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Rethinking Regulation: International Harmonisation and Local Realities

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Rethinking Regulation: International Harmonisation and Local Realities

The STEPS Rethinking Regulation project is examining the harmonising regulation of two widely available technologies - transgenic cotton seeds and antibiotics - in China and Argentina. We wish to explore how their regulation - in terms of property/access and quality/risk – overlaps, compares and contrasts with the way poorer users experience these properties. What issues, for example, are being raised through the actual use of these artefacts, and that the regulatory view does not reach? Where regulatory reach is absent, what strategies do the users themselves deploy in order to assure themselves of technological benefits and guard against risks? As the initial step in this project, this working paper provides an overview of the project's objectives and a discussion of two relevant bodies of literature. The first of these concerns the regulation of pharmaceutical drugs and transgenic seeds in a globalising context, and the second concerns the informal reality of drug and seed use in developing country settings. We are interested in the what is known about how international regulatory harmonisation processes influence the development of national regulations, and the ways in which actual patterns of technology use amongst poorer communities have been documented, and in particular how they might differ from the assumptions and expectations of policymakers, regulators and other actors about appropriate technological practices.

Patrick van Zwanenberg, Adrian Ely and Adrian Smith

Regulation

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The STEPS Centre is based at the Institute of Development Studies and SPRU Science and Technology Policy Research at the University of Sussex, with partners in Africa, Asia and Latin America. We are funded by the ESRC, the UK's largest funding agency for research and training relating to social and economic issues.

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1. INTRODUCTION

Rapid technological and economic change is extending the availability of modern technologies around the world, and fuelling aspirations to use them. Their portability means technologies 'released' in one context are soon felt in others. This means, first, the variety of dynamic social and environmental user contexts increases; second the performance and effects of the technologies becomes more uncertain; and third, sources of production and modes of access proliferate.

Such dynamics pose significant challenges for policy-makers attempting to govern technology. Regulations remain important instruments of (technology) governance (Braithwaite *et al* 2007). Technologies are subject to multiple procedures for setting norms and standards in relation to quality, safety, effectiveness, intellectual property, environmental protection and so on. Indeed, in fields like agricultural biotechnology and pharmaceuticals, the formulation of regulatory assurances is an important aspect of the technology development process. Regulatory and technological pathways co-evolve.

The international harmonisation of regulations often facilitates particular forms of technology governance, and in doing so encourages technological diffusion and serves to reinforce particular socio-technical pathways, whilst obstructing others. Harmonising assumptions are reproduced through capacity building initiatives and regulatory frameworks transposed across countries (including into developing countries with weaker regulatory institutions). Developing countries often have little choice but to comply with regulations set by international institutions if they wish to trade. There are intense pressures to standardize and harmonize globally.

The STEPS *Rethinking Regulation* project is examining the harmonising regulation of two widely available technologies - transgenic cotton seeds and antibiotics - in China and Argentina. We wish to explore how their regulation - in terms of property/access and quality/risk - overlaps, compares and contrasts with the way poorer users experience these properties. How, for example, do regulators' understandings of the efficacious and safe use of antibiotics compare with poorer users' experiences? What issues are being raised through the actual use of these artefacts, and that the regulatory view does not reach? Where regulatory reach is absent, what strategies do the users themselves deploy in order to assure themselves of technological benefits and guard against risks? In sum, how inclusive are the regulatory framings of medicines and seeds towards the actual experiences and concerns amongst poorer communities?

We will use the findings from these case studies to explore the implementation challenges facing regulators, and to explore the potential for more reflexive regulatory capacities that can appreciate technology issues and performance priorities as experienced and valued by poorer communities, and that can reflect upon the role of regulation in signposting pathways to Sustainability.

As the initial step in this project, this working paper provides a brief description of the project's objectives and, more substantively, a discussion of two relevant bodies of literature. The first of these concerns empirical accounts of the regulation of pharmaceutical drugs and transgenic seeds in a globalising context. We are interested in what is known about how international regulatory harmonisation processes influence the development of national regulations in the medicines and transgenic seed sectors, and how, once refracted through national institutions, those regulations impact on seed/drug technology access and use. The second body of literature concerns empirical discussion of the informal reality of drug and seed use in developing country settings. Here we are interested in the ways in which actual patterns of technology use amongst poorer communities have been documented, and in particular how they might differ from the assumptions and expectations of policymakers, regulators and other actors about appropriate technological practices. Several additional bodies of literature, especially analytical literatures, are relevant to our project too, but out purpose in this document is not to explore how various analytical approaches might be useful for our endeavour; rather we wish to discuss what we know empirically about globalising drug and seed regulation and drug and seed use in developing countries. We do, however, end with a summary interpretation of this literature by reference to the core STEPS Centre themes of scales, dynamics, framings, and pathways.

2. THE *RETHINKING REGULATION* PROJECT

Regulation remains a key device available to states interested in shaping technology for socially desired purposes. The ways in which technology is regulated have important implications for, *inter alia*, investment decisions, innovation processes, whether particular kinds of artefacts are produced at all, the forms in which particular artefacts are made available, how and to whom access is provided, and the type, levels and distribution, of benefits, costs and risks that they pose to different actors. Yet regulation is never determined solely by nation state concerns. Multiple, incommensurable understandings - or 'framings' - of regulatory issues and problems exist amongst different stakeholders, for example assuring access to export markets, or protecting the intellectual property of inward investors, or responding to local safety concerns, and these interact across scales - as international agreements between states, the political economy of globalising production processes and local campaigns for greater protection

attest. State regulation can become susceptible to capture by powerful interests. It may lack sufficient capacity for effective implementation, become insensitive to circumstances on the ground, or simply fail to keep up with events. Regulators struggle to bring technological practices into line with their mandates. Despite this, regulations continue to provide influential signals about the (contested) direction of technology development, which is why states, businesses and citizens continually engage in their negotiation.

Regulatory harmonisation processes and associated capacity building efforts, whether multilateral, bilateral or domestic, often presume stable and certain worlds and widely shared goals. They contain explicit and implicit assumptions about the contexts of technology use that may not apply across all localities. This raises questions about the responsiveness and adaptability of regulations to local needs and the issues of particular groups, especially poorer communities. Regulatory harmonisation may seek to bring those localities into line, but there can be aspects to the local context that are beyond the reach of these regulatory attempts and that constantly undermine unreflexive attempts at harmonisation.

In practice, regulators struggle with diverse and dynamic ecological and user contexts. Disease ecologies, markets and social and demographic change, for example, interact in ways that vary across regions and localities producing multiple patterns, multiple needs, and shifting uncertainties. Regulators also need to arbitrate between a diverse variety of international, national and local industrial policy and social framings of what exactly the 'regulatory' problems are. Some of these framings will be readily apparent, perhaps articulated by powerful actors and institutions, whilst others may be far less visible. Regulations inevitably privilege some classes of technology producer/user over others, whether deliberately or through insufficiently reflexive framings of the issues and problems that regulations are designed to address. Yet dominant discourses around regulatory harmonisation frequently cast such highly political issues in the narrow light of technical considerations of regulatory design (Francis 1993).

With these issues in mind, the *Rethinking Regulation* project poses the following questions:

- How do regulators understand the world they are regulating; how do they try to bring actual technological practices and their consequences into line with their regulatory framings?

- How and why do these regulatory worlds contrast with the ways technologies are experienced amongst poorer users; how do poorer users develop informal strategies for assuring themselves of benefits and guarding against risks?

- How far do regulatory reforms and capacity building efforts bridge these divergent socio-technical worlds; which initiatives improve the reach of regulation for the poor in diverse and uncertain contexts?

◆ How does the global political economy of technology development, coupled with unequal access to regulatory negotiations, shape the space for regulatory alternatives at different scales?

This project will thus trace the relationships between global and local forms of governance and regulation, asking how, for specific issues and settings, global and national regulatory regimes actually work, or fail to work, in practice. We will explore the interactions between formal regulation and informal practices that may emerge to fill the vacuum (or resist unwelcome regulatory intrusions upon existing practices), whether based on citizen action and social networks, everyday means of getting-by, or semi-legal activities. Exploring who gains and who loses from these interactions, this project will work towards identifying alternative regulatory pathways that work for Sustainability.

PROJECT CASE STUDIES AND LOCATIONS

Our chosen case study artefacts are antibiotic medicines and transgenic cotton seeds. Other artefacts could have been chosen but the two case study technologies satisfy some general criteria: both are in global circulation and are used by poorer people in both project locations. They represent two of the three domains - health, agriculture, and water – that the STEPS Centre is focusing on. Antibiotic medicines and transgenic cotton seeds are important technologies with the potential to significantly impact on poverty alleviation and sustainability in various ways. They are also subject to significant controversy around regulation and use. Antibiotics and transgenic cotton seeds are both associated with regulatory pressures at a global level that frame the room for manoeuvre of national regulators, who have also to confront domestic political issues. Such multi-level regulatory combinations generate different opportunities and concerns in different locations.

In the area of pharmaceuticals, a geographically concentrated and oligarchic industrial structure has co-evolved with public regulatory frameworks over a long period. This situation is increasingly unsettled, however, by new producers in new locations, and by new markets which by-pass controlled, but sometimes limited, public health provision. Established regulatory purposes and processes are challenged and re-opened by these new issues. For example, public health services may experience capacity pressures at a time of growing demand, creating space for alternative providers to respond through less regulated private markets. Alongside these informal markets, intellectual property regulation can support high prices for protected drugs. When combined with poorly implemented controls on trade, manufacture, or distribution, this opens space for (highly tradable) counterfeit products. This mixed picture of different regulatory logics, enforced to varying degrees at different points in the system, raises concerns about the safety of individual users and, in the case of drugs such as antibiotics, avoiding patterns of use that risk microbial resistance at the societal level.

Transgenic seed regulation is in a different situation to the extent that similar globalising processes are evident, but without a prior, stable regulatory regime already in place. Instead, a global regulatory regime that enables multinational seed businesses to operate in multiple markets is contested, and remains seriously challenged in certain key markets. National regulators are forced to arbitrate between international obligations to harmonise seed regulation and their own priorities on the appropriate development, diffusion and use of transgenic technologies within their agricultural sectors. But this regulatory activity also confronts a highly heterogeneous set of realities and concerns on the ground, raising questions about whose framings of the ‘public interest’ are informing regulation.

Argentina and China provide testing locations for contrasting harmonising seed and drug regulation with users’ experiences of those artefacts. We have chosen those two jurisdictions for a variety of reasons: both are relatively powerful developing countries with their own seed and drug business capabilities and associated state interests, and have relatively large domestic markets. However, depending upon the technology in question, they contrast in terms of continued levels of public sector provision, export-orientation, and public regulatory architectures. Both have a variety of distribution channels, some of them open to poorer users, but to different degrees. And, as in other jurisdictions, both have been under pressure to reform their regulations in one or both of the case study areas. China is an increasingly important player in global regulations, and rapidly changing institutional and socio-technical contexts bring further challenges to the implementation of harmonised regulations.

Neither Argentina nor especially China are typical of developing countries, but the objective of our research is not to generalise away from those case studies, nor to draw a direct comparison between these two locations (many others could have been chosen) but rather to use them as test-beds for developing a methodology that explores the ways regulatory systems understand and intervene in socio-technical practices, and to build upon that knowledge by considering programmes for regulatory capacity-building that are more inclusive towards poorer communities.

3. DEFINING ‘TECHNOLOGY REGULATION’

Before turning to the literature on seed and drug regulation and use, it is useful to consider how we have defined ‘technology regulation’ for the purposes of this project. The term regulation is used in very different ways by different authors and it has different meanings in different jurisdictions. Thus far, our own working definition of technology regulation has been: ‘attempts by states to shape the broad governance and specific uses of technology’. Note that this definition, whilst state-centred, is explicitly open to the incorporation of non-state actors. Such actors do not simply use technologies, but are part of its broader governance.

Indeed regulators are reliant upon others to make regulations effective, in terms of creating desired technological practices and ensuring they are followed. Non-state actors' activities include, for example, the work of international organisations, self-regulation in business, informal regulatory initiatives in the absence of effective states, and hybrid forms of social co-ordination.

Our working definition also reflects the fact that regulation is not solely about controls on established technology products and processes - a quite common definition of technology regulation - but extends, more broadly, to a desire to regulate the development of new technologies. Our definition of regulation thus includes deliberate 'front-end' attempts by regulators to support and direct ongoing technology innovation. [1]However, in extending our working definition to include front-end technology policy we are keen not to just redefine regulation as all governmental or governance activities. Here it may be useful to bear in mind the distinction made by Braithwaite *et al*:

> Governments and governance are about providing, distributing, and regulating. Regulation can be conceived as that large subset of governance that is about steering the flow of events and behavior, as opposed to providing and distributing. Of course, when regulators regulate, they often steer the providing and distributing that regulated actors undertake as well (Braithwaite *et al* 2007, p. 3).

Likewise, distribution and provision can also embody regulation. Innovation policies, for example, may be understood in part as 'distributing' (e.g. subsidising private R&D) or 'providing' activities (for instance through direct public R&D and the training of scientists and engineers); but they are nevertheless also regulating activities, to the extent that they might be designed to encourage public and private actors to create, modify, and diffuse *certain kinds* of technologies in relation to a broader set of policy objectives and ambitions.

It is useful briefly to contrast our working definition with the main kinds of working definitions - of regulation in general - that exist in the broader regulation literature. There are unsurprisingly an extremely heterogeneous set of definitions in use but, as Julia Black (2002) has noted, most are of three types. The first, and most narrow, is the setting of rules by government, usually accompanied by mechanisms for monitoring and enforcement. This is perhaps the core understanding that many have of regulation, but it is narrower than our version. It confines regulation to the setting and enforcement of rules, rather than encompassing other means by which behaviour of individuals and institutions may deliberately be influenced. It also leaves no room for non-state actors. A second, broader, but also common definition of regulation is any form of direct state intervention in the economy. This too leaves no room for non-state actors but, in relation to state-centred activities,

[1] Relations between regulation and technology also have to be considered dynamically and within a systems context, since existing regulatory decisions, even 'back-end' regulation at the point of end use, feed back to influence the planning decisions of technology developers.

it is also broader than our working definition, and would include what Braithwaite *et al* call the 'distributing' and 'providing' functions of the state. A third, extremely broad, but not uncommon definition of regulation is all mechanisms of social control or influence affecting all aspects of behaviour from whatever source, whether they are intentional or not. This definition, whilst allowing space for non-state actors, provides no boundary as to where regulation might end. It encompasses every kind of state/market/cultural influence on behaviour. For the moment, we note that our own working definition of regulation is state-centred, but nevertheless seeks to open up regulation to include non-state actors and activities. It also encompasses a wider range of activities than just rule setting, but nevertheless maintains a focus on the purposeful steering of behaviour.

The vast, long-standing literature on regulation is dedicated to understanding the mechanisms by which governments establish rules; studying responses amongst the regulated; debating the most efficient ways of reforming regulations; and the processes by which the public interest is identified and regulatory objectives subsequently understood. John Francis makes the important point that much in regulation is ambiguous since regulations rarely prohibit an activity outright, but rather constrain the way that activity is performed; and, of course, defining the 'public interest' is a highly political activity involving negotiations within the state and between the state and other actors (Francis 1993). However, in all this, much of the regulation literature sees divergence between formal regulatory mandates and informal realities as problematic and something to be overcome through better regulatory design and further capacity-building.

We will be drawing on some of the analytical themes in this regulation literature in our project. One body of work, on decentred understandings of regulation, in particular, may prove fruitful in *Rethinking Regulation*. Decentred understandings of regulation recognise that regulation is not centred on the state, but instead is diffused throughout society. It is concerned with how actors other than the state are, and might be, harnessed in the design of hybrid mechanisms in order to further public policy objectives. Amongst other things, it takes seriously the complexity of interactions between actors in society, the fragmentation and socially constructed nature of knowledge in society, the dispersal of power between social actors and between actors and the state, the relative autonomy and ungovernability of actors and systems, and the collapse of clear public/private distinctions (Black 2002). The decentred literature is used to both describe regulatory experience, and to provide prescriptive analyses, both strands of which we might find useful. However as emphasised above, our intention in this paper is not to explore which kinds of analytical literatures might prove fruitful for our purposes, but rather to discuss what we know empirically about drug and seed regulation in a globalising context, and about drug and seed use, especially informal patterns of use, in developing countries. We now turn to each of these in turn.

4. THE REGULATION OF MEDICINES AND TRANSGENIC SEEDS IN A GLOBALISING CONTEXT

Across diverse fields, technological and otherwise, regulatory solutions that were shaped in North America and Europe are increasingly internationalized and projected globally. As Levi-Faur (2005, p.13) puts it: "…the reality is that many supposedly sovereign polities are increasingly rule takers rather than rule makers …" We are interested in how international regulatory harmonisation processes enable, constrain, or otherwise influence the development of national regulations, and through these, technology access and use in the drug and transgenic seed sectors. This section is therefore a brief description of the main areas of regulation that are intended to control the use of drugs and transgenic seeds and that are subject to globalizing pressures, and a brief discussion of some of the policy issues in relation to developing countries that regulatory harmonisation raises.

A variety of forces are driving the adoption of harmonised forms of technology regulation in developing countries. One important source of pressure arises from developing countries' participation in global supply chains (Newell 2002). Developing countries may have little choice but to comply with the regulatory requirements established in places where they wish to export to, or import from. Another form of pressure to harmonise standards and regulatory approaches are the formal obligations that arise as a result of membership of multilateral trade and environmental agreements, covering issues such as intellectual property rights and sanitary and phytosanitary standards. Bilateral trade and investment agreements between developing and developed countries are also an important harmonising force. These often oblige developing countries to adopt particular forms of regulatory control, or dismantle others, often beyond the minimum required by multilateral agreements and obligations. Often associated with multilateral and bilateral trade and environment, agreements are a variety of international regulatory harmonisation activities and capacity building exercises co-ordinated by institutions such as World Bank, OECD, WHO, FAO, and UNDP. These may not necessarily seek to harmonise particular regulatory standards, but they often imply common regulatory frameworks through, for instance, a common insistence that good regulatory principles or best practices are those that do not inhibit international trade (OECD 2007).

Regulations intended to control seed and drug use and that are subject to the kinds of globalizing pressures mentioned above are discussed below under the headings: a) regulation of intellectual property, b) regulation of the technological artefact, and c) regulation of the supply chain (i.e. producers, suppliers and users of the technological artefact).

REGULATION OF INTELLECTUAL PROPERTY

Membership of the WTO (Argentina has been a member since 1995 and China joined in 2001) involves a significant obligation to put in place particular kinds of intellectual property protection. Under the Trade Related Aspects of Intellectual Property Rights (TRIPs) Agreement all developing countries that are members of the WTO have had to establish minimum standards of intellectual property protection.

The TRIPs Agreement, which entered into force in 1994, requires that 20-year patents be available for the products and processes of all types of technology, regardless of the place of invention, or whether products are imported or locally produced. Prior to the signing of the Agreement, the right of different countries to implement different systems of intellectual property protection, according to their level of economic development, was recognised by the international agreements covering patent protection (Coriat *et al* 2006). Given very limited technological capabilities, it was generally in developing countries' interests not to grant patents, so that domestic firms could 'learn by copying'. Indeed, a common feature of all successful cases in the 19th and 20th centuries in those countries which were, at that time, less developed countries that later 'caught up' with the then leading economies is that they operated with intellectual property regimes that did not restrict the abilities of domestic firms to copy the technologies used in the most advanced countries (Mazzoleni and Nelson 2007).

Most developing countries had a deadline of 2000, and for pharmaceuticals 2005, to comply with TRIPs, whilst the least developed countries were given a deadline of 2006, later extended to 2013. Under bilateral pressure many developing countries complied with TRIPs before those deadlines. There are some important exceptions to the general requirement that patents should be available for all types of technology, and there are allowances for flexibility, both of which affect the seeds and pharmaceutical sectors in different ways.

TRANSGENIC SEEDS

Under Article 27 of the TRIPs Agreement, novel plant varieties can be excluded from the general requirement that all inventions be patentable. However, if WTO members choose to make that exclusion they still have to provide for the protection of novel plant varieties using 'an effective sui generis [of its own kind] system.' Most developing countries have chosen to avoid granting patents to plant varieties as a result of TRIPs obligations and have instead relied on existing, or have adopted new, *sui generis* systems. The most widely used of such systems is the International Convention for the Protection of New Varieties of Plants (the UPOV Convention). It is designed to give plant breeders the right to control the commercial use of their new plant varieties, while at the same time allowing other breeders to use the new varieties as an initial source of variation in their own work. It was, however,

designed with the commercialised farming systems of developed countries in mind and was initially ratified by a small number of industrialised countries (Tripp *et al* 2007).

Two forms of the Convention exist, UPOV 1978 and the stronger UPOV 1991, which new UPOV members are now required to join (Tripp *et al* 2007). Under UPOV 1978, breeders' rights are a copyright-like form of intellectual property which allows the variety owner to have a monopoly on the commercial propagation and marketing of the variety, but little control over other uses. Farmers are free to multiply seed for their own use - including for non-commercial seed exchange among farmers - for as long as they wish. Other breeders can also freely use protected varieties to develop their own material. Only those plant varieties or species listed by the country have to be covered by the Convention.

Under UPOV 1991, breeders' rights are strengthened at the expense of farmers' rights. There is still an exception for farm-saved seed but this does not extend to informal trade and exchange among farmers. Furthermore, the exception is not automatic. Governments have to legislate to allow farm-saved seed to be reused by farmers. The plant breeder also has the right to a royalty payment on farmers' use of saved seed. Other breeders are still allowed to use protected varieties to develop their own material, but if a new variety is only marginally different from an existing one, it does not qualify for plant protection on its own. Finally, all plant species and varieties have to be covered by UPOV 1991 (Tripp *et al* 2007).

The TRIPs Agreement does not require that countries seeking a *sui generis* system sign up to the UPOV Conventions but a large number of developing countries have either adopted UPOV-like plant variety protection legislation or have joined the UPOV (Tripp *et al* 2007). Argentina joined UPOV in 1994 and China joined in 1999, in both cases signing up to the 1978 Convention. In practice, bilateral trade and investment agreements with industrialised countries often include provisions that require either patents on plants or UPOV membership or both. For example, recently concluded free trade agreements between the United States and at least eight Latin American countries (although not Argentina) require all parties to join UPOV and make "all reasonable efforts" to allow patents on plants. The agreements also state that this policy shift must never be reversed (Grain 2007a).

For many developing countries, the TRIPs requirements imposed a marked change in policy since their own needs and conditions had meant that many had a weak or non-existent form of IPR for seeds. This is because crop variety development and seed production was often dominated by the public sector, and/or operated at farmer level, rather than being a commercial business. Where farmers are used to using and reproducing varieties that elsewhere are protected, and where domestic research capacities are not internationally competitive, strengthened IPRs are unlikely to provide much in the way of benefits for either the informal breeding sector or the farming communities.

Where a seed industry existed it was usually based on the production of hybrid seed (i.e. the first-generation cross of two or more inbred lines) for which IPRs are not crucial. This is because the inbred parent lines are secret which prevents competitors from producing the same variety. Second generation hybrid seed also loses some of its yield potential and uniformity which means that farmers often prefer to re-purchase seed. In theory, IPRs may stimulate seed firms to invest in R&D, yet what limited evidence exists suggests that strengthened IPRs do not lead to increased plant breeding; rather, they allow seed firms to get a better return on existing investments, at the expense of farmers (Van Wijk 1996).

One important argument in favour of introducing plant variety protection in developing countries is that improved varieties, bred elsewhere, may not be made available to domestic seed firms for incorporation into their own breeding programmes unless sufficiently strong IPRs exist. Although strengthened IPR systems may increase the flow of protected material from elsewhere, Srinivasan (2003) argues that developing countries are likely to find that the terms of access for domestic seed companies wishing to get hold of protected plant material are set by a very limited number of monopoly suppliers, and that the implications of this for control of plant resources and future innovation in plant breeding need to be carefully considered.

DRUGS

Unlike seeds, pharmaceuticals are not excluded from the general TRIPs requirement that all inventions be patentable. Again the TRIPs Agreement represents a substantial change for developing countries as many of those countries historically had not granted patent protection, or indeed any form of IPR, for pharmaceutical products, as the then multilateral agreements permitted. In the absence of innovative pharmaceutical firms, it was not in most developing countries' interests to grant pharmaceutical patents to their firms.

The absence of patent protection for pharmaceutical molecules is also partly explained by the fact that social security systems in most developing countries could not guarantee the affordability of medicines. Widespread access to treatment could therefore only be assured by bringing prices down close to production costs, which did not include the additional rent derived from the granting of pharmaceutical patent rights. Prior to the TRIPs Agreement, the organization of the international pharmaceutical industry was therefore characterized by the existence of a dual market: first, a market mainly based on patented products, established in developed countries where social transfer systems could assure the affordability of highly priced medicines, and second, a market of generic drugs established on the grounds of the legal copy of patented medicines (Coriat *et al* 2006). This was implemented in most developing countries either through local production or importation. In countries such as Brazil, Argentina, India and China reverse engineering of patented medicines enabled local drug manufacturing capacities to produce 'generic' drugs for the domestic population at low cost. However, as

developing countries become TRIPs compliant, (by 2005 all but the least developed countries were obliged to be TRIPs compliant) all production of generic copies of patented products becomes impossible.

The TRIPs Agreement contains a number of public-health safeguards which enable countries to obtain cheaper patented medicines or generic equivalents of patented medicines. For example, Article 31 of the TRIPs Agreement allows governments to temporarily override a patent and authorise production of generic equivalents of patented medicines in the public interest ('compulsory licensing and government use', Oxfam 2006).This was a well established principle prior to the advent of TRIPs and had often been (and continues to be) used by developed countries.

Tensions concerning the grounds on which the public-health safeguards in TRIPs could be used came to a head in 2001 at the Fourth WTO Ministerial Conference in Doha. The Ministerial Conference issued a declaration which reaffirmed the exceptions provided for in the TRIPs Agreement. It also acknowledged the need to allow developing countries with insufficient or no drug manufacturing capacities to import generic versions of patented medicines under compulsory licenses. This was because the TRIPs Agreement states that compulsory licensing must be predominantly for the domestic market, which meant that developing countries without the necessary manufacturing capacity could not rely upon other countries to provide medicines (Coriat *et al* 2006).

As is the case with plant varieties, higher standards of IPR than mandated by TRIPs have been agreed with some developing countries as part of bilateral free trade agreements between developed and developing countries (so called 'TRIPs-plus' rules). Amongst other things, these typically insist that countries expand the scope of pharmaceutical patents to include new therapeutic uses of existing medicines (effectively helping to block generic entry), to limit the grounds for issuing compulsory licenses to emergencies, government non-commercial use, and competition cases, and to prevent parallel trade of patented medicines sold more cheaply elsewhere (*Médecins sans Frontières* 2004).

REGULATION OF THE TECHNOLOGICAL ARTEFACT

Several types of regulations, for both transgenic seeds and drugs, are aimed primarily, or at least partially, at the technological artefact itself.[2] In particular, both seeds and drugs may be subject to product registration requirements before they can be commercially marketed. Most product registration regulations are subject to varying degrees of harmonising pressure, as described briefly below.

[2] Since technological artefacts embody particular assumptions about the social world in which they are produced, distributed and used, rules concerned with the control of those artefacts are concerned indirectly with the control of producers, suppliers and users.

TRANSGENIC SEED REGISTRATION

In many countries, including China and Argentina, new seed varieties must be registered before they can lawfully be marketed. Registration typically requires that seed varieties meet established agronomical criteria such as a minimum percentage of seed purity and rates of germination, as well as compliance with standards of distinctiveness, uniformity and stability. Transgenic seeds often require additional regulatory authorisation and there are a number of globalising initiatives that have influenced the ways in which developing (and developed) countries design and define the registration rules, and more broadly regulatory regimes, for transgenic seeds.

Sanitary and Phytosanitary (SPS) standards are regulations covering the protection of human health, animal health and plant health. The SPS Agreement states that SPS standards that adversely affect international trade, must be "…based on scientific principles and…not maintained without sufficient scientific evidence" (GATT 2003, para. 6). The existence of a physical risk, supported by scientific evidence, is therefore the only legitimate basis upon which the commercialisation of traded products and technologies can be restricted or delayed on health or environmental grounds. The intention is to discourage members from adopting regulatory standards that purport to protect human, animal or plant life or health but which function as disguised restrictions on trade.

Regulatory standards established by certain international institutions (the Codex Alimentarius Commission, the International Office of Epizootics and organizations operating within the framework of the International Plant Protection Convention) are assumed to meet the obligations established by the SPS Agreement, and members are expected to "…base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist…" (Art.3.1) Stricter standards than those established by organisations such as the Codex are permitted under the Agreement, but in the event of a dispute, members may have to demonstrate to a WTO Dispute Panel that they possess a scientific justification for any stricter standard.

The SPS Agreement therefore provides a strong incentive for countries to conform to, or at least not to adopt stricter standards than, international measures, guidelines and recommendations. If scientific standard-setting were a purely scientific, objective process then adopting international standards might not be especially problematic. Yet, as many scholars have argued, technical standards, as well as the underlying methods for establishing those standards, are inevitably premised upon, or framed by, value commitments and social assumptions that are not universally valid or accepted. The definition of international standards, or even a general approach to setting standards or assessing risks, are activities imbued with political and social choices (Jasanoff and Wynne 1998).

For example, in 2003 the Codex Alimentarius Commission, which oversees the development of international food safety standards, published guidelines on foods derived from transgenic organisms (Codex 2003). These identify the information

that Codex considers is needed for an effective assessment of risk as well as the ways in which such risk assessments should be undertaken. They therefore provide a benchmark, as far as the SPS Agreement is concerned, of what constitutes a properly scientific approach to assessment of risk for GMOs, and text similar to that contained in the guidelines often finds its way into the licensing approaches adopted in individual countries.

Those Codex guidelines are not, however, the only conceivable approach to risk assessment of GMOs. For example, they help to define the kinds of risks that get considered by regulatory assessors and those that are ignored, a decision step that is clearly imbued with social preferences. They also help to define the rigour with which particular risks will be assessed. On this point, for example, current Codex guidelines encourage the use of a concept known as 'substantial equivalence' which was introduced by the OECD as a means to compare a GM food with a conventional counterpart for safety purposes. Codex initially interpreted substantial equivalence as requiring a comparison of the chemical composition of a GM food with its non GM antecedent. So long as the chemical composition was broadly similar the novel foodstuff could be deemed safe. Critics argued, however, that crude compositional data provide a very weak screen against the introduction of novel genetic, biochemical, immunological or toxicological hazards. The introduction of transgenic DNA into an organism may bring about a range of unanticipated changes in the expression of other genes, and consequently in the proteins for which the genes code. Codex's interpretation of substantial equivalence effectively assumed that a GM product posed no more risks to health than its conventional antecedent. It therefore resulted in a relatively permissive approach to regulation, but under the guise of a seemingly neutral scientific framework (Millstone *et al* 2004).

Interestingly, however, interpretations of substantial equivalence have subsequently shifted. Under pressure from scientists, some regulatory authorities and NGOs, regulatory policy-makers have progressively reinterpreted the concept. It has been increasingly common for substantial equivalence no longer to be represented as the outcome of a risk assessment but only as a starting point, a way of starting to frame a question, not as the basis for an answer. Thus in 2000 a report of the FAO/WHO Expert Consultation on Foods Derived from Biotechnology noted that "…a consideration of compositional changes was not the sole basis for determining safety" (Millstone *et al* 2004). What is interesting about this shift is that it suggests that there is scope to challenge and revise scientific standard setting within harmonisation processes, but perhaps only on 'scientific' grounds even though, in practice, the issues are better characterised as hybrid social-scientific issues (Levidow *et al* 2007).

The Cartagena Protocol on Biosafety (the Biosafety Protocol) is a multilateral agreement that applies to trans-boundary trade in the products of genetic engineering. It is concerned primarily with protecting the biodiversity of the flora and fauna of the environments into which GM seeds and crops may be introduced, although its negotiation was framed around the need to ensure that regulating environmental

impacts of GMOs was compatible with global trade rules. The Biosafety Protocol works by empowering potential importing countries to exclude GM seeds and crops unless and until they have given 'advanced informed agreement'. Although signatory countries to the Biosafety Protocol are authorised to withhold consent, they can do so only on condition that their decisions are based on a 'scientifically sound' risk assessment (Biosafety Protocol, Art. 15 para 1), and one that indicates an adverse impact from the GMO in question. As with the SPS Agreement, the Biosafety Protocol seeks to minimise the extent to which restrictions on international trade are discriminatory or masquerade as environmental protection measures.

The Biosafety Protocol frames the potential adverse impacts of GMOs as largely physical in nature. Article 26 of the Cartagena Protocol states, however, that countries are entitled to take into account "socio-economic considerations arising from the impact of [GMOs] on the conservation and sustainable use of biological diversity" in determining whether to approve the import of a GMO. This is a relatively narrow range of socio-economic considerations. It is unlikely, for example, that issues such as the distribution of general socio-economic risks and benefits would be consistent with Article 26 of the Biosafety Protocol.

The Biosafety Protocol also calls for capacity building to help countries develop national biosafety frameworks and to expand their scientific, regulatory and administrative capacity. A 2008 review of biosafety and biotechnology training programmes claimed that the majority of developing countries are unable to manage modern biotechnology and implement national biosafety frameworks. It argued that "…the capacity deficiencies are so pervasive and broad that there is no effective international system of biosafety at the moment" (Johnston *et al* 2008).

Under the Biosafety Protocol, the Global Environment Facility (and its hosting agencies, the World Bank, the UNDP and UNEP) is mandated to support capacity building activities. For example, as part of the process of preparing for the Biosafety Protocol, the UNEP has developed "Technical Guidelines for Biosafety" and has worked with up to 130 countries, including China and Argentina, to develop National Biosafety Frameworks. Several other international institutions, including FAO, WHO and the CGIAR alliance, have been involved in providing advice on biosafety assessment approaches. Advice and capacity building activities are also frequently undertaken on a bilateral basis. Regulatory agencies and institutions in countries such as the USA, Canada and the UK that have relatively long-established regulatory agencies and that have interests in harmonizing GM controls run various meetings, workshops and exchanges.

With a diversity of international and national organisations engaged in capacity building, different kinds of interests, regulatory approaches and models of biosafety regulation are being promoted (Gupta and Falkner 2006). There are, however, few empirical studies that explore the way capacity building exercises have actually influenced national frameworks, decision-making criteria and policies. One exception is a study that has explored the impact of the Biosafety Protocol in Mexico, China

and South Africa on national biotechnology policy, although only in general terms. It suggested that there was little influence on domestic biosafety policy as a result of associated capacity building projects, and that the Biosafety Protocol process remained at the margins of political debates around biotechnology (Gupta and Falkner 2006). However, it is not clear the extent to which the impact of the Biosafety Protocol on regulatory processes was examined, as opposed to its impact on broader political and policy debates. Elsewhere, however, it is clear, from a reading of regulatory documents that the regulatory approaches established by at least some developing countries seem to closely mirror those originally developed within international institutions (Scoones 2002; van Zwanenberg 2006). It is unclear then what the impact of agreements such as the Biosafety Protocol on the approaches to regulation established in signatory countries may be, beyond nudging regulatory regimes into compliance with the formal obligations as set out in those agreements.

Recent work examining the scope and effectiveness of international capacity building initiatives in biosafety regulation has noted that international efforts have focussed on improving scientific risk assessment capacity whilst neglecting other important factors prolonging “the biotech divide”, such as transfer of non-proprietary technologies focused on locally defined priority crops, South-South collaboration, networks of experts, exchange mechanisms for information and experience and development of endogenous capacities (Johnston *et al* 2008).

It is an open question as to whether the kinds of seemingly technical transgenic seed registration procedures advanced by these harmonising activities will reflect developing country priorities and interests. For example, for some developing countries the most important impacts, as far as the commercialisation of GMOs is concerned, may be those to do with effects on food security and/or rural employment and livelihoods. Biosafety concerns may be comparatively less important, but in developed countries those priorities may be reversed, and thus issues of food security and employment may be crowded out of international regulatory agendas for GMOs. These choices are inevitably a reflection of the social, economic and environmental priorities and concerns of industrialised countries, and the particular interests that are powerful within those countries. But they do not necessarily correspond to the priorities and interests that developing countries might wish to promote.

DRUG REGISTRATION

Regulations governing the commercial registration of drugs generally focus on ensuring that a drug meets acceptable standards of efficacy, quality and safety. Controls on drug manufacturing processes and of the actors and components in pharmaceutical supply chains are covered in a subsequent section. Registration requirements, at least in developed economies, began in the mid twentieth century with standards concerned with controlling adulteration and unsubstantiated therapeutic claims, and from the 1960s onwards, with efficacy and safety.

Most developing countries have formal requirements for registering medicine but these vary substantially as to what is required and in terms of the resources made available for registration. Registration ranges from, at minimum, a simple notification scheme, providing centralised information as to whether a particular drug is on sale in a country, through to authorisation schemes in which a licence needs to be issued before a drug can be lawfully sold but based on registration information obtained from other countries. More extensive is full regulatory review, in which, for new drugs, evidence for efficacy and safety on the basis of pre-clinical toxicology studies and human clinical trials is required from manufacturers prior to registration.

Given the demands on expertise and time, it is difficult for small regulatory agencies to undertake a full regulatory review of new drugs, and many therefore limit themselves to a partial review, which basically involves trusting the assessment conducted by well resourced agencies such as the European Medicines Evaluation Agency and the US Food and Drug Administration. The WHO estimates that fewer than one in six WHO Member States have well developed drug regulation capacity and two in six have no or very little drug regulatory capacity.

Drugs can be classified into three categories, all of which tend to be subject to registration requirements: (i) in¬novative, or proprietary, drugs, (ii) similar drugs or copies and (iii) generic drugs. Similar drugs or copies are pharmaceutically equivalent to the proprie¬tary product — that is, they contain the same active ingredients in the same dosage and are intended to be administered by the same route. They may not, however, be bioequivalent, (i.e. have the same extent and rate of absorption), for example because they have a different excipient or shelf-life. True generic drugs are both pharmaceutically equivalent and bioequivalent; they are entirely interchangeable with the proprietary drug. For new generic drugs or for similar drugs, the data required is largely about the pharmaceutical chemistry of the product, to allow a comparison with the innovative drug.

Harmonisation efforts, as far as drug registration is concerned, have been driven in part by increasing trade in pharmaceuticals but in particular because the pharmaceutical industry would like to bring new drugs to market faster, in a wider market, and at a reduced cost. The focus of international harmonization efforts to date has been led by the pharmaceutical industry and regulators in the European Union, Japan and the USA (which together account for 75% of the world’s production of medicines, 90% of global pharmaceutical research and development and 90% of the worldwide market for drugs). Since 1990, a process of harmonization of drug registration known as the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, or ICH, has began the task of harmonising the testing procedures required to register new medicines.

Although currently focused on harmonisation between Europe, Japan and the USA, Abraham and Reed (2001) note that some in industry regard the ICH as the first step towards global harmonisation and the production of a global registration dossier,

which would contain all the data necessary for marketing approval in any country[3]. They note that it has been suggested by some senior officials that new drugs approved by the USA, Japan and EU might simply be approved administratively by developing countries without any additional data review by their governments.

Furthermore, as a WHO report notes, many developing countries may adopt ICH standards domestically as a means of retaining access to global pharmaceutical markets: "ICH has never claimed, and does not have international authority or capacity, to produce global standards. Nevertheless, although ICH countries import large quantities of pharmaceuticals from non-ICH countries with weak regulatory systems, many countries are led to think that adoption of guidelines is a necessary move to gain access to the pharmaceutical markets of ICH countries" (WHO 2001).

Inevitably, the ICH process's view of the drug registration problem corresponds to developed countries' views of the pharmaceutical world, and the content of the harmonised guidance largely reflects US, European and Japanese industrial concerns. Seemingly technical issues may involve quite important policy choices. For example, a report for *Médecins Sans Frontières* notes that methodological choices by the ICH process to assess the efficacy of a new product on the basis of superiority to a placebo rather than choosing an active comparator will only show that a new drug works, not that it works better than existing therapies. They will therefore promote pseudo-innovative medicines - product innovations as opposed to purely therapeutic innovations (Abraham 2006). As *Médecins Sans Frontières* put it "[w]hile some ICH countries can afford this irrational approach, this is not the case for all non-ICH countries, as they cannot offset such additional health costs" (Trouiller *et al* 2002).

Harmonized standards may presume a degree of universality that does not apply in practice, in that there may be a warrant for country-specific requirements for particular types of pharmacokinetic or clinical safety studies. The pattern of clinical practice varies from country to country and so what may be a reasonable indication (i.e. a reason for prescribing a particular drug or treatment) for a product based on the data in one country may not fit with the style of clinical practice in another.

REGULATION OF THE SUPPLY CHAIN

The supply chains for transgenic seeds and drugs include manufacturers, importers, distributors, vendors and users/consumers. Aspects of these regulations, particularly those subject to globalising pressures, are briefly discussed below.

[3] In addition to the ICH process there are various regional harmonisation initiatives, such as within the Mercado Común del Sur, or MERCOSUR, which covers Argentina, Brazil, Uruguay and Paraguay, and the Pan American Network on Drug Regulatory Harmonization. The second conference for the latter noted that harmonization should encompass regulations governing not only the registration of drugs but their marketing as well.

TRANSGENIC SEEDS

Regulations governing the supply chain for transgenic seeds cover licensing of seed companies, distributors, and dealers and in some cases, controls on farmers' use of seed. Most controls on farmers use of seed is either very tangential (i.e. via the regulation of how herbicides or insecticides should be applied), a consequence of 'soft regulation' (i.e. via the provision of advice from agricultural extension services) or essentially private regulation (i.e. terms of use in the contract with suppliers). The latter takes the form, typically, of purchase agreements which, in some jurisdictions, private seed companies have begun setting up directly with farmers. These originated in the USA and are often designed to restrict farmer practices of saving seed or of selling saved seed, without having to rely on plant variety protection legislation. Indeed they often have a far wider scope than restrictions ensuing from plant variety protection. In some countries these enable the company to use breach of contract claims in local courts to enforce ownership of seeds (Van Wijk 1996). Similar purchase agreements have been used, again in the USA, to ensure compliance with legally-mandated resistance management strategies for Bt crops (Ely 2006).

DRUGS

Regulations governing the supply chain for drugs cover issues such as good manufacturing practice - a system for ensuring that products are consistently produced and controlled according to quality standards - the right to prescribe drugs, the right to sell drugs, and controls on promotion and marketing.

One significant globalising influence on supply chain regulation is concerned with the WHO's Essential Drug Policies. These were intended to guide drug selection, registration and procurement by governments and they also recommended the implementation of policies to promote the use of generic drugs. The purpose was to make essential drugs and vaccines available under favourable conditions to governments of developing countries. WHO listed around 200 drugs and vaccines that were considered to be safe, effective and affordable. Most of these were no longer protected by patent rights, and were available at low cost in the form of generics.

Van de Geest notes that the implementation of the programme proved difficult:

> "Pharmaceutical companies that saw their most lucrative products suddenly excluded from the market lobbied among political authorities and medical professionals to keep their products on the list. Ministries of Health trying to satisfy the medical profession and the industry, and keeping their own interests in mind, were slow to implement the programme or only paid lip service to it. Pharmacists resisted because it meant throwing out their stock of the more expensive medicines. Moreover, both doctors and pharmacists believed that some of the new, 'non-essential' drugs were superior to those on the WHO list and protested against the interference in their professional work. Finally, and quite ironically, the patients, those for whom the program had been designed, often felt they were being cheated with inferior or second hand medicines" (Van de Geest 2006, p. 306).

Reynolds Whyte *et al* have noted that an evaluation of the WHO programme showed that health planners have a blind spot for drug use outside the channels of health care that fall under their mandate. They assume that people use public health centres and that they take medicines on prescription (Reynolds Whyte *et al* 2002). As Van de Geest (2006, p. 306) notes: "In most cases where local governments did implement [the essential drugs policy] it only affected the public sector, allowing private institutions to continue prescribing and dispensing 'non-essential' drugs. What exactly happened on the ground, however, no one really knows for it was rarely documented."

The WHO is also involved in other harmonising activities concerning the regulation of the drug supply chain. For example, the WHO has developed and published guidelines for the development of measures to combat counterfeit medicines and heads an International Medical Products Anti-Counterfeiting Taskforce.[4]

DISCUSSION

A number of points are worth highlighting about the regulation of drugs and transgenic seeds in a globalising context. Most generally, there is a latent tension between globalising 'one size fits all' regulations and the diverse particularities of the conditions, interests, and use contexts within developing countries (Orsi and Coriat 2006). This kind of misalignment may arise in several different ways. One relatively obvious source of mismatch is where regulatory policies that have been developed in Northern settings, and which are then applied elsewhere, reflect the particular interests and circumstances of the settings in which they were designed. Thus, the internationalisation of intellectual property rights via the TRIPs Agreement involves the imposition of obligations that overtly reflect the conditions and interests of the pharmaceutical and agricultural and life science sectors in the major industrialised countries; in particular, the interests of the dominant firms operating in those sectors. There is, however, strong evidence, partly discussed above, that the obligations set out in the TRIPs Agreement may not always be, or even often be, appropriate for the priorities and needs of the industrial sectors and populations of developing countries. Indeed, depending on sector, many less developed countries' interests in economic development might be better served in the absence of a patent system, or with a very weak IPR system. The relation between forms of intellectual property and development remains controversial.

Another example of global/national mismatches concerns the degree of stringency insisted upon with respect to transgenic seed biosafety. For example, Scoones notes that strict biosafety regulations raise entry barriers to all but MNCs, in turn meaning fewer locally adapted crops, on the basis that local firms are better positioned to do this than MNCs (cited in Fukuda-Parr 2007, p. 231). Stringent regulation may

[4] See http://www.who.int/medicines/services/counterfeit/en/

also encourage the informal sector, as Fukada-Parr (2007) notes, with companies avoiding official regulatory processes (which may thus give rise to higher biosafety risks). The point is not that regulations should or should not be strict, but rather there may be consequences of adopting particular levels or forms of stringency that can and do vary as between Northern and Southern settings, and yet globalised forms of regulation sometimes effectively assume that those consequences will be uniform.

Regulatory policies and approaches developed at a global level or in Northern settings may also involve making more implicit assumptions about the nature of institutions, markets, and practices that turn out not to apply in some developing country contexts. For example, the essential drugs policies pushed by the WHO focused on public sector aspects of health systems, perhaps failing to recognise just how extensive private markets were in the delivery of pharmaceutical products. Similarly, the extension of intellectual property rights to seeds may not only be inappropriate given the particular conditions of, and policy objectives for, the agricultural sectors in developing countries, but the capacity for effective enforcement of those regulations may not exist either.

Many authors, especially those that have been influenced by the field of science and technology studies, note that the same broad point - that regulatory harmonisation often reflects the conditions and circumstances of a handful of powerful industrialised countries and often reproduces the interests of their already globally dominant firms - holds true when seemingly technical regulations and regulatory frameworks are transferred from Northern to Southern settings. Thus, in the case of environmental safety or food safety assessment procedures, as outlined by bodies such as UNDP or Codex, what is being transferred are not just technical rules and procedures but also a set of values and assumptions about what is important, what kinds of risks are acceptable, what biological processes are relevant.

Levi-Faur makes a similar point, arguing that where harmonising regulations reflect a set of problems and solutions that were socially and politically constructed in some dominant countries and regions "[d]emocratic governance is no longer about the delegation of authority to elected representatives but a form of second-level indirect representative democracy - citizens elect representatives who control and supervise 'experts' who formulate and administer policies in an autonomous fashion from their regulatory bastions" (Levi-Faur 2005, p. 13).

There are important caveats to these rather broad-brush points about the imposition of Northern country interests and perspectives, via globalising regulatory processes, on developing countries. International regulations are often in tension with explicit regulatory policies of entirely domestic origin. For example, the WTO and Biosafety Protocol Agreements generally stress that it is scientific criteria that should determine whether transgenic seeds can be adopted for commercial use for domestic production. Yet national priorities for the technology may be overtly or covertly linked to socio-economic criteria, which individual jurisdictions adopt when making regulatory decisions. For example, in Argentina transgenic seeds are not

generally approved for commercial use unless their main export markets have also approved the seed/foodstuff, but this kind of criterion is probably inconsistent with the WTO/Biosafety Protocol Agreements.

Newell (2003) notes that it is too simplistic to assume that developing countries always passively adopt global regulations and regulatory designs. International agreements are often fairly ambiguous, and there may be multiple, competing interests within any one jurisdiction in relation to such agreements. Newell describes how domestic policy networks in India and China sought to translate policy commitments contained in international agreements on trade and biosafety into domestic policy in ways that consolidated their position in the bureaucracy. He also argues that each country has enough of a clearly defined national interest in biotechnology that international processes are regarded as an opportunity to internationalise domestic policy preferences and secure scope for discretion in national policy-making. In other words, multi-level regulatory processes provide different venues where negotiating attempts can be made to realise domestic priorities; although the ability to negotiate may be compromised, especially beyond national policy and industrial elites. It is an open question as to how the position of poorer communities is reflected in the power relations that affect how national states seek to interpret international regulations.

Similar arguments about how the domestication of international obligations involves, or could involve, reinterpretation and refashioning of global standards to make them compatible with local normative frameworks and the interests of local actors is made by van Wijk and Ramanna (2007) about IPR in Indian seed markets, and by Gupta and Falkner (2006) about implementation of the Biosafety Protocol in Mexico, South Africa and China. Millstone and van Zwanenberg (2003) have argued that the requirements in the SPS and Biosafety Protocol Agreements in principle allow countries more flexibility than most commentators assume in deciding whether they have to conform to the standards set by international bodies and powerful trade partners.

Some authors, whilst acknowledging that there are opportunities contained in multilateral agreements for relative flexibility, have argued that capacity building exercises and other forms of technical assistance may end up diminishing the extent to which some developing countries actually exploit those flexibilities. For example, Carlos Correa notes, in relation to patents, that most of the technical assistance that has gone to developing countries is more concerned with compliance with the provisions relating to the rights of the patent holders than the application of flexibilities within the multilateral framework to promote and protect public health (South Centre 1997). Jansen and Roquas (2005) argue that capacity building exercises encourage standardised approaches that have been designed by ‘absentee experts’ detached from local contexts, who are brought together for short periods to provide guidance on apparently technical issues, imported more often than not from other contexts. They note that although translation of such frameworks, standards, guidelines etc. into national and local contexts allows

countries to adapt them to their own needs, in practice many weak states do not have the capacity to develop legislation with domestic needs identified and built in. However, in all this it is worth remembering that some developing country states have little capacity to implement regulatory frameworks no matter what form they take, whether imported unaltered or adapted appropriately.

Another point to draw from the literature on seed and drug regulation in a globalising context concerns the diversity in the kinds of regulations that are subject to processes of harmonisation. Different international obligations may be concerned essentially with different kinds of objectives, and their objectives and remits may sometimes overlap or conflict with each other. For example, there are unresolved tensions between the Sanitary and Phytosanitary (SPS) Agreement and the Biosafety Protocol. Article 26 of the Biosafety Protocol allows signatories to take into account “socio-economic considerations arising from the impact of [GMOs] on the conservation and sustainable use of biological diversity” in determining whether to approve the import of a GMO. The SPS Agreement, on the other hand, does not allow for stricter standards on a GMO import than is otherwise deemed scientifically necessary to protect human or plant health. Where responsibility for implementing the Biosafety Protocol sits in a different Ministry to that of ensuring compliance with the SPS Agreement (e.g. an Environment versus an Agricultural Ministry) such tensions may come to the fore in domestic politics. To take another example, the underlying objectives of the essential drugs policies, promoted by the WHO – that of ensuring that drugs and vaccines are available under favourable conditions to governments of developing countries – are in tension with the objectives of TRIPs Agreement which are concerned primarily with extending intellectual property rights both geographically and across a wider range of artefacts.

Two further points are worth making in relation to this body of literature. The first is that, in general, the diversity of use contexts within developing countries is not addressed, at least to any great extent, in most of the literature pointing to the different contexts and interests between Northern and Southern settings in situations of globalising regulation. Clearly there are competing constituencies and interests within developing countries, and no single set of conditions, priorities, values and interests that are relevant to the development of regulatory institutions, policies and standards. Indeed, compared to more developed countries there is typically greater heterogeneity within a given developing country as to levels of income, living conditions, farming practices, health and so on. In countries like Argentina or Brazil, for example, large, highly mechanised, commercial farms producing commodities for export co-exist with poorly resourced small holders where production is primarily for subsistence, and where cultivation relies on animal traction or human labour. Given such heterogeneous use contexts, it makes little sense to talk about an unambiguous set of national priorities, interests, or perspectives regarding a technology and its appropriate forms of regulation. Where ‘national interests’ are mobilised in international negotiations, then they are more likely to be those of the elite power bases within those nations, rather than the marginal and poor, except in instances when the two happen to coincide.

The second more general point is that these general observations and arguments about the transfer, under processes of globalisation, of particular regulatory assumptions and perspectives from one jurisdiction to another are related to a broader analytical issue about the discourses and framing of regulation that has been raised and explored within the field of science and technology studies (Levidow *et al* 1997; Brickman *et al* 1985; Jasanoff and Wynne 1998). This issue is not just confined to the general definitions of what is considered to be at risk but also extends to the seemingly more technical aspects of regulation, such as scientific risk assessments. The latter, as several authors have explored, reflect particular social and political commitments that could be otherwise. For example, technical assessments of risk are often conditional on assumptions about the behaviour of human agents and institutions (Wynne 1989). People and organisations may behave as assessors expect, or want them to, but such assumptions are by no means a foregone conclusion. They are conditional social commitments rather than part of what purport to be purely technical claims. These points are not made in the context of globalising regulations, but are more really about scientific cultures of risk and about making explicit the otherwise unexamined assumptions about the social contexts within which potentially risky activities take place, and that therefore in part constitute the supposedly technical risks to be regulated. The critique has been one of the scientistic tradition in risk analysis (i.e. the view that problems of risk are matters for science, and science alone, to resolve), rather than the extra variability that arises when regulations are exported from one context to another. But the point is key, we feel, and the question that we can ask is, where do conditional assumptions about users and their behaviour come from? Unexamined scientific cultures prevailing in international negotiation? Or circumstances that are examined, but only valid in one context, which is the location in which the regulations originated? An important corollary to this is the need to attend to the local realities of drug and seed use.

5. INFORMAL USE OF DRUGS AND SEEDS

This section reviews general literature on the use of drugs and seeds, especially informal patterns of use (i.e. that are not mandated by regulations) amongst poorer communities. For the purposes of this review we are interested in the extent to which actual patterns of use amongst poor communities differ from the assumptions and expectations of policymakers, regulators and other actors about technological practices. Here we can define informal use not only as some of the ways in which final consumers of drugs and seeds learn about, obtain and use seeds and drugs, but also some of the ways in which producers and distributors make them available to those consumers. National policies and other actions on the part of state agencies may sometimes facilitate informal patterns of production, trade and use (in the sense that these occur in ways

that are not mandated by international or national rules). In such cases, state practices themselves might be thought of as part of the informal system of use of those artefacts.

DRUGS

As recently as 1987, Sjaak van der Geest (1987) noted that there has been hardly any field research into the ways drugs are actually used in developing countries. That lacuna has begun to be addressed over the last 20 years, especially after researchers and policy-makers, concerned with the policy implications of the essential drugs programmes that were promoted by the WHO in the 1980s, began to document the local realities in which medicines were actually made available and used. There are now many studies of medicines sales practices, prescription practices, and consumption practices in developing countries.

Researchers have shown the significance of the commercial and informal channels for medicines transactions (van der Geest *et al* 1996). For example, a valid prescription is not a prerequisite for receiving scheduled drugs at pharmacies in many developing countries. The literature suggests that up to 80% of all drugs in some countries are purchased by people for themselves or for a family member without prescription (cited in Homedes & Ugalde 2001). Pharmacists, or untrained assistants, ‘prescribe’ medicines themselves, giving advice to customers over the counter and acting as doctors (van der Geest *et al* 1996). Health workers may also distribute and sell pharmaceuticals both within the institutions where they work and outside them from their homes and in informal practices (van der Geest *et al* 1996). There are also various informal and untrained vendors of medicines: pharmaceuticals are sold in general stores and in markets (van der Geest *et al* 1996).

Researchers have argued that informal medicine sellers are often closer to their customers than doctors and pharmacists, geographically, financially, and socially (van der Geest *et al* 1996). Yet the sales practices of informal pharmaceutical suppliers are driven more by a logic of commercial exchange than that of the delivery of professional services. Hence potentially dangerous practices (in both the legal sector as well as in the illegal market) occur. These include the sale of loose medication, the sale of prescription medication without requiring the buyer to provide a prescription, the sale of only part of a course of medicine when customers do have a prescription, the inadequate substitution of prescriptions, the lack of advice and information on the use of the products, and employment of unqualified staff (Maiga *et al* 2003). These practices contribute to biomedical definitions of inappropriate use of medication, such as inadequate therapeutic use, over-consumption of drugs, excessive use of antibiotics and injectables and premature discontinuation of treatment (Maiga *et al* 2003).

Van der Geest *et al* note that many authors comment on the difficulty of distinguishing between commercial, informal channels and more public, formal distribution systems for drugs; the two are in practice tightly intertwined (van der Geest *et al* 1996). For example, the development of an informal medicine market is attributed to an inability on the part of the public system to make professional health workers accessible to the entire population, to cope with drug shortages in state health institutions, and to provide adequate wages to health workers so that they try and supplement their incomes (van der Geest *et al* 1996). These failures of the state's policy force people into a self-help culture of medicine and create space for the development of an informal medicine market and patterns of use very different to those presumed by the pharmaceutical companies developing the medicine.

Many biomedical commentators have criticised the quality of prescribing – in all countries not just in developing countries. The most common criticism here is that there is over-prescribing - too many medicines, too many varieties, unnecessary antibiotics and/or injections, and too expensive medicines. Over-prescribing can be the result of poor or biased information disseminated to prescribers, profit making, or the fact that it is easier to satisfy patients with drugs than with words (van der Geest *et al* 1996; Homedes & Ugalde 2001). Where medication is seen as the essence of medical practice, prescribing is the main thing expected from a physician. One concern of over-prescribing is that people tend to imitate doctors' prescriptions in self-medication (van der Geest *et al* 1996).

Turning to consumption practices, research has emphasised the fact that most pharmaceuticals, even regulated prescription-only drugs, are taken as self-medication (van der Geest *et al* 1996). Pharmacists, shop attendants and other informal suppliers of medicines obviously can and do foster self-medication by bolstering the easy availability of drugs but commentators have also argued that rising levels of self-medication in developing countries are associated with decreases in thresholds of tolerance for symptoms, greater familiarity with drugs and medicine vendors, changing health concerns related to modernisation (e.g. environmental degradation, adulteration of food), dramatic increases in the number of products available in the marketplace and changes in the purchasing power of consumers (Kamat & Nichter 1998).

Beckerlega *et al* note that the increasing tendency of people, particularly the poor, to equate health care with the consumption of pharmaceutical products is a hallmark of the commodification of health. They note that:

> [w]here people are unable to exercise control over their physical and social environments they tend to suffer ill health as a direct or indirect result. Under such circumstances, medicines which can be readily purchased may be attributed almost magical properties by those who use them. The use of medicines as a means of gaining health takes place within particular social and cultural contexts and such drugs are popular in contexts where there is considerable social insecurity and where people try to address short term problems. A context where functional health (the ability to perform work roles in the short term) increasingly takes precedence over long term concerns about well being is a fertile ground for a flourishing trade in medical fixes (Beckerlega *et al* 1999).

Nichter and various co-authors note that the public at once desires the fast relief that 'strong' allopathic medicines deliver and at the same time fears the potential long-term side effects. Consequently, people are less inclined to take long-term courses of medicines particularly when symptoms subside. Medicines are often not used as intended. Curative drugs are sometimes purchased for preventive and promotive health purposes by people who feel at risk of disease, given a particular living or work environment, or a state of ill health they fear may develop into a more serious illness (cited in Saradamma *et al* 2000).

Many researchers have also investigated the cultural and symbolic meanings of medicines. They have stressed that decisions to prescribe, dispense and use medicines take place in cultural contexts where medicines are used for other than clinical reasons, and that meaningful changes to those practices cannot take place unless this context is understood. For example, patients may have good reasons for taking their medicines in a way other than that indicated by a prescriber, and conceptions of health, illness, and medicine that differ from bio-medical views may affect the way people take medicines (van der Geest *et al* 1996).

Turning specifically to antibiotics (our case study medicine) many of the points above regarding consumption practices are all manifest. Thus, antibiotics are commonly purchased for self-medication by customers. Their ability to cure bacterial infections has helped to create the image of antibiotics as miracle drugs, an image which has contributed to their inappropriate prescription and use (Saradamma *et al* 2000). Saradamma *et al* (2000) cite several studies showing that self-medication of antibiotics means that they are often taken in inadequate doses for too few days. For example, one such study noted that only 18% of self-purchasers and 40% of prescription holders purchased a full course of antibiotics and that 30% of self-purchasers acquired only a one-day supply of an antibiotic requested. Self-medication with antibiotics has led the World Health Organization to call attention to the dangers of self-medication as a cause of antibiotic resistance (Kamat 1998). The politically acceptable and widely proposed response to this problem is one of education, of both healthcare providers and patients alike. The WHO has also highlighted the importance of regulations around licensing and prescribing drugs, the establishment of essential drugs lists and national standard treatment guidelines, and monitoring and surveillance for antibiotic resistance.

Broadening our perspective on informal drug use - from informal patterns of prescription, sale and consumption to informal modes of producing and distributing drugs - raises a set of issues that has emerged, especially in recent years, about the quality of pharmaceuticals available in both public and private sectors, and in particular the problems of counterfeit drug production, smuggling, and distribution/sale.

Counterfeits can occur with both branded and generic medicines, but expensive patented drugs rather than cheap generics are generally the target of counterfeiters (Outterson 2004). Counterfeits include products with the correct ingredients but fake packaging or the correct ingredients but which are in some other sense

'sub-standard', for example because they are manufactured by an unlicensed source. Such products may be safe and effective but just illegal. The issues raised with unlicensed but safe and effective drugs are somewhat different to those that occur where counterfeits contain the wrong ingredients, improper doses of the active ingredients, sub-potent or super-potent ingredients, no active ingredient, or are contaminated. The latter type of counterfeit is unreliable, useless, or dangerous. They are a threat to public health, as well as to the established pharmaceutical industry.

Estimates of the total number of counterfeit drugs available in different markets vary quite widely. The WHO reports estimates ranging from around 1% of all drugs in developed countries to between 10% and 30% in developing countries, with quite large likely variations within countries, especially between urban and rural areas, but the sources of these estimates are not provided (WHO 2006). It is very difficult to gauge the reliability of these estimates, or to know what proportion of different kinds of counterfeit are included in the definition of 'counterfeit'. It is very likely, however, that there is a significant problem with counterfeit drugs, especially in some countries/regions.

The existence of counterfeits raises general questions about the factors and policies that might variously encourage and discourage counterfeiting. For example, counterfeiting is only potentially attractive so long as the actual product has a high value relative to the cost of manufacturing a plausible placebo. Generics wipe out many of the incentives to counterfeit by lowering retail prices down towards the cost of production. To take another example, whilst policy measures to combat counterfeiting may have the effect of helping to remove potentially dangerous drugs from developing country markets they may also or alternatively mean that safe, effective, copies of branded drugs are removed too, with negative consequences for poor consumers.

TRANSGENIC SEEDS

Most farmers in developing countries save their own seed on¬-farm, or obtain seeds through farmer to farmer exchanges, or through an unofficial seed trade (this applies to all seed, not only transgenic varieties). Around 80% of the seed requirements in developing countries are met in this way (van Wijk 1995). Seed saving and farmer to farmer exchange of seed is important for farmers because it can considerably reduce seed costs and it makes farmers less dependent on external suppliers. Farmer to farmer exchange is often based on traditional social alliances and family relations (Badstue *et al* 2007). Farmer saved seed is not exclusively a developing country phenomenon. In 2005 the International Seed Federation produced estimates from 18 mostly developed countries in which typically 20–40% of the seed requirements were met by farm-saved seed, but for some crops and countries they were much higher (Grain 2007b).

Unofficial seed trade sometimes takes the form of grain for seed exchanges with dealers or grain elevators. Grain/seed swaps involve a credit system in kind: the farmer receives a bag of seed from a dealer during planting time. This seed is actually conditioned grain that has been produced by other farmers. In return, the farmer hands over a double or triple quantity of grain to the dealer during harvest time. For the farmer, this transaction has advantages of lower seed prices and avoidance of cash payment. Payment in kind makes farmers less vulnerable to inflation and lessens the pressure to market their produce. The benefit for the dealer is that they can get two or three bags of grain for the price of one, and that it is an unofficial transaction: both royalty and tax payment can be avoided (van Wijk, 1995).

For transgenic seeds, the unofficial trade in developing countries has not just constituted farmers saving GM seed varieties and selling them on to dealers or other farmers, but also one of a proliferation of clandestine seed breeding, i.e. seeds from suppliers who have not licensed the products from the original seed producers and whose products are not certified as the varieties that have been officially released. Keshav Raj Kranthi, a scientist at the Central Institute of Cotton Research based in Nagpur, pointed out in 2006 that there were many spurious cotton varieties labelled Bt cotton, as well as unauthorised companies selling Bt cotton in India. He said there were four kinds of Bt cotton in India: "Legal, illegal, fake legal and fake illegal." (SciDev 2006). Kranthi noted that amongst samples tested by CICR, on average, 28% of the illegal seed brands are non-Bt, only 26% of the Bt cotton was true first-generation hybrid, while 46% was contaminated with non-Bt cotton.

Also in India it was discovered in 2001 that Bt cotton had been grown in Gujarat and many other states for some years prior to authorisation, having been supplied by the company Navbharat Seeds without government approval. This occurred whilst regulators were going through the politically difficult process of deciding upon the fate of an application by a joint venture between Monsanto and a local company, Mayhco, to commercialise Monsanto's Bt cotton variety. As Scoones (2003, p. 9) put it: "A section of the vast, largely unregulated network of seed bulking, supply and distribution outfits had made good use of an apparently good new product and, to the delight of many farmers, had sold it at a reasonable, if slightly marked up, price. While the regulators were deliberating in Delhi, the farmers of the cotton belt were reaping the benefits of Bt cotton across large areas." He adds: "As the 'transgenic chaos' in Gujarat – repeated elsewhere, although less dramatically – has shown, informal markets, astute entrepreneurs and farmers demanding effective products combine to undermine any neat, regulatory system imposed from elsewhere." (Scoones 2003; p. 41).

The scale on which transgenic seed use at a global level has relied either on farmers saving their own seed or from uncertified sources (whether from farmers and seed dealers selling farmer saved seed, or as a result of uncertified seed multiplication and/or clandestine plant breeding activities) is really quite extensive. Trigo *et al* note that as measured by area of adoption, herbicide tolerant soybeans

in Argentina and Bt cotton in China have been the industries' two greatest GMO successes. But GMO developers have not been able to capture revenue from even half the planted area in either case because of seed piracy (Trigo *et al* 2000).

As well as commentaries on the sources of transgenic seeds, there is attention in the literature to how farmers, especially poorer farmers, obtain information about transgenic seeds and why they choose to plant them. This relates to a much broader and longer standing literature on seed diffusion amongst small farmers which, in general terms, points to farmers' complex production environment, and their lack of access to adequate information (Tripp 2001).

Drawing on knowledge about farmer adoption of Green Revolution seed varieties, Tripp argues that many transgenic seeds feature qualities that may not be obvious to many farmers, and that this raises a series of questions about the information requirements that would allow farmers to develop experience about transgenic varieties and to make informed choices (Tripp 2001). The characteristics of a seed variety cannot usually be recognised by the farmer prior to purchase. Instead farmers can only appreciate the qualities of a seed variety during and after it has been grown, but even then they must judge performance under their specific growing conditions. For transgenic seeds the characteristics of the seed may not be immediately obvious. This means that farmers have to take it on faith that the seed will, for example, be resistant to a stress condition that appears infrequently (Tripp 2001).

Tripp also notes that the delivery of new seeds requires functioning input and output markets that stimulate demand for the seed as well as effective intellectual property rights. Where these conditions are less likely to be met, private seed industry activity is less feasible and the delivery of new varieties more problematic (Tripp 2001). He notes, for example, that the potential of transgenic virus-resistant potatoes in Mexico showed positive returns for smallholders but that the analysis assumed that a seed potato market exists that serves those farmers. In practice Mexican farmers do not use commercial seed potato for reasons that include the high cost of the seed, the location of the seed industry close to the areas where there are big farms, and smallholders lack of familiarity with the advantages and management of certified seed (Tripp 2001).

Glenn Davis Stone reported on an ethnographic study of cotton farmers in a district in Andhra Pradesh, India in which Bt cotton was rapidly taken up by farmers (Davis Stone 2007). He argued that farmer experimentation and evaluation play a much smaller part in seed choices than innovation-diffusion theorists and seed companies would have us believe. He argues that there has been a process of agricultural deskilling, in which the link between environmental learning (about performance, in agro-ecological terms, of a seed) and social learning (about, for example, who is using new seeds) is disrupted, with only the latter taking place. The failure to evaluate and experiment with seeds arises because of the unpredictability of key variables in cotton cultivation, such as climate, insect pests in any given year, crop yield, and seed quality. The unpredictability of seed quality, Stone notes, increases

with purchasing of marketed seed compared to farm-saved seed. He notes that there are over 800 input shops in the district and 125 cotton brands from 61 companies in the 37 vendors in the main city. There are fakes, deceptive labelling, and problems of quality control with the seeds, and apparently different seeds that are identical.

Similarly, Devparna *et al* (2007) note that a study of Gujarati cotton farmers shows that unreliable seeds and adulteration plague Indian cotton farmers. They note there is often a shortage of certified seed and that this necessitates seed trading with fellow farmers and with unauthorised seed traders. They note that farmers are continuously trying new varieties of cotton and are wary of dependence on a single variety, even if one of these has a reputation for high yields. Rather the dominant strategy is continual experimentation and mixing of varieties.

In commentary on the Stone article, Busch notes that the standards for germination, purity and variety that characterise the European and North American seed markets are poorly enforced in India with the result that the technology's identity is itself in question (Davis Stone 2007). Scoones, in another commentary, emphasises that the reform of the seed market, with complex licensing deals, and illegal pirate arrangements, hugely complicates the ways in which farmers have to deal with uncertainty in decisions about technology choice (Davis Stone, 2007). Farmers are thus faced not only with environmental and agronomic uncertainties, but also market uncertainties. Of course, any attempt to regulate these local market issues will have to do so in the context of broader national and international regulatory frameworks and standards. More pertinently, even where those standards can contribute to local market regulation, there are big questions concerning the capacity of local regulators to monitor and enforce them in a very dynamic, informal market setting.

DISCUSSION

A number of points are worth highlighting in regard to the literature on informal seed and drug use. First, in both the drugs and seeds sectors, assumptions and expectations about the nature of supply markets may be at odds with informal realities. In the medicines sector, commercial markets are probably more widespread and certainly less well regulated than policy-makers perhaps assume or certainly wish for. These informal medicine markets, operating outside of formal regulatory control, occur not only in the supply of drugs, but in some locations in their manufacture and distribution too. In the seeds sector, seed delivery markets to poor farmers may be both less prevalent, or function less well, than some policy-makers might wish for. Where seed input markets do operate, they often, as in the drugs sector, operate as clandestine markets, necessarily outside of regulatory oversight. Informal practices are not confined to the existence or absence and functioning of markets however. Practices desired by regulators, such as the medical supervision of drug prescription, may be absent on the ground. Clearly, many people self-prescribe, or obtain advice on drug use from non-medical sources.

Informal practices are not necessarily confined to poor communities, or to developing countries, but they appear to be more prevalent in some less developed countries and amongst poorer farmers and consumers in those countries, although this is likely to vary depending on the artefact, country and practice. For example, in some countries large commercial farmers appear to be just as likely to sell and purchase black-market seeds as smaller farmers, whereas informal medicines vendors are more likely to supply drugs to poorer, rural communities in some countries than wealthy urban citizens.

Nevertheless, it is likely that poorer farmers and poorer consumers are more likely than their wealthier counterparts to be subject to, and to participate in, informal practices (in the sense of practices that are not mandated by regulatory controls). Yet, poorer users want assurances too that technologies are beneficial and not unduly risky. If regulatory systems are primarily operating in ways that serve wealthier actors we need to ask whether poorer users would like a regulatory system geared to their needs. Hence, in the *Rethinking Regulation* project we shall adopt a backward mapping methodology that begins with the realities of artefact use amongst poorer users, asking how those users experience the technology and would like to experience it. Our approach uses that lower level experience to interrogate regulatory framings and practices at successively higher levels.

Returning to the existing literature, in general, the *diversity* of use patterns, as between richer and poorer farmers and consumers or between urban and rural dwellers, for example, is not an issue that a great deal of attention is paid to in the literature. We know something about how particular groups of people might use seeds and drugs but less about the level of variance within particular jurisdictions. Whilst it is difficult to get accurate data – indeed, the illicit nature of some informal practices renders data gathering highly problematic – the literature nevertheless points repeatedly to instances of divergence between regulatory assumptions or objectives and informal realities on the ground.

There are several reasons accounting for the prevalence of informal practices around seed and drug use. Sometimes, those practices are a reflection of the fact that what is rational or logical for particular groups of people is at odds with the rationality operating through regulatory standards and practices. The ways in which patients opt to use drugs may reflect different cultural rationalities to professionalised bio-medical modes of reasoning, or they may simply be a reflection of the economic and social position that poorer people find themselves in, perhaps facilitated by weak health institutions. Thus, informal patterns of drug and seed use may be the best means poor farmers and citizens have of getting by, whether these involve obtaining seeds without payment of cash or need for credit, or the taking of certain drugs for prophylactic reasons, so as to try and avoid the risk of ill health, or in inadequate length of time, so as to avoid high costs. In other cases, informal practices may simply be an opportunity to make money that, in the absence of effective regulation, offers rewards for relatively little risk.

Informal patterns of seed and drug use also have different kinds of implications, depending on which artefact, practice and setting one is looking at. There are often many different kinds of benefits and risks associated with informal use, as compared to formal practices, and these are usually distributed unevenly amongst different groups and interests. Given the range of consequences of informal seed and drug use, as well as the variety of reasons as to why informal practices are sustained, and the different points in production, distribution and use in which informal practices occur, there are unlikely to be many simple, universal, or unambiguously desirable, 'fixes'. Effective policy intervention, or rather changes to regulatory practice, will require an adequate understanding of such practices, their consequences, both beneficial and adverse, and of how and why such practices prevail.

Appreciating informal use patterns also raises the issue of the extent to which formal regulatory control can in fact be imposed on behaviour. Perhaps seeds and drugs are far less governable than we would like to believe? How then might we respond when thinking about more appropriate regulatory intervention; and for which purposes? Are there alternative ways that involve living to some extent at least with the fact that peoples' behaviour around artefact use cannot always be brought into line with policy-makers expectations?

6. SOME IMPLICATIONS FOR THE *RETHINKING REGULATION* PROJECT

In this final section we briefly summarise the evidence that we have collated in this review on how harmonising forms of technology regulation (notably intellectual property, technology licensing and regulation of the supply chain) are being (re)interpreted across scales and in different contexts, and how they affect, and contrast with, the ways seed and drug technologies are experienced by poorer communities in developing countries. We do this by reference to the core STEPS Centre themes of scales, dynamics, framings, and pathways. We want to identify areas of research that are less well covered than others, and issues and questions that emerge from our reading of the literature that might be further pursued in the *Rethinking Regulation* project.

SCALES

The first point to make by way of empirical summary is that although the literature frequently points to how globalising regulations may, in principle, have a wide range of impacts on the ways in which seed and drug technologies are experienced by poorer communities (as both technologies and their regulation become globally

available and applicable), there is only patchy empirical evidence documenting these impacts. How do regulations get interpreted and reinterpreted as they move between scales and across contexts? What is the actual impact of global rules in particular settings on local technological practices? What sorts of mismatches, if any, are there between global expectations and local realities?

The literature summarised here suggests that regulations are not necessarily adopted passively by national governments. Instead, as the case studies included in this document indicate, they may be reinterpreted and unevenly implemented. This is one reason why the question is not only one of how globalising regulations have sometimes brought national and local practices into line with global regulatory intentions (with all the potential tensions and effects that then arise), but also of how global regulations have not necessarily had their desired effects. Yet we often don't know, at least from English language sources, how in particular countries international rules have been interpreted, and especially how national implementation takes place, and how the position of poorer communities is affected by patterns of regulatory implementation. A scrutiny of legislative changes by national governments is not sufficient because it is not always clear how far national practices align themselves to international rules or just appear to be doing so. If we shift to consider how local level regulators have interpreted and implemented the regulatory mandates handed down to them from national legislators, then the general literature on implementation of global regulation makes little reference to local, as opposed to national, level interpretation and implementation.

What about the ways globalising forms of seed and drug regulation have affected how poorer communities have actually experienced seed and drug technologies? Domestic *production* of seeds and drugs is in principle constrained by harmonising regulations (intellectual property rules in particular) but little in the literature summarised here has analysed how, in practice, domestic drug and seed firms have responded to global regulations (once refracted through national governments and local regulators). Production activities and firm behaviours have not necessarily conformed to international rules. Thus, uncertified production of seeds and drugs, essentially counterfeiting, though not necessarily of ineffective artefacts, clearly occurs in many settings, although there is little reliable information on the scale of these practices (and they appear to be quite extensive in some settings), or on the nature of the production and distribution networks that sustain them. The literature also highlights how intellectual property protection, and associated increases in seed and drug costs, have affected access to seeds and drugs (and how national governments, especially in relation to key drugs, have responded) but there is little commentary on how the *kinds* of seeds and drugs that are produced and made available may have changed in response to intellectual property and licensing/ trade rules.

In many countries both seeds and drugs are purchased or obtained through informal markets, in ways that are not mandated by global rules. For example, survey evidence in many countries indicates that uncertified seed use is extensive (copies

of transgenic seeds protected by intellectual property rules and GM seed varieties that have not been licensed can be obtained by farmers). There is also a large literature on informal use practices in the case of drugs and again this points to how people access and use drugs in ways that are often inconsistent with international and national regulatory expectations of appropriate or lawful practice.

Overall, then, the literature suggests that whilst harmonising regulations may place quite significant disciplining constraints on technology production and use in developing countries, there are many quite marked mismatches between international regulatory expectations as to how global rules should impact on the ways in which technologies are experienced, and the local realities of artefact production, exchange and use in poorer communities. The interesting question is therefore as much 'why have global regulations not had their intended effects?' as it is about which kinds of practices they have altered and disciplined, and with what implications. We now move on to consider how that issue - a divergence in expectations and realities - has been addressed in the literature by reference to the STEPS Centre themes of dynamics, framings and pathways.

DYNAMICS AND DIVERSITY

As seed and drug regulations move between polities, and as the technological artefacts themselves enter into global circulation, the social, political and ecological contexts in which those specific technologies are used, and in which specific modes of globalised regulation encounter technological practices, become more diverse. Yet, whilst that increase in diversity of contexts may be true for a specific technology or from the perspective of a single mode of regulation, this does not equate with increasing socio-ecological, technological or regulatory diversity *per se*. Indeed, it may be at the expense of diversity in other types of technology or modes of regulation. We cannot therefore speak so easily of diversity in unqualified aggregate terms.

Much of the literature on globalising regulation, summarised here, highlights an increased diversity of socio-technical-ecological contexts, relative to the homogeneity of regulatory intentions. Thus the literature on globalising intellectual property rights in both the seeds and medicines sectors points to the different contexts, interests and institutional and financial capacities in many developing countries, as compared to industrialised countries, as regards the granting and enforcement of patent protection (such as the absence of innovative firms or even the absence of a drug manufacturing industry, the inability of social transfer systems to pay for universal access to patented medicines, the importance of farmer-saved seed in rural livelihoods and the existence of informal credit systems in seed provision). The literature on global seed and drug licensing and trade rules also notes the diversity of agricultural policy priorities across countries, the diversity of available resources for regulatory assessment, the range of different physical environments into which transgenic seeds might be introduced, the greater scope

for informal seed production to step in and circumvent official regulations in some settings, and the relative significance of informal means and channels for drug production and distribution.

In pointing to this diversity of contexts, from the point of view of homogenous regulatory systems, as technologies circulate at a global scale, the focus in much of the literature is on two sets of issues. One is on the implications of those different contexts and conditions for the interests and priorities of developing countries in domestic agricultural production and health provision, whether or not these interests and priorities are actually exercised in global negotiations and in the ways global agreements are interpreted and implemented. The second is on whether or not regulation can adequately manage seed and drug technologies given an important aspect of those local contexts and conditions; namely, the relatively weak scientific, legal, policy, monitoring and enforcement capacity in many countries.

These two different foci give rise to two kinds of explanation for why global regulations have not always had their intended effects. One is essentially that it is not in many developing countries' domestic political and economic interests to implement and enforce global regulations in the ways envisaged by international rules. The other is that there is inadequate capacity for regulatory implementation. In the latter case, the emphasis, at least in the official literature, is thus on providing support for institutional, financial and scientific resources to help regulators fulfil their mandates and bring the world into line with the regulatory designs handed down to them.

Somewhat less explicit emphasis in the literature is placed on how the very diversity of contexts and conditions can increase uncertainties over the performance and effects of seed and drug technologies. In other words, as sources of (often informal) production, modes of access, and contexts of use proliferate, from the point of view of globalised regulatory systems, there may be extra difficulties for regulatory control whatever the scientific and administrative capacity. The nature of contexts and conditions in some settings may just mean that certain regulatory designs are inherently harder to implement.

The literature does touch on this issue; for example, attention is drawn to how the sources of seed and drug production that are officially attended to in harmonizing regulatory ambitions have become more diverse (from the perspective of that homogenous regulatory system), with many entrepreneurs able to operate with relative ease outside of regulatory control producing unregistered seed varieties or in some settings, counterfeit medicines. In the latter case, the regulatory difficulties associated with controlling counterfeit medicines have been explicitly discussed, especially because they have potentially serious consequences (and reach well beyond local or even national boundaries).

Yet, on other issues, the literature is less explicit at detailing how the increased diversity of contexts and conditions encountered by globalised regulatory systems, especially in poorer communities, gives rise to informal systems of production,

exchange and use, with corresponding problems for regulation. What, for example, might informal practices around the exchange and sale of insect resistant seeds imply for the ability to enforce rules on managing resistance, or for meeting importing country requirements, such as segregation of GM and non GM crops? What do informal antibiotic use patterns imply for regulatory controls designed to maximise drug efficacy, or to minimise the development of disease resistance? Such questions push us to consider how well regulators at different levels conceive of, or 'frame', the practices that they try to control.

FRAMINGS

By framings we are referring here to different actors' views, judgements and assumptions about, and representations of, the object and problematic of regulation (Goffman 1974). The notion of framings attempts to combine deliberately formed views, for example, as reflected in specific policy goals and actors' preferences, with a more tacit set of assumptions which may reflect taken-for-granted institutional or cultural commitments and routines as much as consciously formed choices. As our definition suggests there are two aspects of regulatory framing here and it is important to distinguish between them. First are views and assumptions about what it is that is potentially problematic about a technology and requires regulatory control (as well as what appropriate solutions might look like). Such framings include judgements and assumptions concerning nominally technical aspects of regulation, such as the kinds of risks and patterns of causation considered important or significant.

The second aspect of regulatory framing, and arguably prior to the first, are framings of the object of regulation. In particular, how is the socio-technical-ecological system understood - the linked social, technical and natural aspects of the production, exchange and use of technological artefacts - that regulation aims to intervene in, and which gives rise to particular regulatory problems? Which actors, institutions, networks and relationships comprise seed and drug socio-technical-ecological systems, and how might these be understood in different ways by different actors in different contexts? What are the main functions of that socio-technical-ecological system, and how might those particular social, economic or ecological functions or services be understood by different actors? How do these different framings characterise systems dynamics, and what aspirations and vulnerabilities do they highlight? Clearly, competing framings of the object of regulation are likely to imply competing framings of the problem that regulations are supposed to address (and the appropriate solutions).

We can expect framings of the object of, and problem for, regulation to vary between different actors, especially across institutions and scales. A large body of work on technology regulation, much of it focused only on Northern countries, has documented competing framings, as between different countries' regulatory systems and as between scientists, policy-makers and citizens. The question here however is what do we know empirically about how the socio-technological systems of seed and drug provision and use, and the regulatory problems those

systems give rise to, are framed by regulators in global institutions, and regulators at national and provincial level? In addition, how do these framings compare to the realities that are implicit in the experiences and concerns of poorer users of technology at local levels in developing countries?

One kind of possible contrast is between framings of regulatory objects/problems explicit or implicit in international regulations, and in developing countries' national and provincial regulatory systems. The literature summarised here provides some indications, and many hints, of competing framings. For example, in the seeds sector, competing views between countries, as to the problem that regulation should control (e.g. social or technical impacts), were made explicit in the negotiations leading up to the signing of the Biosafety Protocol (Stabinsky 2000). In the drugs sector, the literature notes how international regulators within the WHO involved in constructing Essential Drugs Policies may have assumed that the object of regulation was the public sector, thus overlooking the significance of private and more informal drug provision systems in developing countries. Otherwise, the evidence really consists of the occasional observation. For example, in Argentina, the regulatory problem, as far as granting licenses to GM crops are concerned, is partly one of ensuring that there are adequate export markets available, but that issue falls outside the problem definitions implicit in the licensing procedures advocated in, or constrained by, the Biosafety Protocol and WTO Agreements.

A second contrast is between framings of regulatory objects/problems held by international, national or provincial regulatory bodies and those implicit in the actual experiences and concerns of poorer technology users. The literature summarised here provides almost no commentary on those framings. One exception is from the drugs sector where the literature suggests that international regulators within the WHO failed to recognise that drug purchasers and users in developing countries often did not take medicines on prescription nor obtain them through formal channels; nor did they necessarily understand that branded international medicines were sometimes assumed by local users to be superior to generic equivalents.

Overall then, the literature reviewed here on seeds and drugs has rarely documented explicitly the extent to which there might be similar or competing framings between various kinds of actors and across various levels. This is especially so in terms of competing framings of the object of regulation: those aspects of the socio-technical system of seed and drug use that are within and outside the regulatory frame. It is also especially so in terms of how poorer users frame regulatory objects/problems. Those poorer user framings are partly a reflection of those components of the seed and drug socio-technical systems that impinge on how poorer users actually experience a technology, and partly a reflection of what poorer users themselves are concerned about in respect of that system.

The absence of explicit attention to how framing of regulatory objects/problems compare, both amongst regulators at different scales and between regulators and poorer users, is a gap in the literature that we feel deserves to be filled. It may be

extremely helpful in shedding light on why regulatory objectives sought by policy-makers in Rome, Geneva, and Washington, and in Beijing and Buenos Aires, fail to materialise in the realities of seed and drug regulation and use in particular localities in China or Argentina.

PATHWAYS

Socio-technological-ecological systems are not static. Rather, interacting social, technological and ecological systems co-evolve over time, in particular directions (with framings, discussed above, constituting the epistemic dimension of such pathways). Multiple, self-reinforcing mechanisms are involved in that process of co-evolution resulting in specific pathways of change which typically display properties of lock-in, momentum and path-dependency.

Regulations are arguably one of the mechanisms that contribute to the processes which set and maintain particular pathways. Indeed, as highlighted at the beginning of this paper, regulatory assurances are an important aspect of the technology development process, helping to shape investment decisions, product development, markets and the nature and distribution of risks and benefits. Indeed, this is partly why political disputes over the design and functioning of regulatory regimes can be so heated: regulatory regimes contribute to reinforcing or hindering the unfolding of particular kinds of socio-technical-ecological pathways.

The literature on globalising regulation certainly recognises this key function of regulation. It forms the backdrop against which international and national regulatory priorities sometimes diverge, as, for example, national governments seek to interpret and selectively implement global regulations in ways that promote domestic preferences as to desired pathways of socio-technical change. In the field of agricultural biotechnology, for example, the desirability or otherwise of transgenic agriculture in its entirety, as well as the particular crop/trait combinations that receive attention and those that do not, are often explicitly the focus of regulatory politics.

Yet, this function played by regulation - of reinforcing or hindering the unfolding of particular kinds of socio-technical-ecological pathways – generally exists in the literature only as a context for discussing regulatory manoeuvring, rather than a central object of research. There is little empirical analysis of potential changes in socio-technical practices, and associated pathways of change, as a result of particular forms of regulation. What, for example, happens to an existing set of socio-technical practices, and associated socio-technical-ecological pathways of change in response to processes of globalising regulatory harmonisation? Do some practices and pathways disappear? Do new ones emerge? Are some strengthened and others weakened? And what might the implications of these changes be for Sustainability, as defined and valued by particular communities?

One contributing factor to the relative neglect of how regulation might influence socio-technical-ecological pathways of change is that innovation policies are often excluded from definitions of regulation. Instead, attention focuses largely on rule-making activities for established or emerging technology products and processes, especially since it is these that are subject to harmonisation processes, and less so on policies for supporting and directing on-going technology innovation. As discussed at the beginning of this document, our own working definition of technology regulation is '*attempts by states to shape the broader governance and specific uses of technology*', a definition which deliberately includes aspects of 'front-end' innovation policy. Innovation policies and practices are not subject to direct harmonisation initiatives but they are affected by them. Changes to intellectual property rules, for example, can have profound effects on science, technology and innovation policies and practices within a particular jurisdiction.

In exploring the interactions between formal regulation of transgenic cotton seeds and antibiotics, and informal practices, we will pay explicit attention to how regulations might help set, maintain and/or undermine particular pathways of socio-technical-ecological change. Dominant pathways are likely to be associated with the framings, interests, and actions of powerful actors, including regulators, and with powerful, entrenched disciplinary perspectives or policy discourses. Other potential pathways, that perhaps do not, or only barely, exist may emanate from the 'bottom-up', starting from user practices, concerns and aspirations in all their diversity, and in those cases we want to document and explore their status. Of particular interest are those pathways that lead to improved outcomes in terms of Sustainability.

CONCLUSIONS

Despite the many 'gaps' discussed above, the literature does suggest that harmonisation aspirations may be confounded by a twofold and interacting dynamic. The first is the way global regulatory obligations are interpreted and implemented at the national (and perhaps also the local) level. The second is the actual practices of users of the regulated technologies at the local level. Neither the national or local regulatory idea of 'proper use', nor the 'actual use' of the artefact in poorer communities, needs accord with harmonised regulatory expectations for appropriate technological practices. Both dynamics are acknowledged in (parts of) the literature on seed and drug regulation and use, but, as far as we can tell, they have not been investigated jointly. This is a key aim of the *Rethinking Regulation* project.

In seeking to investigate these twin dynamics, two broad analytical literatures stand out as clearly relevant to the research project. The first is political science insights into the transfer and implementation of regulations across different settings and levels. This enables us to appreciate that there are limitations on top-down policy implementation. Local regulators reinterpret their mandates from above, and in

important respects policy implementation is constituted by the politics of local-level practices. The second body of literature is science and technology studies' insights into how technologies can be understood as hybrid social-technical objects or systems, rather than context free physical artefacts (Latour 1993). This perspective enables us to appreciate that technologies are flexible: they change as they move from one context to another. As the institutional and social arrangements in which artefacts are manufactured, exchanged and used alter, so technologies 'work' in different ways too, and have different kinds of effects and consequences.

Central to our task of unpacking the twin dynamics of (i) regulatory implementation and (ii) the actual practices of users of regulated technologies are notions of how socio-technical systems and regulatory problems are 'framed' by users and regulators. As highlighted by the science and technology studies literature, socio-technical systems of seed and medicine provision and use will vary across contexts as very different kinds of actors in very different kinds of relationships with each other, and in different socio-economic and ecological settings, innovate, produce, exchange and use technological artefacts in specific ways. This point strongly suggests that these systems are likely to be explicitly and implicitly understood, or framed, by users, regulators, and legislators in different ways. If so, the important question that arises is whether regulatory framings of seed and medicine systems include or exclude the practices of poorer communities, and with what consequences. In other words do regulatory framings capture and understand, and thus potentially intervene in, the realities of how poorer communities experience seed and drug artefacts, and do those framings of both seed/drug technological systems and the problems they pose reflect the actual concerns of poorer communities?

We intend to use our comparative analysis of regulatory framings and practices to engage critically with regulatory reform and regulatory capacity building initiatives that take place as part of broader processes of regulatory harmonization. The literature reviewed here suggests that there might be a need to nurture flexibility in regulatory approaches, which adapt to local conditions and norms (albeit sensitive to the correspondingly greater risks of local capture under prevailing power relations). In other words, the classic concerns of regulatory design and regulatory implementation, traditionally considered sequentially, need to be considered in the round and situated together in specific contexts. Capacity-building, according to this view, needs to attend to and support the development of more locally specific, inclusive, and collaborative regulatory approaches, able to work with the grain of the situation on the ground. We will therefore be asking in our empirical domains if there is greater potential for more reflexive regulatory capabilities, for policy-makers to recognise the effects of regulatory framing and for regulations to become more adaptive to diverse, dynamic and uncertain contexts, thus working towards regulatory pathways that work for Sustainability.

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