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Abstract

Global pharmaceutical policies are currently dominated by debates on access to medicines and in support of research and development for neglected diseases in developing countries. This paper argues that, between 'North' and 'South', there are more common health interests in pharmaceutical policies, within broader global public policies, than are currently articulated. Moreover, the current global policy focus may as well undermine the importance of these common health policy interests as well as conflicts of interest between health policy interests and corporate interests at international and national level in both developing and high income countries. The divisions concerning global regulatory issues and intellectual property rights do not fall neatly between rich and poor countries. Rather, they cut across corporate and commercial policy interests, and health and pharmaceutical policy interests within countries, and concern global regulatory processes and the interface between commercial policies and health policy. The issues of concern include pricing of and access to medicines, but also the broader public health issues of rational use or medicines and appropriate incentives for research and development so as to guarantee research efforts on key health policy areas as well as support access to knowledge and data. There is a danger that, if common health policy interests and concerns are not better understood and more strongly articulated, then global policy making on access to medicines and support for R&D will become increasingly guided by commercial policy priorities across countries. This can not only undermine effective global public health policies as well as reduce policy space for health and pharmaceutical policies at national level.

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1. Background

The global debates on pharmaceutical policies, and in particular on intellectual property rights (IPRs) and medicines, have been dominated by the topics of access to medicines in developing countries and the lack of resources for research and development (R&D) on tropical and neglected diseases. This focus of attention, while crucially important in gaining further resources in support of both research and development and access to medicines for particular diseases such as HIV/AIDS, malaria and tuberculosis, has however distracted attention from the potential common and more systemic health policy interests in pharmaceutical policies that are shared across countries. How far and how long can the current narrow policy focus be sustained without further compromising pharmaceutical and health policy interests that form part of broader public policies? And how can the concerns of middle-income countries, and the changing disease profile within lower income countries, come to influence the context and the nature of the current global discourse.

I argue in this paper that there are more common interests across countries in health and pharmaceutical policies than the current global policy processes indicate. Rich countries, in particular United States and the European Union, have failed to recognise and act upon these shared interests. In the World Health Organisation (WHO), two intergovernmental negotiation processes seen their health policy agenda diverted as a result of debate on intellectual property rights policies.

The health policy negotiations of the International Working Group on Public Health, Innovation and Intellectual Property Rights (IGWG) were influenced by efforts to limit the focus of the work to a small number of diseases in poor countries, and to limit the role of WHO in dealing with health-related aspects of intellectual property rights (Koivusalo and Mackintosh 2009). The International Meeting on Pandemic Influenza Preparedness, Sharing of Viruses and Access to Vaccines and other benefits (IGM-PIP) gained agreement on virus-sharing but much less movement on ensuring that products developed on the basis of these shared viruses would be available for those in need.

In both of the negotiations, deep divisions were created between poor and middle-income countries and rich countries. In both negotiations rich countries initially blamed others for

efforts to compromise intellectual property rights. In response, there is questioning of the extent to which rich country efforts to safeguard industrial priorities and IPRs may be compromising shared health policy concerns under the auspices of the World Health Organisation (WHO), as well as the ways in which the imposition of IPR enforcement concerns on health policies under the heading of action on counterfeiting in various fora (see e.g. Sell 2008ab).

The global context of pharmaceutical policies, and in particular access to medicines, has been strongly divided and dominated by trade disputes. This paper argues that if health and medicines policy concerns were put at the core of global policy concerns, many more common interests would become evident. Furthermore, it is possible that a more permanent solution or basis for global action on access to medicines can only be sought through recognition of the common and more systemic interests in health across countries.

2. Global pharmaceutical policies

National pharmaceutical policies, including essential drugs policies, are not a new idea. In the early 1990s they formed part of broader global support to countries' health policies in the context of WHO technical cooperation. Essential drugs policies were initially more focussed on developed countries, but issues common to all countries have been reflected in the WHO work. This includes medicines policies and rational use of medicines; the WHO support for national drugs policies; WHO setting of norms and standards; and its quality assurance efforts and work on supply and procurement as well as the recent WHO/HAI work on medicines prices. However, WHO activities in this area remain contested, facing continuous if not increasing efforts to shift global regulatory activity towards the International Conference on Harmonisation (ICH). ICH is driven more by corporate interests, but is treated as an important international player, for example in the new European Commission communication on pharmaceuticals (European Commission 2008a) as part of the recently approved pharmaceutical package (European Commission 2008a-d). While the OECD tends to be considered as a more corporate friendly alternative to WHO, the OECD work on pharmaceutical policies and pricing has also challenged industry interests in the recent analysis on global pharmaceutical markets (OECD 2008).

The WHO Commission on Public Health, Innovation and Intellectual Property Rights focused, in particular, on diseases more prevalent in developing countries (WHO 2006). Global policies

in pharmaceuticals have shifted major resources towards pharmaceuticals purchase and access to medicines in low income countries for HIV/AIDS, tuberculosis and malaria. Health and pharmaceuticals related trade policy issues form a part of broader global policies on health, but so far the emphasis has been on gathering new resources to fund pharmaceuticals through mechanisms and institutions such as the Global Fund, UNITAID and GAVI, to promote access to medicines and to create new measures to finance R&D for vaccines and medicines for neglected tropical diseases. These new means of support have been influenced by G8 negotiations, as well as civil society campaigning (Koivusalo and Mackintosh 2009). Public-private partnerships have increased in influence both within both global financing and policy development, and corporate actors are included as key stakeholders. Corporate representation has been greater in the governance of public-private partnerships than their share in financing would indicate as well as in contrast to under representation of global regulatory authorities such as WHO (see e.g. Buse and Harmer 2007; 2004; Richter 2004). Some of the most recent estimates of the role of for-profit sector in R&D for a number of neglected diseases put it at less than 10% of the global financing of R&D (Moran et al. 2009). This raises questions about the extent to which for-profit corporate presence in governance of allocation of financing for R&D should be taken for granted as appropriate.

As part of global pharmaceutical policies measures to support innovation for health entails conflicts of interest which are likely to be sharper between health policy and commercial policy priorities than between rich and poor countries. At national and global level innovation policies and their promotion as such often serve as a medium for the articulation of industry-driven policies. The purpose of this paper is thus to dissect and discuss the extent of common interests within health policy, where health and commercial policy priorities conflict, and to identify cases where common interests are emerging within the broader national and global policy arena and agenda.

3. Defining common interests in pharmaceutical policies

The idea of common health and pharmaceutical policy interests is reflected, for example, in the essential medicines debates within the WHO. While essential medicines were initially articulated at global level only in the context of developing countries, the emphasis on price and clinical value have become increasingly important in many other countries' policies even

though those priorities may not be articulated under an 'essential medicines' rubric. However, particular concerns and issues in each country are dependent on the disease profile and health system within that country, as well as the role of both research-based and generic pharmaceutical industries within the national economy.

In the context of broader global policies an indicative list of twelve common pharmaceutical policy concerns across countries can be established[1]:

1) *Safety, efficacy and cost-effectiveness* of *existing products on the market,* quality assurance and regulatory action on substandard products.

This is the basic regulatory task for governments and requires sufficient capacity for supervision and focus. WHO programmes and activities that relate to these tasks include, for example, the pre-qualification of manufacturers, the programme of work on good manufacturing practice as well as work on quality assurance. At national level, these activities would include measures to define the national list of essential drugs, and decisions about which medicines are reimbursed as part of national health programmes, where these apply to products already on the market. The basic regulatory capacity covering existing products on the market is central to battling substandard medicines and counterfeiting, since majority of problems with substandard medicines that occur in developing countries, where this problem is most serious, concern "genuine" medicines of poor quality (Caudron et al 2008). These health concerns are sharply different from the corporate concerns related to trademarks and patent infringements that currently drive the focus on measures related to counterfeiting. (Sell 2008ab)

2) *Safety, efficacy and cost-effectiveness* of *new* products, quality assurance and regulatory action on substandard *new* products.

The second common interest applies to measures concerning the approval process of new drugs. It covers new treatments, as well as any specific measures that would apply to approval or licensing process with respect to specific life-threatening conditions, measures in terms of epidemics and pandemics, and also the extent to which any other assessments or international requirements are applied or required at national level. This would cover the measures

[1] This list is at the moment indicative and not necessarily an exhaustive list of necessary items.

concerning granting of data exclusivity and if so the length of exclusivity that can be granted to products to enhance the position of the licensed product in the given markets. It covers as well the policy choices of utilising or not utilising any other measures to enhance exclusivity, such as patent-linkages, extensions or measures to recoup time spent in approval processes in the form of additional exclusivity. While many of these issues have become substance of trade agreements at bilateral level (see e.g. Finch and Reichenmiller 2005; Roffe and Spenneman 2006), they remain essentially part of pharmaceutical policies due to implications to pricing of products and access to medicines. The use of cost-effectiveness analysis gives a regulator scope to assess the clinical value of new drugs in comparison to those already in the market enhancing potential for value-based pricing. The scope for addressing this issue has been taken up in particular in the recent OECD assessment on pricing policies in a global market (OECD 2008). The potential of value-based pricing has also drawn interest as part of broader context of incentives to research and development (Baker 2003; 2008; Jayadev and Stiglitz 2008).The emphasis on safety, efficacy and cost-effectiveness of new products includes as well measures to define whether newly approved products should be included in the national list of essential or reimbursed drugs.

3) Ensuring *equitable access and pricing* of pharmaceuticals to consumers, so that ability to pay does not hinder access to necessary treatment. This can be done through different mechanisms, including reimbursement practices, insurance or institutional involvement in distribution of pharmaceuticals.

This task covers the establishment of mechanisms, for example, of reimbursement, distribution or social or private insurance systems, so as to ensure affordability of pharmaceuticals to individuals. The main costs of pharmaceuticals should not be not paid out-of-pocket by those who are ill since this leads to poverty through sales of assets or indebtedness. In many countries, different systems addressing this issue are already at place, but in many low income countries, where people can least afford charges when ill, out-of-pocket payments are the only means of access to most medicines. In addition to pricing, a crucial aspect of this task is to ensure the availability of and access to medicines in rural and more remote areas. Public pharmaceutical policies also have the responsibility for ensuring that the financing of pharmaceuticals is not regressive, with the poorest paying proportionately more, and that reimbursement and insurance policy practices do not create further inequities. Priority in action and in ensuring access should be given to access to drugs included in the national list of

essential drugs or approved by other means of assessing clinical value and cost-effectiveness of the products.

4) *Affordability,* ensuring that pharmaceutical and vaccine prices are affordable for the purchasers and those who need them, taking into account the overall resources available for health policy within the region or country.

This is a separate issue from ensuring equitable access and pricing covering measures to ensure that medicines, vaccines and diagnostic technologies are affordable for the level of purchasing power of the country or region. The issue is thus the purchasing power of national health systems and national and regional governments. This covers sound procurement practices, including, where appropriate, pooled purchasing or procurement of sufficiently large quantities so as to take benefit from purchases of scale. Furthermore, it covers the use of competitive measures, including, where necessary, compulsory licensing, to ensure that pricing of the products is at the level that can be met within national policies. National insurance or reimbursement strategies address the problem at the level of individuals, but do not solve the issue of affordability at national level. Further measures relate to the assessment of the cost-effectiveness of new drugs, as well as to the ways in which doctors prescribe and use different types of treatments. The issues of affordability thus concern national/regional aspects of pricing policies, the overall patterns of use and prescription of medicines as well as other mechanisms that are available through public policies, such as enhancing competition, entry and use of generic products. The task of ensuring affordability includes as well measures with respect to local or government production, to ensure availability of essential pharmaceutical products such as vaccines.

5) *Guiding R&D investments on the basis of health needs*.

This task covers all measures responding to public health needs in research and development and ensuring that sufficient research and development efforts focus on diseases and problems that are relevant to health and health policy priorities, and in particular those of countries and groups with lack of purchasing power.

It has been argued that the more uncertain terrain of antibiotics as well as the shorter course treatments such as those for TB do not offer sufficient financial incentives for commercial

R&D (Wenzel 2004; Norrby 2005). This is an example of an emerging global and national debate, as disease profiles and treatment practices vary across countries. At global level this is of particular importance for diseases that are prevalent only in developing countries or endemic amongst poorer groups within societies. It is reflected at global level in the broader discussion on neglected tropical diseases and was also raised in the report of the WHO Commission on Public Health, Innovation and Intellectual Property (WHO 2006). However, the issue is not merely that of patching up failures of market forces. Everything that is commercially viable may not be sound public health practice. For example, while research and product development for enhancing the capacities of healthy people might be a lucrative commercial strategy, it is not focussed on what is *necessary* from a health policy perspective. Another problem area relates to the extent to which marketing and advertising costs are built into prices of medicines in the name of incentives for R&D or as part of research. There has, for example, been criticism of so called 'seeding trials', which are phase IV clinical trials geared more to serve marketing priorities (Hill et al. 2008).

6) Ensuring *sustainable availability of affordable and effective products,* in particular, ensuring availability of necessary products irrespective of profitability of production. Vaccines are particularly important under this heading.

Some old and widely used remedies remain good and appropriate for use. Yet the essential process of ensuring that production of cheap and solid older products remains sustainable faces an incentive problem: it may be undermined by the higher profit expectations of newer products. Vaccines are a key example, since continuity of vaccine production has been a recurrent problem due to heavy concentration in production. Measures to ensure sustainable and timely production are also central to responses to epidemics: for example, in ensuring sufficient availability of products in the case of a pandemic. In this sphere all options, including non-profit, government production and wider licensing of commercial production should be considered as potential avenues. Global or regional measures and cooperation might be necessary with respect to very rare diseases and conditions, and in relation to needs of smaller countries and economies.

7) Regulatory measures to *prohibit misuse and limit inappropriate use of products,* including regulatory measures concerning sale and distribution of pharmaceuticals and

operation and guidance given in pharmacies, dispensaries and related facilities for selling or distributing medicines.

Pharmaceutical policies are not only about access to medicines, but also about ensuring that products are used appropriately. This is of crucial importance, since some medicines are simply dangerous if not used correctly and others can have dangerous interactions with other medicines. Inappropriate use is likely to increase risk of bacterial and viral resistance, an issue which is gaining increasing attention. There are also particular issues with respect to misuse or overuse of some pharmaceutical products. Oversight in relation to use, toxicity, environmental contamination and resistance has to cover both human and agricultural use of medicines, as medicines such as antibiotics and hormones are also used in agriculture and animal husbandry, Regulatory measures in this field cover both the knowledge gathering and oversight on indications of misuse or inappropriate use, follow up and measures in relation to the status of resistance. It also covers measures with respect to sale and distribution of medicines and guidance on their use, so as to limit misuse and inappropriate use (e.g. delivery of prescription medicine without prescription; delivery of medicines in portions without guidance on use, storage and last selling date; use and sale of old medicines).

8) Regulatory measures to *ensure appropriate use and marketing* of pharmaceuticals and *oversight* on advertising, marketing practices and influence on prescription and distribution practices; and on appropriate management of pharmaceutical waste and unused pharmaceuticals.

It is meaningful to separate efforts to prohibit and limit inappropriate use from regulation of measures claimed to enhance appropriate use, in particular, measures related to marketing and advertising practices for medical doctors and consumers. This covers the use of medication according to specified indications and measures that inappropriately aim to expand indications, lengthen time of use or otherwise inappropriately broaden the use of the products (for example, ‘disease mongering’) (Moynihan, Heath and Henry 2002; Moynihan and Henry 2006). Limitation of direct-to-consumer advertising to non-prescription medicines is part of this task, as well as oversight of advertising and promotion medicines. Many countries also lack oversight of distribution practices and quality of information and advice in dispensaries and pharmacies, which could enhance appropriate use, and where inadequate or failing efforts contribute to misuse and inappropriate use of products.

9) *Ethical regulatory issues* in pharmaceutical policy and in R&D of pharmaceuticals, including clinical trials.

As clinical trials are increasingly emerging as a global industry and research is also shifting in countries with less regulatory capacity new issues and concerns emerge in the regulatory front (see e.g. Glickman et al 2009; Rowland 2004; Petryna 2007). There is already basis for global guidance in the field as provided by WHO on good clinical practice, WHO/CIOMS, the Helsinki Declaration, and more industry-based guidance by ICH. However, the changing context of clinical trials is likely to require further regulation of those aspects more vulnerable to commercial pressures and priorities.

CIOMS is the Council for International Organisations of Medical Sciences, which together with the WHO has made International Ethical Guidelines for Biomedical Research Involving Human Subjects. The Helsinki Declaration is a policy statement by the World Medical Association, which was first adopted in 1964 and last amended in 2008 (WMA 2009). WHO has enhanced transparency of clinical trials through establishment of a clinical trials registry platform (WHO 2009). The establishment of the International Conference on Harmonisation Good Clinical Practice guidelines in the 1990s was seen as 'forum shifting' to an industry-friendly institution by key countries and the pharmaceutical industry. ICH-GCP guidelines have been harmonised in Japan, European Communities and United States resulting in widely used ICH-GCP standards. However, as a global standard these are limited by the limited number of stakeholders and the key role of International Federation of Pharmaceutical Manufacturers Associations (IFPMA) in ICH. The United States 2008 substitution of compliance with ICH-GCP guidelines for required compliance with the Helsinki Declaration was seen problematic in the light of the globalizing nature of clinical research (Kimmelman, Weijer and Meslin 2009). The ICH guidelines have also been criticised as potentially impeding rather than facilitating research (Grimes, Hubacher, Nanda et al 2005).

Current debate focuses also on how clinical trials are undertaken and how results are reported, including so called ghost-writing practices (Ross et al. 2008), where corporate funded professional writers write up articles formally authored by academics or medical doctors. Ethical regulatory issues also include whether comparison is made with the best available

treatment and whether a new trial needs to be done when generic products are brought to the market. Commercialisation and outsourcing of clinical trials to corporate research organisations raise new ethical dilemmas, since there are conflicts of interests in cases where the organisation undertaking the trial is more likely to gain financially from positive results of the trial, for example, in terms of undertaking an advertising campaign.

10) ***Public policies in support of innovation and research and development in the field of health and related sciences.*** **The areas that affect pharmaceutical policies cover research and development measures and policies; research on pharmaceutical use; ensuring R&D on areas with less ability to exert leverage; and also policies and measures to assess value for money of different types of incentives and mechanisms.**

This is currently an important field in health and in pharmaceutical policies, and of particular importance due to the limited clinical value of the current incremental nature of innovation in medicines, while R&D costs are rising rapidly. Although questions have been raised with respect to the basis of these calculations, this is a feature which is indirectly recognised in the context of recent assessments of pharmaceutical industry and pricing (see e.g. CBO 2006, OECD 2008). There is a common health interest in this field to ensure that public support to R&D is based on sound policies and that it contributes to health priorities. It is also important to ensure that national, regional or global support to R&D efforts do not end up merely as public subsidies for commercial firms, in particular as many of them are already investing more in marketing than research. Another related task as part of sound use of public funds is to ensure that research is not paid for twice, first through increasing direct support to R&D and then additional support through intellectual property rights and application of market exclusivity. This is of particular importance because of the high costs of marketing in the field often exceeding R&D spending as well as financial implications from the delay of the entry of generic products to the markets (see e.g. Gagnon and Lexchin 2008; European Commission 2008e).

11) ***Access to information and data*** **on clinical trials, including negative clinical trials, so as to enable further research and appropriate evaluation and decision-making concerning both clinical benefits as well as potential areas of concern.**

The WHO IGWG process drew global attention to this matter in relation to the legitimacy of the use of regulatory exception in TRIPS. The Vioxx case is an example of the failure to assess the risks appropriately (see e.g. Topol 2004; Law 2006). Data on clinical trials has to be available for research purposes beyond the regulatory administration, so as to ensure that indications of potential problems are considered early. This includes possibilities of utilising legitimate means and mechanisms available including, for example, licensing requirements for publicly funded research as well as the utilisation of the regulatory exception in TRIPS Agreement.

12) Ensuring basis and resources for *the establishment of consumer rights and policies* in the field of health products and pharmaceuticals

It is important that global action and representation of the global pharmaceutical industry be balanced by that of consumers and by independent sources of research, information and guidance. Mechanisms to enhance and financially support this are available. This applies also to good pharmacy practice and what kind of knowledge and guidance consumers should expect from the personnel of dispensaries and pharmacies for the appropriate use of the medicine. The lack of appropriate consumer guidance is a very severe issue in low income developing countries (see e.g. Mujinja 2008). However it has also recently been emphasised in a WHICH (consumer organisation) study of pharmacies in the United Kingdom (Which 2008).

4. Relevance of common interests in pharmaceutical policies

This list is based on the normative assumption that pharmaceutical policies are considered to be integral to broader *health policies*, so health policy concerns are assumed to dominate pharmaceutical policies. This assumption derives global support from a WHO resolution 51.19 on revised drug strategy (WHA 1999). Health policy priorities are not necessarily equal to use of highest medical technologies or newest medicines. Health policy may thus not prioritise or be equivalent to the use of the highest level of technology, newest products or the attainment of the highest possible level of all quality indicators, for example in bioavailability, of products in use. Health policy frameworks must take into account a broader array of considerations, including overall costs and access to the treatment in question. Furthermore, it is usually not desirable to expand the use of new products extremely fast, because of the unknown profile of

side-effects; often rapid diffusion is done more for commercial interest rather than to respond to health needs. While there are exceptions in relation to life-threatening diseases with no other comparable cure these cases form a rather small group of diseases and conditions. Finally, health policy priorities and their relevance differ across countries, in relation to existing practices and cultural priorities. However, the emphasis here is on potential shared health policy concerns.

The list of common interests above has been compiled on the basis of existing writing and materials on national pharmaceutical policies available in international literature as well as global documents on essential drugs policies and medicines policies within the WHO, which are to a large extent available from the WHO website (www.who.int); omissions or mistakes remain those of the authors of this working paper. The list is also an indicative list presenting a perspective from which common interests across countries can be identified and further analysed.

The emphasis in the list is on health policy as opposed to merely medical benefits or evidence. This emphasis highlights the need to take seriously *costs, clinical value* and *rational use* of health products, as part of an overall health policy framework. Pharmaceuticals are paid for either predominantly by the public sector; or through social or private insurance; or directly by those who are ill. Social and compulsory private insurance, where they have a universal basis, do function to redistribute risk between the ill and the well, and, in the case of social insurance, may redistribute resources vertically or at least be distributionally neutral. In OECD countries pharmaceuticals are mostly paid by public sector reimbursement, by insurance or through other arrangements that limit direct costs to individuals at the point of use. Pharmaceutical costs and in particular costs of new products represent a major concern for cost containment in health also within OECD countries (OECD 2005; OECD 2008).

The emphasis on health and public policy as a starting point also cast further light on industry fears of compulsory licensing. In the context of health priorities, compulsory licensing is likely to affect a small minority of pharmaceuticals, where real innovations with clinical relevance and value have taken place. Global campaigning and emphasis on dangers of compulsory licensing have contributed to an impression that great innovations are flowing down the pipelines, when in practice substantial share of corporate innovation is focussed on

pharmaceuticals that are not worthy of compulsory licensing efforts. An OECD study on global pharmaceutical markets argues:

> "As is true in other industries, most pharmaceutical innovation has been incremental rather than radical. Most such innovation has little or no added therapeutic value over existing treatments" (OECD 2008, p12)

Health policy priorities and requirements are separate from commercial priorities and based on different rationale. For example, health policy aims and priorities would imply that, *the better and the more clinically effective a new drug is in comparison to existing treatments, the cheaper it should be so as to allow the broadest possible use*. This applies as well to incentives with respect to the use compulsory licensing so as to ensure availability and affordability of medicines. There are thus more health policy incentives to use compulsory licensing and pricing policies to ensure access to effective and innovative medicines in comparison to so called me-too products providing little added clinical value in comparison to products already on the market.

Pharmaceutical industry and pharmaceutical policy priorities have also come under increasing criticism during recent years in the high income countries (see e.g. Angell, 2004; Law 2006; Abrahams 2002a). Their concerns are shaped by availability of more resources, but are not fundamentally different from those of the developing world, and in particular concerns within middle income countries. A recent OECD study on pharmaceutical pricing and global markets concurs that access to medicines remains an issue within OECD countries (OECD 2008). The issues and concerns of the rich countries are not distinct from those of poorer countries. However, in practice the politics and policy stances of the rich countries in global forums tend to reflect the concerns of the global pharmaceutical industry, and to focus on poor or low income countries in trade debates to the exclusion of middle income countries's interests and even those of lower income pharmaceutical producing countries, such as India.

If we accept that there are common interests in pharmaceutical policies in health and pricing policies between rich countries and developing countries, then we should also consider whether there are common health policy interests in relation to innovation and policies on protection of intellectual property rights (IPRs). IPRs are currently considered an important means of ensuring investment in R&D in pharmaceuticals, and considered central to policies for

enhancing "innovation". In the commercial sector decisions do not need to be health needs driven, but can and do respond more to expected markets and profit margins. This has implications for health policies across the globe. It is also in this context that particular common health policy interests can be envisaged across countries. In the next section the interface - and conflicts - between industrial and health policy interests are discussed in more detail.

5. The interface between industrial and health policy interests

Pharmaceutical policy issues have always been a contested area in global politics. The establishment of the essential drugs programme within WHO was a hard won battle in the 1980s. As part of global health policies, rational use of medicines, securing supply of medicines, and maintaining regulatory capacities and scope for pharmaceutical policies are at the forefront of the issues that need to be tackled. However, they have been sidelined within global debates, which have focused on addressing issues within developing countries or in relation to particular diseases, such as HIV/AIDS, malaria and tuberculosis and neglected and endemic diseases in developing countries.

The European Union and the United States sought to transfer issues from the WHO towards the International Conference on Harmonisation (ICH), which was more industry driven and indeed, has its secretariat with International Federation of Pharmaceutical Industry Associations (IFPMA). Braithwaithe and Drahos (1999) have drawn attention to this as an example of so called "forum shopping", where issues are shifted to be dealt with on forums where best results can be achieved for powerful actors. The role of ICH is again at the forefront of the new European Commission pharmaceutical package, in the context of strengthening transatlantic cooperation (European Commission 2008). The division between industry and health interests was reflected strongly in the recent Intergovernmental Working Group on Public Health, Innovation and Intellectual Property Rights, where even the WHO role on pharmaceutical policy or pricing issues remained strongly debated and contested.

At the same time, global pharmaceutical industry promotional practices, policy influence and protection of pharmaceutical monopoly rights have become a target of increasing attention and extensive criticism, from health polic commentators and those worried that current mechanisms

in support of innovation may fail to contribute to essential health priorities (see e.g. Angell 2004; Law 2006; Avorn 2005; Goozner 2004; Kassirer 2005; Henry and Lexchin 2002; Abrahams 2002; Morgan, Barer and Evans 2000; Baker 2004; Jayadev and Stiglitz 2008). These critical insights are also not merely those of activists, investigative journalists or political economy researchers, but have emerged from former editors of the *New England Journal of Medicine* (Kassirer 2005, Angell 2004) and from Scrip (Law 2006), internationally known journal following in particular pharmaceutical industry. Thus, concern about ethical and political dilemmas in current practice are not restricted to market-hostile marginal critics, but are embedded in much broader concerns about pharmaceutical industry trajectories.

The systemic conflicts of interest

The systemic conflicts of interests between health policy priorities and the interests of pharmaceutical industry can be divided into five main substantive categories:

1) Issues about *marketing, advertising* and various means of increasing sale of prescription drugs. This is in principle an old dilemma, which has traditionally involved conflicts of interest in the relationship between doctors and health-professionals on the one hand and the industry on the other. Now it has broadened because of the expansion of direct-to-consumer advertising of prescription drugs, and the increasing role of corporate funding and engagement with patient organisations.

2) Issues with *pricing and limiting competition*, which includes the role of intellectual property rights, but also other means of market protection, such as extending data exclusivity; efforts to limit the use of non-proprietary names (non brand-names); litigation; and other mechanisms used to delay generic entry or otherwise limit competition in the field.

3) Issues related to the *magnitude, organisation and productivity of R&D* efforts within the industry. This applies to the arguments about value for money in R&D, given the high and rising prices of new medicines and assessments of the clinical value of medicines; also the role of public financing in R&D, its potential for misallocation of public resources as industrial subsidies, and the costs of litigation as part of overall costs of current incentive mechanisms.

4) Issues concerning how and *for what purpose research and development efforts are conducted*. This applies to dissemination and access to data and knowledge, as well as such problems as the use of phase four clinical trials as marketing efforts (see above). These issues include the ways in which R&D can be designed and funded to create different mechanisms to tackle a problem (e.g. stem cell research vs. pharmaceuticals).

5) Discrepancies across *health policy priorities and commercial needs* and priorities. This includes, for example, the basic problem that from a health policy perspective, treatment should be curative and short-term where possible, while the commercial incentives support keeping people on continuous or long-term treatments. In some areas, such as antibiotics, health policy interests run against their rapid introduction to markets and wide use, in order to limit development of antibiotic resistance, yet in the context of IPRs rapid diffusion is crucial for maximising profits.

6. Innovation and the canvassing of industrial policy priorities over health priorities

The conflicts of interests across commercial and health policies remain largely unacknowledged, if not undermined by the mainstream emphasis on pharmaceutical innovation and R&D. While access to lower priced medicines has become an accepted public health and trade-related strategy, alongside emphasis on generic production in the South, this link is under increasing pressure from industrial policy-driven requirements for innovation. Adherence to strong IPR protection in all countries and contexts may, however, not be appropriate, while it is necessary to consider that also commercially driven generic industries are geared towards the more lucrative markets (Chaudhuri 2005; 2008). Innovation, and intellectual property rights as the backbone of innovation, are increasingly promoted as a hegemonic strategy, for example, in the context of G8 Heiligendam agenda and declaration; however it is likely that there are in practice fewer "common interests" between different countries in terms of industrial policy and pharmaceuticals, than in relation to health and pharmaceutical policies.

In the North ,innovation concerns have been used as a means to question health policy measures such as price controls and other means to lower prices of pharmaceuticals (Doran and Henry 2007). Furthermore, the emphasis on innovation policies creates an industrial policy

ratchet towards tightening IPRs as a policy priority to be sold to the Ministries of Trade and Industry in middle income countries and lower income countries with substantial high-technology industry. This diminishes the national policy space available to Ministries of Health to address issues of access to medicines. Yet this overtaking of health by innovation policies is taking place at the very moment that common interests across countries within health policy are becoming more evident to richer countries where Ministries of Health are faced with increasing costs of pharmaceuticals combined with pressures to lower public spending. However, demands for new and highly expensive cancer medicines are increasingly met with questioning of the reasons why such drugs are so expensive (Hinchliff 2008).

While the link between pharmaceutical industry greed and need in South has become an issue in global campaigning, the issue of why prices are high is now emerging into public debate. The high prices were until recently taken as if these were a starting point for demanding that they be made available. However, the work of the United Kingdom National Institute for Health and Clinical Excellence (NICE) is an example of an organisation and initiative which is garnering interest across countries. NICE produces guidance in three areas of health: 1) public health - guidance on the promotion of good health and the prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector; 2) health technologies - guidance on the use of new and existing medicines, treatments and procedures within the NHS, 3) clinical practice - guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS.

Furthermore, in earlier studies on new cancer medicines it was found that where there was little added clinical value, the prices of new drugs could still be substantially higher than the older ones (Garattini and Bertele 2002). The high cost of new cancer drugs remains an issue of concern in NICE assessments in spite of further adjustments in criteria for appraising end of life treatments (Raftery 2009). It is in this context that new alliances and understanding across countries about health policy priorities, and in particular alliances between middle income and high income countries could be found, yet the global politics seem to be driving in the direction of increasingly high costs of pharmaceuticals in both developed and middle-income countries, due to tightening intellectual property rights protection.

Common interests emerge also from competition in pricing. Conflicts evident in the developing world are emerging more clearly in politics and pharmaceutical policies in developed countries.

One recent example is to be found in the European Commission competition pharmaceutical sectoral survey, and a commentary by Commissioner Neelie Kroes that indicates that all is not functioning well in Europe (Kroes 2008):

> Individuals and governments want a strong pharmaceuticals sector that delivers better products and value for money. But if innovative products are not being produced, and cheaper generic alternatives to existing products are being delayed, then we need to find out why and, if necessary, take action.

These concerns over competition failures were highlighted in the preliminary sectoral report that noted that earlier generic entry would have saved European governments €3 billion (European Commission 2008e). However, these concerns have not appeared at the top of European policy priorities when relevant international negotiations have taken place, as for example in the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property Rights.

6. National policy space for health and pharmaceutical policies

TRIPS and bilateral agreements are no longer considered merely as a trade agreements. Rather they are seen as measures for attracting foreign investment and tools of industrial policy. Hence, there are pressures to limit the use of flexibilities within TRIPS, to avoid loopholes in compliance that might weaken national industrial strategies. The problem of sustaining national policy space – that is, to keep broad policy choices available to national governments - has faced middle income countries negotiating trade agreements, where TRIPS+ clauses have directly addressed pharmaceutical policy (see e.g. Fink and Reichemiller 2005; Roffe and Spenneman 2004; Sell 2007). However, pharmaceutical policies are increasingly challenged in bilateral trade agreement negotiations and even in trade policy debates between developed countries.

Intellectual property rights have been globally contested in relation to developing and middle income countries, and in activism on access to medicines (see e.g. Sell 2004, Sell and Prakash 2004; t'Hoen 2009; Drahos 2004). However, pharmaceutical matters have also been dealt with in the bilateral agreements between rich countries. US-Australia FTA is a good example of the

ways in which mechanisms to tackle national pricing policies were introduced through the FTA negotiations (see e.g. Doran and Henry 2008; Faunce et al 2005). The creeping impact of particular industrial policy interests on health policy space is thus mediated through the emphasis on innovation policies in particular in the context of trade policies. This agenda is based on the assumption that, if countries cannot pay high prices for pharmaceuticals or accept lengthening periods of monopoly protection through data exclusivity agreements in bilateral treaties, they are against innovation. This policy emphasis has been particularly prominent in the United States policies in early 2000s', but has emerged also in European Union.

The US 301 US government trade policy documents have taken up specific policies on reference pricing and price controls as trade-related matters (USTR 2006; USTR 2008). The US Trade "Special 301 report" of the US government in 2006 articulated clearly, under the emphasis on supporting pharmaceutical innovation, that:

> "Historically, the Special 301 process has focused on the strength of intellectual property protection and enforcement by our trading partners. However, even when a country's IPR regime is adequate, price controls and regulatory and other market access barriers can serve to discourage the development of new drugs. These barriers can arise in a variety of contexts, including reference pricing, approval delays and procedural barriers to approvals, restrictions on dispensing and prescribing, and unfair reimbursement policies."

There is a health policy problem if legitimate measures to lower the price of pharmaceuticals, based on public health concerns, are considered to be in conflict with trade policies even when the IPR regime would comply with TRIPS. The European Union has similarly become more involved in negotiating stronger provisions in FTAs on IPRs, including enforcement of IP rights along the lines of the EC Enforcement Directive (European Commission 2006).

Some European countries' pharmaceutical policies have been attacked through commercial and foreign policy disputes. Norway is currently on the US 301 watch-list due to their policies enhancing the use of generic drugs (USTR 2008). The pharmaceutical industry in Finland has threatened the government with the same problem if it goes further with plans for reference pricing policies and legislation (Lääketeollisuus 2008). Finland introduced product patents later than some other European countries and thus products covered by process patents remain still

on the market. An earlier act on generic exchange of pharmaceutical products contained an exclusion of products covered with process patent in Finland when a product patent or supplementary protection within five EU or EEA countries could be provided (Salmi and Tokola 2008) The act on reference pricing removed this exclusion allowing broader generic competition. In the parliamentary process attention was drawn to the ways in which this could result in sanctions against major Finnish trading interests in the United States, including position of Finland to the 301 list, affect reputation of Finland as supporter of innovation and the future availability of medicines on national market as corporations could withdraw products from national markets (Ulkoasiainvaliokunta 2008). The ammunition used in the Finnish case to prevent government from using reference pricing and taking advantage of savings as result of generic competition was substantial, in particular, as the proposed national legislation was compatible with TRIPS Agreement and European law. As the push towards considering patent status with respect to reference pricing programme eligibility can be claimed to represent in practice a linkage between patent status and regulatory decisions this practice becomes even more problematic. Patent linkage is considered unlawful under Regulation (EC) No 726/2004 and Directive (EC) No 2001/83 (European Commission 2008e). The issue here is to what extent governments will be able to undertake appropriate pharmaceutical policy regulatory decisions in the context of pharmaceutical policies without coming under attack and losing scope for controlling rising costs of medicines due to pressures from industrial, innovation and trade policies. The attack may be either by pharmaceutical industry directly or through foreign policies and broader trade and industry interests. In the Finnish context the knowledge that the US government would change most probably helped in pushing the legislative changes through the parliament during autumn 2008.

Diminishing national policy space in pharmaceutical policies is an issue for all governments, since the capacity of governments to interfere with the medicines pricing may be narrowing sharply. Patient group campaigning for access to new and more expensive medicines can also be seen as another tool for the industry, since it may counter government regulatory authorities' reluctance to include very expensive new drugs as part of their reimbursement programmes. Patient groups can operate as effective allies of industrial interests by demanding access to new drugs as part of reimbursement programmes and decisions, since it is in their interests to gain access to new drugs even if additional benefits were small. Many patient groups and their international representatives are funded by industry (Herxheimer 2003).

Ministries of Health across the world have a poorly articulated but strong common interest in pharmaceutical policies, since they face corporate interests as payers of pharmaceuticals. Only some countries have major national industrial pharmaceutical interests. The European expansion in data exclusivity requirements, for example, was done before the enlargement of the European Community. It is likely that if the pharmaceutical legislation had been drafted after enlargement, there would have been a different balance of priorities within the European Community. The enhancement of monopoly rights in the field of pharmaceutical policies has so far been done with little if any consideration of consequences of these policies for the pricing of medicines within countries. It is likely that economic crisis and cost-escalation within countries may drive a reassessment of these priorities in developed countries, possibly paving the way for a better understanding of the health impact of pharmaceutical policies in middle-income countries as well. We should reflect however on initial stages of the global public action in South Africa for the access to HIV/AIDS medicines and the way drug companies responded with litigation to the South African government measures to enhance generic exchange and parallel imports. The reaction to the South African court case, when not only United States, but also the European Commission initially and explicitly promoted the corporate case (Brittan 1998), parallels the reasons why Norway or Finland were pressured by the United States policies.

While in some countries governments may opt to promote industry interests as a national priority, this should require compensatory action and funding for the health sector for the consequences of these policies. Otherwise there is a danger that industrial policy needs impose ineffective and inappropriate use of health resources. However, in addition to resource issues, pricing and financing, there are also other policy areas where health concerns are likely to counteract industrial policy concerns. Inappropriate advertising and sales practices, including internet-based activities, remain a global health concern. Maintaining a sufficient research basis and dealing with global epidemics, as well as problems of antibiotic resistance, are common global concerns and not merely matters of markets and consumer demand.

Quality and sustainability of production is one example, as is action to deal with substandard and counterfeit products, where these present a health concern. Due to the negotiations of the Anti-Counterfeiting Trade Agreement (ACTA) and in the light of the European consignments of medicines in transit (ICTSD 2008), the issue of counterfeiting is at the forefront of the international agenda. However, patent infringement or trademark issues are not health but

commercial policy matters and when accompanied with maximalist IPR agenda are not representing health priorities (see e.g. Sell 2008ab). While substandard and counterfeited drugs do represent an important health-related problem and regulatory challenge in many countries and in particular developing countries (see e.g. Caudron et al. 2008), there is a danger that with focus geared towards patent infringement and trademark-related concerns, the actual health-related problems of substandard - legitimate or counterfeited - medicines remains poorly addressed or even further hampered as has been shown in the case of consignments of legitimate medicines in transit.

In some areas of global and national governance, specific interest group resources and capacities are overwhelming the scope and resources of other activities. Analysis of corporate influence is largely based on Northern American policies and issues (Angell 2004; Kassirer 2005; Avorn 2005), but the role of corporate influence on policy decisions is likely to become more important also in the context of European policies and in particular in European approaches to global health and pharmaceutical policies. The United Kingdom parliament held an inquiry into the influence of the pharmaceutical industry in 2005 (House of Commons 2005). The pharmaceutical industry has been one of the most effective lobbying groups within the European Union (Greenwood 1997). The role and practice of medicines regulation within Europe has been criticised on these grounds (Abraham 2002b), while European Commission work remains based and focused on industrial rather than health policy issues and priorities. Corporate influence was reflected, for example, in the European Commission led negotiations of WHA resolution in 2006. The European Commission had been given competence by the Member States, on the basis of the leaked documents the European stances on the proposed WHO resolution were almost identical to those promoted by the pharmaceutical industry (Balasubramaniam 2006).

The increasing role of European Commission and European coordination in international health policies is complicates matters and is particularly unclear with respect to how European Commission priorities external policy priorities support national health and pharmaceutical policies. While the ratification of the proposed Lisbon Treaty would streamline administrative responsibilities and enhance the role of European Commission in international health policies, it is unlikely to strengthen the role of health considerations in comparison to those promoting innovation and competitiveness. Alongside analysis of United States policies, we need more examination of the ways in which policies in support of commercial priorities are articulated in

the European Union and also in emerging global policy fora such as G8 where intellectual property rights have been defined as the backbone of innovation in the Heiligendamm declaration (Heiligendam 2007):

> "35. A fully functioning intellectual property system is an essential factor for the sustainable development of the global economy through promoting innovation. We recognize the importance of streamlining and harmonizing the international patent system in order to improve the acquisition and protection of intellectual property rights"

The Heiligendam emphasis reflects the challenge for public policies to tackle the ways in which promotion of innovation and competitiveness is associated with emphasis on strengthening of intellectual property rights. The new European trade policy strategy is also explicit in its support of 'seeking to strengthen IPR provisions in future bilateral agreements and enforcement, including, for example, provisions on enforcement along the lines of the EG Enforcement directive' (European Commission 2006 p. 11).

8. Conclusions

There is a danger that the current global context of policy-making through various networks, coalitions and partnerships and the strong presence of corporate interest groups as part of this public-private process, may not adequately respond to the normative and regulatory issues emerging within countries in a globalising world. The strong presence of corporate actors and their role in defining commercial and innovation policy priorities at global level may overwhelm health and pharmaceutical policy interests and priorities as well as undermine common regulatory interests across countries.

There is a substantial number of common policy interests across countries in health and pharmaceutical policies. However, the role and importance of these is subject to negotiation and coordination of broader national interests defined not only in the context of health policies, but as well and often more importantly in the context of commercial policies. These common interests need also to be better articulated and defined. There are also a substantial number of conflicts of interests between commercial policy and health policy priorities, which have not

been recognised as part of global debates. The different roles of health and commercial policies are set the context in which articulation of national policy space for health takes place as well as the extent to which health considerations are considered as part of trade and commercial policies and vice versa.

The global policy and politics debate on access to medicines has to be seen in the context of national and global health policies and policy priorities. While it is likely that global focus on specific diseases and measures can be maintained without compromising commercial policy interests within developed countries, it can be argued that addressing broader health and pharmaceutical policy concerns or enhancing health-related global regulatory action is likely to be limited or go beyond specific neglected diseases unless these are considered relevant also in the context of health policies in middle income and rich countries. The global focus on aid and development has been of importance, but also strengthened articulation of corporate interest groups and their agenda. If global policies on access to medicines are to reach beyond addressing specific diseases and support pharmaceutical policies, rational use of medicines and national regulatory needs and priorities in health policies in longer-term, there is a need to open up and explore common interests and issues across countries in the area of pharmaceutical policies. Otherwise there is a risk that alongside the establishment of global measures addressing limited number of diseases and needs of poorest countries, these measures become coupled with a more commercially driven global policies undermining health policy priorities and global and national regulatory needs in pharmaceutical policies more broadly.

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