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Global public action in health and pharmaceutical policies: politics and policy priorities

Meri Koivusalo* and Maureen Mackintosh**

Abstract

This paper analyses and discusses global public action in the context of global health policies. It discusses how public action on pharmaceuticals has influenced on the one hand global health, and on the other the institutional basis of global health governance. It argues that while nongovernmental public action has been effective in terms of influencing agenda-setting in global policies, its role in influencing solutions to the problems has been more limited. In contrast to trade policies, more substantial changes have taken place within global health policies and global health governance. Furthermore, some of the directions supported by global public action may not be conducive to the democratic accountability of global health governance, the wise use of public resources, health systems development, and longer term access to health care within developing countries. The scope for nongovernmental public action is further challenged by the changing context and commercialisation of global public action itself, whereby calls for access to medicines can also be seen as a means of demand creation for new and more expensive medicines in developed countries too, with further articulation of requests for more public funds in support of innovation and clinical trials to tackle the issue of lack of research and development (R&D).

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Introduction

The academic and policy analysis of global public action tends to be dominated by global campaigns and a focus on human rights, environmental and gender issues, with relatively less work on health policies, and even less on what have been the contents of health policies. The focus on health or social policies in global action is also dominated by a focus on access to medicines and on HIV/AIDS. The magnitude of the HIV/AIDS-related public health crisis makes this legitimate, but it does also create a vertical disease-based focus for the conceptualisation of global action for health. Furthermore, while there is some analysis of global health policy-making and the role of public action, this mostly relates to different power structures and actors. This implies that the *content of the politics* of global public action remain to a large extent left aside: implicit assumptions are often made that campaigning of nongovernmental organisations, and that other global public action on health is inherently based on the greater good, such as access to medicines or reduction of poverty.

In this paper, public action is discussed in relation to the *content* of policies promoted and the ways in which public action not only shapes, but also becomes shaped by different actors, ideas, institutions and interests at global level. The paper considers the extent to which *framing* of the issues, as part of the politics of global governance on trade and health has influenced 1) the *solutions* sought to the problems and 2) the understanding *of common and different interests across countries* and *across public and private sectors*. In particular, to what extent does the emphasis on different interests between countries contribute to undermining the more important conflicts of interests across commercial and public sectors? The second part of the paper focuses more on *the politics and policy priorities* of public action as participation itself is becoming commercialised and moulded by commercial interests. It is in this context that *challenging* the *content of policies* emerges as a necessity for global public action, asking what kind of pharmaceutical policies we want to promote and how these relate to institutional structure and policy priorities in health at both national and global levels?

The paper argues that at global level, public action has reached a stage where the content of policies needs to be tackled more explicitly and clearly. While the campaign on public health issues has generated a different, health-focussed emphasis in the trade debates, and has raised health concerns high up the political agenda of actors such as G8, this has also had repercussions on global health policy and health priorities. The paper thus asks to what extent the current

campaigning and processes are at a stage where discussion and debate on *common interests between countries, and on the global health governance and health policy priorities of global public action, needs to take place*?

Methods

This paper is based on five sources and types of material: the international literature in the field; documentation and formal materials and statements from different global policy actors; interviews with fifteen public action practitioners and five members of public administrations at global, regional and national level; and "grey" literature followed up on e-mail lists open to public in the field; and personal observation and participation in relevant processes, in particular, the WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property Rights.

Background

Global public action in relation to access to medicines has been analysed and reported in detail (see e.g. t'Hoen 2002; Sell 2005; Sell and Prakash 2004; Velasquez et al 2004; Bond 2005; Matthews 2006 and Matthews 2007). This literature has been based to a substantial extent on reports and interviews of those involved in activities, focusing on the field of trade policies and campaigning. It has contributed, in particular, to discussion of power relations between health and trade proponents, but has paid less attention to the content of global and national health policies. This focus on actors and process is been complemented by a literature on legal, human rights and policy aspects and issues, notably trade policy options and choices under negotiation, with a focus on substantive changes (e.g. Sun 2004; Cullet 2003; Matthews 2004).

At the same time there is a thinner literature on the content of global health polices, in terms of broader agendas and issues at stake (Thomas and Weber 2004, Kickbush 2000; Ollila 2005ab; Beigbeder 2005). Further analysis has been given to issues related to HIV/AIDS and to mobilisation and nongovernmental action in relation to HIV/AIDS (Seckinelgin 2002, 2006; Hein and Kohlmorgen 2008, Hein et al. 2007). An additional strand analyses the nature and role of public-private partnerships as part of global health governance (Buse and Walt 2000ab; Buse 2004, Buse and Harmer 2004; Buse and Harmer 2007), but considers in less depth how these may or may not have shaped the policy content and agendas. Attention has been given to the legitimacy and accountability of global public-private partnerships and nongovernmental action

(Doyle and Patel 2008). While concern over global PPP agendas in relation to intergovernmental organisations has been raised (Richter 2004; Ollila 2005b), this has not been dealt with in detail in relation to nongovernmental organisations and/or networks in this process, even though they have clearly played a role in articulating change.

This paper contributes to this gap in the literature by asking what is at stake in terms of *public health and global governance of health,* with a focus on the *health policy content* of nongovernmental public action. It thus discusses global public action and the politics and framing of global public action in the context of health policy consequences, and considers how the *intended and unintended consequences of public action* have shaped the institutional context and influenced the scope and nature of health-related policy-making at global level. It makes a case *why health policy and governance considerations should be moved up the agenda of global campaigning* and *why nongovernmental public action in health is facing new challenges as result of changing context of corporate strategies and influence.*

In early work on global governance and international relations, the emphasis on nongovernmental organisations has been seen as a challenge to the predominant analysis and focus on states and governments as primary actors (O'Brien et al 2000). This challenge is complemented, on the other hand, by analysis of transnational advocacy networks and more global or transnational approaches, and a focus on a variety of actors beyond nation states (Nelson 2003; Carpenter 2007; Joachim 2003). In this paper we take a more global or transnational approach as basis for analysis. The main questions are, *what kind of health policies are promoted at global level and how do global policies contribute to the sustainability and contents of health policies at national level*? Issues of accountability and legitimacy have been taken up in the context of analysis of global health policies (Doyle and Patel 2008). However, while aspects of accountability, legitimacy and representativeness arise in this paper, these are not our main focus in this study. This study is also not focussed on relationship between transnational advocacy networks and nongovernmental public action within countries or relationship across North and South. Our focus in contrast is more on *the content of global public action*; how nongovernmental campaigning relates to issues at stake in global health policies, the institutional structures and nature of global health governance; and in the context of current trends in nongovernmental public action, what are the likely challenges of this?

The conceptual analysis in this paper recognises health policies as part of public policies, and pharmaceutical policies as part of health policies. It is further grounded in the understanding that public policies can take place at different levels of governance, including local, national and global and that these, whether explicit or implicit, frame the overall framework of action. In this context the role and influence of nongovernmental public action is analysed both in relation to the *content of policies raised* as well as the *relationship of this to global health governance and global actors.*

The main scope of analysis of nongovernmental public action has traditionally been on nongovernmental non-profit organisations. Defining research scope in this way obscures a key theme of this paper: the impact of the corporate sector in changing the context and nature of public action. The recognition and more explicit involvement of the corporate sector as a member of civil society includes participation in hearings and consultations, financing of work in other organisations and membership of coalitions and alliances. This involvement forces and challenges those involved with public action to be increasingly clear about the policy implications of their suggestions and the purpose of the politics that occurs, including the ways in which different actors and interests gain voice and space in the public arenas.

THE IMPORTANCE OF FRAMING IN GLOBAL PUBLIC ACTION

In the literature on transnational activism and activist networks, Keck and Sikkink (1998) emphasise the role of framing in the context of public action. However. their analysis, like more traditional analysis of transnational advocacy, focuses more on environmental, women's groups and human rights activism, which by their nature differ from the context and actors involved in global health policy making. The particular framing of issues is of interest in the field of health since we do need to ask *to what extent common health policy interests have been strengthened, compromised or changed on the basis of the particular framing of the problems in the context of global public action.*

Two aspects of framing are explored here. First, framing is examined in relation to the *focus on developing countries* on TRIPS, intellectual property rights and patenting-related debates and conflicts in the sphere of health. Second, the paper asks how the focus on *particular diseases and*

issues, such as HIV/AIDS, tuberculosis and malaria and *access to medicines* have also framed - or contributed to the framing of - the global policy debates and global action in health.

The current campaigning on access to medicines does not arise merely from the dismal situation of access to medicines in many developing countries, or from policy lobbying of transnational networks, but is owed to three particular historical and political processes.

The first is the establishment of the essential drugs programme within the WHO and the evolution of pharmaceutical policies in the context of rational use of drugs and *WHO medicines strategy*. This stream was also present in the context of initial efforts to change South African pharmaceutical legislation (see e.g. Bond 1999): pressing for government policy efforts to enhance use of generic medicines and achieve lower prices of pharmaceuticals. While the global campaigning on the South African case emphasised access to HIV/AIDS drugs, the court case was first initiated by measures to tackle a broader pharmaceutical policy issue. The case thus fits more into the emphasis put on national pharmaceutical policies than into a focus on HIV/AIDS. It fits more within the broader concepts of essential drugs and rational use of medicines, which have been policies promoted by the World Health Organisation. Nongovernmental organisations with focus on consumer and pharmaceutical policies include Consumer project on technology, CPTECH[1], which has later become Knowledge Ecology International, KEI. Another well known international operator was Health Action International, supporting essential drugs policies and rational use of medicines. CPTECH was one of the global consumer organisations. HAI related to consumer organisations but had done more work in excluding bad drugs from markets and limiting inappropriate advertising practices, rather than calling for access to particular pharmaceuticals.

However, the court case about HIV/AIDS did provide an important framework for action. We can see this as the second stream of process and influence. It resulted from the increasing concerns over HIV/AIDS and the realisation of the magnitude of HIV/AIDS problems in the 1990s. South African action, through the activities of the Treatment Action Campaign contributed also independently to addressing the matter, because of the reluctance of the

[1] Consumer Project on Technology, was part of American consumer movement and thus part of global consumer movement and linkages which have been present through consumer activities and engagement with pharmaceutical policies. This has been, for example, mediated in the context of the discussions and role within Transatlantic Consumer Dialogue (TACD) between United States and European Community. Health Action International had also consumer links with Consumer International, whose Malaysian office served also as a contact point for Southern consumer movement activists, including linkages with Third World Network.

government to recognise the magnitude of the HIV/AIDS problem. The main emphasis of the second stream of nongovernmental organisations' activities operated, however, through the presence of global actors. In the 1990s the role of nongovernmental organisations as global and national actors was expanding, and became more prominent also in the context of aid policies. This was the case in particular in relation to emergency operations. There was an increasing and emerging role for new, more medically and health oriented service provider organisations, such as *Médecins Sans Frontières*, which was granted the Nobel Peace price in 1999. The medical concerns were related both to the lack of treatment options for HIV/AIDS and the lack of medicines to treat malaria and tuberculosis.

The third stream and background influence for the global context and campaigning has been the establishment of World Trade Organisation, and trade negotiations which led to the signing of the Agreement on trade-related aspects of intellectual property rights (TRIPS). Developing country governments soon became aware of the implications of the treaty for national pharmaceutical policies, local production of pharmaceuticals and issues related to local industry. This built a broader developing country interest on the matter, from an industrial policy perspective.

Concern over implications of intellectual property rights were first raised in the North by consumer organisations and think tanks, such as CPTECH, which addressed this broad area including copyrights. The legitimacy and presence of consumer representatives and networks in this context is clear, although it has in practice been dominated by North American expertise and initiatives. The scope and implications of intellectual property rights (IPRs) for pharmaceutical policies were raised first by American consumer activists in the early 1990s and were introduced to European networks later, in the mid-1990s (see also Sell and Prakash 2004; Sell 2004). The focus on new treatment options and access to new drugs fits more into the American context of health care, which has been more technology-centred and in which new medicines have been used, sought and marketed more actively than in, for example, many European countries. However, in practice activists in developing countries such as India may have been aware of the concerns over the IPR issue earlier than European actors, through global consumer, biodiversity and other trade-related linkages. The concern over intellectual property rights was thus not based

merely on North-South transfer of networks and influence, but also on South-South networks and exchange[2].

Setting the campaigning agenda

The content of campaigning thus draws on three different background contexts, each contributing to the global articulation of issues: 1) pharmaceutical policy and rational use of medicines; 2) medical action and development aid, and 3) legal and IPR-related consumer issues around access to new technology. Although the overall framework has evolved as interests involved with the campaigning have altered, these three main streams still dominate global action. A key moment in global - Northern - cooperation took place in a seminar organised by the BUKO, a German NGO and member of the Health Action International (HAI) network in 1996, an early forum for global campaigning. The BUKO meeting and seminar led to closer cooperation with pharmaceutical and consumer activists, and shortly with more medically and aid-oriented NGOs, such as *Médecins Sans Frontières* (MSF). The jointly organised Amsterdam meeting and Statement of the three main NGOs - HAI, CPTECH and MSF - established the initial platforms of global public action in this field. It also established a more dominant position for *Médecins Sans Frontières*, whose status and public profile was strengthened as result of the Nobel Peace prize and its close links with the French government and European Union's trade policies.

The Amsterdam Statement (1999) was focussed initially rather clearly and explicitly on trade issues. Many of these have remained on the agenda since then. The initial Amsterdam Statement included the following aims with respect to trade :

- Compulsory licensing of patents, as permitted under Article 31 of the TRIPS Agreement. The working group should look for ways to best operationalise this article.
- Allowing for exceptions to patent rights (under Article 30 of TRIPS) for production of medicines for export markets, when the medicine is exported to a country with a compulsory licence. This would ensure that countries with small domestic markets can benefit from compulsory licensing.
- Allowing for exceptions to patent rights (under Article 30 of TRIPS) for medical research, so that patents are not used to stop research and hamper the introduction of generic medicines.
- Avoiding overly restrictive and anti-competitive interpretations of TRIPS rules regarding protections of health registration data or other unnecessary regulatory barriers to competition.

[2] The role of early South-South cooperation was emphasised in the interviews of Indian activists.

- Avoiding restrictive interpretations of trademark rights on issues such as generic labelling and prescribing practices.
- Assessing the impact of inadequate reviews of patentability standards (novelty and usefulness) on access to medicines.
- Recommending differential rules for essential medicines, such as simplified and fast track compulsory licensing procedures.
- Examining new paradigms for intellectual property rights and health care, including "burden sharing" approaches for R&D that permit countries to consider a wider range of policy instruments to promote R&D.
- Assessing the practical burdens on poor countries of administrating patent systems and resolving disputes over rights.

It also had the following aims with respect to national governments' need to develop mechanisms to ensure funding for R&D for neglected diseases. As part of this new and innovative approaches to stimulating research in essential medicines were promoted, including**:**

- Increased public and donor funding of health care research:
- Compulsory research obligations, such as requirements that companies reinvest a percentage of pharmaceutical sales into R&D, either directly or through public or private sector R&D programs;
- Development of a "Neglected Disease Act" that could be used to stimulate private investment for communicable disease vaccines and medicines.

The initial call made was aiming at a standing WTO working group on access to medicines. However, the political agenda and trade policy emphasis of the Amsterdam Statement can be seen as setting NGO policy agenda within the context of broader pharmaceutical policy and trade issues. The articulation of measures related to Article 30 in TRIPS was important in the process prior to Doha, but was in practice dropped during post-Doha negotiations.

In terms of global action, the South African court case provided further linkages with active and internationally linked patient organisations, such as TAC, as well as with campaigning on access to medicines, while similar government efforts in Thailand in late 1990s were withdrawn.[3] It is important to note that the form of campaigning through "bilateral" global support of national struggles has remained an important part and was important in relation to the Gleevec-Novartis in India case as well as more recent campaigning and lobbying in relation to Thailand FTA negotiations and pharmaceutical policies (Ecks 2008; MSF 2006). This has been an important avenue in particular with respect to bilateral treaty negotiations and relates as well to the more traditional form of global public action with cooperation across countries on bilateral basis.

[3] This paragraph draws strongly from the interviews, document and campaigning materials of the nongovernmental organisations. This was complemented by checking the dates in publicly accessible email-lists.

It is clear that nongovernmental public actors, and in particular CPTECH and MSF, focus on particular policy measures and advice to governments, and have contributed to the ideas and contexts within which national governments act on these issues in both North and South. However, the issues were not only of interest to nongovernmental actors, so the stands taken by a Southern government cannot be directly attributed to nongovernmental public action. Other actors also pushed the issue up the global agenda. The role of civil society organisations should not be underestimated, acting as triggers and operating globally both directly, and indirectly through governments, and in particular developing country governments. However there has also been some critical assessment of their engagement, in particular in relation to the positions and policies of the developed countries in the field of trade policies, and the stated aims of campaigning in the North (Drezner 2005; Dur et al 2007).

The role of public action and governments in shaping the agenda

Developing country governments were highly concerned about the TRIPS agreement. They also raised early questions about medicines access within the WHO, leading to the compilation of a book on Globalisation and Access to Medicines (Velasquez and Boulet 1998). Nongovernmental public action was involved with writing a resolution, and notably with promotion of the still contested emphasis on primacy of health, in contrast to commercial interests (see e.g. Sell 2005; Sell 2004; t'Hoen 2001). However the issue was already taken seriously by many developing country governments, as the implications of WTO agreements for national pharmaceutical policies and local pharmaceutical industries begun unfold. It is in this context that analysis and networking *within* South was important, where analysis provided, for example, through the South Centre in Geneva, and analysis by academics such as Carlos Correa, contributed to the definition of problems and the scope of action. This exchange of ideas, including exchanges with generic pharmaceutical industry, took place in the South and between networks, well before the issue was raised prominently at global level[4].

The role of *Medécins Sans Frontières* was key in pushing the issue up the political agenda, given that both CPTECH and HAI were relatively weak actors in lobbying and policy influence in terms of public action visibility. While it is clear that CPTECH and HAI did influence policies and government substantive policy positions on these matters, the weight of these NGOs was

[4] Interviews in India with Indian activists identified these early concerns and exchanges over TRIPS before the "global" campaign, occurring already during the Uruguay Round negotiations. Some of these exchanges concerned in particular the fate of Indian generic medicines industry, South-South networking took thus place relatively early.

more in the field of policy advice and in joint campaigning, and less in independent publicity and media campaigning. In United States, action on HIV/AIDS seems to have gained substantial ground only when more activism-oriented groups started campaigning, with capacity to draw publicity and exert power through demonstrations on the matter. In Europe, this role was taken more by MSF whose global support and visibility had relevance also in relation of support to national struggles. The importance of TAC linking up with *Médecins sans Frontières* has been noted in analysis of the South African court case (Olesen 2006). However, the role of MSF was important also in raising the publicity threshold of the whole global campaigning on the matter, since the engagement of MSF strengthened the articulation of access to medicines as a leading emphasis, as well as a different level of lobbying and capacity to extend campaigns through national offices.

The shift of HIV/AIDS from a killer towards a chronic disease also implied a different framework for action, legitimating calls for access to medicines and treatment. The linkage with trade-related intellectual property rights was stronger in this case, since HIV/AIDS was *a global epidemic legitimating action* even in the context of narrow interpretations of TRIPS, and clauses in bilateral trade treaties limiting the scope for compulsory licensing. Secondly, HIV/AIDS medicines were new and still protected by intellectual property rights, with high prices of medicines beyond the purchasing capacities of developing countries. The HIV/AIDS framework therefore provided the necessary link between more general pharmaceutical policies, medical concerns and intellectual property rights, since there would not have been a good case for trade policy activism without the HIV/AIDS crisis. In the 1990s the emphasis on access to medicines in the context of TRIPS was therefore dominated by HIV/AIDS medicines. The Brazilian government decision to pay for treatment of HIV/AIDS was based on broader human rights-related legislation, although it has became best known in the context of the decision about the HIV/AIDS programme (see e.g. Hogerzeil 2006). While South African campaigning on HIV/AIDS had to deal also with the lack of, or failed, government action on HIV/AIDS, this was not the case in Brazil. The treatment programme in Brazil has functioned as an example of what could be possible, as well as bringing evidence on the magnitude of costs involved, both in terms of the overall programme and the savings from use of compulsory licensing (Nunn 2007).

In the context of global campaigning, access to medicines and HIV/AIDS provided a more easily addressed campaigning ground, since in practice campaigning about TRIPS Article 31f or 30 does not make sense beyond those committed to understanding legal trade policy detail.

However, it is also important to emphasise that from the public health perspective, the access to medicines issue was never clear cut. There were substantial concerns over implications of the use of new medicines in countries with a lack of adequate public health infrastructure. There were worries about overestimating the positive and underestimating the negative implications of expansion of treatment regimes in HIV/AIDS, when treatment had to be continuous, the probability of increasing resistance was high, and strong measures in prevention were equally necessary. In this context, nongovernmental organisations influenced the public health community and treatment options by introducing new fixed-dose proposals, lowering prices of medication, and expanding treatment through their own channels, and challenging international agencies to act (e.g. the WHO 3by5 commitment). It is also in this context that NGOs such as MSF, with links at country level, procured medicines themselves and created projects with local nongovernmental organisations, and could provide important and concrete examples for broader global campaigning. Furthermore, the linkage with nongovernmental public action often provided channels separate from governments which have not always been keen to take specific and comprehensive measures against HIV/AIDS.

However, while the scope and implications of increasing viral resistance have been long anticipated within public health circles, the financial and structural consequences for health systems of the strong global focus on HIV/AIDS without comparative focus to overall health systems strengthening were realised only later. Additional concern is emerging about the pricing of and access to second-line HIV/AIDS treatment. The initial measures to address HIV/AIDS treatment were countered by corporate programmes and voluntary donations both as means to provide access to treatment, and to make the case that the issue was not high prices of medicines, but other failures which could be remedied by further economic development and specific health financing. However, the long-term consequences of substantial and specific funding to HIV/AIDS, with the engagement of a plurality of providers and NGOs have become a growing concern within countries. In this context, particular attention has been drawn to the distribution by the pharmaceutical industry of a study by Attaran and Lee (2000) that argues that TRIPS is not a problem for access to HIV/AIDS medicines in developing countries (see e.g. t'Hoen 2001; Sell 2004). It is likely that corporate lobbying, and this line of argument, has *gained indirectly* from the broader public health-related concerns about medicines issues and appropriate policy approaches to tackle HIV/AIDS, including the sustainability and limited resources and capacities of health systems within many countries. The particular concern over lack of doctors in

developing countries has also gained publicity since the Global Fund has been driven to finance salaries, to avoid the risk of ending up with "medicines without doctors" (Ooms et al 2007).

The framing of the problem in terms of access to medicines, and in particular access to medicines for HIV/AIDS, malaria and tuberculosis, was not merely a result of public action, but also stemmed from the willingness of developed countries governments to see and present the issue *only as a problem of developing or poor countries* and *only of particular diseases*. Nongovernmental public action pushed for access to medicines and for R&D on neglected diseases in addition to the three diseases. However from the early stages of campaigning the main development organisations with most resources and scope for global action, such as MSF and OXFAM, have been bound to emphasise access to medicines *only* in developing countries, because of their status as development NGOs. In other words, nongovernmental organisations, such as Oxfam and MSF, have little to say about what we do with our health sector and pharmaceutical policies in the North.

However, as the NGOs were bound to emphasise the concern over access to medicines in developing countries, this opened up the scope for developed country governments and in particular actors, such as European Commission or G8, *to focus on this developmental problem through other means than trade-related measures*. It is in this context that global campaigning by development NGOs contributed to the shifts of funds within the global aid regime towards financing access to medicines for the three diseases, HIV/AIDS, TB and malaria, through the establishment of Global Fund and UNITAID. This emphasis can be seen as great support for developing country efforts to address the issues, since global action focuses on measures to address developing countries problems. However, this global focus of attention also contributed to the definition of the framework within which discussion, lobbying and global debate on health policies has since taken place.

THE POLITICS OF DEVELOPMENT

The answers that are sought for "development" problems tend to be different from those sought for global policy problems. This has implied in practice that while global public action has resulted in changes in aid policies, and in particular measures towards least developed countries, this has come as a further impediment for middle income countries. The latter are assumed to be

able to comply with the IPR regime without concessions, or have to cope with even stronger requirements established by bilateral agreements[5]. If the establishment of these global measures to address the problem of access to medicines is seen as part of response to the criticism of global standards on intellectual property rights, then this was at least a partial failure, since although access to medicines was enhanced through the new mechanisms, the global regulatory framework in relation to IPR has remained untouched.

On the other hand, if the success is measured by enhanced access, this was achieved by the new mechanisms as well as by increasing the role for generic medicines. It can also be argued that the process of global procurement policies and campaigning on the use of generic drugs did also result in strengthening the role of the WHO in the contested fields of prequalification of medicines producers and quality assurance of medicines, as well as creating scope for strengthening the global regulatory role of that organisation. Furthermore, legitimising issues and changing discourses are not quick, requiring years of work in articulating the problem and identifying implications and appropriate responses.

The role of developing countries governments has been important during the trade negotiations leading towards Doha. While nongovernmental public action was present and articulate before and during Doha, the agenda was also clearly set by the key developing country governments and their ability to provide a more unified front on the issue (see e.g. t'Hoen 2001). However, politics in Doha, and since Doha, have been characterised by efforts at splitting up the developing country front, and promoting a focus on least developed countries or "poor developing countries". This focus appears in the emphasis on countries with an absolute lack of production capacity, in the context of the so called Para. 6 solution and the required commitments of middle income countries that they would not use the mechanism (discussed further below).

The politics of splitting developing country block interests is an important part of pharmaceutical industry lobbying. It also helped to emphasise the irrelevance of TRIPS to access to medicines, since least developed countries are not required to comply with TRIPS. Commitments to address the crisis in countries where TRIPS is strictly speaking not directly relevant to access to medicines can be seen as a clear industry strategy, and has also been reflected in corporate

[5] There is currently ample literature on bilateral agreements and their relationship with TRIPS and so called TRIPS+ considerations (see e.g. Fink and Reichemiller 2005; Roffe and Spenneman 2004).

lobbying and action on the matter since Doha. Thus, in relation to the objectives of IPR policy, the campaign on access to medicines was vulnerable to political intervention that emphasised that access to medicines *in least developed countries* was the issue of most concern. This type of articulation also shifted the access to medicines issue from a *trade-related problem* to a *developmental* problem, to be dealt with through increasing allocation of resources through aid policies. This also occurred at the global level. It became clear that TRIPS had to be seen as the basic reference point, while increasing demands on developing countries shifted to bilateral and regional negotiations, which were more difficult to address through global campaigning measures.

The gains from the Doha process were clear in terms of interpretational issues, which remain of importance in the sphere of global policy-making. On the other hand, the role and relevance of the so called Para. 6 decision in Cancun[6], amended as part of the TRIPS agreement in Hong Kong in 2005, can be seen as something which offers defined benefits to the global pharmaceutical industry interests in the North. The predominant criticism of the Para. 6 solution has so far centred on complexity and lack of relevance to developing countries, which are at the core of the aims of the measures proposed. Relatively less attention has been paid to its *potential implications and benefits in relation to pharmaceutical policies in other countries*, nor to the extent to which it can be seen as a means to limit the scope and use of this mechanism in future by smaller middle income countries and developed countries, so as to counteract the impact and implications of extremely highly priced drugs for rare diseases or those tailored for a particular genetic profile. Through the definition and framing of the exception solely in the context of poor developing countries, it effectively denies the case that countries could seek compulsory licences for imports on the basis of economic reasons for products where prices are too high but consumption levels too low to legitimate starting of own production. In providing a definition and basis for legitimacy of compulsory licensing for imports, it can be argued that the exception also *makes it harder to seek compulsory licenses for import in the North.*

[6] The wording Para. 6 refers to the paragraph 6 in the Doha Declaration (2001) on public health, which recognises that countries with insufficient or no manufacturing capacities of pharmaceuticals, would face difficulties in making effective use of compulsory licensing under the TRIPS agreement and instructs Council of TRIPS to find an expeditious solution to this problem and to report to the general council before the end of 2002. The negotiations on the Para. 6 led to the acceptance of the proposal in Cancun and the consecutive integration of this measure to the TRIPS Agreement. The solution proposed, its feasibility and role as solution to the problems faced in low income countries has been a matter of strong debate since, which will be dealt with also in the later sections of this paper.

In this context of commercial policy benefits in terms of framing how compulsory licenses for imports are dealt with, it could also become more understandable that the European Commission so actively sought the inclusion of the mechanism in the TRIPS agreement, considering that before the Hong Kong Ministerial in 2005, no single country had done so, and the European Union was facing a hard time in pushing for legislation enabling this mechanism within Europe. In making this concession for the benefit of developing countries, the developed countries and middle income countries may thus have also approved a more explicit basis for compulsory licensing for import in the context of TRIPS. This limits in practice the scope for using this measure in middle income countries and developed countries, where issues such as tackling very expensive medicines for small patient groups through compulsory licensing, or recognising needs of small economies, were not considered.

While the impact on global trade policies has thus remained limited, the main global influence has been mediated by the global policies of aid.

DISEASE-BASED ACTION AND THE REVISITING OF VERTICAL PROGRAMMES CONCERNS

In relation to global health policies, an underlying debate has taken place with respect to so-called vertical and horizontal approaches to health and international health policies. The emphasis on vertical approaches originated from the global disease eradication programmes, which tackled particular diseases. The best known example in this era is the eradication of small-pox. However, the disease-based vertical programmes resulted in the general problems of lack of integration of services and "disease-silo" approaches, and in the case of malaria eradication were a major failure. The failure of the vertical programmes was an important reason for the WHO policy change in strategy and emphasis towards more horizontal issues, such as primary health care and health systems (Bryant 1988). The Alma Ata conference and launch of the primary health care approach were thus part of the response to failures of the vertical programmes. However, different approaches were also debated including so-called selective and comprehensive health-care models, the former being promoted by UNICEF and to some extent World Bank, and the latter by the WHO[7].

[7] In terms of discussions and debates on selective and comprehensive health care most of the discussions were held in the 1980s and early 1990s (Unger and Killingsworth 1986, Walsh and Warren 1979). In many ways the renewed

The focus on particular diseases became an issue again in the 1990s, as malaria programmes and the re-emergence of tuberculosis became a concern, and in particular in relation to HIV/AIDS. This global trend was also strengthened by the WHO Commission on Macroeconomics and Health, which recommended action on communicable diseases, while leaving treatment of non-communicable diseases out of the scope of global policies (Commission on Macroeconomics and Health 2001). The 1990s version of vertical programmes was a focus on the 'three diseases', that is: HIV/AIDS, malaria and tuberculosis. In the context of aid and international policies, HIV/AIDS had been the major concern; however, the plight of people with malaria and tuberculosis was difficult to ignore given high numbers of deaths, and in particular the effect of HIV/AIDS in contributing to the re-emergence of tuberculosis, where new resistant strains were also a concern. The United Nations declaration on HIV/AIDS in 2001 framed this action (UN 2001), but nongovernmental public action with a focus on the three diseases also contributed to the G8 commitments in the area, and to the decision to establish the Global Fund as a separate organisation.

While it is clear that essential health policy concerns should not be diverted by the debate on horizontal *or* vertical focus, there is a limit to disease-specific and disease-based activities in the context of overall health policy priority setting at national or even at global level. Allocating substantial amounts of funds and attention to single diseases creates *inequalities on the basis of diagnosis*. There are also well-known institutional and structural issues, as funds and efforts contributed to single disease-based activities and if this results in separate organisation and basis for work can also draw resources away from, rather than contribute to, the overall health system, or fragment the context of health policies and action. As the magnitude of HIV/AIDS funding within a country can be higher than the rest of national health budgets (Lewis 2005), the impact of vertical measures cannot be set aside merely by denouncing horizontal vs vertical issues as "theoretical disputes". Furthermore, if this new funding is channelled through predominantly nongovernmental actors and alternative providers rather than those operating on the basis of public funding, it is likely to have impact on human resources divisions and practice at country level. On the other hand, from the viewpoint of public action, there are also obvious reasons why a disease-based focus is often easier for global campaigning and action at global level as it leaves a more clearly defined field for lobbying and arguments on the basis of a more defined group and

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emphasis on single diseases approaches and cure rather than prevention were a return from the more medically and less public health driven era of global health policies before health for all policies (Koivusalo and Ollila 1997).

numbers. It also opens more concrete scope for cooperation with disease-based organisations and patient groups. A disease-based focus is beneficial for disease-based nongovernmental organisations and pressure groups, as their legitimacy is, by definition, based on particular diseases. This applies especially to patient groups, which can legitimately only represent interests of patients who have the disease.

The focus on a limited number of diseases has also served well the interests of the proponents of strong IPR protection, since it diverts the focus from all diseases to particular diseases - in WHO Intergovernmental Working Group (IGWG) language, those disproportionately affecting developing countries or with epidemic potential. On the other hand, in relation to IPRs, an emphasis on HIV/AIDS was necessary for global public action campaigns for the use of compulsory licensing. This was for three reasons: the *magnitude of the crisis demanding global action*; the development and existence of global *disease-specific solidarity and action groups and sense of common concern;* and the fact that it was the only disease of epidemic proportions that could *fit even into the narrowest interpretations of compulsory licensing and where patent-related pricing of drugs was easy and clear to present as a problem*.

The other side of the focus on HIV/AIDS was that money flowing to HIV/AIDS resulted in the creation of vertical programmes in practice, and hence a revisiting of the old and known problems of single disease emphasis. The issue was disseminated to a broader policy-making audience by Laurie Garrett's critical article arguing that "tide has not lifted all boats" (Garret 2007). The impacts of HIV/AIDS funding on other programmes have become a concern also in the evaluation of aid programmes (Management 2006). HIV/AIDS and the magnitude of funding of HIV/AIDS has also made it a major example of problems related to vertical programmes and focus (England 2008ab). It has also been articulated that in the context of overall resource needs and policy aims achieving universal treatment of HIV/AIDS and primary health care are complementary. It has been emphasised in this context that the allocation of additional resources through HIV/AIDS work and aims for universal access to HIV/AIDS treatment has contributed to the health systems functioning and emphasis of primary health care within countries (Yu et al 2008; Ooms 2008). However, it is clear that the relevance and importance of ensuring that health systems as a whole have sufficient human and financial resources to function and that disease-based programmes work within and contribute to the overall health system and population needs is a challenge, which risks undermining also the

longer-term viability and sustainability of these internationally funded disease-based programmes (see e.g. Oomann et al 2008).

On the other hand, all non-governmental organisations do not necessarily frame issues or aim for influence in terms of their particular focus, and indeed nongovernmental public action can be pursued - at least for some time or in relation to some issues - against what are understood as an organisations' particular main interests. One example of this is the Drugs for Neglected Diseases Initiative (DnDi), which focuses on neglected diseases, but has in practice, together with other public-private partnerships (PPPs) offered critical insights about the role and relevance of PPPs. While it cannot be assumed that specific groups or representatives of specific groups are concerned only about their particular interests, they do face constraints on how far they can extend their remit of representing particular disease-groups' interests and views. Otherwise questions will be raised, for example, about why HIV/AIDS patients should speak on behalf of other patient groups, if these can be heard directly. While broader support groups or campaign groups can expand their focus, this is not necessarily the case for patient groups. Thus in practice, disease-based patient groups have greater organisational pressures and thus likelihood to either deliberately or unintentionally end up supporting disease- and treatment-based approaches within global level health policies. On the other hand global NGOs can also be somewhat contradictory in their lobbying efforts: for example the MSF both emphasises that the focus should not be on particular diseases within the Intergovernmental Working Group (IGWG) process (MSF 2007; 2008), and promotes tuberculosis to be particularly addressed in this context (Gerhardsen 2007).

Nongovernmental public action continues to engage with support and argument for more broad-based health policies and health systems development. However the context for this is made difficult within the global debates on intellectual property rights (IPRs) because corporate actors choose to use health systems problems as part of their lobbying on IPRs and focus on disease-based initiatives and coalitions with "all stakeholders" to address particular issues with respect to neglected diseases or diseases that disproportionally affect poor in developing countries. This approach has been further reinforced by the donor community as well as the role of private foundations in global health, in particular, the Gates Foundation's emphasis on particular diseases and on technology-based solutions. The role of the Gates Foundation has been important in particular in malaria-related efforts and global action, to the extent that the WHO malaria department has reportedly raised concern over the growing dominance of malaria research by the

Gates Foundation, on the grounds that it risks stifling a diversity of views among scientists and wiping out the world health agency's policy-making function (McNeil 2008).

GLOBAL PUBLIC ACTION AND THE GLOBAL INSTITUTIONAL ARCHITECTURE AND GOVERNANCE

Nongovernmental public action has been important in global governance and in the ways in which 1) solutions have been sought to the problems identified and 2) institutional structures have been created and developed. Two types of action have been key: the *emerging emphasis on public-private partnerships* and the *role of new forums and coalitions, such as G8, in addressing and dealing with health policies and health policy concerns*. NGOs have contributed to the definition of *where and when global policies are made*. The emergence of the G8 as a forum for global pressure resulted as much from demonstrations against the G8 as from the lobbying of the G8; where, NGO public action on, in particular, debt and poverty campaigning has became important, especially Jubilee 2000 campaigns (Donnelly 2002). In this context, public action in general exerts more leverage than particular lobbying and actions on health issues. An assessment of the G8 health commitments and their realisation has been made elsewhere (Labonte et al. 2004); the main emphasis here is on the ways in which operation through the G8 influences the context and participants amongst whom decisions are made.

Although the formal decision was made in the WHO, the effective decision to finance the Global Fund was made in the context of G8 policies and actions (Kirton 2004). The paradox of this G8 role and nongovernmental public action is that, to a large extent, it occurred despite a focus of public action on opposing the G8 and on emphasising issues related to poverty and health systems in general. The establishment of the Global Fund outside from the UN family, as an independent organisation has, on the other hand, strengthened the emphasis on public-private partnerships and the increasing role of private sector in governance of global institutions. The G8 focus on novel innovative approaches may have in practice been less influenced by public action than by particular government policies and consultants, notably. in this case the United Kingdom Cabinet office project on Global Health. This project was also advised by Michael Kremer, known for his later promotion of Advance Market Commitments, by Glaxo-Smith Kline and the Brookings Institution amongst others. No participant from the key global public action groups was directly involved (PIU 2001).

The ways in which nongovernmental action has concentrated on making G8 accountable, have been influenced by close relationships amongst United States-based researchers, think tanks and corporations. Furthermore, perhaps the earliest United Nations announcement on global fund was made, not in a meeting with nongovernmental organisations, but with CEOs from major global pharmaceutical companies alongside UN, UNAIDS and WHO leaders (UN/UNAIDS/WHO 2001). The positions of nongovernmental organisations were in support of a fund with substantial resources. However, concerns with respect to industry vs consumer representation, focus, and the role of generic drugs, emerged in the early phase of planning and establishment of the Global Fund (Public Interest Organisations 2001; MSF 2001). In this light it is not clear to what extent the establishment of the Global Fund may have been oriented less towards addressing concerns of developing countries or calls by nongovernmental organisations than towards addressing the needs of the global pharmaceutical industry in a context of growing criticism of lack of access to medicines in developing countries.

However, while the Global Fund was promoted as a solution to global problems of access to medicines, the lack of focus on research and development remained an issue. The global archipelago of initiatives cannot, again, be seen as a direct result of public action campaigning, but rather, or also, as a result of problem management, industrial policy interests, and industry responses to the need to act on the matter. The actual configuration of many public-private-partnerships (PPPs) has been biased towards private sector representation in their governance (Buse and Harmer 2004; Ollila 2005). While it was hoped that private sector engagement would bring in more funds, the share of corporate sector funding, except for private foundations such as Gates Foundation, has been limited (Ollila 2005). Since NGOs have been part of public-private partnerships, and since they are often considered private in the context of PPPs, it has become difficult for NGOs to gain critical edge in relation to PPPs and product-development-partnerships (PDPs) or to the ways in which these shape and structure national and global health policy choices and options. The crucial challenge for nongovernmental public action is that it is difficult for nongovernmental actors to call for further participation and engagement in policy-making without allowing the presence of industry associations and actors in at the same time. Yet their presence has in practice provided further scope and legitimacy for corporate actors in global health policies, and in particular has influenced the regulatory scope and basis of these policies.

Thus, while the broader NGO community has been influential in raising the issues on the global agenda in terms of identifying problems, the *means and mechanisms* to address this have become dominated more by industry-friendly responses, influence and choices, particularly in the context of G8. The further paradox of NGO campaigning and focus has been that in this context public action has in practice contributed to the establishment and empowerment of the G8 policies and institutions outside the United Nations, rather than of United Nations institutions, contributing to a shift of decision-making and power away from bodies where developing countries have more leverage. Furthermore, the prominence of PPPs and related activities have legitimated the presence of corporate sector in the governance of institutions, which still remain predominantly publicly funded.

A development focus as means to limiting global regulatory measures

The focus on development opens up more scope for funds for global action as result of aid policies. However, the other side of the development emphasis within global institutions is the it's link to global institutional issues. The focus on developing countries implies not only preference for solidarity, but often, if not more importantly, a lack of focus on global regulatory issues and policy changes within developed countries.

One example can be drawn from the case of tobacco before the tobacco framework agreement. The tobacco industry has emphasised the importance of WHO development work in comparison to work on non-communicable diseases, where tobacco plays a more important role as a determinant of health, thus legitimating national and global regulatory action to address the public health issue. The tobacco industry emphasised the great public health problems in developing countries and suggested that the WHO was tinkering with health promotion (i.e. tobacco) and with issues related to non-communicable diseases and developed countries, rather than addressing the *real* health concerns of communicable diseases in developing countries. Braithwaite and Drahos in a study on global business regulation identify the problem of 'forum-shifting', especially in relation to diverting pharmaceutical policies away from the WHO or shifting IPR issues from UNESCO to WIPO (Drahos and Braithwaithe 2000).

One challenge around 'shifting' of decision forums relates as well to the role of G8, since it is unclear to what extent global public action in the area of health and medicines have opened up scope for further corporate lobbying in that arena. The extent to which G8 has become the medium, for example, to progress the anti-counterfeiting treaty and enforcement of intellectual

property rights, as well as promoting intellectual property rights as the backbone of innovation, were on the agenda of the G8 under the theme of innovation (Heiligendam 2007). The G8 is a particularly relevant forum for industry interests since it strengthens the role of countries and actors with prominent R&D pharmaceutical and biotechnology industry interests, such as United States, United Kingdom, Germany, France, European Commission and Japan, which are all represented within the G8. Furthermore, when G8 decisions have been made, these can and do emerge within European Union or OECD policies, potentially tying other countries into decisions that these countries have not been able to influence initially, but then have to take up or join in with later.

Another key concern is policy coherence, and the relative roles and mandates of different international organisations. The shift of health-related IPR issues from the WHO to the WTO or WIPO is part of broader politics and "forum shifting", whereby issues are shifted to the organisations where influential actors assume they will gain greatest returns. This applies also to the ways in which developed countries have sought to diminish the WHO role on health-related IPR issues, calling for the WHO to "stick to its mandate" (European Union 2007). On the other hand, the rather sad paradox of the WHO role in defining the content of new policies and IPR issues is that some IPR issues seem to be taken further in WTO or WIPO policies than in the WHO. This can be explained by the magnitude of lobbying, and the presence of the pharmaceutical industry within WHO as the dominating industry interest, but also by the nature of the negotiation process within WHO. IPR-related matters, including health-related IPR issues, are in practice often delegated from Ministries of Health to Ministries of Trade and Industry or related persons in the missions in Geneva, which set the tune on the matter. As a result, the IPR and health-related stands are dominated by IPR concerns rather than health concerns, in particular amongst the developed countries and in particular on matters which are not assumed to apply to national health policies within developed countries.

Policy solutions and global nongovernmental public action

The nature and emphasis of solutions and policies sought through the influence of global public action is of importance also in itself. It is known that nongovernmental public action has the capacity to raise issues to intergovernmental organisations' agenda. Nongovernmental public action has contributed to raising issues related to IPRs onto the global policy agenda in the WHO and has influenced decisions made in the context of the WTO. In the WHO, one example is the early WHO resolution on medicines (WHO/EB 1998), which at that time was set in the context

of a revised drug strategy. Perhaps the most heavily contested paragraph of the proposed Executive Board resolution asked the Member States 'to ensure that public health rather than commercial interests have primacy in pharmaceutical and health policies and to review their options under the Agreement on Trade Related Aspects of Intellectual Property Rights to safeguard access to essential drugs' (WHO/EB 1998). Another resolution in which the interests of nongovernmental public action were taken on board was the Kenya-Brazil proposed resolution in 2006 (WHO/EB 2006), which contributed to the basis for the negotiations of the WHO IGWG process and the global plan of action.

However, while nongovernmental organisations have been active in getting issues onto the agenda, their capacities to influence action has been more limited, with stronger influence from corporate or more corporate-friendly priorities. The solutions sought to address problems of both lack of access and lack of R&D can be divided in four different categories, with focus either on access to medicines, R&D incentives or both:

1) Voluntary efforts and engagement by corporations (donations, differential pricing, PPPs and PDPs)
2) Channelling additional public funds (PPPs, PDPs, Global Fund)
3) New financing mechanisms and incentives for research (UNITAID, AMCs)
4) Regulatory measures (Doha declaration, Para 6 solution, WHO IGWG working group, ACTA)

Voluntary measures

The emphasis and implementation of the first set of voluntary measures can be seen as an immediate reaction by industry and as part of their efforts to keep the issue out of the WTO or WHO framework. This was predominant in the aftermath of the South African court case, as donations and other avenues to supply HIV/AIDS drugs were sought through different types of initiatives and partnerships. Voluntary measures were also important in the activities concerning differential pricing. This was first brought up in the WTO and at the WHO Hosbjorn meeting organised in Norway in 2001 together with Norwegian Ministry of Foreign Affairs and the Global Health Council. The European Commission actually took this initiative furthest, and got through a formal measure giving support to voluntary measures (European Council 2003). This however never attracted substantial numbers of companies to contribute, as by 2007 the list of products seems to cover only HIV/AIDS products of one company (Glaxo-Smith Kline)

(European Commission 2007). The cooperation with and emphasis on voluntary measures has also been an important aspect of public-private partnerships, coalitions and product-development-partnerships. These are another element of voluntary measures, which continue and are frequently rearticulated in the context of the large amount of charitable work, donations and other related activities in which the pharmaceutical industry is involved.

Drug donations have been a particularly problematic aspect of these voluntary measures, since in practice, longer term efforts towards rational use of medicines have tried hard to limit this activity; these efforts include the development of WHO Guidelines on drug donations (Hogerzeil 1997). This has been an area where nongovernmental consumer organisations, such as the Health Action International, has been active and together with other nongovernmental organisations not only lobbied WHO, but as well amongst other NGOs. The emphasis on access to medicines has unfortunately also opened up further scope for industry to argue in support of drug donations as at least a partial solution to the problem. Another aspect of this issue is the extent to which practicing corporate charity can, from the commercial policy and public relations point of view, be more rewarding for the company than voluntary licensing or other measures. This would also contribute to the keeping of the price levels uniformly higher across countries for medicines, whose consumption levels in low-income countries remain low in comparison to developed and middle-income countries (see e.g. Ecks 2008).

Channelling additional public funds

The second line of approach is channelling of further public funds, as the solution to both access to medicines and lack of innovation. The industry has proposed a complementary global fund for R&D. This emphasis on global funds evolved in the late 1990s, but gained most prominence in 2001, when the Global Fund to fight AIDS, tuberculosis and malaria was established through decisions in WHO, United Nations special session on HIV/AIDS and G8. There were institutional peculiarities of this initiative, since the United States contributed to the establishment of the Global Fund, but it withdrew from it and established PEPFAR. While important changes have taken place concerning the criteria for pharmaceuticals that could be purchased by these organisations, it is clear that the operations of Global Fund and PEPFAR do not affect major industry interests in developed countries to any large extent.

In public-private partnerships and in particular in product-development partnerships, corporate participation can also take place through in-house resources, whereby public financing can in

effect be used as sponsorship for private research. While it can be argued that this is legitimate action in order to meet the desired ends, in this context the *form of support is more public sponsorship of research and development*. The role of financing by private foundations also further complicates any assessments of public-private partnerships. There is a need adequately to distinguish non-profit and for-profit efforts in public-private partnerships and product-development partnerships.

New Incentive mechanisms for research and development

The channelling of further funds through new or emerging incentive mechanisms has been the dominating feature of the UNITAID[8], which utilises genuinely novel types of measures to cover the costs. However, while UNITAID and the International Finance Facility for Immunization[9] (IFFIm) both raise more funds in support of access, the Advance Market Commitments (AMC)[10] initiatives create more industry-friendly incentives for financing of research. The AMCs rely more on utilising existing public funds rather than new and additional forms of financing, such as the UNITAID initiative. The new more corporate friendly incentive schemes promoted in this context include also measures such as the United States priority review vouchers (FDA 2008); proposals within the European Union for accelerated action to use patent extensions (European Commission 2005); patent buy outs and "wild-cards" as incentives for research and development and also support for clinical trials (see e.g. European Commission 2001; 2005).

The Knowledge Ecology International[11] (KEI, before Consumer Project on Technology) promotion of an R&D Treaty by nongovernmental organisations has been perhaps the most

[8] On the basis of website information on UNITAID: In 2006, France, Brazil, Chile, Norway and the United Kingdom decided to create an international drug purchase facility called UNITAID to be financed with sustainable, predictable resources. As an economically neutral tool the tax on air tickets was considered as the most suitable instrument. It is financed primarily from the proceeds of a solidarity tax on airline tickets which ensures a steady flow of contributions. The revenue generated from the tax is also a truly additional, new source of funds for global public health. (UNITAID 2009)

[9] On the basis of information on the website: The International Finance Facility for Immunisation was launched in 2006 thanks to the initiative of the United Kingdom Government. IFFIm is also supported by France, Italy, Spain, Sweden, Norway and South Africa who have together pledged to contribute US$ 5.3 billion to IFFIm over 20 years. IFFim raises finance by issuing bonds in the capital markets and so converts the long-term government pledges into immediately available cash resources. The long-term government pledges will be used to repay the IFFim bonds. (IFFim 2009)

[10] Advance Market Commitments are currently promoted through an initiative on vaccines under GAVI Alliance, the Global Alliance for Vaccines and Immunization. On the basis of the website on AMCs for vaccines: Advance Market Commitments (AMCs) are a new approach to public health funding designed to stimulate the development and manufacture of vaccines for developing countries. Donors commit money to guarantee the price of vaccines once they have been developed, thus creating the potential for a viable future market. (AMC 2009).

[11] KEI is thus a follow up organisation of the Consumer Project on Technology, which has been part of international consumer movement, but KEI has as an organisation a more independent and research and think-tank type of organisational presence. CPTECH and KEI have become of global knowledge as well through the maintenance of listserves, such as IP-Health.

controversial agenda setting exercise, although it has not been realised as envisaged. While part of the initial purpose of the Kenya/Brazil proposed resolution in the WHO was to gain consideration of the R&D Treaty on the WHO agenda, with focus on new incentive mechanisms, any discussion of the Treaty or even related proposals in the context of the WHO faced substantial opposition from the developed countries. This opposition was such that even the main NGO lobbying by KEI shifted its focus in part to setting out the benefits of prize funds, rather than arguing predominantly for the proposed treaty. The problem with this process and with the WHO IGWG negotiation was that the particular treaty proposal and its merits, faults and feasibility effectively influenced other negotiations concerning any new incentive mechanisms for R&D on the basis of health needs, or any measures that could have been moving towards a Treaty (e.g. a declaration as one of the final products of the IGWG negotiation process). Yet the process of the IGWG negotiation in relation to the strategy was very detailed and became closer to negotiation of a treaty than a strategy. While specific proposals are often welcomed, the very specificity of the proposed agenda also limited the scope for a genuine process on the matter.

The proposals closest to broad global approval are prize funds, which have been proposed by Knowledge Ecology International (KEI) in particular (see Love and Hubbard 2007). These were also promoted in the context of the IGWG through Member States and the so-called 2B2 (Barbados/Bolivia) proposal made to the IGWG[12]. Prize funds have important elements, and could offer substantial potential to address current problems in the incentive system for R&D in specific diseases or problems. However the crucial question is, under what kind of overall context would these operate? Prize funds separate financing from the pricing of products. In contrast to the more traditional use of grants and direct support of R&D on the basis of bids and proposals this assumes that R&D takes place in organisations that can afford to invest on R&D. We can question whether NGO lobbying is tending to enhance these new mechanisms with forms of financing that take the commercialisation of R&D as a basis and overarching framework. This questioning applies, for example, to the extent to which open/competitive licensing policies are part of the proposals or not (Love 2008)? The thrust of this lobbying may undermine acceptance of the benefits and potential of simpler forms of public financing of R&D and of market-based competitive production of medicines, through the emphasis on different forms and varieties of new market-oriented incentives, initiatives and funds. Furthermore, there are emerging trends to further commercialise R&D within universities following the path taken

[12] On lobbying in IGWG and the particular proposals presented see compiled documentation on the Knowledge Ecology International website : http://www.keionline.org/index.php?option=com_content&task=view&id=3&Itemid=1

in the United States Bayh-Dole Act, in spite of a lack of evidence of benefits of doing so (So et al. 2008).

The challenge for public action is thus to ensure that the means promoted on the one hand do respond to the problems at stake, and on the other, that the mechanisms sought do not take commercialisation of R&D for granted.

Regulatory measures

In the World Trade Organisation, the Doha declaration on public health has been important since it confirmed the right of countries to use compulsory licensing, and provided grounds for clarification of differences between use and a more restricted practice of "emergency" use of compulsory licensing. Doha, in making agreed text more explicit, ensured interpretation on the basis of public health priorities. However, this interpretational focus is likely to remain a challenge in relation to data exclusivity requirements and data protection as required in TRIPS, as well as what are understood by research and regulatory exceptions, which were, for example, all discussed in the context of the recent IGWG process.

The only actual addition to the TRIPS agreement that has been made in the Doha process is the addition of the so-called Para. 6 changes to enable importation of pharmaceuticals under compulsory licensing. The initial reactions from the 14 key nongovernmental organisations describe the "gift" for the poor countries as wrapped in red tape (Joint NGO statement 2003). The para 6 solution has been considered as "the solution" for the issues in the context of trade. Together with amendment of the TRIPS agreement this is, as discussed before, relevant to the industry interests. The analysis of the role of NGOs in European Commission trade policies has provided rather sombre account of the limited scope and influence on Commission trade policy stands, with reference to "inclusion without influence" (Dur and De Bievre 2007). On the other hand this does not seem to be the case with respect to commercial interests as the leaked European Commission positions in the World Health Assembly negotiations on resolution 59.24 were shown to be almost identical to the pharmaceutical industry briefing document and guidance on the matter (Balasubramaniam 2007).

Matthews (2006) has analysed the importance of international NGOs for developing countries in terms of advice and broader views, drawing attention to the complexity of issues and difficulties of NGOs in keeping up with the agendas being dealt with in different places. In health it is clear

that there are limits to this capacity within NGOs, while there is increasing capacity to tackle the matter amongst larger developing countries themselves. To a large extent the public action campaigning globally has been heavily dependent on CPTECH/KEI, MSF and South Centre capacities and expertise alongside key researchers and analysts, such as Correa, Reichman and Abbott. However, sufficient articulation and understanding of relationships between IPR and health may not be merely a problem for developing countries. The *lack of capacity - or interest - to address health policy concerns in health-related IPR matters*, for example, was found also in the IGWG process within developed countries, where the capacities to put forward trade and industrial policy interests were far stronger than the capacity to represent health-related interests in IPR-issues. The role and focus of many European countries also reflected the fact IPR-related health policy concerns were considered merely as a development issues, and thus not of great relevance to their own countries' interests which were represented by diplomats in the missions rather than by anyone with pharmaceutical or research policy expertise.

While nongovernmental public action initiatives have challenged the context of global rule-setting, this context is increasingly modified to fit the interests of key pharmaceutical industry actors. The initiatives and key roles of US-based actors, such as KEI, tend also to reflect the relatively more commercialised, medicalized and new technologies-oriented health system within the United States than in many other countries. The risk of the failure of IGWG negotiations in the context of the WHO were not only that it would result in no action, but that it would result in an actual *backward movement* in terms of broader health and global regulatory policies in the field of pharmaceuticals and research and development.

Furthermore, in contrast to the initial fears that the WHO would impose regulatory action on global pharmaceutical policies in ways, which could interfere with commercial rights, intellectual property protection and other privileges, the issue of agreement on counterfeiting was taken into the context of IGWG, where it was used as part of negotiation leverage across countries. Measures with respect to counterfeiting, and addressing this through legislative action, has become one of the most controversial agendas because of the close connection to the negotiation of the anti-counterfeiting treaty (ACTA). The latter has been raised as the means to implement enforcement of intellectual property rights, seen as an upward ratchet by which intellectual property rights strengthen IPR protection, and undermine rather than support health concerns with respect to IPRs (see e.g. Sell 2008).

The issue of counterfeit drugs has gained huge attention and has played a major role in the campaigning in favour of ACTA, despite the knowledge that developing countries' major concerns are about substandard drugs rather than counterfeit drugs (Caudron et al. 2008). While the extent and nature of counterfeited products in medicines remains debated, it is clear that the current agenda on counterfeiting and measures suggested are not primarily driven by public health needs, but arise from industrial and commercial policy priorities within developed countries. It is also clear that counterfeited products are and are likely to be most pressing problem where regulatory capacities remain weak as is the case in lower income countries. The high profitability of counterfeited drugs also derives from the large price difference between price and actual production costs. While public action operators have tried to tackle the matter both in terms of process (secrecy) and contents (generic medicines and parallel importing) (see e.g. KEI 2008), the lack of openness in the negotiation process has limited participation of non-profit public action.

The global regulatory sphere is the arena where global corporate actors have substantial interests, and thus the difficulties and strong influencing pressures within the WHO in this sphere are not exceptional. On the other hand, this also reflects the balance of power between commercial policy and health policy priorities within nation states. The danger is that trade policy debates and emphases are merely shifted to the WHO, without a focus on health-related issues and potential conflicts of interests across health and trade policies within countries.

ACCESS TO MEDICINES AND THE CHANGING CONTEXT OF GLOBAL NONGOVERNMENTAL PUBLIC ACTION

The political strength of the access to medicines agenda in relation to health policy is perhaps greatest in the articulation of universal rights to access to treatment and care across countries. However, these rights have become constrained by the focus on particular diseases and treatment options, and also reflected in the broader failures of health systems. While global public action on access to medicines may have won the argument for decency of access to medicines and about the lack of research and development on, in particular, neglected diseases, it is however in danger of losing the war, because of the increasing commercialisation not only of the solutions, but also of the whole context and purpose of global nongovernmental public action.

Many NGOs have to focus on developing countries, since their legitimacy as global actors is based on their work on development. However, emphasis on access to medicines can be seen more as a political choice. In arguing for increased access to medicines, the older agenda of essential medicines campaigning which emphasised not only access, but also rational use of medicines, has slowly become constrained, if not in danger of being abandoned, as access and R&D issues are increasingly addressed through channels other than medicines policy.

This can be seen to result from *three reasons* First, industry-speak and emphasis on failures of health systems have been used as counter arguments, with the consequence that raising health system failure in the context of access to medicines runs the risk of allying with or being associated with "anti-access" industry arguments. Second, there has been a decline in public concern and voice about public health issues such as antibiotic resistance or inappropriate use of medicines. And third, there has been a major change in the actors and groups that were lobbying on the matter, through the engagement of patient organisations and development NGOs.

However, these effects of outside constraints have opened up within global public action and civil society lobbying new ground for consideration of a new phase of global health politics. The access to medicines agenda as part of global politics has slowly become at risk of transformation into an agenda about access to information in the context of direct-to-consumer advertising for new products, and articulation in favour of access to new health products and technologies in general. The shift avoids the questions, why prices remain so high and whether alternative means than pharmaceuticals could deliver the same results more effectively? The calls for access to medicines and *right of access* can in this context become transformed into a *means of demand creation for new and more expensive pharmaceutical products*, which might not otherwise be easily included as part of vaccination or other national health programmes.

The role of patients' and disease-based organisations in this demand creation is particularly important, and must be grasped within the context of global politics, policy aims and constituents. Many patient organisations in the developing world and in particular in relation to HIV/AIDS at national level policies do raise their critical voices on prices, and have been crucial as pressure groups in the South (e.g. South Africa, India, Thailand). However it is striking that the same critical emphasis is increasingly missing in the Northern patient organisations' voices, whether involved in diseases other than HIV/AIDS or in the context of international organisations of patients more generally. Furthermore, while the role of consumer organisations

has been of long-term importance in the pharmaceutical debates (e.g. CPTEH/KEI and HAI), the emergence of the international patient organisations' lobbying, such as the large International Association of Patients Organisations (IAPO) presence in the WHO IGWG working group, has been much more recent and has predominantly emphasised pharmaceutical industry positions and, allegedly, financing (e.g. Essential Action 2007; 2008; Herxheimer 2003).

While Northern patient organisations have become increasingly industry-oriented, consumer organisations have become the main critical reference group on industry endeavours both at regional and global level. This split is clearly visible in the context of IPR-related matters, but has emerged also in the context of European Union politics about direct-to-consumer advertising (DTC). While some patient organisations have been keen to support moves towards the controversial proposals to permit direct-to-consumer advertising, in the name of "access to information", the European consumer organisations' representative BEUC has made it clear that it supports more information for patients from independent sources rather than expanding the right of corporations to provide this material (BEUC 2007).

The activities of industry-funded NGOs and movements portraying themselves as NGOs are widespread in the United States, where a specific description, "astro turf" organisations, has been applied to them. Earlier "astro-turf" engagement of a pharmaceutical company in promotion of access to hepatitis-C vaccine was reported by the Washington Post in 2000 (O'Harrow 2000). In Europe, concern over Patient Forum's financing and background has been raised, as many of the patient groups have gained substantial funding from industry (HAI 2005). The European Union has also initiated a process of registration of NGOs, in order to enhance clarity on the matter, although it has not so far been very effective in health and patient organisations. While all patient organisations receiving industry funds cannot be seen merely as industry mouthpieces, the close relationship and magnitude of funding from pharmaceutical industry is a concern.

In Brazil, where national legislation on rights to access to medicines enables litigation on an individual basis, there has been increasing concern about the nature of litigation on access to medicines. Da Silva and Terrazas (2008), for example, in their study on litigation on right to health, conclude about the expected mobilisation of civil society that "this seems to be rather a strategy of the pharmaceutical industry, to take advantage of the large number of judicial decisions granting individuals a right to receive expensive medicines this industry produces". This conclusion is supported by a recent litigation against laboratories of Abbott, Novartis,

Serono, Wyeth and the firm Benatti on the basis of a letter sent by two citizens, who identified themselves as former employees of Wyeth (Jurbergl 2008).

The practice of demand creation is of importance in three contexts. First, the *focus on pharmaceuticals as a solution to all health concerns and in relation to broader public health policies* is a problem. If the health concerns focus on access to new pharmaceuticals and technologies, this easily becomes a key defining term for quality of health service. Second, that focus also increases the extent to which *citizen demands on access to new technologies and information on these become key issues in public action*, in comparison to other issues such as essential drugs policies, information and emphasis on appropriate use of pharmaceuticals and regulatory measures on pricing, quality and information on drugs. Third, *it creates channels for purely commercially funded articulation of demand and rights to access, which looks like public action but serves more commercial purposes*, where national governments and regulatory authorities become representatives of the bad and ugly, restricting rights to access and denying patients from life-saving treatments.

The politics of commercialisation of public action were clearly visible in the context of the WHO intergovernmental working group, where patient organisations were represented in large numbers. The first public reflection of this was a *Lancet* letter, expressing concern about the financial background of many of the patient representatives (Wilpulpolprasert et al. 2007). An analysis of the background of the first WHO public hearing contributors was also made by one of the nongovernmental organisations (Essential Action 2007). The activities however increased in the context of the actual IGWG meetings, where numbers of patient organisation and industry representatives far outweighed the numbers of NGOs traditionally involved with the matter at global level. A website on patients and patents (patientsandpatents.com) hosts a patient declaration in support of pharmaceutical industry-compatible stands. It states that "*other groups, however well intentioned, do not speak on behalf of patients*", and illustrates this type of activities, notably since the website also publicises text critical to the task and focus of the WHO Intergovernmental Working Group (IGWG) (Patient declaration 2008). The funding of the maintenance of the website, and its links with industry, are not made clear, although it is acknowledged that industry has supported a meeting prior to the World Health Assembly as it *shares the same stakeholder views* (Patients speak out 2008). According to a study by Essential Action, itself a nongovernmental organisation, the organisation *Patients and Patents* and key

individuals behind the organisation and the respective Patient Declaration had direct or indirect ties to the brand-name drug industry (Essential Action 2008).

This type of concern and presence implies that a number of patient organisations are willing to cooperate or speak on behalf of industry by articulating needs for particular new treatments and arguing for their own role as *the representatives of patients' voice central to all action*. Among the WHO IGWG civil society participants, the greatest numbers of "civil society" representatives were from IFPMA (International Federations of Pharmaceutical Manufacturers Associations) and representatives of patient organisations through IAPO (International Association of Patients Organisations). IAPO is over 90 percent industry funded and has a substantial basis in North America and Canada. Another example of more corporate-friendly presence is the ways in which the IPN (the International Policy Network) has presented itself as the voice of "the" civil society during World Health Assembly 2006 and in the context of the IGWG process. In practice IPN represents different conservative or free market-oriented think tanks and networks. This type of activities blur the notion of "civil society", which is important on the one hand in influencing delegations and, on the other, in distracting from any scope for more collective action within the civil society, thus weakening the basis in NGO cooperation for their argumentation and presence.

While attention has been drawn to the ways in which NGOs can act as watch-dogs for government stands, and that these deliver what has been promised, we should also note that in practice the same applies to industry representatives within global negotiations. In the context of health-related IPR negotiations in the WHO IGWG process, this was clear in relation to industry representatives and their "watch" with respect to actions and positions of trade and IPR representatives within the delegations.

In the current context questions need to be raised as to what extent *corporate contamination of global public participation* is leading towards more industry-friendly policies, in terms of policy substance and options within the emphasis on access to medicines. This may have the effect at the same time of challenging and discrediting the role of those nongovernmental organisations, which have in different forms been jointly campaigning on the matter since the 1990s. This effect requires nongovernmental public action to consider and seek alliances outside corporate-driven public-private partnership coalitions and frameworks. One area and issue which could be explored is *the scope of common interests within health and pharmaceutical policies as part of public policies in North and South*. While non-governmental public action has so far emphasised

the interests of South against those of the North, the focus might need to be taken more strongly back to the emphasis of *health policy interests against corporate interests* and the role of public policies in North *and* South.

CONCLUSIONS

This paper analyses the relationship between global campaigning on access to medicines and the ways in which this has become reflected in the changing contents and context of global governance and within global health policies. These are not merely theoretical concerns, but are relevant to the ways in which resource allocation and national health policies are structured, as well as how boundaries between global and national level action are defined. These are not necessarily primary "consequences" of global nongovernmental public action, but neither are they irrelevant to policies promoted through global public action. As global efforts to address the lack of access to medicines have become identified predominantly with the sphere of health and development policies, this has had positive impacts in terms of access to medicines in particular with respect to HIV/AIDS medicines, but also negative repercussions in terms of sustainability, global governance, organisation and overall balance of resourcing within health systems.

The emphasis on access to medicines as a development issue has also however served the core interests of industry better than it has served the health interests of the developing world. Furthermore, in the context of development aid and financing, there is increasing concern over pressures for (mis)allocation of aid funds as public subsidies to commercial R&D. Yet it has to be recognised that without public financing and global support, it is unlikely that R&D will focus on conditions and diseases of particular concern for developing countries.

The context of global policy-making and the presence of disease-based campaigning is not unproblematic in the sphere of health services and health systems. After ten years of focus particularly on HIV/AIDS, the broader context of health systems and the creation of specific channels for financing and delivery of HIV/AIDS treatment has become a real issue of concern in many countries. The presence and active engagement of patient organisations has also opened scope for further commercialisation and the creation of the organisational basis for increased demand for new pharmaceuticals through corporate financing.

The progress on normative issues or trade policies has been at best meagre, with scope for backward movement in the context of the para 6 solution at Doha, and increasing agendas of strengthening and these and expanding data exclusivity in the context of counterfeiting and bilateral treaties in particular with middle-income countries. Progress has been limited in part because of stronger politics and policy priorities in support of corporate agendas and of the tightening of intellectual property rights protection amongst developed countries. However, this could also imply that it is unlikely that a more sustainable change can take place without tackling issues as more *systemic in nature, and as related to conflicting interests across commercial and health policy promoters, rather than as particular issues that relate only to the developing world*. The conflicting priorities between commercial and health policy interests in pharmaceuticals are emerging slowly in developed countries as costs of medicines are becoming harder to bear, but are likely to become more pronounced also amongst middle-income countries, where particular industrial and innovation policy interests may more easily be imposed upon governments as core national interests associated with attracting foreign direct investment, leading to further undermining of national policy space within national polities.

In this context, identification of common interests across countries in health policies and their relationship to commercial policies and policy priorities is of interest. It is also in this context that a shift from disease-based towards public or health policy-based campaigning could take place, emphasising that pharmaceutical policies form part of broader health policies. This would also allow a higher profile for rational and appropriate use of medicines within a broader set of health policy options and choices beyond pharmaceutical or vaccine based solutions.

The challenge for nongovernmental public action is to be able to tackle the commercialising context of public participation and to see the broader health policy implications of various initiatives and actions. While disease-based and case-based studies are necessary and important in making issues concrete, the increasing challenge for nongovernmental public action lies in how it relates to public policies and responsibilities for health and regulatory action at both national and global levels.

While nongovernmental public action has been crucial in bringing up issues related to essential medicines, human rights and in particular access to medicines, there is an increasing need to recognise the broader public policy context in the field, as well as to tackle pressures of commercialisation of the very process and priorities of nongovernmental public action itself at

regional and global level. Global public action also needs to be set in the context of global and national democratic accountability, governance and longer-term sustainability. The more explicit expression and articulation of common health policy interests across countries, and analysis of the means and efforts to enhance access to medicines as part of broader national health and industrial policy strategies measures, could be an essential part of this process.

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