Common Health Policy Interests and the Shaping of Global Pharmaceutical Policies

*Meri Koivusalo**

The global focus on pharmaceutical policies and, in particular, on intellectual property rights (IPR) and medicines has been dominated by debates over access to medicines in developing countries and the lack of resources for research and development (R&D) to address tropical and neglected diseases. These concerns were reflected in the negotiations before the World Trade Organization's (WTO) Doha Declaration on public health;[1] the establishment of the Global Fund to Fight AIDS, Tuberculosis, and Malaria, and other global initiatives addressing access to medicines for these three diseases; the work of the World Health Organization's (WHO) Commission on Intellectual Property Rights, Innovation, and Public Health; and, most recently, during negotiations for the World Health Assembly's Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property.[2] However, while the provision of additional resources for tackling HIV/AIDS, tuberculosis, and malaria and the investment in research and development in neglected diseases are certainly important, such resources alone are not sufficient to tackle global health challenges. Access to medicines and inadequate research and development are usually framed as problems that prevail only with regard to specific diseases and only in the poorest developing countries, and which can be remedied through an increased allocation of aid without further changes to innovation, trade, or industrial policies globally. But this approach is becoming untenable. For example, middle-income

* This paper is based on work that was part of an Economic and Social Research Council (UK)–funded project on Non-Governmental Public Action and on an earlier working paper on the issue. Maureen Mackintosh, Sudip Chaudhuri, and Phares Mujinja have kindly made invaluable contributions to the earlier versions, and in particular to the articulation of common interests. The paper also benefits from the kind editorial assistance of this journal. A draft of this article was presented at the 2009 International Studies Association conference in New York.

Ethics & International Affairs, 24, no. 4 (2010), pp. 395–414.

countries, such as Brazil and Thailand, have been embroiled in legal disputes for their efforts to ensure access to affordable drugs to their populations, while the link between intellectual property rights and the pricing of medicines is a concern for an increasing number of countries.[3]

In order to achieve more ethical global health outcomes, health policies must be driven by health priorities and should take into account broader health policy requirements, including the needs of specific national health systems. It is thus important to recognize that the division of interests in key policy areas are not necessarily between the priorities of rich and poor countries, but between (1) pharmaceutical industry interests and health policy interests, and (2) national industrial and trade policy interests and public health policies. If common interests in health policies across countries remain unrecognized, they are more easily undermined by the lobbying efforts of the pharmaceutical industry.[4] Furthermore, governments that effectively defend the interests of the global pharmaceutical industry at the international level may in effect undermine the priorities of their own health systems and citizens, who could benefit from stronger government intervention in pharmaceutical policies and pricing. The issue is thus not only about the ethics of forcing developing countries to follow equal or more demanding requirements for intellectual property protection than what is required in rich countries but also the extent to which the lack of recognition of common policy concerns limits and delays actions that could benefit all countries.[5]

Health has remained to a large extent outside "high" politics and is rarely the focus of international or external policies. The prominence of trade over health considerations in international relations has the potential to lead toward a more systemic undermining of national health systems—to the benefit of corporate rather than health policy needs. Further, the focus on pharmaceutical policies as a mere development issue, rather than a health policy matter, has enabled the separation of pharmaceutical policy from the broader discussions of such substantive issues as the appropriate and rational use of medicines, measures to limit microbial and viral resistance, and medicines as part of a broader health system, including the allocation of resources across different disease groups and health needs. There is also a danger that without recognizing such common health policy interests, national ministries or departments of health will be left to either battle with a multinational pharmaceutical industry increasingly empowered by

https://doi.org/10.1111/j.1747-7093.2010.00278.x Published online by Cambridge University Press

commercial law and provisions made at the bilateral and multinational level, or to merely implement policies at the margin of multinational industry priorities.

In this article I will focus on two broad common interests for health policy officials. Both have become important in the context of current global negotiations relating to access to medicines, pandemic influenza, and public health, innovation, and intellectual property rights. These are (1) ensuring access, availability, and the safety of pharmaceuticals, and (2) ensuring that research-and-development efforts respond to public health needs. I argue that these issues are not solely the concern of developing countries because the diminishing national policy space for health in pharmaceutical policies presents a challenge to all governments, including rich ones.

Global Pharmaceutical Policies

Global pharmaceutical policies have always been formed at the junction between industrial and health policy needs; but as international trade policies have strengthened the global legal framework governing trade and intellectual property rights, industry needs have figured even more prominently—further distancing pharmaceutical policies from health needs within societies. In addition, as pharmaceutical policies have become subordinate to commercial policies, the role of health policies in guiding and framing these policies has declined. The WHO has had a long-term engagement with standard setting in the area of the safety and efficacy of pharmaceuticals. One aspect of the organization's role in this area is the promotion of and assistance with the establishment of national pharmaceutical policies. By the 1980s and early 1990s, such policies, which originated in a World Health Assembly resolution in 1975, formed part of a broader global effort to support developing countries through WHO technical cooperation. The general aim of national drugs policies was to ensure (1) *access*—that is, the equitable availability and affordability of essential drugs; (2) *quality*—the quality, safety, and efficacy of all medicines; and (3) *rational use*—the promotion of therapeutically sound and cost-effective use of drugs by health professionals and consumers.[6] The introduction of the concept of "essential drugs" was groundbreaking, as it made explicit the notion that not *all* medicines were essential, and that there were health grounds for regulating medicines not only with respect to medical safety but also with respect to costs and medical needs.

https://doi.org/10.1111/j.1747-7093.2010.00278.x Published online by Cambridge University Press

Initially, the WHO's essential drugs program was strongly opposed by the United States, which argued that the WHO should not be involved in efforts to regulate or control the commercial practices of private industry. The United States also withheld its 1986 and 1987 contributions to the WHO budget, allegedly because of its disapproval of the WHO's policies on breast milk substitutes and essential drugs.[7] However, despite the initial criticism of and opposition to essential drugs policies, similar measures have since been introduced by many rich countries—including the United States—many of which have adopted their own reimbursement criteria, drugs lists, and treatment guidelines, and have promoted the use of generic medicines.[8]

The WHO constitution is clear with respect to health governance, with specific language on pharmaceuticals in terms of developing, establishing, and promoting international standards relating to food, biological, pharmaceutical, and similar products.[9] The WHO should in principle have the legitimacy and capacity to play the role of a neutral arbiter in the area of global health. It is reasonable to assume that in order to avoid policy capture and conflict of interest, public health–related regulatory policies should be distanced from industries with a direct interest in influencing standards and guidelines in the area—in this case, the pharmaceutical and biotechnology industries. It is worrying, therefore, that both the European Union and the United States have sought to transfer pharmaceutical policy issues from the WHO to the International Conference on Harmonisation (ICH), an organization that is primarily industry-driven and has its secretariat provided by the International Federation of Pharmaceutical Manufacturers & Associations. John Braithwaite and Peter Drahos have drawn attention to this matter, describing the EU and United States' activities as "forum shopping," whereby issues are shifted to those forums that promise the best outcomes for key national policy interests.[10] These do not need to represent commercial policy interests, but they often do. The role of the ICH is brought up, for example, as part of the European Commission's new pharmaceutical package in the context of the promotion of global harmonization.[11] In addition to the WHO, the Organisation for Economic Co-operation and Development (OECD) is also active in the area of pharmaceutical policy and pricing, although the OECD is generally understood as a more industry-oriented actor in comparison to the WHO, where health policy concerns are expected to be dominant.

Further, the WHO's mandate to promote global health is challenged by global trade rules, and the role of the WHO and the WTO can be in tension. To make

https://doi.org/10.1111/j.1747-7093.2010.00278.x Published online by Cambridge University Press

matters even more complicated, global industrial and trade policies are governed by negotiations and agreements made in the context of multilateral trade agreements under the WTO; bilateral and regional trade and investment agreements; and agreements and other related work negotiated and agreed to within the World Intellectual Property Organization (WIPO).

The WHO's status as the premier international institution in the area of global health became strongly contested in the late 1990s, due in part to policy concerns raised in the context of guidance for developing countries and a resolution on the revision of the drugs policy in the World Health Assembly.[12] WHO negotiations were taking place at the same time as a global pharmaceutical industry court case against the South African government, challenging its 1997 amendments to the Medicines and Related Substances Act. South Africa's proposed legislation met with great resistance from the pharmaceutical industry, with international support from the United States, which claimed in the context of its 1999 Special 301 Report on trade policy (more on this below) that "South Africa's Medicines Act appears to grant the Health Minister ill defined authority to issue compulsory licenses, authorize parallel imports, and potentially otherwise abrogate patent rights." The report also reflected concern over WHO negotiations, noting that "South African representatives have led a faction of nations in the World Health Organization in calling for a reduction in the level of protection provided for pharmaceuticals in TRIPS [Trade-related Aspects of Intellectual Property Rights]".[13] Health and pharmaceutical policy–related negotiations in the WHO thus became an area of significant concern for those organizations, states, and ministries engaged in the creation, regulation, and enforcement of trade policies. The discussions on the right to and conditions for the use of compulsory licenses and parallel imports were shifted more to trade policy arenas, and were clarified in the WTO Doha Ministerial Conference in the Doha Declaration on the TRIPS Agreement and Public Health (2001).[14]

The Doha Declaration, however, did little to enhance research and development on treatments for diseases that disproportionately affect developing countries, and as a consequence the lack of R&D in tropical diseases remained on the policy agenda. This led to the decision to establish the WHO's Commission on Intellectual Property Rights, Innovation, and Public Health in May 2003. Since the commission's report in 2006, intergovernmental negotiations on these issues have continued not only via the World Health Assembly's Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property Rights (2008) but

also as part of negotiations on virus and benefit sharing in pandemics and the counterfeiting of medicines. All these negotiations have been marked by broad divisions between poor/middle-income and rich countries, as well as between those whose views are shaped by commercial and industrial interests and those emphasizing public health priorities.

In the meantime, the global pharmaceutical industry's promotional practices, influence over policy, and the various means it uses to protect its monopoly rights have become the target of sharp criticism from policy-makers, medical researchers, and commentators within wealthy countries. These criticisms reflect a variety of concerns, such as the influence of commercial interests on prescribing practices and regulatory decisions, the limited clinical value of new products, and the unethical high price and costly practices of promoting new medicines—all of which relate to the extent to which pharmaceutical policies serve the public interest.[15]

Common and Conflicting Interests in Health Policies

Pharmaceuticals and medicines policies have always been controversial within the WHO, and have faced substantial pressure from corporate lobbying. The specific concerns that shape the national interests of individual countries in this area are typically dependent on the disease profile, organization, and financing of the health system within each individual country, as well as the economic and institutional relevance of both research-based and generic pharmaceutical industries in the national economy. However, when global pharmaceutical policies are examined from a health policy perspective, it is easier to find greater disagreement between commercial and health policy priorities *within and across* countries than between the health policy priorities of rich and middle-income/poor countries. In other words, if global health policy negotiations would be based on the primacy of health policy considerations, there would be more scope for agreement than currently seems to be the case.

Access, Availability, and the Safety of Medicines

Ensuring equitable access, availability, and the safety of medicines is an important part of health system obligations. Equitable access includes the responsibility to ensure that pharmaceuticals are affordable for patients and that gaining access to essential medicines does not lead individuals to poverty or indebtedness. Equitable

https://doi.org/10.1111/j.1747-7093.2010.00278.x Published online by Cambridge University Press

access and affordability for patients can be sought, for example, in the form of direct public financing or through different types of reimbursement or insurance arrangements. Governments can intervene to enhance affordability of medicines for individual patients. This requires political will, but is also dependent on the level of available public and private resources. Affordability has become particularly prominent in debates on access to HIV/AIDS antiretrovirals and costly cancer medicines protected by patents or other exclusivity requirements. For many of these treatments the national policy space allowing governments to intervene to increase access to and affordability of medicines is in tension with the need to provide incentives for innovation through intellectual property rights, longer exclusivity periods, and higher profits. Yet, if governments do not have the resources to buy medicines or to reimburse citizens for them, as is the case in many poorer or even middle-income countries, this incentive for research and development cannot be realized: the drugs remain unobtainable for citizens, and no additional resources flow to the industry. Further, these types of decisions are not simply commercial but also relate to broader considerations of social justice and public interests in terms of the level of pharmaceutical spending that can be sustained within societies.

The rising cost of pharmaceuticals does not concern developing countries only. For example, a recent OECD study on pharmaceutical pricing and global pharmaceutical markets explicitly noted that access to medicines is an issue in all OECD countries. Per capita spending on medicine in these states varies due to a variety of reasons, with the United States spending about twice as much ($792) as, for example, Norway ($398), Finland ($380), and the United Kingdom ($366) in 2005.[16] While in many OECD countries pharmaceutical spending remains a relatively small part of overall health expenditure, there are increasing concerns about (1) the limited clinical benefits of more expensive new products in comparison to existing treatments, and (2) new, very expensive treatments priced on the basis of "what markets can bear." These concerns are reflected in the work of the United Kingdom's National Institute for Health and Clinical Excellence (NICE), an independent organization providing guidance to the UK government, which is generating international interest. As Sir Michael Rawlins, the chairman of NICE, noted in a published debate in the *Economist* on comparative effectiveness reviews, cost-benefit analyses, and medical innovation:

> To meet the needs of patients and the public, innovators must provide their products at an affordable cost. If they cannot do so, it is a failure of the innovative process rather

https://doi.org/10.1111/j.1747-7093.2010.00278.x Published online by Cambridge University Press

than a failure of the need to examine the cost-effectiveness of innovations themselves. Putting it another way, unaffordable innovation is not an innovation.[17]

While global campaigns have sought to link pharmaceutical industry practices and decreased or insufficient access to medicines in the Global South, the issue of *why* prices are high has not featured as prominently in campaigns or debates on access to new medicines in the North. But this is changing. In discussions on the proper pricing of drugs, participants are beginning to take a closer look at the added clinical value of new medicines in comparison to existing products, especially since new medicines providing limited or no clinical value can still be substantially more expensive than older products.[18]

Finally, regulatory capacity in health policy is also crucial to battling substandard medicines and counterfeiting; and in developing countries a substantial part of the problem relates to legitimate medicines that are of substandard quality.[19] From a health policy perspective, protecting patients and consumers from dangerous or ineffective medicines is a core concern, yet global efforts on counterfeiting have been geared more toward protecting trademarks and patents from infringement.[20] Meanwhile, the real regulatory challenges go unaddressed. Global health and trade policies have thus produced heated disputes both in the WHO and WTO. For instance, India and Brazil recently initiated a trade dispute at the WTO against the EU's repeated seizures of medicines, which the EU has done on the basis of alleged violations of patent or trademark laws.[21] The presence and danger of fake and substandard medicines in global markets is a real public health concern, and should be guided by ethical and global public health concerns, rather than requirements for protection of intellectual property rights.

Further, governments need to be able to regulate the quality and safety of medicines, as well as have sufficient knowledge, capacity, and time to do so. The issue of assessing safety is particularly important in light of increasing pressure to shorten the time necessary for the approval of new drugs and to maximize their reach and profit during the period of exclusivity. The pressure to expand sales quickly is exemplified by the case of Vioxx, a painkiller that had to be withdrawn from the marketplace due to serious side effects. The Vioxx case generated a controversy over the extent to which the company not only delayed action but also actively undermined safety concerns in its marketing to maintain sales.[22] It is also useful to remember the tragic lessons from thalidomide—a drug once sold on European markets but whose safety was not evaluated by independent authorities

https://doi.org/10.1111/j.1747-7093.2010.00278.x Published online by Cambridge University Press

in Europe—which helped trigger an increased national and global focus on the safety of medicines.[23]

Guidance on Research-and-Development Efforts on the Basis of Public Health Needs

It is now recognized that current IPR-based incentives for research and development do not ensure results relevant to diseases where profitable markets for pharmaceutical products do not exist.[24] In response, major global campaigns have been launched to promote R&D on diseases that disproportionately affect developing countries, including neglected tropical diseases[25] (for example, Chagas disease, leishmaniasis, and dengue fever), in the context of negotiations of the Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property Rights.[26] Both the WHO Expert Working Group on R&D Financing and the European Commission have had an interest in enhancing the financial incentives for research for neglected tropical diseases and diseases that particularly affect developing countries utilizing a strategy already used to promote R&D on "orphan drugs" (medical products for the diagnosis, prevention, and treatment of rare diseases), which require additional incentives for R&D because there are too few patients to make them profitable. However, this strategy has proved to be expensive and not effective for all types of diseases, although it is popular with the pharmaceutical industry.[27] New innovations have thus come with a high price tag. This is easier to tolerate in the case of treatments for a few very rare diseases in rich countries, but becomes much more problematic when treating tropical diseases, if the total number of diseases requiring very expensive medicines rises, or if these treatments are extended to a larger number of patients. The European Commission and the United States already consider tropical diseases eligible for designation as orphaned or rare diseases—since they are rare within the EU and the United States—which has relevance to the magnitude of new R&D that can be expected to result from this and the affordability of new (designated) products in middle-income and poor countries.[28]

While intellectual property rights and exclusivity periods provide ways of rewarding innovation and investment in research and development, they do not help guide where resources are invested. For instance, despite the recognized public health need for new kinds of antibiotics, the R&D pipelines of major industry actors have been drying up due to insufficient financial incentives, partially because of the short course of treatments.[29] The field of antimicrobials also suffers from more stringent public health rules on use—due in part to concerns over microbial

https://doi.org/10.1111/j.1747-7093.2010.00278.x Published online by Cambridge University Press

resistance—which limit markets and the profitability of products. On the other hand, the establishment in 2009 of an EU-U.S. task force to address antibiotic resistance, prevention of drug-resistant infections, and strategies for improving the pipeline for new antimicrobial drugs is a reflection of the growing importance of the issue in "high" politics.[30]

The emerging cracks in the current incentive system for R&D in diseases that disproportionately affect developing countries, rare diseases, and antibiotics pose an important question: Are the problems in the current system such that they may be patched with greater public funds and incentives, thus further entrenching the current strategy, or should more fundamental questions regarding the current driving forces for R&D be raised? In light of current failures to respond to the health needs of large populations, it is necessary to keep an open mind toward a variety of potential options that could enhance and guide R&D, including, for example, strengthening traditionally publicly-funded research institutions while encouraging open or adjusted licensing for pharmaceuticals to ensure access to knowledge and the affordability of medicines. The fact that there are alternatives should thus be kept in mind, especially because of commercial interests in further enhancing the current system of incentives, which may pose very high costs to consumers. Some of these desired enhancements include the use of transferable benefits to companies as a reward for new products in desired areas of research, such as priority review vouchers or patent "wild cards," which would allow shifting the benefit of early review or patent extension to another, more profitable drug.[31]

In a market-driven context of R&D, investments are made on the basis of commercial prospects, which are not necessarily the same as health or health policy needs. For example, while research and product development focusing on enhancing the capacities of healthy people, such as performance-enhancement drugs, might be a lucrative commercial strategy, it is not what is *necessary* from a health policy perspective. Through the high prices of medicines, we also subsidize other activities that do not relate to research, are unnecessary, or may not support health policy priorities: in the commercial sector, marketing and advertising costs are often of equal magnitude—if not far greater—than direct research costs, and must also be built into the price of medicines or research processes. The concerns over ethics, quality, and conflicts of interest with respect to the commercialization of clinical trials represent another failure of the market-driven research-and-development environment. We also see inappropriate practices, such

as the use of phase IV clinical trials—initially aimed to serve as a means to provide scientific evidence on the efficacy and safety of a licensed drug—to serve marketing priorities as "seeding trials" intended to engage key professionals and to promote their prescribing of the product.[32]

The OECD's analysis of global pharmaceutical markets has emphasized that despite rising R&D costs, most innovation has been incremental, with little or no added therapeutic value.[33] Although questions have been raised about the calculations of R&D costs, the industry's low productivity has also been directly or indirectly recognized in recent assessments.[34] There is, therefore, a common health policy interest across governments to ensure that public support for R&D enables access to knowledge, provides added therapeutic value, contributes to health policy priorities, does not waste public resources, and focuses on areas where new innovations are essential. It is also a common health policy concern to ensure that national, regional, or global support for global R&D efforts on diseases that disproportionately affect developing countries is based on the wise use of resources, does not end up merely as public subsidies for private companies, and that research is not doubly funded—first through increasing direct support for R&D, and then through higher prices of medicines as a result of intellectual property rights and the application of market exclusivity through data exclusivity provisions.

National Policy Space for Health and Pharmaceutical Policies

One of the main goals of national health and pharmaceutical policies is to ensure that citizens have access to affordable medicines. However, the scope of policy measures that governments can apply within the health sector is often limited by commitments made as part of trade agreements. Compliance with TRIPS under the auspices of the WTO (and, often more important, with further provisions in bilateral or regional trade and investment agreements) are increasingly seen as a condition for attracting foreign investment and the means for the "modernization" of a country's economy. Bilateral and regional trade and investment agreements have directly addressed pharmaceutical policy issues through the inclusion of requirements exceeding TRIPS (so-called TRIPS+ measures), which extend exclusivity periods. Such measures are present in recent agreements between the United States and various developing, middle-income, and high-income countries (for example, CAFTA with Central American countries, as well as bilateral agreements with Australia, Jordan, Singapore, and Vietnam). They have also appeared in

trade agreements between the European Union and its trading partners, and are currently part of the negotiations of a free-trade agreement with India.[35]

Pharmaceutical matters have also been dealt with in bilateral agreements between wealthy countries. The United States–Australia Free Trade Agreement is a good example of how the regulatory context of pharmaceutical policies, including the pharmaceutical benefit scheme that establishes the basis on which pharmaceuticals are subsidized to patients, can become part of trade negotiations, with the inevitable movement away from the public good and toward a more private rights–oriented system better attuned to private investment and profit making.[36] In the Australian example, enhanced intellectual property protections were cast as policies designed to strengthen competitiveness and innovation, shifting regulatory support more toward private investments, and emphasizing commercial and private rights. According to this reasoning, which has become commonplace in commercial policy and trade negotiations, countries or institutions that refuse to pay sufficient margins for innovative pharmaceuticals are accused of being "against innovation" and of "not playing by the rules" by limiting market access for highly priced innovative products.

Moreover, legitimate policy measures to contain the costs of pharmaceuticals are often considered to be in conflict with trade policies, even if the intellectual property rights regime complies with TRIPS. This is a problematic view, not least because it privileges pharmaceutical company profits over affordable access to drugs. The Office of the United States Trade Representative (USTR), for example, issues an annual Special 301 Report, which examines the adequacy and effectiveness of U.S. trading partners' protection of intellectual property rights. The report lists problem countries in the categories of "priority watch," "watch," and "Section 306 monitoring list," and provides a means for the United States to communicate its concerns about the need to protect and enforce intellectual property rights and to "fight IPR theft in overseas markets."[37] These reports have also examined national pharmaceutical policies, such as reference pricing and price controls of pharmaceuticals, as a trade-related matter.[38] The Special 301 Report in 2006 clearly articulated, under the heading "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 intellectual property rights regime is adequate, price controls and regulatory and other market access barriers can serve to discourage the development of new drugs. These

https://doi.org/10.1111/j.1747-7093.2010.00278.x Published online by Cambridge University Press

barriers can rise in a variety of contexts, including reference pricing, approval delays and procedural barriers to approvals, restriction on dispensing and prescribing, and unfair reimbursement policies.[39]

The Special 301 reports do not apply to poor or middle-income countries only. The pharmaceutical policies of several European countries have come under scrutiny in the context of their trade relations with the United States. For example, Norway is on the U.S. 301 watch list due to its national pharmaceutical policies and alleged lack of sufficient patent protection.[40] In April 2009, Finland appeared on the U.S. 301 watch list with a similar reference to pharmaceutical policies, and remains on the list in 2010.[41] When considering the legislation that eventually contributed to the Finnish listing, the Finnish government had been pressured by the pharmaceutical industry by the threat of inclusion on the list if it were to go forward with its proposed policies[42]; and in the parliamentary hearing the statement of the foreign affairs committee drew attention to the ways such a listing could result in major economic consequences and hurt the Finnish reputation in innovation, potentially discouraging foreign investments in research-and-development activities in Finland.[43] It is important to note that the Finnish national legislation remained compatible with European and international law. Thus, the Finnish example is worrying not only because it shows how expectations extend beyond legally defined margins in international trade agreements, but also because it makes evident the lobbying powers of a multinational industry and how this influence is reflected in pressure from stronger ministries, such as trade, foreign affairs, or industry, in national policy-making. (To date, the initial Finnish legislation has not been changed or challenged, possibly because it has resulted in an overall savings of €109 million in government reimbursements of medicines during the first year of operation.[44])

To sum up, ministries of health across the world are likely to have common interests in pharmaceutical policies that are not equal to and are often in conflict with global pharmaceutical industry interests—particularly because they are often the main payers of the costs of medicines and are accountable for health policies, including the safety and appropriate use of pharmaceuticals, within countries. On the other hand, pharmaceutical industry interests are increasingly articulated as part of broader policies intending to enhance competitiveness and innovation. This leads to increasing tensions between governments' objectives.

The imperative of separating corporate and public interests also applies to broader public health measures, such as vaccination programs that are paid for by

public funds.[45] In June 2010 the *British Medical Journal* published an analysis that pointed to conflicts of interests with respect to scientists advising the WHO in the context of pandemic influenza. The analysis included concerns over the role of a 100 percent industry-funded European Scientific Working Group on Influenza, as well as inconsistencies with respect to how conflicts of interests were dealt within the WHO, concluding that "there is a danger of credibility of the WHO and the trust in the global public health system." While the WHO has recognized the need "to establish, and enforce, stricter rules of engagement with industry," it has strongly maintained that "accusations that WHO changed its definition of a pandemic in order to accommodate a less severe event (and thus benefit industry) are not supported by the facts."[46]

Finally, focusing only on the role of global or bilateral trade agreements and negotiations may be insufficient where differences in policy priorities between industrial and health policies at the national level are significant. Innovation policies are increasingly considered a necessary requirement for competitiveness in the global economy. The emphasis on innovation policies as a key element in industrial policy contributes to establishing IPRs as a national priority for the ministries of trade and industry, while at the same time ignoring the resultant resource or policy space constraints that affect ministries of health. Policies and priorities set within governments in support of innovation can and have been used, for example, in Australia, more directly as a means to question or contest health policy measures, such as price controls and other means to lower the prices of pharmaceuticals.[47]

Industry Influence and the Challenge of Global Public Policies

Maintaining national—and global—policy space for health and pharmaceutical policies is at the core of the current disputes. Global standard setting and regulatory policies, or the lack thereof, are naturally of great interest to the global pharmaceutical industry. For example, there is a substantial literature on industry and interest group influence on North American policies.[48] The United States is by far the most important pharmaceutical market, with an estimated 45.1 percent of global pharmaceutical sales in 2006, while Europe (including Switzerland) accounts for 29.9 percent, and Japan is a distant third at 9.3 percent.[49] While growth in market share is likely to take place in middle-income countries,

both North America and Europe will remain important markets for the global pharmaceutical industry.

The pharmaceutical industry has been and remains one of the most effective lobbying groups in the European Union.[50] Research on European regulatory policies has shown that EU pharmaceutical policies have been dominated by industrial policy interests, with regulatory capture by a strong and active pharmaceutical industry representation, resulting in, for example, longer data exclusivity provisions.[51] In the United Kingdom, a parliamentary inquiry on the influence of the pharmaceutical industry issued a critical report in 2005,[52] and the practice of medicines regulation within Europe has similarly drawn critical attention.[53] In the negotiations of the World Health Assembly resolution that framed the negotiations on intellectual property, innovation, and public health, the European Commission negotiating position was, based on a leaked document, found to be almost identical to that promoted by the pharmaceutical industry.[54] Given that the European Commission is likely to have an increasing role in global health and international health policies,[55] it is reasonable to assume that commercial policy considerations would strengthen in comparison to those of health, even though the formal responsibility for pharmaceuticals has now been moved from the EU industrial policy directorate to the EU health policy directorate.

European trade policy and strategy is explicit in its support for IPR protection and enforcement.[56] It is also difficult to separate European industry interests from global and multinational corporate interests, which are able to shop across the Atlantic for policy openings and options. Thus, while the United States has traditionally been the main ally of the global pharmaceutical industry, the role and relevance of the European Union should not be underestimated in the future.

Conclusions

The articulation of global health policies in the field of pharmaceuticals is currently dominated by efforts to address access to medicines and R&D needs for neglected diseases in the developing world. These worthy goals need to be examined against the history and context of global and national pharmaceutical policies and regulatory efforts so as to ensure that the current focus does not serve to legitimize further a lack of attention to common policy goals, obscure systemic problems, and postpone necessary change.

https://doi.org/10.1111/j.1747-7093.2010.00278.x Published online by Cambridge University Press

Domestic politics are key to determining national positions in international negotiations. In the case of pharmaceuticals, however, the ''national interest'' is heavily influenced by interest-group lobbying and global corporate networking, together with the more traditional power politics between trade and health ministries and the institutionalized protection of intellectual property. While the issues of pharmaceutical pricing, licensing practices, competition and access to generic medicines, ensuring the quality and safety of medicines, limiting drug resistance, responding to and preparing for pandemics, and addressing priority needs and gaps in research and development all remain concerns for national health policy agendas, the lack of recognition of common interests between national and international health policy-making makes the articulation and pursuit of these interests much more difficult.

Multilateral normative agencies, such as the WHO, have an essential role to play in identifying and promoting common health policy priorities, especially those that are in conflict with or becoming undermined by the priorities of powerful global corporate actors. The tobacco framework convention is an example of such efforts.[57] Ensuring that health considerations are paramount in the definition of global health and pharmaceutical policies is likely to require further transparency and focus on the financing, public accountability, and conflicts of interest of all participants in global-level policy-making. This requires not only scrutiny of WHO policies and practices but also recognition that having the WHO undertake this normative role in pharmaceutical policies—and building up the necessary resources, knowledge, and capacities—is in the interests of all member states.

Thus, the key lessons to bear in mind are that: (1) health policy priorities differ from those of commercial and corporate interests, and require government intervention; (2) we have a common ground for global pharmaceutical policies within the WHO that could be used for the benefit of all member states; (3) recognition of common health policy interests in pharmaceutical policies could help all countries to control costs domestically and help in the regulation of the increasingly multinational pharmaceutical and clinical trials industries; (4) conversely, *not* recognizing common health policy interests is likely to hurt not only developing countries but also wealthy countries, which are the main financial resource for the global pharmaceutical and R&D industry; and (5) from a health policy perspective, it is in the interest of all countries that global and national support for R&D and innovation seeks to enhance our knowledge, results in affordable products, and represents a wise use of public resources.

https://doi.org/10.1111/j.1747-7093.2010.00278.x Published online by Cambridge University Press

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[1] World Trade Organization, "Doha Declaration on the TRIPS Agreement and Public Health" (WT/MIN(01)/DEC/W/2 14 November, 2001).

[2] World Health Organization, *Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights, Innovation and Public Health* (Geneva: WHO Publications, 2006); and World Health Assembly, "Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, WHA 61.21" (Geneva: WHO Publications, 2008).

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[10] John Braithwaite and Peter Drahos, *Global Business Regulation* (Cambridge: Cambridge University Press, 2000).

[11] See, e.g., European Commission, "Safe, Innovative and Accessible Medicines: A Renewed Vision for the Pharmaceutical Sector" (Brussels, 10.12.2008, COM (2008) 666 final).

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[25] The World Health Organization currently lists fourteen diseases on its list of neglected tropical diseases; see www.who.int/neglected_diseases/diseases/en/. On the other hand, a broader number of diseases disproportionately affect developing countries.

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[31] The case against patent extensions and transferable patent extensions as appropriate financial incentives has been made in Kevin Outterson, Julie Balch Samora, and Karen Keller-Cuda, "Will Longer Antimicrobial Patents Improve Global Public Health?" *Lancet Infectious Diseases* 7 (2007), pp. 559–66. For a more general discussion on the issue, see also Baker, "A Free Market Solution to Prescription Drug Crises." On critical questions with respect to priority review vouchers, see, e.g., Aaron Kesselheim, "Drug Development for Neglected Diseases—The Trouble with FDA Review Vouchers," *New England Journal of Medicine* 359, no. 19 (2008), pp. 1981–83.

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