6

Transnational Norm-Building in Global Health: The Important Role of Non-State Actors in Post-Westphalian Politics

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Introduction

The International Compact on Economic, Social and Cultural (ESC) Human Rights constitutes codified international law, but many of its provisions are still far from being respected. This paper discusses the hypothesis that global civil society strengthens subsidiary norms (as the right to access to essential medicines) and that the successful fight for the implementation of the norm 'universal access to essential medicines' proves the discursive power of civil society organisations (CSOs) in the field of human rights.

We will explain that this role of CSOs in the norm-building process is related to the transformation of international relations dominated by nation states to a global system of politics including a variety of non-state actors and hybrid institutions challenging the dominant role of states. Whereas in the Westphalian system the nation-states and their governments were the main institutions as well as actors in setting and implementing norms (the *norm carriers*), this changed with the greater relevance of the global level of politics and of private actors at least in some policy fields. We will analyse the role of CSOs as norm carriers in the norm-building process for the field of access to medicines and use the Finnemore and Sikkink (1998) approach of the *norm-building cycle* as a starting-point. We suggest that – while international law continues to depend on the acceptance of legal norms by nation states – in post-Westphalian global politics multiple actor constellations are playing a growing role in substantiating the content of primary norms of international law by subsidiary norms, which are to a large degree implemented through non-state actors in an increasingly global society. We argue that ESC human rights constitute a field of international law, in which this interaction is of particular importance, referring to the field of health.

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Then, the dynamics of post-Westphalian politics related to norm-building processes are explained and finally the norm-building process in the case of access to essential medicines is analysed in more detail.

Norms and the norm-building cycle

We understand a *norm* – following Martha Finnemore and Kathryn Sikkink (1998, p. 891) – as 'a standard of appropriate behaviour for actors with a given identity'. In contrast, *institutions* describe the way norms and behavioural rules are interrelated, combined and structured in a 'common surrounding' or – referring to a definition by March and Olsen (1989) – 'for specific groups of actors in specific situations' (Finnemore and Sikkink, 1998, p. 891). With *subsidiary norms* we refer to norms that are supplementing primary norms fixed in international law and that are not necessarily legally binding for nation states (or, at least, do not imply serious sanctions if they are not respected), but which might in fact constitute a necessary component for a substantial implementation of international legal norms.

Within a national legal system, these primary and subsidiary norms are mostly defined by law, backed by the state monopoly of legitimate use of force. In international politics, primary norms are agreed upon – in spite of the transformations of the international system – by nation states and therefore need the persuasion of a critical mass of nation states (Finnemore and Sikkink, 1998, p. 895). However, mostly rather general rules are defined, which lack a specification for effective implementation in legal form, as there is no consensus between the many states. With the transformation to a post-Westphalian system, frequently (see below for exceptions) implementation depends on the development of socio-political norms by transnational non-state actors which might increasingly be able to use their discursive power to implement norms. While subsidiary norms are developed as a means to guide the implementation of primary norms, they are much more contested if they 'only' take the form of legally non-binding socio-political norms. Thus, norms of this type often take a long time to reach the 'taken for granted quality' that Finnemore and Sikkink (1998, p. 904) assume for internalized norms in general. They describe these norms as not being controversial. In contrast, we argue that socio-political subsidiary norms are contested and controversial during and even after their implementation, but that they are still an important substitute for legally guaranteed secondary norms.

To better understand the dynamics of the norm-building process and the role of the different involved actors (CSOs in our case) we refer to policy analysis (Anderson, 1975; Hill, 1997; Sabatier, 1999) and to the approach to theorizing norms by Finnemore and Sikkink (1998). They conceptualize a norm 'life cycle', distinguishing 'norm emergence', 'norm cascade' and 'internalisation'. We modify their approach and differentiate – creating

a heuristic model – between the following three stages of a *norm-building cycle*:

1. *Norm generation*: Norm entrepreneurs (Finnemore and Sikkink, 1998) – we prefer to call them *norm carriers* – such as CSOs, International Governmental Organizations (IGOs) and governments raise a certain issue and try to disseminate and generalize these in the general public and among decision-makers, aiming to make the underlying ideas and concept hegemonic by making claims and framing the discourse. As the acceptance and implementation of norms depend mainly on governments and nation states, it is most important to convince a critical mass of governments and decision-makers to agree to the norm and to support its dissemination. However, in this phase of agenda setting, civil society actors play a very important role, as it is an open and not formalized process of communication. At this stage, of course, the further diffusion of the norm can fail, if the norm carrier cannot convince a critical mass of the other actors and thus cannot put through and generalize his or her ideas.
2. *Norm diffusion and norm acceptance*: If a critical mass of states – but also of the general public – is convinced, the norm reaches the 'tipping point' and is accepted by more and more governments and other actors – Finnemore and Sikkink (1998, p. 895ff.) call this 'norm cascade'. The norm then diffuses and results in a broad acceptance. Whereas the general public – in both the national and global spheres – is important for a norm to gain recognition, the formal acceptance of norms normally occurs in state formal institutions such as governments and IGOs. Whereas Finnemore and Sikkink (1998, p. 899) include nongovernmental organizations as organizational platforms only in the phase of norm emergence, but see no role for them in the other two phases, we argue that not only states, but various types of global actors, play a crucial role in all phases. We will show this for the case of access to medicines in the following.
3. *Norm implementation*: After the norm is accepted by a majority of actors (including critical actors) it is implemented. We already differentiated between primary and subsidiary norms in the global realm and outlined that the latter can also be implemented by non-state actors, for example, if they run programmes to provide drugs in developing countries. Subsidiary norms are often accepted by almost all actors, including the governments of critical nation states (such as 'fighting poverty' or 'access to medicines'), but not implemented by all actors (in particular nation states); in some cases civil society actors are the main implementing force.

Of course in reality the generation of a norm is never as clear as suggested in this heuristic model. The different phases cannot be separated strictly

and sometimes overlap. The question 'When does a norm become a norm?' is often difficult to answer. This also points to the fact that the 'identity of actors' who act according to a specific norm is increasingly determined in a transnational space. 'Access to essential medicines' might be guaranteed by national health systems, but where health systems are not in a position to implement this guarantee implementation depends on transnational networks like CSOs and Public–Private Partnerships, which are able to create islands of norm implementation already in early phases of norm development. Moreover, norms are not static and do not retain their original meaning throughout the norm-building cycle, but are modified – sometimes even significantly – in the conflictive process of norm-building (see, for example, van Kersbergen and Verbeek, 2007, p. 218ff.).

Economic, social and cultural human rights and the right to health

In the Western world in particular, civil and political rights have been treated for a long time as the core of human rights. In effect, the inclusion of ESC Rights in the Universal Declaration of Human Rights and the negotiation of an international covenant on ESC Rights have been largely pushed by developing and socialist countries. Though the World Conference on Human Rights in Vienna (1995) declares that both are 'universal, indivisible and interdependent', there is a fundamental difference between them. While civil and political rights refer to specific rights of citizens (and also foreigners) against the state and their protection against the illegitimate use of force (which is basically independent of the level of economic development), ESC rights refer to the duty of states to deliver specific goods. Frequently, one finds these distinguished as 'negative rights' and 'positive rights' respectively. In the case of ESC rights, a state may simply not dispose of the necessary resources to deliver these goods. Article 2(1) of the International Covenant on Economic, Social and Cultural Rights (ICESCR) recognizes this problem, stating that a state ought to implement these rights 'to the maximum of its available resources' and 'with a view to achieving (them) progressively'. In addition, Article 11 stresses the importance of international cooperation.

This leads to a significant difference with respect to extraterritorial obligations, which basically refer to the conditions under which military force might be used to force compliance. In the case of ESC rights, however, the situation is much more complex as it implies a transfer of resources without the existence of institutions to make binding decisions on the level and character of resource transfers. Furthermore, as has been argued in the human rights discourse (Windfuhr, 2005), it should oblige member states not to take over international obligations which might have adverse effects on the realization of ESC rights.

The ICESCR states that all 'States Parties recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health' (Art. 12.1), which includes 'The prevention, treatment and control of epidemic, endemic, occupational and other diseases' as well as 'the creation of conditions which would assure to all medical service and medical attention in the event of sickness' (Art. 12.2) (http://www1.umn.edu/humanrts/instree/b2esc.htm). These documents, however, are rather inconclusive with respect to the 'standard of health' which is supposed to be 'attainable'. The Committee on Economic, Social and Cultural Rights (CESCR), which was established to carry out the monitoring functions assigned to ECOSOC in the Covenant, also publishes interpretations of its provisions in the form of General Comments.

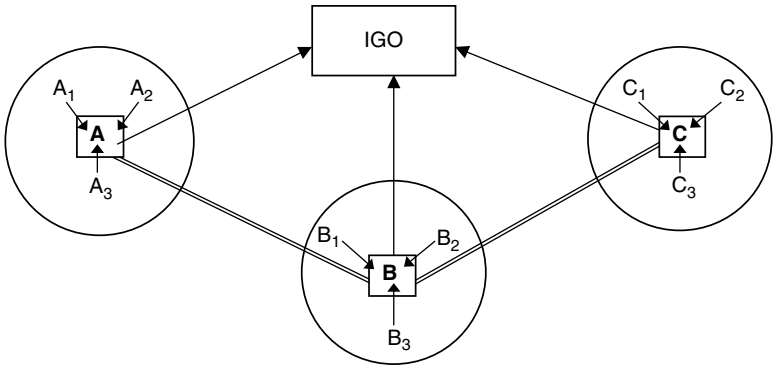
In 2000, the ICESCR adopted a 20-page document on 'The right to the highest attainable standard of health',[1] confirming that state parties have an obligation '... to provide essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs' and 'to ensure equitable distribution of all health facilities, goods and services'. As drugs for an antiretroviral therapy are on the WHO Essential Drugs List, states are formally obliged to provide this therapy to HIV/AIDS patients, but many sub-Saharan African states (with per capita public annual health expenditures of between US$20 and 80)[2] are certainly not in a position to fulfil such an obligation. States, however, also have the obligation to assist other states in fully realizing the right to health.

Moreover, the 'Right to Health' is codified in slightly different formulations in a number of other international agreements.[3] As such, it constitutes binding international law, but it is widely seen as a typical example of 'soft law', which corresponds to principles of basic human rights but is certainly also far from being an obligation enforceable by any institutionalized processes.

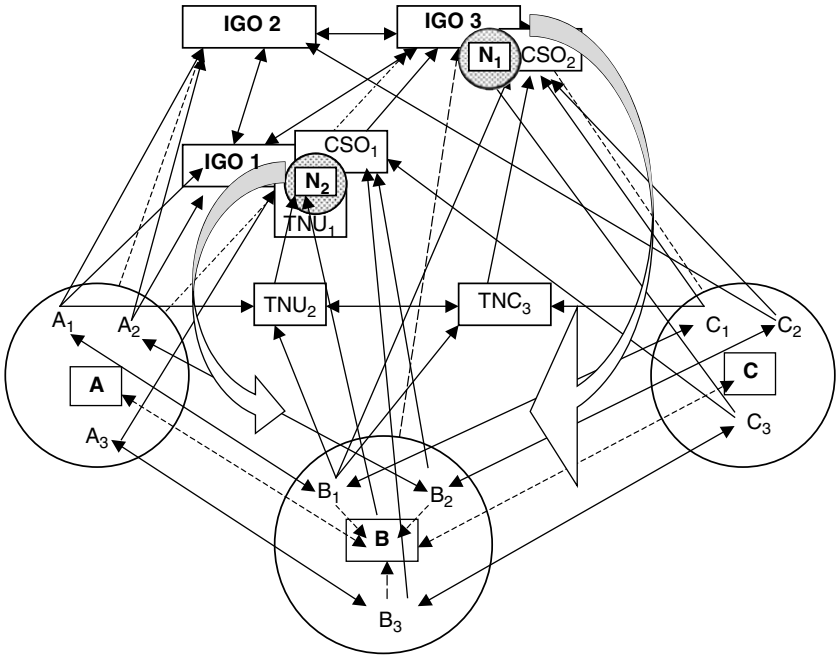
Transformation from a Westphalian international system to a post-Westphalian global system

We have argued that some weaker and poorer states, in sub-Saharan Africa in particular, are not able to fulfil the obligations deriving from international ESC human rights law. Additionally, due to internal power relations and the interests of national elites, some of these states are not even willing to direct available resources to fight infectious diseases and to guarantee a right to health for their citizens. Furthermore, with the transformations of the international political system we can observe a shift of political authority away from nation states. Capacities to regulate and conduct policies are transferred upwards and downwards from the nation state to international actors on the one hand (internationalization) and local actors on the other hand (regionalization, localization), as well as sidewards from state actors in general to a

wide range of non-state actors (privatization, transnationalization) (Rosenau, 1997; Jessop, 2004). The following figure gives a schematic representation of this spatial shift of authority and of the transformation of a *Westphalian*[4] *international system of politics* to a *post-Westphalian global system of politics*.[5]



(a) International relations in a Westphalian system



(b) Global politics in a post-Westphalian system

Figure 6.1 Transformation of international relations into a system of global politics

The traditional system of international relations was based on *an aggregation of interests at the national level* (see Figure 6.1: A1, A2 and A3 represent the various interest groups – business, unions, CSO – in nation A, and so on). Thus, negotiations at the international level were led by governments on the basis of these nationally aggregated positions, which, in the first instance, reflected power relations within nation states. The outcome of these negotiations was a result of power relations between nation states, partially mediated by decision-making procedures within International Governmental Organizations (IGOs). Meanwhile, globalization, the liberalization of markets, and the increasing need to deal with transnational and global problems created opportunities for the direct interaction of non-state actors, thus establishing new transnational spaces of interests and power that prevent a full aggregation of interests on the national level but produce dynamics and opportunities through a transnational cooperation of non-state actors, which increasingly limit the political options of nation states.

We have arrived at quite a complex structure of interaction and relations between the different actors. Whereas in the ideal Westphalian system there are basically the two alternatives of cooperation in an IGO or a bilateral cooperation between states, in the post-Westphalian structure there are many possibilities for cooperation and conflicts among nation states, IGOs, CSOs, and transnational corporations. The 'old' actors of the Westphalian systems are included, but their roles are transformed by challenging their political monopoly through the emergence of new, genuinely transnational actors. New nodes appear in the transnational political space (N_1; N; see Hein et al., 2009, for the concept of nodal governance), which coordinate power resources and compete for shaping global governance processes. These nodes, which might be CSO networks linked to IGOs but also specific coordinating bodies within IGOs integrating other transnational actors, interfere with the aggregation of interests at the level of the nation state. As the nation state was the main institution for norm-setting in the Westphalian System, we can now observe new modes, spatial levels and institutions that are additionally important for norm-setting.

International law: mechanisms of norm-building and compliance when a unified state authority is missing

Compliance with respect to the adaptation of internal politics and national law to international rules

In a system of global politics the high density of transnational social relations and of systems of international law and transnational rules in many different policy fields have created a very high complexity of relations beyond the nation state: powerful non-state actors (in particular, transnational corporations) challenge the hegemonic position of powerful nation states and norms set in one policy field challenge norms in other fields (such as regarding the WTO and human rights).

These developments are closely linked to the question of extraterritorial obligations of international human rights laws. In a Westphalian system of sovereign states it might have been a moral issue (or an issue of 'national interest'), but there was a lack of power to support these obligations in an *international* human rights system, while at the same time contravening interests prevented compliance with human rights norms in national political systems. With the increasing power of a global civil society and a growing interest in solving problems which historically were treated as internal matters of foreign countries, the issue has changed its character: to accept extraterritorial obligations might become a matter of legitimacy in a global society.

International Organizations and non-state actors in the development of transnational norms

WHO is the formally legitimized UN organisation in the norm-building process in international health. The WHO sets internationally accepted norms and standards and gives technical guidance and advice to member countries in promoting health. But it is not only involved in building subsidiary norms; the WHO offers an institutional basis on which to propose and negotiate rules, conventions, and thus forms of international law (for example, the WHO Framework Convention on Tobacco Control, International Health Regulations). Thus, the WHO is (or should be) at the centre of the norm-building process in global health governance.

Although these described functions generally have not changed in the transformation of the international system, WHO plays a different role as a norm carrier. In the Westphalian System, WHO was both the 'organisational platform' (Finnemore and Sikkink, 1998) for nation states as norm carriers and an important norm carrier as actor itself. However, in spite of some relevance at the international level, the nation state constituted the main area of politics. In the post-Westphalian System, IGOs such as the WHO are supposed to become more important due to the increased international and transnational interconnectedness. At the same time, nation states (and IGOs) have to compete with CSOs and other non-state actors in the process of generating and disseminating claims and norms. Also within the WHO, non-state actors have – informally – more influence: first, as the WHO is influenced by the activities and discourses of global health governance and thus internalizes trends and claims form 'outside'; and second, as the WHO has opened itself at least to some extent for more participation of non-state actors, for example, of CSOs but also of private for-profit actors or by attending and creating global public–private partnerships (Bartsch and Kohlmorgen, 2007). As actor in the more important global realm of health politics, the WHO has to face competition in establishing norms by non-state actors, and at the same time is criticized very often for being ineffective or for being not forceful enough in striving for human rights by CSOs.

The case of health: from 'health for all' to 'access to medicines'

In the following, we analyse how the broad universal norm 'health for all' has been concretized – under the influence, besides other factors, of CSOs – to the norm 'access to medicines'. The WHO constitution declares that 'the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being'. 'Health for All' is not only the aim of WHO as an organization but is also established as the central objective of international and national health activities by the nation states throughout the world. The International Conference on Primary Health Care in Alma Ata in 1978 proposed, and the World Health Assembly in 1979 endorsed, Primary Health Care as a strategy to achieve the objective of 'Health for All by the Year 2000', not just by giving the poor a minimum of health services (in a more liberal sense), but by providing health services for all as the foundation of a comprehensive health system (in a more universalistic sense). During the 1980s the concept of Selective Primary Health Care became dominant in discourses and in health activities. This strategy focused on specific diseases in developing countries and on the lack of immunization and defined so-called attainable goals. Some donors, international organizations and scholars favoured this concept, and its influence reaches to the current focus on fighting specific (mainly infectious) diseases.

As we know, by 2000 the objective of 'Health for All' was not attained, and the likelihood of attaining it in the near future remains rather slim. Nevertheless, in 1998, WHO (to be precise, the World Health Assembly) renewed this objective under the label of 'Health for All in the 21st century'. This statement also proclaims that the availability of essentials of Primary Health Care should be ensured. We can state that 'Health for all' has been established as a norm since the 1980s, even if it is contested and not implemented in all countries (Cueto, 2004; Thomas and Weber, 2004, p. 192 *et seq.*; Kohlmorgen, 2007).

Norm generation and diffusion: campaign for access to essential medicines

Since the 1990s, 'Health for all' has been in a sense substantiated by focusing on the fight against poverty-related diseases, other specific fields (for example vaccination campaigns) and the claim 'access to medicines'. Initially, the discussion focused on neglected diseases, but then the process gained momentum around access to antiretrovirals (ARVs) in the fight against HIV/AIDS. The new focus on infectious diseases and access to medicines is a differentiation of the general norm 'health for all'. While 'health for all' seems to be an overambitious target, 'universal access to essential medicines' appears as much more manageable and realistic – in particular, since it is widely known that the generic production of medicines can

be comparatively cheap. Thus, it seems obvious that the denial of access to life-saving medicine constitutes a global scandal. Picking up this scandal for campaigns together with a rapidly growing global civil society with corresponding means of communication developed a high level of discursive power of CSOs. Since the late 1990s, a large network of CSOs, led by Médecins Sans Frontières (MSF)[6] and Health Action International, have been advocating and campaigning for access of poor AIDS victims to ARVs in the 'Campaign for Access to Essential Medicines' (Sell, 2002; Schultz and Walker, 2005). The campaign for low-cost medicine was carried out not only at the global level – by means of activities and lobbying within the WTO and other IGOs – but also in particular countries.[7]

The high prominence of the fight against infectious diseases, however, can only be partly explained by the influence of CSOs and perspectives on poverty reduction that became relevant in the 1990s. Its significance was also a result of the perception that ill health in developing countries and the global spread of infectious diseases like HIV/AIDS, SARS, or tuberculosis could pose a dual threat to global security: one that results from the global spread of these diseases, and one that is linked to political and economic instability resulting from ill health, poverty, and underdevelopment and that has an indirect effect on national and international security (Peterson, 2002; Fidler, 2004). In July 2000, the UN Security Council convened its first-ever session on health and acknowledged 'that the HIV/AIDS pandemic, if unchecked, may pose a risk to stability and security' (SC Resolution 1308, p. 2). The report of the UN 'High Level Panel on Threats, Challenges and Change' stresses that 'any event or process that leads to large-scale death or lessening of life chances and undermines States as the basic unit of the international system is a threat to international security', listing infectious diseases and other social threats like poverty as one of six clusters of threats (UN, 2004, p. 23).

Thus, we argue, the social and human rights interests of CSOs coincide with the self-interests of industrialized countries, such as containing the risks of a global spread of infectious diseases and of political instability. This political constellation of interests provided an environment that made it possible to run an at least partially successful campaign for access to medicines (Hein and Kohlmorgen, 2008). The claim 'access to essential medicines' was first and foremost raised and postulated by CSOs, so we can identify them as main norm carriers in the norm-building phase of *norm generation*. Besides CSOs also some Southern governments, particularly the Brazilian government, argued for increased treatment, for a strengthened involvement of treatment in the HIV/AIDS programmes of international governmental organizations (such as WHO and UNAIDS) and for greater commitments of G8 to enhance access to medicines.

At this stage of the norm-building process, in particular the TRIPS agreement within the World Trade Organization (WTO) became the centre of the CSO campaigns. CSOs argued that intellectual property rights were not

only a trade but also a public health issue and thus managed to link these two aspects.

Thus, after the claim 'access to medicines' was established in the global health and development discourses, and many hesitant actors (such as some G8 countries and IGOs) were convinced and/or morally compelled not to reject these demands, the *diffusion of the norm* proceeded and led finally to a broad *acceptance* at least on the level of agreements, statements, commitments, and programmes. The Doha Declaration (which supplemented the TRIPS agreement) and the agreement on §6 of that Declaration on 30 August 2003 can be interpreted as a result of the activities of the main norm carriers, the CSOs, in cooperation with some governments of developing countries. CSOs not only lobbied representatives of IGOs and Northern governments, but also became increasingly important as advisors to developing country members of WTO and helped them coordinate their positions in the subsequent renegotiations of the TRIPS agreement (UNDP, 2002, p. 104ff.). Hence, during this process, CSOs were changing their character from basically mobilizing and advocatory actors towards cooperating experts and actors with a negotiating role in the global political process.

The influence of CSOs is also apparent in the initiative for a 'Global Framework on Essential Health Research' at WHO, which links up the question of prices of medicines with the problem of investments in research and development (R&D) and the organization of incentives for research (which patents are expected to provide). This initiative was influenced and kicked off by a proposal for a 'Medical Research and Development Treaty' made by the US-NGO Cp-Tech and supported by many CSOs in 2005. It was brought into the Executive Board in January 2006 by Kenya and Brazil and thereafter debated in the World Health Assembly in May 2006, which then decided to establish the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG), which worked until May 2008 and made some recommendations for an improvement of health research for neglected diseases and for the conflict between intellectual property rights (IPRs) and public health. These recommendations (concerning, for example, prices, patent pools and a research and development treaty) remain vague but will be further discussed within the WHO until the World Health Assembly in May 2009. Although it seems quite improbable that we can expect quick concrete measures and that this will result in the incorporation of the 'right of universal access to essential medicines' as an effective norm into international law, this initiative shows that the norm 'universal access to essential medicines' is widely accepted globally.

Norm implementation: many commitments but slow progress

Taking into account the complexity of international rules and global social and economic inequality impinging on the problem of access to medicines, it is obvious that this norm cannot be implemented as a simple legal norm

(for example, based on the General Comment of the CESCR quoted above). As shown in Table 6.1 (see next section), compliance with this norm is based on its acceptance and creative adaptation by multiple actors in the post-Westphalian global polity, which has led to a considerable fall in prices of ARVs, making it basically affordable to the international community to pursue a strategy of universal access to treatment for HIV-infected people. Since the late 1990s the prices for AIDS treatments in developing countries fell from well over US$10,000 to about US$140 (for generics, per person and year, in some countries) in 2005 (MSF, 2005, p. 10). The main reason for this decline in prices was the competition by generic producers. But also the CSO campaigns – which, aside from TRIPS-focused activities, include campaigns against transnational pharmaceutical corporations (TNPCs) with the objective of reaching low prices – and the increased global consciousness concerning the need for AIDS treatment have led to a price reduction. However, even though it is to some extent an accepted global norm, its *implementation* lacks progress. Still most poor countries are dependent on financial transfers to pay for medicines and treatment institutions.

Indeed, the G8 countries, and Kofi Annan and the UN, supported the establishment of the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria in 2001. The Global Fund is a new form of hybrid regulation typical of current structures of global health governance (Bartsch, 2007). It can be characterized as a multilateral funding mechanism that works like a global public–private partnership (GPPP). It has a new and – compared with IGOs – unconventional governance structure as it includes nation states (eight from the North, seven from the South), CSOs (three), foundations (one) and companies (one) as voting members in its Executive Board. Recipient countries have to create a Country Coordinating Mechanism with the participation of all stakeholders (including civil society and private sector) to apply for funds to conduct programmes. The Global Fund has attracted pledges of US$9.7 billion until 2008 and has received US$6.7 billion to support programmes in 132 countries thus far (June 2007).[8] Although 95.5 per cent of the money donated is provided by governments (almost exclusively from OECD countries), the Global Fund can be interpreted as a governance mechanism that gives non-state actors a greater influence in the implementation of the global norm 'access to medicines'.

Furthermore, the role of private foundations shows that non-state actors have an important function for the implementation of the norm. In particular, the Bill and Melinda Gates Foundation is a very influential actor. After Warren Buffet's gift of more than US$30 billion and with annual spending grants for global health initiatives and programmes of approximately US$900,000 million[9] it is one of the greatest funders of global health promotion and the fight against infectious diseases. Also the activities and negotiations of the Clinton Foundation play an important role in the diffusion and implementation of the 'access to medicines' norm. For example,

it initiated negotiations – with participation of the World Bank, UNICEF and the Global Fund – with Indian generic producers to reduce the prices of ARVs for developing countries.

Besides the Global Fund, state (or IGO)-run programmes such as the Multi-Country HIV/AIDS Program (MAP) and the President's Emergency Plan for AIDS Relief (PEPFAR)[10] contribute to an expansion of treatment in the field of HIV/AIDS. Although there are significant improvements – the number of people receiving antiretrovirals increased from 300,000 in 2002 to 2 million in 2006 (WHO/UNAIDS/UNICEF, 2007: 5) – it is obvious that there are great challenges for the international community. In 2006, 7.1 million people still were in need of ARV treatment (WHO/UNAIDS/UNICEF, 2007: 5). To some extent the commitments of the powerful Northern governments seem to be lip service only. For example, there are manifold conflicts between developing countries and industrialized countries, as the governments of industrialized countries are still not ready to lower the protection of intellectual property rights. There are a number of issues which need further analysis before the question whether 'universal access to essential medicines' can be considered to constitute a firm norm in global politics:

- The pharmaceutical industry successively accepted the need to improve access of the poor to medicines and, in effect, provided some mechanisms to support this goal (differential pricing, participation in global public–private partnerships to ease access). Nevertheless, they pursued their agenda of trying to secure strong international IPRs, now shifting the forum of their activities towards bilateral and multilateral trade agreements. Taking into account the possibility of a limited impact of the newly introduced patent right in India with the possible use of compulsory licenses for producing second-line ARVs and, for example, Tamiflu, the main drug against the virus-borne influenza , TNPCs did everything to include clauses which forced the trade partners to exclude the possibility of using flexibilities included in TRIPS, therefore called TRIPS+ clauses. If 'universal access' had been established as a true global norm, one would assume that these clauses in bilateral trade agreements could not become effective without mobilizing large resistance. This is an important question to pursue.
- *Universal access to essential medicines* has developed as a norm due to the conflicts around access to ARVs. Of course, there are many other essential medicines and the norm must be applicable to all of them. The question of the so-called neglected diseases has been the focus of the second great debate in this field; it refers to another aspect of the global medical R&D system that creates incentives only for research on medicines which promise to have a large monetary demand.[11] Another field similar to the situation of ARVs is developing with the increasing importance of the so-called 'diseases of the rich' in poor and middle-income countries: heart

diseases, cancer, and so on, where patent-protected medicines also play a significant role. More recent conflicts in the access field have to be scrutinized in order to exclude the possibility that access to ARVs only constitutes a special case due to the strong international attention paid to HIV/AIDS. In fact, recent conflicts on compulsory licences suggest that the issue will in fact increasingly spread to others. One of the two compulsory licences Thailand issued in early 2007 concerns Clopidogrel, a medicine against heart diseases.[12]

- Still, the problem of financing R&D of medicines cannot be solved by simply providing (or assuring) flexibilities in the use of intellectual property rights. The issue of the neglected diseases points to the fact that differential pricing (to provide cheaper medicines to poor countries) cannot be a successful way to 'save' the property rights system. In addition there also is a growing access problem in industrialized countries due to the scientific and technical potential to develop ever newer medicines and forms of medical treatment which put health systems in rich countries under pressure as well. It remains to be seen whether the discussion on R&D for neglected diseases, patents and innovation within the WHO will show some results and further the incorporation of the 'right of universal access to essential medicines' as an effective subsidiary norm into international law.

Conclusion: the important role of non-state actors in the development of subsidiary ESC norms

In this paper, we have described the transformation of a Westphalian system of international politics to post-Westphalian global politics, which implies a shift of authority from the national to the international and transnational levels of governance and politics. In addition to the 'old' actors – the nation states and IGOs, which retain power – civil society and private-for-profit actors are important players in the global realm. This creates a complex governance structure with manifold interactions and relations between different actors and institutions spanning different levels of action. Thus, whereas in the Westphalian system the nation states and their governments were the main norm carriers setting and implementing norms, this has changed at least in some policy fields. Notwithstanding the greater relevance of IGOs, we can identify a lack of governance at the global level. There is no global state, and IGOs are far from developing global statehood. Social policy-oriented IGOs are sometimes overstrained as they do not have enough resources and formal power to conduct sustainable social and health policies. At the same time, nation states keep their formal power and cannot be forced by existing law to guarantee social rights and implement norm health for all. Thus, there is a kind of vacuum in the global realm, which is filled partially by civil society organizations and foundations. They take

over functions to establish and also implement norms (transnational subsidiary norms) and therefore are important norm carriers in the current system of global governance.

In global health, the norm 'health for all' has been widely accepted since the establishment of the WHO in 1948. However, its implementation lacks progress and many countries do not have the ability to guarantee even a minimum of health care. Since the mid- 1990s, the global health community has focused more and more on specific facets of this general norm, such as neglected diseases, infectious diseases and the issue of access to medicines. The claim 'access to essential medicines' was raised by CSOs, which started a successful campaign focusing on affordable prices and IPR and trade policy inside the WTO and TRIPS against the background of the HIV/AIDS pandemic. Thus, CSOs are the main norm carriers in the phase of *norm generation*. They framed this conflict by addressing the scandal of the disaccord between high prices of drugs and the suffering and dying of millions of AIDS victims. Furthermore, this campaign fell on fertile ground as the governments of industrialized countries were more and more anxious about the transborder spread of infectious diseases and the consequences for international security.

The norm 'access to essential medicines' has been diffused through many organizations and institutions and has been widely accepted in the course of time. There is both formal (or at least implicit) *acceptance* of the norm in state institutions (for example, WHO, World Bank, WTO), programmes (UNAIDS) and agreements (TRIPS) and also acceptance amongst non-state actors such as foundations and other civil society organizations. These non-state actors play an important role in the *implementation* of the access norm. Although state actors (G8 countries, US government (PEPFAR), some Southern countries) increased their efforts and spending to fight HIV/AIDS, foundations such as the Gates Foundation and the Clinton Foundation and many bigger and smaller CSOs are involved in the endeavours to provide access to medicines in poor countries.

Non-state actors are crucial at all stages in the process of building subsidiary norms. However, finally we have to ask whether we can generalize this case to other fields of social policy. Certainly, the case of HIV has a specific character, as the disaccord between the availability of drugs and the suffering of millions of AIDS victims is so obvious. However, this could be also said for the fight against hunger, as globally there are enough resources to end all starvation. We have to ask why scandalizing other dimensions of poverty like the lack of access to clean water and sanitation, chronic hunger and starvation, and so on, does not lead to such a great global awareness as in the case of access to medicines. One reason may be that the fight against one single disease such as HIV/AIDS and/or the focus on the medicines issue is much more concrete and tangible than fighting against poverty in general or against hunger in all poor countries. However, these are just preliminary

Table 6.1 Access to medicines: norm-building process and main norm carriers

Main type of norm carrier/stage of norm-building	**Civil society**	**Private for profit**	**Hybrid**	**State**
Norm generation	• Campaign for Access to essential medicines • Public debate			• Brazilian government conducts HIV and AIDS programme and argues for increased access
Norm diffusion and norm acceptance	• Campaign for access to essential medicines • Public debate		• Conflicts on TRIPS and IPRs: e.g. USA vs. Brazil inside WTO; debates within WTO, WIPO and WHO • WTO: TRIPS and Doha Declaration • WHO: IGWG	• Governments of Southern countries arguing for increased access • WHO, UNAIDS, World Bank and UNICEF arguing for increased access • Conflicts on TRIPS and IPRs; debates within WTO, WIPO and WHO WTO: TRIPS and Doha Declaration WHO: IGWG
Norm implementation	• Codices and guidelines for CSOs Distribution programmes • Continued attention and pressure of CSOs for norm implementation	• Codices and guidelines for companies • Accelerating access initiative • Donation programmes • Activities of Gates Foundation	• Global Fund to Fight HIV and AIDS, TB and Malaria GPPPs (R&D, funding) • 3 by 5 (initiated by WHO) Codices and guidelines for nation states, companies and CSOs • Clinton Foundation negotiates lower prices for ARVs	• Southern governments • Northern governments (funding and treatment programmes, bilateral ODA) • PEPFAR • Commitments of G8 • Activities of IGOs

Source: Compilation by the authors.

explanations. A comparative study of civil society activities and the constellations of interests in different fields of global social policy could be helpful to answer the question of different conditions and outcomes of ESCR norm-building. For the case of health, we can conclude that the densification of global social relations and the strengthening of global civil society, linked to a situation where instability in poor regions is perceived as an increasing threat to the security of 'the rich', have led to the establishment of a norm of helping the poor. This norm is still contested in its implementation, but it is widely accepted and cannot be denied.

Notes

1. This document is part of a series of comments by the CESCR called 'Substantive issues arising in the implementation of the International Covenant on Economic, Social and Cultural Rights' adopted since 1989, here 'General Comment No. 14' (document E/C.12/2000/4) (http://www.unhchr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En).
2. See, for instance, the WHO website at http://www.who.int/countries/en.
3. In addition to the International Covenant on Economic, Social and Cultural Rights, see the Convention on the Elimination of All Forms of Discrimination against Women (Articles 10, 12 and 14), the Convention on the Elimination of All Forms of Racial Discrimination (Art. 5) and the Convention on the Rights of the Child (Art. 24). In addition, Art. 35 of the Charter of Fundamental Rights of the European Union refers to the rights established by 'national laws and practices'. Furthermore, we find commitments by governments to improve human health in a number of declarations and Programmes of Action (Agenda 21, chapter 6, §§ 1 and 12; Cairo Programme of Action, Principle 8 and § 8.6; Copenhagen Declaration, Commitment 6; Beijing Declaration, §§ 17 and 30, Habitat Agenda §§ 36 and 128) and, of course, in the Millennium Declaration.
4. This refers to the role of the Westphalian Peace in 1648 in the development of a system of international relations between sovereign nation states.
5. David Fidler (2004; 2005) has thoroughly analysed 'Post-Westphalian Public Health' with respect to the global reaction to SARS and the revision of the International Health Regulations (IHR); he concludes that the new IHR constitute a shift towards 'an expanded governance strategy that integrates multiple threats, actors and objectives in a flexible, forward-looking and universal manner' (Fidler, 2005, p. 68).
6. MSF invested the money they received for winning the Nobel Price in 1999 for greater parts in this campaign.
7. Prominent examples are the conflicts concerning patents and drug prices in South Africa and Brazil (von Soest and Weinel, 2007; Calcagnotto, 2007; see also Hein, 2007).
8. Fifty-six per cent of these funds are provided for HIV/AIDS measures like prevention and treatment.
9. See http://www.gatesfoundation.org/nr/public/media/annualreports/annualreport06/R2006GrantsPaid.html.
10. The bilateral programme PEPFAR will provide US$15 billion to fight HIV/AIDS until 2009 (US$9 billion for new bilateral programmes in 14 African and Caribbean countries, US$5 billion for existing programmes in 75 countries

and US$1 billion for the Global Fund). In 2008 it was announced that another US$50 billion will be provided until 2013.

11. For a concise report on the links between intellectual property rights and access to medicines see the final report of the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH and WHO, 2006).
12. See various entries of the e-mail list ip-health; for example http://lists.essential.org/pipermail/ip-health/2007-January/010471.html.