophically ambiguous: Just consider the 'equality of what?' debate that has preoccupied philosophers for decades. *Derivative* reasons, by contrast, focus on the concrete situation and living conditions of deprived populations. This can help to develop policy measures that directly address their most important needs by reducing poverty, by improving nutrition and access to essential medicines and by creating fair international decision procedures. Certainly, the resulting policy measures will reduce inequality in the world even if it is not their primary objective. We do not

13 Cf. the Neo-Aristotelian capabilities approach of Martha Nussbaum. She identifies a list of universal *human capabilities* that are all implicit in the idea of a life worthy of human dignity (Nussbaum, 2006, p. 76).

14 Another example are the international trade negotiations about intellectual property rights that resulted in the TRIPS agreement which will raise the cost of technology to poor countries.

argue that global inequality does not matter. Rather, we would like to draw attention to non-egalitarian considerations that are ethically at least as compelling and practically more useful in directing attention to concrete policy measures. However, these arguments still do not provide a sufficient answer to the question of *who* has the responsibility to finance and conduct these policy measures that will eventually reduce global inequality.

Rights to Health and Health Care

Before further pursuing this question, we would like to discuss briefly another line of ethical argument that is often used in the campaign for global access to essential medicines. These arguments are based on human rights, assuming that there is a right to health or a right to health care. The most prominent example certainly is the constitution of the WHO: 'The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being.'[15] While the right to health certainly has both some intuitive appeal and an important rhetorical function in the WHO's campaign for better global health, it is a philosophically highly problematic concept. In general, human rights create corresponding obligations for other people to respect these rights. For example, the right to life (Chapter 3, UN Declaration of Human Rights) requires other people to refrain from killing the bearer of this right to life. Or the right to freedom of movement and residence within the borders of each state (Chapter 13) requires other people to refrain from restricting the freedom of movement of the right-holder. Consequently, rights are only meaningful if there is someone who can fulfil the corresponding obligations. And this is not the case with the right for health: for many medical conditions, no effective treatment is available, so virtually nobody can fulfil the corresponding obligations. 'The main difficulty is that assuring a certain level of health for all is simply not within the domain of social control.' (Buchanan, 1984, p.55.) Hence, it is philosophically incoherent to claim that people have a universal right to health.[16]

A more promising candidate in this respect seems to be a *right to health care*. A right to health care, however, still raises difficult philosophical questions, especially regarding its justification and scope. For the issue 'access to essential medicines', some preliminary remarks will be sufficient. The most promising approach to justify a right to health care has been proposed by Norman Daniels who has extended Rawls' theory of justice to the sphere of health care (Daniels, 1985). According to Daniels, the function of health care is to restore or maintain normal species functioning. As an impairment of normal species functioning through disease and disability restricts an individual's opportunities, health care promotes equal opportunity by preventing and curing diseases. Hence, if people have a right to fair equality of opportunity – which has been established by Rawls' theory of justice – they also have a

15 Alike, the United Nations Secretary-General Kofi Annan refers to health as a human right: 'It is my aspiration that health will finally be seen not as a blessing to be wished for; but as a human right to be fought for.' (www.who.int/hhr/en/)

16 This is not to deny that we have strong beneficence-based obligations to help sick people.

(derivative) right to health care. It is certainly the strength of Daniels' approach to have demonstrated convincingly the moral importance of health care: Health care contributes to maintaining or restoring fair equality of opportunity. As this derivative right for health care is not based on a particular conception of the good, it must be considered a *universal* right that can provide an ethical justification for a global access to essential drugs.

What remains unclear, however, is the *scope* of this derivative right: do people have a right to any health care that is technically feasible no matter what the costs are? Or do they just have a right to a *decent minimum* of health care? Given the resource constraints we face, only the second interpretation seems to be feasible. But Daniels' approach does not tell us what constitutes a decent minimum or basic level of health care.[17] Alike, a rights-based approach does not specify the corresponding obligations: '*Who* ought to do *what* to protect and restore *whose* health?' Therefore, a rights-based approach does not bring us very far in solving the most controversial ethical issue in the access problem, the allocation of obligations. Onora O'Neill rightly has emphasised: 'If we want to establish intellectually robust norms for health policies it would be preferable to start from a systematic account of obligations rather than of rights.' (O'Neill, 2002, p.42.) We should focus on required actions rather than on entitlements to receive.[18]

Three Principles for the Allocation of Obligations

In the following section, we will try to outline how the ethical obligations to improve access to essential drugs should be allocated to different agents and institutions. Who bears *remedial responsibilities* concerning access to essential medicines? 'To be remedially responsible for a bad situation means to have a special obligation to put the bad situation right, in other words to be picked out, either individually or along with others, as having a responsibility towards the deprived or suffering party that is not shared equally among all agents.' (Miller, 2001, p.454.) Remedial responsibility falls on individual agents as well as on social institutions, with individual agents bearing responsibility for those social institutions they are able to restructure in order to improve access to essential drugs.

According to which principles shall we allocate remedial responsibilities? Three different approaches are frequently used in the debate: 'The first appeals to agents' responsibilities based on their *connectedness* with those suffering. The second allocates responsibilities to agents on the basis of their *contribution* to the current crisis. The third claims that remedial responsibilities ought to be allocated according to the *capacity* of different agents to discharge them.' (Barry et al, 2002, p.63) Interestingly, these principles are not only invoked to allocate responsibility but also to evade responsibility, because one has – allegedly – not contributed to the suffering or one has not the capacity to help. The further analysis of the three principles will

17 This argument has been developed in more detail by Ezekiel Emanuel (1991).

18 Or, as Thomas W. Pogge has put it: We need an *active* concept of justice that 'diverts some attention from those who experience justice and injustice to those who produce them'. (Pogge, 2002, p.75.)

show that they have different moral force with the connectedness resulting in the weakest and the contribution resulting in the strongest remedial obligations.

According to the principle of *connectedness*, the agents who are connected in some way to the deprived people bear a special responsibility to alleviate their suffering. The connection can be based on joint activities, shared institutions, membership in the same community or in the same state, for example. It is thereby possible to distinguish between different degrees of connectedness. While intuitively it seems to make sense that we have greater responsibility to care for those with whom we are related in some way, the criterion of connectedness has some disturbing consequences: As the rich tend to be closer connected to the rich and the poor closer to the poor, the criterion will systematically favour the rich. And there is another reason that makes this principle ethically less compelling: Why should we have less ethical obligation to help those in dire need just because we are not so closely connected? With respect to the moral importance of the suffering of the poor, the connectedness seems to be morally somewhat arbitrary and therefore conveys only limited moral binding force.

According to the second principle, people who have the *capacity to act* bear the responsibility to help those in dire need, irrespective of their connectedness or their causal contribution to the deprivation. Consequently, all those agents who have the required technology or resources also have an obligation to improve access to essential drugs. The capacity to act depends not only on the available resources but also on the opportunity costs that are caused by the remedial action. It is important that capacity to act refers both to the capacity of individual agents and to the capacity of several agents to act collectively. Action may be possible within the existing institutional framework, but sometimes it may be required to change the institutional framework itself to alleviate the situation.

According to the third criterion of *contribution*, agents are responsible for situations if they have been involved in causing those situations. This causal relationship is certainly the most compelling ethical reason: If someone has contributed to inflicting harm to someone else, he or she bears an especially strong remedial obligation. The principle of contribution is grounded in the ethical asymmetry between omission and commission: Obligations not to harm others (principle of nonmaleficence) seem to be ethically more stringent than the obligation to help them (principle of beneficence). Given the web of causations that impedes access to essential medicines in low-income countries, it is not surprising that there is much controversy about the causal contribution of different agents and institutions. The pharmaceutical industry, for example, argues that not the patents but rather the severe poverty is the main barrier to access, while NGOs like Médecins sans Frontières (MSF) emphasise the impeding role of patents (Goemaere et al., 2002; Goemaere et al., 2004).

Allocation of Obligations According to the Three Principles

These three principles can now be used to assign responsibility to different agents and institutions. It seems most plausible to apply the principles in combination and give each of them the appropriate weight. In this last section of the paper, we would

like to sketch how remedial responsibility for improving access to essential drugs in low-income countries can be allocated according to these three principles.

We start with the much blamed pharmaceutical industry. Pharmaceutical companies certainly have the *capacity* – and hence the responsibility – to improve access to essential drugs by various means. Intuitively most appealing would be lowering prices for expensive drugs or offering medication for free, as already done by some pharmaceutical companies (Cochrane, 2000). However, while these measures certainly provide some immediate and direct relief, they are no sustainable long-term solution to the access problem. On the contrary, price reductions and drug donations are limited by time and quantity, mainly suitable for the few medicines that are highly effective with short treatment courses (e.g. antihelmintics, antibiotics). The experience of GlaxoSmithKline shows the limits of this approach: Although the company was the first to discount its HIV/AIDS medicines in low-income countries (Cochrane, 2000), NGO activists still considered the prices excessive, inviting other pharmaceutical companies to scorn the effort (Friedman, 2003).[19] This measure is, however, not only of limited utility, but also morally at least ambiguous (Schüklenk, 2002): It perpetuates the dependence of people in low-income countries on charitable action from organisations and companies in high-income countries.

Which other strategies could pharmaceutical companies use to comply with their remedial responsibility? It is commonly assumed that patents impede access to essential medicines in poor countries. Especially NGO activists claim that 'patents [are ….] a barrier in many places to accessing affordable medicines'.[20] Yet, most pharmaceutical companies do not seek patents in poverty-stricken countries very often, since little revenue is at stake (Attaran et al., 2001; Friedman, 2003). Only 17 out of 319 products on the World Health Organization's Model List of Essential Medicines are patentable, although not actually patented, so the overall patent incidence is only 1.4 per cent (Attaran, 2004). Most of these medicines are antiretroviral (ARV) drugs since HIV/AIDS is a rather recent disease. But even ARVs are patented only in a few African countries, and generally only a small subset of them (Attaran, 2001). Moreover, patented drugs are not necessarily more expensive than generics. Since nearly all of the patented essential medicines (except Cipro and Lariam) are already discounted in low-income countries, the brand-name products and their generic counterparts often have similar prices (Attaran, 2004). This also applies to ARVs: a recent study by the Hudson Institute using data collected by Médecins sans Frontières shows that patented ARVs are often provided at even lower prices than ARVs of generic manufacturers (Noehrenberg, 2004).

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19 In addition, the initiative by GlaxoSmithKline seems to be hypocritical: While initiating drug discount programmes in some parts of Africa, its patent on the ARV drug 3TC in China blocks the availability of one of the most simple and affordable AIDS treatments available worldwide, the WHO recommended fixed-dose combination of d4T/3TC/NVP (Goemaere *et al.*, 2004).

20 Médecins Sans Frontières, Canadian HIV-AIDS Legal Network, Oxfam Canada, Interagency Coalition on AIDS and Development, Canadian Council for International Cooperation, Canadian Treatment Action Council. An open letter to all members of the parliament. 25 October 2001. Available at: www.msf.ca (accessed 12 February 2006). See also Goemaere *et al.* (2002, 2004).

Nevertheless, even a minor number of patents can be an obstacle to the development of a competitive market in which prices equal marginal costs of production. It can therefore also be a sufficient – yet sometimes overstated – reason to reform the rules of intellectual property rights. Two different options have been proposed: compulsory and voluntary licensing. Since the Doha 'Declaration on the TRIPS Agreement and Public Health' in 2001, compulsory licensing has received great emphasis as a nation's tool to override patent protection standards which before had been strengthened by the Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1995 (Barton, 2004; Sterckx, 2004). The Doha Declaration confirmed a nation's right to use the exceptions of TRIPS – such as compulsory licensing – to meet public health concerns stating that 'public health crises, including those related to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency'.[21] Compulsory licensing can be ethically justified, both by consequentialist (Schüklenk, 2002) and social contract arguments (Ashcroft, 2005); yet, the practical effect of compulsory licensing has been very limited so far (Attaran, 2003). Its utility seems to lie more in the argumentative power as a possible tool of litigation when negotiating with pharmaceutical companies.

Given the small number of essential medicines that are both patented and overpriced, it seems more effective to concentrate specifically on each of these drugs and find flexible solutions that evoke less conflict and acrimony than compulsory licensing.[22] One promising approach is the use of 'out-licensing' as a form of voluntary licensing: Brand-name companies voluntarily agree to license generic alternatives for their patented essential medicines in low-income countries, but retain their licenses in high-income countries, thus preserving their core pharmaceutical markets in rich countries (Friedman, 2003; Attaran, 2004). As only a few of the essential drugs are patented and the market is far less profitable in low-income countries, these out-licenses would only negligibly affect the companies' revenues.

According to the principle of *contribution*, we must ask: Who is causally responsible for the intellectual property framework? As the TRIPS rules have been set up by the World Trade Organization (WTO), it is the WTO and not the individual pharmaceutical firm operating within this framework that bears primary remedial responsibility in this respect. In fact, as emphasised by the Doha Declaration, the TRIPS agreement already permits compulsory licensing in situations of national emergencies. However, compulsory licensing has been effectively prevented by the intensive lobbying of the pharmaceutical industry. Hence, the pharmaceutical industry is causally connected to the access problem and therefore bears remedial responsibility, at least for refraining from this intensive lobbying. Also, the principle of *capacity to act* applies to this context. Within the framework of TRIPS, there are still many different ways for pharmaceutical companies to alleviate the access problem, e.g. by drug donations, out-licensing or supporting non-profit pharmaceutical

21 World Trade Organization, Declaration on the TRIPS Agreement and Public Health, 20 (November 2001); www.who.int/medicines/areas/policy/tripshealth.pdf (Accessed on 12 February 2006).

22 Accordingly, the WHO Commission on Microeconomics and Health favours voluntary licensing agreements as a primary tool for lowering prices of patented drugs.

companies (see above). In any case, the intellectual property rights play only a minor role in improving the access to essential medicines. It is therefore misleading and often counterproductive to primarily concentrate on the ethical aspects of patents and licensing. Instead of patents and patent laws, a variety of *de facto* barriers impede access to essential drugs, including *inter alia* the high cost of some medicines (e.g. ARVs), national regulatory requirements for medicines, tariffs and sales taxes, and insufficient international financial aids (Attaran, 2001).

Accordingly, also the low-income countries themselves bear responsibilities to improve the access problem. Inasmuch as not only national regulatory requirements and sales taxes, but also corruption and mismanagement inhibit access to and rational usage of essential medications, these countries or their governments respectively bear responsibility to improve these conditions (principle of *contribution*). In addition, they have the *capacity to act* by improving their health care delivery system and ensuring the effective distribution and rational use of essential drugs. One example is the DREAM (Drug Resource Enhancement against AIDS and Malnutrition) project in Mozambique, an innovative programme developed by the Ministry of Health in cooperation with the Community of Sant' Egidio. In this programme, patients get free access to highly active generic anti-retroviral drugs (HAART) and laboratory tests and also receive further support by a nutrition programme and health education. This project does not only show high compliance rates and a decrease in viral loads (Marazzi, 2006), but also an increased overall survival rate (Palombi, 2004; Wenderlein, 2004). Thus, drug programmes specifically tailored to African nations under the responsibility of their national Ministries of Health provide effective means to improve access to essential medicines. The sub-Saharan nations therefore bear the responsibility to establish appropriate regulatory regimes for the utilisation and distribution of these drugs.[23]

Based on the criteria of causal involvement and capacity to act, the *individuals* in low-income countries also bear a responsibility to alleviate the access problem. Their responsibility applies mainly to the field of primary prevention: in low- and high-income countries alike, individuals bear the responsibility to take care of their own health status by avoiding unhealthy life-styles and by engaging in prevention. For example, malnutrition and alcohol or nicotine abuse are wide-spread causes of preventable diseases which often require ongoing expensive treatment. Since sexual transmission is the predominant mode of HIV spread in sub-Saharan Africa (Schmid, 2004), safer sexual behaviour is a major factor in preventing HIV infections and thus for reducing the need for antiretroviral therapy. This in turn will improve – indirectly – the access problem. However, since prevention requires a comprehensive set of interventions backed by wide-scale treatment and political support (Stover et al., 2002; Stover et al., 2006), the reference to individual responsibility for health simultaneously points to new obligations on a national and transnational level.

And last but not least: What obligations do the citizens in high-income countries have to improve access to essential medicines in low-income countries? While they

23 Cf. the report of the WHO Commission on Microeconomics and Health "Macroeconomics and Health: Investing in Health for Economic development" (2001), 88-89 (www.cmhealth.org).

are not closely connected to these poor populations, they bear remedial responsibilities based on the principles of contribution and capacity to act. As citizens who live in rich democratic states, they sustain the global economic order that *contributes* to the severe poverty in many low-income countries, which is itself a major barrier to access to essential drugs. While being greatly concerned about the few cases of patented essential medicines in low-income countries, the WHO hardly criticises the enormous agricultural subsidies ($310 billion) of Asian, European, and North American governments, which prevent the agrarian populations of low-income countries from exporting their own products and accumulating wealth (Attaran, 2004). As pointed out sharply by the President of Uganda, Yoweri Museveni: 'If there were no agricultural subsidies … [we] would earn enough money to buy all drugs we want.'[24] The failure of billions of patients to receive necessary therapies might therefore also be a consequence of economic policies by high-income countries.

But what is ethically even more compelling, is the *capacity to act*: People in affluent countries could prevent so much harm at so little cost to themselves that they have a rather strong obligation to increase financial support for low-income countries. According to estimates of the WHO Commission on Microeconomics and Health, 0.1 per cent of donor-country GNP – that is one penny out of every $10! − would be enough to reduce total deaths in low-income countries due to treatable or preventable diseases by around 8 million/year by 2015.[25] This increased financial assistance would not only improve access to essential drugs but would also stimulate economic development and reduce overall poverty. The people in high-income countries certainly should not miss this opportunity to break the vicious circle of poverty and ill health.

Limitations

The three principles connectedness, capacity to act and contribution provide plausible ethical arguments to allocate remedial responsibility. However, they do not contain sufficient content to address all details of complex, real-world decisions. They rather offer a general ethical framework that requires further interpretation for practical application. To determine the actual remedial obligations, we must specify and balance the different principles:[26] *How much* assistance does the capacity to act require from people in rich countries? Is 0.1% of GDP too much or too little assistance? What concrete measures should the pharmaceutical industry undertake to meet its remedial obligation? What *relative weight* shall we assign to the remedial obligations of different agents, e.g. the obligations of the pharmaceutical industry *vs.* the obligations of the WTO? The openness certainly restricts the problem-solving power of this principled approach: It 'does not offer a mechanical answer to questions of that kind, but it provides a way of thinking about them – highlighting

24 November 2003 Africans for Drug Patents' (Editorial), *Wall Street Journal*, 7.

25 Report of the WHO Commission on Macroeconomics and Health (2001), p. 92 and p. 103.

26 Most ethical approaches that are based on mid-level principles share this problem (e.g. Beauchamp and Childress., 2001, p. 15ff).

their complexity – that may in the end prove to be more illuminating.' (Miller, 2001, p.471.) That we cannot infer straightforward solutions from this ethical approach is certainly a weakness. Given the empirical complexity and moral diversity of our world, however, this openness can also be considered as a chance.

Concluding Remarks

While there is little controversy that something should be done to improve access to essential medicines in low-income countries, there is considerable disagreement about *what* should be done. On the one hand, this is certainly a question of instrumental reasoning: What are the best means to improve access to essential drugs? On the other hand, there is a genuine ethical issue that represents a major obstacle to a solution of the access problem: Who ought to do what for whom to improve access to essential medicines in low-income countries? We have argued that neither theories of distributive justice nor approaches based on a right to health (care) provide sufficient guidance in the allocation of remedial responsibilities. Rather, one should start with a systematic account of obligations that draws attention to required actions rather than to entitlements to receive. We have discussed three principles that can justify the allocation of obligations: connectedness, capacity to act and contribution, with an increasing strength of moral obligations from connectedness to capacity to act and finally to contribution. More exemplary than systematically, we finally gave an outline of how these principles could be applied to specify the obligations of different agents, agencies and institutions for improving access to essential drugs. However, there still remains a considerable degree of discretion in specifying and balancing these principles. These principles do not offer a simple algorithm to solve the access problem, but they provide a useful means to structure the ethical and political discourse on how to allocate remedial responsibility for improving access to essential medicines in low-income countries.

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