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Regulation Multiple: Pharmaceutical Trajectories and Modes of Control in the ASEAN

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This article revisits the conceptualisation of pharmaceutical regulation. While States and multilateral organisations play a central part in devising rules, regulation as a social practice extends beyond their role. Domestic and international interests, geopolitics and spatial configurations, commercial and health considerations, governmental policies and individual behaviours and legal and illegal transactions all contribute to regulating the pharmaceutical milieu. This consideration expands the epistemological range of pharmaceutical regulation, which then appears as the assemblage of heterogeneous laws, rules and codes of conducts. The way in which these layers are connected forms what regulation actually is in practice. Regulation multiple thus appears as the product of tensions between harmonisation efforts and persistent diversity, as well as the result of interactions and overlaps between official regulation and unofficial regulatory practices. This article explores these tensions in the Southeast Asian pharmaceutical market along three themes: circuits and logistic regimes; control and attention to quality; bridges and harmonisations.

THE GLOBALISATION of pharmaceutical markets which has been taking place over the last 30 years is marked by deep transformations in the geographies of production

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and distribution of drugs. Pharmaceutical industries located in the global North still play a central role in defining innovation through financial concentration (Abecassis & Coutinet, 2008), intensive research and development (Chandler, 2005) and aggressive intellectual property policies (Sell, 2010). However, where previously the industry was seen to dominate without rivals, it is now being challenged by new trends: emerging States and regional powers are subverting the established order. The global spread and impact of the Indian pharmaceutical industry (Abrol, Prajapati & Singh, 2011; Chaudhuri, 2005; Chittoor, Sarkar, Ray & Aulakh, 2009; Joseph, 2015; Löfgren, 2012; Sunder Rajan, 2006) and the dramatic rise of China's economic power (Hsieh, 2013; Kim, 2015; Naughton, 2006; Wang, Hong, Marinova & Zhu, 2009; Yeung & Liu, 2008; Yue & Yue, 2010) constitute telling examples. More recently, the emergence of a production and distribution capacity in sub-Saharan African countries also contributes to the reconfiguration of power relations in the pharmaceutical milieu (Mackintosh, Banda, Wamae & Tibandebage, 2015). Similarly, the current attempt to build a strong regional economic community with the liberal opening of the Association of Southeast Asian Nations (ASEAN) carries the potential to further modify the global landscape (Dee, 2009; Ratanawijitrasin, 2009).

Within these contemporary transformations, new regulatory environments have emerged. Most specialists studying this situation continue in a disciplinary tradition that seeks to understand regulation through the prism of institutional power, where the policymaking or legal and economic frameworks are the main focus (Carpenter, 2010; Jirawattanapisal, Kingkaew, Lee & Yang, 2009; Ray & Bhaduri, 2003; Stenson, Tomson & Syhakhang, 1997; Vogel, 1998), as much as the persisting regulatory role of the State amidst globalising forces (Drezner, 2007). While we recognise the importance of these works, our contention is different. The world is also ordered and ruled through myriads of other agents and practices. For instance, individual agency, interrelations and cultural differences do influence regulatory processes (Brhlikova et al., 2011; Kuo, 2008), just as multinational pharmaceutical companies may take on the role of regulators (Peterson, 2014, p. 195). This article takes that on-board and goes a step further by revisiting and expanding the notion of regulation, confronted as it is with multiple realities and real-world practices.

As we will show in the case of pharmaceutical regulation in Southeast Asia, the gravitating forces are as much located within as outside the control of central powers. They also include non-State actors such as private economic agents, manufacturers and distributors (including online shops), brokers, medical representatives, prescribers, traffickers and consumers, as well as material infrastructures in the form of storage warehouses, computers, means of transport and road conditions. In some States, corrupt practices may also be considered as important forces influencing the way in which the pharmaceutical milieu is regulated. In order to take into account the variety of actors involved in drug control, to acknowledge the role of material and technological assets as agents of regulatory practice and to understand how corruption might act as a mode of regulation, this article calls for a semantic clarification. The meaning we give to the word regulation encompasses

common legal, economic and technical understanding but it also relates to all kinds of rules, prescriptions and behaviours, which *in fine* govern social activity. In this perspective, the act of regulating reflects its etymological roots,¹ and involves all the means, people or institutions that control or direct by a rule, a principle, a law or a method, and, by extension, that put or maintain social activity in order. But multiplicity itself should not be considered a sufficient explanation; we are rather interested in describing how multiplicity imposes adjustments, disjunctions and frictions. In that sense, our understanding of multiplicity accounts for the social mechanisms through which heterogeneous forms are juxtaposed and confronted. A central question therefore concerns the way in which these various layers are articulated and how they are linked—fully, in part or not at all—to each other to finally make *what constitutes regulation in practice*.

Founded in 1967, the ASEAN is the political, economic and cultural organisation with ten member countries. In 1992, the ASEAN created its own free trade agreement (AFTA) in order to promote economic cooperation, facilitate commercial flows and attract foreign investments. The ASEAN Economic Community (AEC), which forms part of the ‘ASEAN Vision 2020’, was adopted in 1997 to support the AFTA, to work towards a single market system by 2016 and to boost ASEAN competitiveness and growth (Pettman, 2013). This economic integration involves the suppression of customs fees, the free flow of goods and production factors (labour and capital), and the regional harmonisation of economic policies. With the ASEAN integration process predominantly focused on economic gains (Dee, 2009), it is likely to harness the growth of ASEAN’s rising pharmaceutical sector. This will also have implications on the circulation of pharmaceuticals. How this change will affect the flows of drugs and access to healthcare in general is impossible to predict at this stage because of the loose nature of drug circulation and distribution in the region (Bourdier, Man & Res, 2014; Hancart Petitet, 2015). A sizeable share of drugs circulate through unofficial networks and pharmaceuticals are sold through a variety of outlets—ranging from licensed pharmacies, clinics and hospitals to open markets, illegal sellers, herbal shops and groceries—which may or may not be affected by the establishment of the AEC. Equally important is the fact that globalisation processes, such as the AEC, do not always directly involve health institutions but nevertheless reconfigure access to medicines and foster the emergence of new modes of circulation (Lamy & Phua, 2012).

This is further complicated by the fact that the AEC encompasses two potentially contradictory developments. While integration efforts support the harmonisation of pharmaceutical standards and policies across the region, the opening of borders might complicate the supply chain as it could increase fraudulent transnational circulations of products, including unregistered, fake or substandard pharmaceuticals. In response to these changes, two competing discourses coexist. The first one is institutional in nature: the ‘harmonisation’ of the ASEAN will integrate multiple practices within one big homogenous market; it will smoothen and normalise the circulation of medicines. Opponents underscore that neither integration nor harmonisation will ever happen: markets are multiple, circulatory practices and

the ways of controlling them are heterogeneous and fall beyond the purview of institutional changes.

How, then, should pharmaceutical regulation be understood? How should the presence of both multiple ‘ways of regulating’ drugs (Gaudillière & Hess, 2013) and strong harmonising forces be accounted for? This pair of dual oppositions—harmonisation vs. diversity and official regulation vs. unofficial regulatory practices—must thus be analysed at the policy level, on paper and in practice, as well as at the level of control, supply, retail and consumption. This article takes an interdisciplinary approach and mobilises a variety of actors and situations: regulatory authorities (national and multilateral governing institutions, customs, police, drug administrations, etc.), drug suppliers, intermediaries, sellers and consumers.²

On a methodological ground, we based our analysis on case studies stemming from works in the fields of anthropology, sociology, political science, geography and social pharmacy. The data have been collected between 2010 and 2016 in multiple sites where we could work in and observe pharmaceutical markets and practices in Southeast Asia. To this purpose, we used document analysis, semi-structured interviews and ethnography. In our attempt to revise static, State-based conceptualisation of regulation and to expand its epistemological range, multi-sited and multi-scalar research was equally imperative. In what follows, we will use and add to a number of conceptual tools developed in the social studies of pharmaceuticals (Reynolds Whyte, van der Geest & Hardon, 2002; Sismondo & Greene, 2015) and in postcolonial science studies (Anderson, 2002; Harding, 1998; Philip, Irani & Dourish, 2012; Seth, 2009) in the hope of proposing a reasoned methodological definition for the study of pharmaceutical regulation. To this purpose, this article will examine three strands of discussion: circuits and logistic regimes; control and attention to quality; and bridges and harmonisations.

Circuits and Logistic Regimes

Pharmaceuticals follow multiple, unstable and sometimes unpredictable trajectories. Their routes collide and their networks overlap in a variety of ways that may either prevent or facilitate the emergence of alternative supply chains. How should this multiplicity be accounted for within a common framework? How should the diversity of these trajectories and regulatory configurations be understood without overlooking the singularity of each case? We suggest the notion of ‘logistic regimes’ to make sense of these situations, in the same way that global health is considered to rest on the coexistence of various regimes (Lakoff, 2010).³ Logistic regimes relate to the existence of rules, technologies, geopolitical relationships, economic realities and health concerns that determine the trajectories of pharmaceuticals. These regimes are crucial because they condition the direction, the type of circuits, the means of transport and the value attached to a drug. Different regimes coexist and generate friction between divergent conceptions of legality and value promoted by different social actors.

It is important to note at the outset that there is indeed a prominent logistic regime, or one that is presented as such. It is the official, State-based regime which is regulated at the national level by laws and pharmaceutical policies that are enforced by regulatory institutions; these institutions register the medicines and control their quality but they also oversee all activities connected to drug production and circulation. The regime involves manufacturing companies, the activity of which must be registered by national institutions, and a distribution system which involves both public and private actors (public procurement and national institutions such as hospitals on the one hand, and private importers, wholesalers, transporters, clinics and retailers, on the other hand). It is also affected by international standards or agreements such as the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement or the World Health Organisation good manufacturing or distribution practices guidelines. This logistic regime is defined by the official institutions governing the pharmaceutical milieu and is enacted by actors who comply with their rules and recommendations.

Although it might be the most conspicuous, this regime is by no means the only framework in the circulation of medicines. For various reasons, drugs sometimes circulate without any respect for these rules and recommendations. Their trajectories are defined by alternative logistic regimes that must be explained and understood. The existence of such regimes depends upon multiple reasons: cultural representations, conflicts of need and availability, contradictions between regulation and marketing strategies, commercial initiatives, and so on. They are more difficult to trace back; their identification requires qualitative, ethnographic work. We shall take the case of Thailand. This country initiated a form of State regulation on pharmaceuticals as early as 1909 and the latest law, which covers registration, manufacture, import and distribution, was passed in 1967 with four consecutive amendments. As in most countries in the ASEAN, however, there are other distribution channels than those controlled by official authorities. Such is the case for a number of steroids. These drugs can be found in groceries and in the stalls of illegal drug sellers; they circulate within alternative regimes and are promoted by advertisements on community radio stations, social media and the Internet, as well as digital and cable TV. A preliminary survey that some of us conducted in three provinces along the Thailand–Laos and Thailand–Cambodia borders indicates an abundant presence of unregistered steroids from China and elsewhere in the temporary markets. They may be sold as steroids or found present as a contamination in other medicines, and are actively sought after by consumers. The National Health Assembly took the problem of steroids very seriously and approved a resolution in 2014 aiming to stop the illegal distribution of these products, with the help of the Thai FDA. As of today, this unwanted and barely controllable logistic regime continues to exist.

Other logistic regimes are built in order to overcome contradictions between national or international regulations and local need and purchasing power. The recent case of Sofosbuvir, an antiviral treatment prescribed for hepatitis C, is a case in point. Invented by the firm Pharmasset and subsequently appropriated by Gilead, the specialty initially cost over USD80,000 per patient for a full course

of 3 months. This has generated a number of debates and controversies regarding access to healthcare (in the South and elsewhere) and pharmaceutical capitalism (Cassier, 2016). Several countries, including Thailand, expressed concern as to the need to produce or provide access to low-cost generic versions of the medicine. Part of the answer could be found in India, since companies in this country had been granted a license to produce generics for less than USD1,000 for a complete treatment. However, the agreement that regulated this drug did not cover export to Thailand. Consequently, in order to overcome this situation, patient groups affected by hepatitis C have been smuggling medicines from India to Thailand, which shows not only that patent regulation does not prevent these kinds of ‘leakages’ but also that it leads to a ‘suitcase’ type of import. Although the official regulatory framework may prevent some of the illicit flows of pharmaceuticals, a space was left vacant for other logistic regimes.

The case studies of steroids and sofosbuvir point at the determining role of patients and consumers in configuring logistic regimes. But other actors can play an important part as well. This is illustrated by the case of anti-malarial medicines in Laos and more generally by the problem of cross-border marketing pressures. Due to the geographical location of Laos, pharmaceutical companies from Thailand, Vietnam and China influence the procurement of drugs at the provincial level. This is how one of us learnt that in December 2014, monotherapies produced in Vietnam for treating malaria, still banned from sale in Laos, were found in a public hospital in the province of Champassak. In a different context, a government officer from Cambodia explained that medicines forbidden in neighbouring countries but still produced by their national firms continued to circulate in Cambodia since no action had been taken locally to ban these drugs. These pharmaceuticals had to be sold somewhere: just across the border. Poorer, less institutionally regulated countries can thus be used as a final destination for all kinds of drugs or as transit platforms for fraudulent pharmaceutical distribution (Bourdier et al., 2014). Within the ASEAN, the influence of neighbouring countries and firms can determine whether and how medicines circulate and therefore provide frameworks for other types of regimes.

The contradictions between regulatory ambitions and implementation, public health coverage and infrastructural development also appear as a cause in the emergence of alternative regimes. In Cambodia, a law pertaining to the regulation of transportation of pharmaceutical goods was passed in July 2015, requiring the use of specifically identified and refrigerated vehicles. However, poor infrastructures and the need to bring drugs to the provinces means pharmaceuticals still travel by non-refrigerated vehicles such as private taxis and cars, therefore escaping State regulation (Pordié, 2016). In practice, brokers, taxi drivers, private pharmaceutical transporters or drug outlet owners do follow rules and principles on the transportation of drugs, on, for example, how to organise the shipment or attach a box on the roof of a bus, how much to get paid for that, where and from whom to take it, where and to whom to deliver it. While they do not abide closely to the rules imposed by the State, they still contribute to ordering the pharmaceutical space.

Numerous forms of logistic regimes thus co-exist. As opposed to the official, State-sanctioned regime, these alternatives have to be studied on site, by examining the actual circulations of medicines, and not solely through the laws and guidelines that define ideal and ‘proper’ trajectories. Steroids, sofosbuvir and anti-malarial monotherapies make their way through the ASEAN pharmaceutical market for different reasons, such as socio-cultural representations, local legal and economic restrictions of access, and marketing pressures. They can be carried in refrigerated or non-refrigerated vehicles, or simply moved around in suitcases, cardboard boxes or plastic bags. Their trajectories illustrate specific breaks with the dominant model of circulation but can be accounted for *via* the analysis of circulation in practice.

Observing this multiplicity does not suffice in understanding logistic regimes. They are also characterised by endogenous and exogenous dynamics, as they are reconfigured from within or interact with each other. A logistic regime is not a static entity. It is a moving framework, which raises critiques and conflicts. This is exemplified by the AEC integration, which has implications for the circulation of pharmaceutical goods insofar as its purpose is to open borders, build a single market economy and thus encourage the free movement of both people and goods. Such transformation is not without ambivalence. Economic disparity among ASEAN member countries implies that an open market policy may benefit some countries less than others. By attempting to ease mobility, the AEC will also orientate the flows of drugs and redefine the terms of the official logistic regime. Regulatory authorities in Cambodia, Laos, Myanmar and Vietnam—countries with lower GDPs than their fellow ASEAN member States—have expressed their concerns as they fear they are not able to compete with the pharmaceutical sectors of Singapore or Thailand. This means that their dependence on external national markets and manufacturing firms would remain or even increase. Authorities in Laos and Cambodia also suggested that the growth of their pharmaceutical sector may not be as efficient as that of their neighbours, leading to challenges in the management of registration applications and in the circulation of new products from ASEAN member states. The mode of regulation sought by the AEC raises new problems in the pharmaceutical milieu, fostering the emergence of forms of logistics which tend to redefine, if not the whole circuit, at least the direction the drugs taken from one country to the other.

Another important explanatory component concerns the interactions between logistic regimes—that is, their exogenous dynamics. It is crucial to provide an overview of the interactions between logistic regimes since the circuits cannot be entirely regulated and controlled by State authorities, nor by international organisations. Circulation and transport involve multiple actors and practices. For example, drugs may be bought by the government to supply a hospital but end up in the private market; they can be procured freely by NGOs and patients may still end up paying for them; they can be forbidden by the law or unregistered by the authorities and still be available in clinics and pharmacies. Thai–Myanmar shelters located in Western Thailand provide an example of the coexistence of, and interactions between, logistic regimes. In spite of the availability of family-planning

services, two brands of unregistered contraceptive pills were sold in grocery shops, together with Myanmar-produced haemagogues indicated for inducing menstrual flow. One shop owner asserted that many female clients purchased these medicines daily and that he could provide contraceptive injections on demand. According to the Karen ethnic group, unmarried women are not supposed to have pre-marital relationships or use contraceptives and are therefore reluctant to use official reproductive health services (Vungsiriphisal & Chusri, 2013). A particular logistic regime thus emerged to ensure drug availability and cultural acceptance. This sociocultural complexity and the overlap between licit and illicit networks and circuits are generally overlooked in institutional manuals for the analysis of drug circulation.⁴ The routes taken by medicines depend only partly on official regulations and agreements. Drugs follow their own trails, according to economic rationality, marketing efficiency, availability of transport or consumer demands. In that sense, different logistic regimes are often combined.

Economic, political, geographic, cultural, material, technological and health concerns thus factor in the way logistic regimes are structured and interact. Their configurations are therefore multiple. This raises a series of problems pertaining to the overlap and coordination of the regimes, which in turn has consequences upon the quality of drugs and the risks they represent for public health. End users ultimately depend on the logistic regimes in their quest for health. This is why, in the eyes of regulatory authorities, the question of control is a priority. But again, control is multiple.

Ways of Controlling and Attention to Quality

The coexistence of various logistic regimes in the same territorial space implies a range of modes of regulation, control and securitisation.⁵ These are important components in the wider realm of regulatory practices as they have great influence on drug quality and patient safety. Pharmaceutical control and security operate at different scales; they take various shapes that may intersect or compete. Many different actors are involved in control and securitisation. Drug inspection authorities, custom officers, qualified physicians and pharmacists try to ensure the quality of medicines. But most manufacturers, importers, transporters, licensed retailers and unqualified drug sellers also share this concern in their own way.⁶ Although they may not always comply with the official biomedical or administrative agendas, pharmaceutical actors have developed means of protection, analysis and identification in order to evaluate and ensure the quality of the products. Umbrellas may thus be used to protect medicines from the sun, as Carine Baxerres (2013) has shown in her work on the ‘informal’ pharmaceutical market in Benin. Security and safety measures are not only ensured by the State but by the countless people involved in the production and distribution of medicines. Their understandings of quality and safety often differ but most actors in the State-led and unofficial sectors nevertheless share a common *attention to quality*.

This attention to quality can of course be seen at the level of the ASEAN. Following the 1990 International Conference on the Harmonisation of Technical

Requirements for the Registration of Pharmaceuticals for Human Use (ICH), efforts towards the harmonisation of ASEAN pharmaceutical regulations were initiated in 1992 through the ASEAN Consultative Committee for Standards and Quality (ACCSQ). By 1999, the ASEAN introduced the concept of pharmaceutical harmonisation to its process of integration. The ASEAN Pharmaceutical Product Working Group (PPWG) was set up the same year. It includes representatives from all regulatory bodies and aims to incorporate elements of the ICH into regional guidelines (Speers, Benton & Rose, 2016). The benefit of working towards the harmonisation of pharmaceutical product regulation is to promote unity and coherence in the ASEAN pharmaceutical sector for greater economies of scale (Baker McKenzie, 2015) and to compete against rising markets such as the Indian or Chinese generic markets. The focus of integration efforts in this sector was on harmonising pharmaceutical products registration procedures, first and foremost, as a means of guaranteeing quality—we should note that perceptions of quality may differ among the ASEAN regulators themselves. The main difference between ICH recommendations and the ASEAN guidelines for product registration is a greater focus on generics in the latter so as to improve access to more affordable medicines. The ACCSQ-PPWG produced several guidelines including the ASEAN Common Technical Requirements (ACTR) and the ASEAN Common Technical Dossier (ACTD) as a template registration form for medicines. Other guidelines, also contributing to the establishment of a normative ‘pharmaceutical nexus’ (Petryna & Kleinman, 2006), include but are not limited to good manufacturing practices (GMP) inspection and the Bioavailability and Bioequivalence (BA/BE) report. In practice however, these guidelines are implemented to varying degrees among ASEAN member states. Each country has its own timeline for registration and some do not yet accept the ASEAN Common Technical Dossier in lieu of their own registration forms to facilitate the registration process (Speers et al., 2016). This poses the risk of duplication of application systems for registration.

This supra-national initiative constitutes one institutional end of the spectrum. There is no need for our purpose to detail national policies as we seek here instead to demonstrate the existence of attention to quality in other, non-State directed spheres. The practice of unqualified personnel in Cambodia stands at the other end of the spectrum. In this country, a majority of drug sellers rent their licences from qualified pharmacists who act as representatives (Ovesen & Trankell, 2010, p. 235). The fact that these sellers are unqualified does not mean they are not trained. Most of them do practice with the intention of doing it well without compromising their patients’ safety. For that reason, they say they must possess some knowledge about drugs and they tend to develop this over the course of their practice. They acquire their knowledge and their skills from day-to-day experiences, but also from relatives or medical representatives; some read the pharmaceuticals leaflets contained in boxes of drugs, and—more rarely—learn from physicians’ prescriptions or possess a book manuscript provided as a manual by their representative pharmacist (Pordié, 2016). They do have specific conceptions of safety and security in the supply chain, which should be understood as a form of attention to quality

adapted to local constraints. Though they often challenge established rules of public health and pharmaceutical practice, they nevertheless carry a sought after quality and pharmaceutical value.

Taking into account the broad and heterogeneous ‘attention to quality’ rather than a more restricted ‘drug safety control’ has a two-sided advantage for the analysis of pharmaceutical markets. It provides a non-normative descriptive framework in order to study the diversity of operations of quality control, which does not reject *a priori* operations that are usually considered as illegitimate (illegal practices, corruption, non-compliant or substandard procedures) and it shows that regulation practices are always embedded in particular logistic regimes. An illustrative example from Laos underscores the need to move away from the usual normative take on regulation and control. While it is mandatory for drug producers to register their drug before entering the market, many studies conducted in this country show that a high number of unregistered drugs can be found for sale in pharmacies—from 40 per cent to 70 per cent according to the recent annual reports of the Food and Drug Department of the Ministry of Health (2010–2015). Besides, drug controls are scarce. Several interlocutors met in Vientiane further emphasised the limitations that exist in the enforcement of drug quality control. Even if problems pertaining to drug quality surface, few actions are taken against the perpetrators. Some representatives of International Organisations in Vientiane implied that drug control activities were not always transparent. They suggested, for example, that some drug quality inspectors may have vested interests in the pharmaceutical industry or favourable connections with other inspectors, which could lead to fraudulent practices. The owners may bribe the inspectors (Jönsson, 2002, p. 139) or the inspectors sometimes inform the pharmacists prior to their visit so that they can ‘clean the house’. The situation is quite similar elsewhere in Southeast Asia. There is a non-alignment between policy formulation and its enforcement. In normative and functionalist terms, this amounts to a dysfunction of the pharmaceutical system.

A more comprehensive view in which we grant greater attention to real-world practices should nevertheless take into account the different components of the logistic regimes in a given country. This approach highlights the tensions among financial resources, technical capacity and public health needs. We shall continue with the Laos case on the subject of registration. The Food and Drug Department in Vientiane is in charge of the drug registration process but this unit encounters difficulties linked to low budget, limited human resources and old software equipment. The registration process can thus be long (up to 18 months) and functions as a disincentive in a poorly attractive market since Laos has less than 7 million inhabitants. This context may explain why there is a degree of tolerance towards unregistered drugs sold in both public and private pharmacies. An official in Vientiane confided that this tolerance applied to drugs used for the treatment of rare conditions and to brand-new products imported in small quantities as a sample to test the market. The same applies to routine drug control in pharmacies. This relies heavily on the quality of the control laboratory, the number of inspectors and inspections, and the measures adopted against the pharmacists found to be in

irregularity. While laboratory analyses are costly, the meagre budget allocated by the Ministry of Health for laboratory activities does not allow for yearly quality tests on significant drug sample sizes. Moreover, the standards in Laotian laboratories are often not sufficient and most samples have to be sent to Vietnam or Thailand. And to make the situation even more challenging, the practice of control also involves external pressures that affect particular logistic regimes. A sensitive issue was raised in Vientiane and Oudomxay, a city in Northern Laos, about the lack of control of drugs issued from China and sold in ‘Chinese pharmacies’. A drug control officer from Vientiane said that he and his counterparts ‘have no licence and no right to control [these pharmacies]’. This assertion was later corroborated by an official at the provincial health office in Oudomxay, who demonstrated unease with the situation: ‘we have no authorisation. It’s annoying because it’s hard to control these foreign structures... For more information, ask the Ministry of Health in Vientiane directly’. In the case of registration and control, attention to quality exists in Laos but it cannot be separated from other determinants of the logistic regime, such as the discrepancy between technical capacity and local needs or external commercial and political pressures.

‘Attention to quality’ broadens safety concerns (and regulation practices more generally) and offers a non-normative framework. However, it does not preclude the fact that there are, for us as for all the people involved on the ground, disagreements, critiques, declared failures and ineffective or dangerous practices. The superimposition of distinct logistic regimes and modes of attention to quality often generates these conflicts. However, these superimpositions also open a space of possibilities for those involved to custom-build their pharmaceutical milieu. They bridge different networks, connect entities otherwise distant (both geographically and structurally), and they deploy various strategies to secure their products, their income and their activity. This assemblage of heterogeneous, unconnected elements leads to a number of original combinations that, once put together, play an essential role in the functioning of the pharmaceutical sector. As we will see in the next section, these *bridging processes* are at the core of pharmaceutical regulation.

Bridges and Harmonisations

Based on his thoughtful analysis of Taiwan’s compliance to international guidelines on clinical trials, Wen-Hua Kuo (2009) proposes studying international harmonisation processes as ‘bridging’ processes. This author resorts to the metaphor of the bridge in order to show how standards and harmonisation processes are supposed to connect islets (the nations) but also how ‘circulation’ is regulated on these bridges.

The conventional function of bridges, and the one the pharmaceutical industry favors, is to connect places that are separated. [...] However, a bridge is also a channel whose traffic can be restricted, and thus the very fact of being connected provides States at each end with a juridical means of control. [...] Just as an isolated islet cannot be reached without the labor of building a bridge,

globalization, according to this worldview, cannot be achieved in a single step. (Kuo, 2009, p. 54)

The notion of bridging indicates that harmonisation processes do not only give people and institutions opportunities to connect and control, but also that the making of these forms of connections and control is necessarily negotiated and lengthy. This is a useful notion to understand some of the dynamics of the ASEAN's turn towards economic integration and harmonisation of pharmaceutical rules. Here, harmonisation aims to solve the current fragmentation that characterises the policy space. There is, for instance, a discrepancy between laws and regulations related to pharmaceutical products in neighbouring countries within the Mekong region and the reality of the region's porous borders, especially because of the high amount of migrant labour in forests and plantations at border areas. The lack of control of movement of pharmaceuticals pouring in from neighbouring countries poses a challenge for national regulators who appeal for more cooperation with neighbouring authorities. To harness the need to align policies and to share expertise among customs officials and regulators, an additional level of regulation that extends beyond the nation state becomes relevant. This is a strong defence for the case of ASEAN harmonisation—indicating that member countries must build bridges between different systems of control.

Zooming down to more localised practices in the countries studied in this article, these bridges appear to be important characteristics as well. They link together the multiple dimensions of regulation. They connect components of circulation, distribution, security, safety and control from both within and outside the prerogatives of the States. However, these bridging processes existed long before any official national or supra-national harmonisation policies were even thought of. There are various categories of bridges that ordinary pharmaceutical actors have already built and are currently building, so as to *harmonise* regulatory processes by connecting distinct logistic regimes and combining distinct attentions to quality. In this framework, it is obvious that the harmonisation of standards is not the only process through which these people build continuity. Bridging operations have to be subdivided: the harmonisation of registration, circulation and control are among the many issues that constitute the ASEAN harmonisation process. This is quite complex in practice because if the intention is to harmonise regulation, then any attempt should cover all aspects of regulation. In other words, harmonisation such as is conceived in this article goes beyond State-directed policies and practices and combines State-led logistic regimes and modes of control with a variety of subgenres of logistics and controls that stem from unofficial initiatives. This is why not only the junctions, but also the overlaps, the superimpositions and the ruptures have to be taken into account to better understand how and why a particular bridge is being built to help cement the entire edifice.

Bridging operations also occur at the level of the State. To cope with the predominance of unqualified and illegal drug sellers, the government of Cambodia has recently been organising training sessions with the help of a national organisation.

These men and women undertake a 3-month long training that takes place on weekends. They are taught the basics of pharmacy, including pharmacology, anatomy, aetiology, galenics, quality assurance, drug safety and related matters, as well as law, finance and marketing pertaining to pharmaceuticals. Rather than punishing the drug sellers for illegal practice, the aim is to provide them with more knowledge—as long as they have a ‘pharmacist representative’—so as to increase the safety of their patients/clients. These people are often the only health resource available and, in all situations, the patients’ first choice for most common ailments. This peculiar situation is governed by the need to ensure comprehensive health coverage. The participants are awarded an official certificate attesting to their competence as drug sellers. This is a regulatory activity that integrates actors considered as marginal from the point of view of law and policies but who are central in the citizens’ day-to-day life. This is also a form of bridging between the official and unofficial sectors, the aim of which is to harmonise the entire system and make it work, or work better.

However, institutional regulation should not be considered as the sole point of reference. Multiple ways of harmonising coexist in the ASEAN pharmaceutical sector. ‘Bridging’ can thus be any action which safeguards the integrity of a logistic regime or ensures the link among various logistic regimes (or several attentions to quality). This is why the taxi driver, transporting medicines without any license to do so but using the air-conditioning in his cab is bridging; this is also why the pharmaceutical importer or the foreign firm, facilitating the registration of a medicine they sell by bribing the official in charge is bridging; and, this is why the retailer who occasionally hides some medicines from the drug inspectors controlling her or his shop is bridging. These bridges are not of the same robustness and they do not lead to the same destination. But in all these cases, actions are taken in order to ensure the continuity of one trajectory and the solidity of a logistic regime.

Such ‘unofficial’ bridging takes place in the case of unqualified drug sellers in Cambodia. As presented above, countless people rent their licenses, often from government officers, including Ministry of Health employees and other official agents who may be involved in pharmaceutical security operations (Pordié, 2016). This includes drug inspectors. In this case, the act of control amounts to the collection of a tax—since the inspector knows that the inspected is breaking the law as she or he is renting her or his own licence. The fact that the drug inspectors control the people to whom they are renting a license is an act of bridging. This configuration connects illicit practices with forms of State control and ensures both the continuity of the rental system and the circulation of medicines.

Bridging processes can also be caught in contradictions. In Laos, there are three different types of pharmacies according to the educational level of the person in charge (Stenson, Tomson & Syhakhang, 1997). The lowest category is the class III, which functions with a nurse, a technician pharmacist or a retired physician rather than a fully qualified pharmacist. The Vientiane authorities saw this as a potential undermining of drug prescription and quality. As a result, all class III pharmacies have been closed down in the capital’s district. However, this

category of pharmacy still exists in the provinces, as they often are the only realistic option to provide access to drugs and healthcare. The government has opted to leave these pharmacies open and to promote (more or less) regular inspections on the quality of drugs therein. These two different treatments demonstrate two variations of State-led regulatory regimes. But there are, of course, exceptions. In 2009, a class III pharmacy was closed down in the province of Attapeu due to a problem pertaining to drug quality, and eight others were reported to the Ministry of Health. The policy thus seems to be gradually shifting towards more enforcement at the provincial level. However, these controls are often considered to be weak, as a pharmacy must fail two consecutive checks to be closed—the first negative control often concludes with a warning and a fine. In practice, while Vientiane showcases good pharmaceutical governance, the rest of the country follows its own rules. The bridge supposedly linking the central regulatory scheme to provincial practices is fragile, if not a work-in-progress. Besides, behind the claimed success story of Vientiane—a useful showcase for international donors—the practices in the capital's pharmacies are never the exact projection of official regulation theory. In spite of the law, many owners of class I pharmacies only work part-time and are therefore absent from their pharmacies, as they are often employed elsewhere at the Ministry of Health, in provincial health offices or in hospitals. They are not subject to any form of control at this level. Guided by the need to secure a better income, they build their own, contradictory bridges to render the system viable.

Bridging processes do bring harmonisation but this does not mean, as it is often assumed, that harmonisation is consubstantial to homogenisation. These *harmonisations* are multi-layered and variable processes, the rationale of which is generally agreed upon by the persons involved. They result in the patch-work we noted above, a structure that brings incongruous pieces together while maintaining their singularity. This type of harmonisation is crucial in the working of pharmaceutical regulation in practice. Things are thus put in order.

Conclusion

This article concerns pharmaceutical regulation in practice and the way multiple realities are enacted into heterogeneous patterns that as an ensemble form a 'regulation multiple'. Domestic and international interests, geopolitics and spatial configurations, commercial and health considerations, governmental policies and individual behaviours and perceptions and legal and illegal transactions all contribute to regulating the pharmaceutical milieu. The complexity of this architecture, the variety of practices and opinions, the potential financial gains, and the fact that the point of convergence is people's health unsurprisingly gives rise to tensions. These tensions also involve power relations. Logistic regimes are influenced, sometimes moulded, by multiple forces which stem from colonial history and geopolitical tensions as well as technological forms of imperialism or particular blends of developmental will and capitalist methods. Regulatory practices as envisioned at a State or multi-State level have broader reach than the individual care of an informal

retailer, and a license-renting system works better with the support of people with more capital—be it symbolic, economic or political. We have contended in this article that these power relations should be analysed in their variety; they cannot be reduced to the opposition between the State and its subjects.

As multiple networks and supply chains coexist, they involve a plurality of safety and security practices, and the adjustments between logistic regimes and practices of control also often create friction. These frictions have the power to destabilise, transform or displace logistic regimes. They account for fluid realities. The ethnography of multiple realities is possible because, as noted by Annemarie Mol (2002), they are also reflected in practice. The fact that pharmaceutical regulation is multiple in practise does not mean, however, that it is fragmented. Logistic regimes and attentions to quality may vary greatly but are not incommensurable. People build connections and create junctions that recognise and maintain existing logistic regimes, tolerate official and unofficial modes of control, and thus contribute to the functioning of the whole ensemble. Regulation multiple accounts for what pharmaceutical governance is on the ground: a plurality of regimes that cohabit, overlap, interact and feed each other. The State is only one player among many others. This is the reason why our privileged sites of observation have been the relation between harmonisation processes and persisting diversity, as well as the relations between official and unofficial regulatory regimes.

The other players do not constitute an informal ensemble where the counterpart would be a formal organisation. This opposition does not account for the mingling of licit and illicit networks, neither does it ‘capture this interconnection between the official and unofficial’ (Peterson, 2014, p. 83). Unofficial practices are not confined to allegedly marginal spaces either. Although they vary in degree in the countries we have studied, alternative routes, corrupt practices and other forms of arrangements are rather pervasive, sometimes inescapable and deeply embedded in official regulatory processes.⁷ Of course, those who undertake outlawed or unofficial practices know their position and the risks associated with it but this is in no way an indication that they consider their mode of operation as hierarchically inferior, marginal or aberrant. They often say that it is more functional. We concur on this point with Janet Roitman (2005, pp. 19–20) when she writes that these unofficial practices and networks of actors can take centre stage and should not be labelled as informal. The author provides a brilliant illustration of how emergent regulatory regimes came to dominate certain sectors of economic activity in Cameroon. Competing sources of regulatory authority, a ‘military-commercial nexus’, managed to regulate local population and regional exchanges, and account for ‘a pluralisation of regulatory authority’ (p. 18). Roitman follows by recognising that these new regimes of accumulation and wealth exercise their power through an array on ‘unregulated’ economic activities (p. 19), as they are non-State regulatory actors. This conundrum indicates a strong departure from the argument presented in this article. We contend that regulation refers to a much larger set of rules and practices than that prescribed by the State and other official actors, which should not, for the sake of analysis, be taken as points of reference. By looking at regulation in the

ASEAN in this way, we can hint at the manner in which other regulatory universes, such as economic regulation, are assumed and enacted by those involved. It all depends on where the point of reference is placed. In fact, there is no such thing as unregulated pharmaceutical transactions, procedures or exchanges. They all answer to particular regulatory regimes, organised mechanisms involving dynamic and interacting forms of logistics, control and bridging processes. Regulation is about social order(ing).

NOTES

1. The verb 'to regulate' stems from the Latin *regulatus*, past participle of *regulare*, 'to control by rule, direct'.
2. This article results from a collective work that began in 2013, which first led to the organization of the workshop 'Pharmaceutical practices in Southeast Asia', held in Bangkok in June 2015. All contributing authors have subsequently expanded their individual, multidisciplinary research in their respective fields and met again during a writing workshop held in Paris in June 2016. This event allowed for the consensual drafting of the architecture of the article, which was further consolidated and elaborated by the two leading authors, with contributions from all. Funding from these works stems from various sources: Research Institute on Contemporary Southeast Asia (IRASEC) in Bangkok, Partnership Hubert Curien SIAM, GLOBHEALTH Project of the European Research Council (ERC), Research Center on Science, Medicine, Health and Society (CERMES3, Paris), Centre Populations et Développement (CEPED, Paris) and University of Paris Ouest.
3. Our understanding of regime draws from Dominique Pestre's notion of 'regime(s) of knowledge production' (2003), in which he underscores the interactions between knowledge production and social, economic, historical and legal transformations. The notion of logistic regimes applies this kind of reading to logistics and the ways goods are circulating in a given society, highlighting the coexistence of distinct logistic regimes for similar goods at the same point in time and space.
4. See, for example, the guide to economic analysis of drugs' circuits produced by the World Health Organization (Dumoulin, Kadar & Velásquez, 2001).
5. Pharmaceutical securitization is a trend in international public health policy, which consists of protecting the integrity of pharmaceutical flows mostly through legal interventions (intellectual property), police operations and brand authentication procedures rather than assessing the content quality of a pharmaceutical (Quet, 2015).
6. See, for example, the work by Khan et al. (2011) on the perception of drug quality among pharmaceutical wholesalers in Cambodia, and the paper by Syhakhang, Freudenthal, Tomson and Wahlström (2004) on drug sellers and consumers in Laos.
7. This kind of configuration is facilitated by the poor enforcement of State regulation and fact that the regulation of pharmaceuticals by the State is relatively recent in some countries. In Cambodia, for instance, the trade of pharmaceuticals from ordinary markets was only banned in 1994 (Ovesen & Trankell, 2010, p. 239), the year United Nations left a country that already suffered over a decade of civil war and armed conflicts.

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