Not Quite the Same: Regulatory Intermediaries in the Governance of Pharmaceuticals and Medical Devices

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This article compares the role of regulatory intermediaries in the governance of pharmaceuticals and medical devices in Australia and Switzerland. We argue that the creation, selection, and activation of specific intermediaries depend on the organizational capacity of the regulator and on the potential of the intermediary to be captured by the target. To limit the risk of capture of intermediaries where the regulated industries are powerful, regulators tend to keep intermediaries under their control. To do so, the regulator must be well-funded and well-staffed, or supported by its political principal. However, when the target has limited capture potential, regulators will rely more heavily on externalized intermediaries. These intermediaries typically consist of transnational organizations in charge of multiple regulatory issues in several jurisdictions, and can provide unique expertise in an efficient way. Four case studies of the Australian and Swiss regulatory regimes for therapeutic products support this argument.

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In this article, we explore the role of regulatory intermediaries in the authorization of pharmaceuticals and approval of medical devices, using Australia and Switzerland as case studies. Governance of these therapeutic

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products is a crucial policy problem that is both complex and salient. Therapeutic products are primarily governed through regulation—that is, through the promulgation of rules and the establishment of mechanisms that ensure compliance with these rules (Jordana and Levi-Faur 2004; Levi-Faur 2011); fiscal policies and redistributive mechanisms are less prominent. Developers, producers, and importers of therapeutic products must perform very strict tests and controls, for which a great deal of scientific knowledge is required, to ensure safety and effectiveness before products are admitted to domestic markets. Intermediaries (Abbott, Levi-Faur, and Snidal, this volume) play an important role in the regulation of therapeutic products because they can provide unique expertise to the regulators in an efficient way. However, intermediaries are also prone to regulatory capture, especially by powerful regulated industries.

Policy-makers and regulators face a dilemma. On one hand, they must ensure effective certification and admission of therapeutic products, which is in the interest of the industries; but also of consumers and patients, who need timely and innovative therapeutic products. On the other hand, they must also guarantee product safety, which requires time and resources. This demand entails keeping the actors that provide or interpret evidence regarding product safety reasonably autonomous from the regulated industries, especially in situations in which a risk of capture is anticipated.

Research has shown that this dilemma is a structuring feature of therapeutic product regulation. For instance, Carpenter (2002) demonstrated that the timing of drug approval by the United States Food and Drug Administration (FDA) depends on the balance between the costs and benefits of waiting. Regulators tend to prefer a risk-reduction approach that increases the length of the process, while interest groups lobby for quick approvals. Furthermore, as Daemmrich and Krücken (2000) showed in their comparative study of Germany and the United States, the opportunity structure available to interest groups in different countries influences the regulatory decision-making of the agency in charge. Specifically, this structure shapes the balance between the risk of extensive premarket testing and review and the risk of side effects from rapidly introduced drugs. However, the role of regulatory intermediaries in this type of regulatory regime has been so far overlooked.

To fill this gap, we pursue an exploratory analysis of the role of intermediaries with respect to domestic regulatory agencies for therapeutic products. We start with the assumption that effective regulation requires that regulators possess certain

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capacities, such as expertise, legitimacy, and operational capacity, especially including staff and budget (Abbott, Levi-Faur, and Snidal, this volume). Regulatory intermediaries provide sector-specific expertise and are usually well-suited to effectively support the regulatory process by delivering scientific knowledge to assist regulatory decision-making or directly certifying therapeutic products. Nevertheless, strong target groups can potentially capture regulatory intermediaries (Abbott, Levi-Faur, and Snidal, this volume) to influence regulatory outputs according to their special interests. To deter attempts at capture, a regulator with strong organizational capacity can exert strict control over its intermediaries. Conversely, if the regulator has weak organizational capacity, it can exert little control over its intermediaries, making them more vulnerable to capture.

Furthermore, we distinguish between intermediaries that work "under the shadow" of the regulator and those that are "fully externalized." Regulatory intermediaries that operate under the shadow of the regulator are not staffed by the regulator's employees but are established and mandated by the regulator and depend on it for organizational resources. Examples are advisory committees convened and funded by the regulator but comprising independent experts. Fully externalized intermediaries are fully fledged separate organizations on which the regulator relies to execute an intermediation function, such as transnational certification bodies. They do not depend on the resources of the regulator.

We argue that strong regulators tend to use intermediaries that are under their shadow, especially when the target has high capture potential. This type of intermediary can be easily shielded from capture, so long as the regulator has the resources and will to do so. However, shielding comes at the price of higher operational and monitoring costs for the regulator. In contrast, when the target has less potential and incentives to capture intermediaries, even strong regulators prefer to rely on fully externalized intermediaries. These are not only less costly but can also be more effective than directly controlled ones, as they have experience with many regulatory issues and usually span several jurisdictions. They further have the flexibility and competences to keep up with the fast pace of innovations in highly technical sectors.

Our findings indicate that regulators tend to rely extensively on external intermediaries when the risk of capture is considered low. In particular, our analysis suggests that, to fully understand the role of intermediaries within the RIT framework (Abbott, Levi-Faur, and Snidal, this volume), it is useful to distinguish between intermediaries working under the shadow of the regulator and fully externalized intermediaries. The following section presents our theoretical model. After the methodological section, we present the four case studies. Then we discuss our findings and their implications cross-nationally and cross-sectoral. Conclusions follow.

Theory and Hypotheses

We start from the assumption that a regulatory intermediary can be created, selected, or activated by regulators—or in some cases by regulatory targets—when they require specific capacities to achieve their goals. "Creation" refers to

the establishment of a body performing a regulatory intermediation function. "Selection" implies the choice of an intermediary from a larger pool, while "activation" refers to prompting an intermediary to act. Regulatory intermediaries may carry out the following tasks: provide operational capacity in service delivery, perform monitoring and enforcement, offer expertise, enhance credibility through their formal independence, provide policy feedback, and increase procedural legitimacy (Abbott, Levi-Faur, and Snidal, this volume). They can thus increase the regulators' regulatory capacities. Independent expertise in particular is a key resource in the regulatory process that intermediaries can efficiently provide to regulators in charge of complex and salient issues.

The relationship between the regulator and its political principal also shapes the intermediary's role. If the regulator is subject to direct supervision by its principal, the latter can provide support to the regulator, especially when the regulator has few resources of its own. Conversely, it is more difficult for an independent regulator to rely on the principal's support (Bernstein 1955; Maggetti 2012). Taken together, the regulator's own resources and/or support from its principal make up its *organizational capacity*, which is crucial for effective implementation (Ting 2011). This capacity further determines whether regulators can exert significant control over intermediaries.

What is more, the role of regulatory intermediaries depends on the *capture potential* of the regulatory target, that is, the regulated industries. When such industries have high stakes in a regulatory regime, they have strong incentives to influence the behavior of all regulatory actors (Laffont and Tirole 1991). The regulatory target's potential to do so increases with its resources and capacity for collective action and coalition-building (Fischer 2015, 60; Baumgartner et al. 2009). Although the regulator itself may be at risk of capture by powerful targets (Carpenter and Moss 2013), intermediaries face an even greater risk, as they are closer to the regulated industries (Abbott, Levi-Faur, and Snidal, this volume).

When a regulated industry has high capture potential, the regulator will react by creating, selecting, and activating the intermediary so as to retain control over it and avoid its regulatory capture.[1] In this case, the intermediary will tend to work "under the shadow" of the regulator. In contrast, when the capture potential of the target is relatively low, the regulator should be both less concerned with capture of intermediaries and less prone to capture itself. The regulator can thus confidently rely on externalized intermediaries.

Bringing these points together, we expect that when a regulator has a strong organizational capacity, its reliance on fully externalized intermediaries will depend on whether the target has high capture potential. When the target does—when the regulator anticipates that the target may capture the intermediaries or when the regulator is itself prone to capture—then the regulator will keep intermediaries under its shadow. In contrast, when the capture potential of the target is relatively low, the regulator has no need to control its intermediaries. It will therefore prefer fully externalized intermediaries that match its preferences as closely as possible, as they are often more efficient: they provide unique resources, and do so efficiently, with limited monitoring and oversight costs.

TABLE 1
Explanatory Typology of I's Relationships with R and T

		Target	
		High Capture Potential	Low Capture Potential
Regulator	Strong organizational capacity	H1: I under shadow; created by R	H2: I externalized; selected/activated by R
	Weak organizational capacity	H3: I externalized; selected/activated by T	H4: I externalized; independent

However, when a regulator has scarce resources and limited support from its principal, reliance on external intermediaries is unavoidable. In this context, when the target has high capture potential, the regulated industry itself may be able to select and/or activate the externalized intermediary. Conversely, when the intermediary is confronted with targets with relatively low capture potential, the externalized intermediary will work relatively autonomously and can develop a central role in the regulatory process.

It is worth noting two clarifications. First, the concept of capture potential refers to the risk of or vulnerability to capture, not its actual occurrence. The latter would suggest a systematic regulatory bias in favor of certain industries but would require much more compelling proof, namely, demonstrating that intentional actions by the regulated industries caused a shift away from the public interest toward industry interest (Carpenter and Moss 2013, 15). Second, our study holds the characteristics of the intermediary comparatively constant. It is certainly possible that certain conditions can make an intermediary more or less resistant to capture, but these fall beyond the scope of this article. The relationships between regulators (R), intermediaries (I), and targets (T) can be formalized in terms of hypotheses, as shown in Table 1.[2]

Methods and Data

Table 1 and the related hypotheses provide an explanatory typology that we illustrate with empirical evidence (Elman 2005). We selected two countries and two industry sectors related to the regulation of therapeutic products according to a compound research design (Levi-Faur 2006), which operationalizes differences between the organizational capacity of regulators and the capture potential of targets. The characteristics of intermediaries do not vary significantly across the paired comparisons. Regulation of therapeutic products is chosen as the object of study because it is a substantively important policy area that is both complex and salient (Gormley 1986; Eshbaugh-Soha 2006). Complexity boosts the need for specialized knowledge, such as that potentially delivered by intermediaries. Salience raises attention and increases demands for regulatory action, thereby

conferring more importance on the use of intermediaries. We therefore expect regulatory intermediaries to be very relevant to our cases, making them suitable for applying our explanatory typology (Seawright and Gerring 2008).

We selected the Australian and Swiss cases following the logic of a most similar systems design (Przeworski and Teune 1970). Both are developed democracies and federal states, with health care systems that provide universal coverage and mix public and private elements of funding and provision. Nevertheless, they offer variation on the first dimension of our argument, the organizational capacity of regulators. Differences in capacity are apparent in terms of both resources and support from the political principal. The Australian Therapeutic Goods Administration (TGA) is a relatively well-funded agency with a staff of about 750 employees; it was established in 1989 and is part of the Department of Health, so it can also rely on departmental infrastructure and staff. Conversely, the Swiss agency Swissmedic has relatively few resources, with around 350 employees; it is quite young, founded in 2002, and is formally independent from the government. It is worth noting that these differences in staff size do not stem from the extent to which intermediaries are externalized, as in both cases intermediaries are not considered part of the agency's staff (De Pietro et al. 2015; Duckett 2007).

The key tasks of therapeutic product regulators are pharmaceutical authorization and approval of medical devices through conformity assessment and certification. The distinction between these two issues provides analytical leverage on the second dimension of interest—the capture potential of the target—as the two industries have very different structures (Scherer 2000; Pammolli et al. 2005; Gaspar 2010). Pharmaceutical regulation deals with a number of large transnational corporations that invest massively in products with long lifecycles and investment recovery periods. Pharmaceutical industries typically have very high stakes in the regulatory process. Even more than other regulated industries, they also have interests that diverge from those of health policy authorities, creating a risk of capture (Abraham and Reed 2001; Abraham 2002). The pharmaceutical industry thus clearly possesses very high capture potential (Abraham and Lewis 2000).

Producers of medical devices, in contrast, are much more heterogeneous: large companies coexist with many small and medium-size firms. Products have a much shorter lifecycle and investment recovery period. The medical device industry thus has relatively low capture potential, especially regarding its capacity for collective action. This contrast is epitomized by the fact that a single global industry association exists for pharmaceutical industries,[3] while many associations are in place for producers of medical devices.[4]

The observable implications of this research strategy are the following. According to hypothesis 1, we should observe intermediaries working under the shadow of the regulator in Australia in the authorization of pharmaceuticals. Hypothesis 2 implies that the Australian regulator should select and/or activate fully externalized intermediaries for medical devices. Following hypothesis 3, we expect the target to select and/or activate external intermediaries in charge of pharmaceutical authorization in Switzerland. Hypothesis 4 predicts an externalized and independent Swiss intermediary for medical devices.

To explore these hypotheses, we conducted four qualitative case studies, mainly based on data from official sources, such as the websites of TGA and Swissmedic, and official reports from both regulators and their principals—that is, the Australian and Swiss federal departments of health. Furthermore, we examined the databases that both regulators maintain on admitted drugs and medical devices, as well as relevant legal texts. We reviewed specialized press and secondary literature. We also drew on insights from a research project comparing health governance in federal states, including Australia and Switzerland (Achtermann et al. 2014). This project included more than sixty semistructured interviews with experts and stakeholders, conducted between 2011 and 2012. These interviews provided general background information for the case studies, and were informative on specific points where indicated (Trein 2015). Finally, we focused on intermediaries that have a direct impact on the authorization of pharmaceuticals and the approval of medical devices. We excluded other wide-ranging intermediaries, which had less impact. For example, the World Health Organization is, strictly speaking, an intermediary, because regulators rely on its technical expertise and efforts to build a global community of experts. However, its impact on core regulatory tasks (i.e., authorization and approval) is marginal and indirect.

Case Studies

Intermediaries in the regulation of pharmaceuticals and medical devices in Australia and Switzerland show systematic patterns (Table 2), which are described in detail in our case studies.

The authorization of pharmaceuticals in Australia

The main objective of the Australian regulatory framework is to ensure the affordability and quality of therapeutic products in a context where the strong capture potential of the pharmaceutical industry and its attempts to influence regulation were mentioned repeatedly during interviews. TGA is responsible for ensuring the quality of both pharmaceuticals and medical devices in the Australian market. It also regulates sunscreens, vaccines, blood and blood-based products, and similar goods related to human health (McLean, Stewart, and Kerridge 2014), under the Therapeutic Goods Act 1989 (the *Act*) and the Therapeutic Goods (Medical Devices) Regulations 2002 (the *Regulations*). In fiscal year 2014–2015, TGA relied on a staff of about 750 full-time equivalents (TGA 2016). It is thus well-equipped to fulfill its objective, particularly because it has in-house experts on both pharmaceuticals and medical devices.

TGA evaluates each new drug after its producer (the "sponsor" of the drug) applies to market it in Australia. For this evaluation, TGA requires "proof" of the drug's efficacy, safety, and quality (*Act*, s. 3). TGA also monitors the performance of drugs after they have entered the Australian market. It may withdraw approval

TABLE 2
Regulatory Intermediaries in Australian and Swiss Health Policy

Country	Issue	Main Intermediaries	Intermediary Type
AUS (strong org. capacity)	Pharmaceuticals (high capture potential)	Expert committees	Under shadow of R (TGA), which is supported by principal (Ministry of Health)
		Transnational bodies (e.g., EMA)	Externalized
	Medical devices (low capture potential)	Expert committees	Under shadow of R (TGA), which is supported by principal (Ministry of Health)
		Notified bodies	Externalized
CH (weak org. capacity)	Pharmaceuticals (high capture potential)	Expert committees	Under shadow of R (Swissmedic), but close to Ts
		Transnational bodies, (i.e., foreign regulators)	Externalized, partially selected and activated by Ts; independent from R (Swissmedic) and principal (Federal Department of Domestic Affairs)
	Medical devices (low capture potential)	Notified bodies	Externalized

of any drug, thus removing it from the list of authorized medicines (Faunce 2009).

In the authorization of pharmaceuticals, TGA relies on several intermediaries, which can be divided between those working under its shadow and those that are fully externalized. In the first category, TGA has fourteen committees of independent experts, which was established in 2010. Six of these (including subcommittees) are dedicated to pharmaceuticals; they work on complementary medicines, medicine scheduling, nonprescription medicines, prescription medicines, pharmaceuticals (subcommittee), medicine safety, and vaccine safety. As of this writing, sixty-nine individuals are members of these committees (TGA 2016). TGA not only invites external experts of its own choice to join the committees but also determines the topics to be discussed. Hence, creation, selection, and activation of these intermediaries are fully controlled by TGA.

The experts within the committees are scientists, practitioners such as pharmacists, and public servants from both domestic and international organizations. They support TGA in decision-making in two principal ways: first, they provide technical and regulatory expertise; second, as they come directly "from the field," they provide direct access to the regulatory targets and give feedback on policy

implementation. TGA has substantial resources of its own, and the employment of expert committees as intermediaries further increases its (already high) operational capacity, especially regarding access to the industry. At the same time, the industry has limited access to these committees. Their members may come from industry but require invitation from TGA.

TGA also relies on several intermediaries that are externalized, although less important in the regulatory process. As mentioned above, TGA requires evidence of the efficacy and safety of drugs before admitting them to the market. One interview partner[5] expressed concerns about the "tame academics" the industry employs to provide such evidence, evidence "no one believes." TGA addresses those concerns by accepting evidence from the industry only if it adheres to recognized standards (*Act*, s. 25), which are established by organizations including the European Medical Agency (EMA), U.S. National Health Council, and Australian National Health, and Medical Research Council. These organizations also serve as intermediaries with respect to the admission of pharmaceuticals to the Australian market. EMA and the others provide standards that support the applications of sponsors by ensuring the quality of information needed to make informed regulatory decisions.

These external intermediaries have wide coverage. That is to say, they are relevant for every application of every sponsor. However, their regulatory impact is limited to a supportive role. Note that all of these intermediaries are external to both TGA and sponsors. Sponsors, however, have some discretion in choosing which guidelines to follow or which studies to include in their applications. Hence, TGA did not create these external intermediaries, but requested to follow their standards. However, sponsors usually do the selecting. Finally, EMA and others are used as intermediaries not by TGA but by drug sponsors.

TGA has rather high organizational capacities and relies largely on in-house resources to evaluate the efficacy and safety of pharmaceuticals. But it also employs two types of intermediaries: expert committees working under its shadow, as primary intermediaries; and fully externalized transnational organizations that provide research guidelines, as secondary ones. As predicted by hypothesis 1, the regulator primarily uses intermediaries under its control, given that the target has high capture potential. However, qualifying that hypothesis, the regulator also requires that the targets employ the standards of externalized intermediaries for the production of evidence.

The approval of medical devices in Australia

The process of approving medical devices for the Australian market is quite similar to the authorization of pharmaceuticals, as it is the responsibility of TGA (McLean, Stewart, and Kerridge 2014). TGA relies primarily on in-house expertise, complemented by several expert committees that work under its shadow. However, only three committees (including subcommittees) exist for medical devices; these are also less specialized than pharmaceutical regulation committees and meet less often. They focus on medical devices in general, the safety of medical devices, and orthopedic devices (subcommittee).

In total, thirty experts currently serve on these committees. Their individual backgrounds are diverse, including not only academics, practitioners, and public servants, but also, for example, nurses and electrical engineers. This diversity reflects the variety of issues raised by medical devices, such as their development, medical efficacy, and application (TGA 2016). Hence, the committees as intermediaries provide much less support than in the case of pharmaceuticals, based on the number of involved experts and active committees. As with pharmaceuticals, however, these intermediaries work under the shadow of TGA, which has created them and activates them at its discretion.

TGA requires that medical devices comply with safety and performance standards. It does not provide these standards on its own but refers to standards adopted by fully externalized international bodies. In particular, the following organizations are acknowledged as standard setters in the *Act* (s. 41CC): the International Organisation for Standardization, the International Electrotechnical Commission, the European Committee for Standardization, and the European Committee for Electrotechnical Standardization. These organizations are formally independent of both TGA and the target. They serve as intermediaries by producing more precise (technical) regulation of medical devices to complement domestic regulations. However, they do not approve devices for the Australian market, a task controlled by TGA.

Conformity assessments regarding safety and performance standards are also required. In fact, such assessments are the most essential step in approving medical devices for the Australian market (*Act*, s. 41FC). Assessments entail comprehensive inspections of the devices under review, and may also include inspections of the premises of the sponsor and full access to relevant documentation (*Act*, s. 41EJ). Conformity assessments are, in principle, carried out by TGA while an application is being handled.

However, little research and development of therapeutic products are actually done in Australia,[6] so TGA also accepts conformity assessments from foreign bodies (*Regulations*, S. 3, c. 1.8), called conformity assessment bodies (CAB). Most notably, it accepts assessments from European Notified Bodies (see Galland, this volume, for a detailed discussion) under a mutual recognition agreement between the EU and Australia (Official Journal of the European Union [OJ] L 229 of 1998 and OJ L 359 of 2012). Notified Bodies are accredited under EU regulation and serve similar functions for the regulation of medical devices in Europe (see also the medical devices in Switzerland case below). These bodies include both private and public actors, and their evaluations are based on standards developed by the standard-setters mentioned above. The sponsor may choose which Notified Body to employ—and to pay—for conducting a conformity assessment. The sponsor and Notified Body are mutually dependent, because they engage in a commercial relationship. The sponsor requires the certificate, while the Notified Body requires payment (Galland, this volume).

It is noteworthy that TGA is itself an accredited Notified Body. Thus, TGA plays a double role. On one hand, it serves as the regulator approving medical devices for the Australian market, for which it demands certification by an intermediary. On the other hand, it also provides such certifications and, hence, also

serves as an intermediary for the European market. What is more, the choice of which Notified Body to employ is still up to the sponsor. Considering this, TGA is able and willing to evaluate and certify medical products for the Australian market on its own, using its resources and a few expert committees as intermediaries. At the same time, and "encouraging greater international harmonisation" (OJ L 229), it also accepts Notified Bodies as external intermediaries. Compared to pharmaceuticals, the Australian regime on medical devices puts more emphasis on external intermediaries.

To summarize, TGA uses intermediaries working under its shadow less intensively than it does in the case of pharmaceuticals. However, Notified Bodies play an important part as external intermediaries, insofar as they assess quality and performance of medical devices under international safety and performance standards. Hence, this case study is in line with hypothesis 2. TGA does not strive to keep full control over the intermediation function; it allows—but does not require—extensive reliance on external intermediaries. Yet industry sponsors, which have rather low capture potential, can choose which intermediaries to employ; they therefore have a slightly more active role than expected.

The authorization of pharmaceuticals in Switzerland

Swissmedic was established in 2002 to replace a previous intercantonal agreement on the regulation of therapeutic products (Gilardi, Maggetti, and Servalli 2013). Swissmedic is a legally independent regulator whose revenue comes from fees and federal contributions. The federal government adopts a "performance contract" for Swissmedic every four years, defining its tasks and financing. A "service contract" is then signed annually between Swissmedic and the Federal Department of Home Affairs to define these objectives precisely. The Swiss regulator has fewer resources than its counterparts, with a staff of around 350 in 2014 (Swissmedic 2014).

The authorization of pharmaceuticals in Switzerland involves two distinct types of intermediaries. The intermediaries working under the shadow of the regulator are the Swissmedic Medicines Expert Committees (SMECs)—in particular the Human Medicines Expert Committee—mandated by Swissmedic itself. SMECs comprise up to eight experts in medicine, pharmacology, and legal medicine, plus some additional number of invited members (Swissmedic 2016c). The committees provide Swissmedic with scientific expertise on application documentation related to marketing, market surveillance, and drug authorization. Their advice deals with issues independent of pending proceedings, judgments about issues related to pending procedures, assessment and evaluation documentation, the drafting of evaluation reports, and safety issues in general. SMECs comprise professionals who may have tight connections with the regulated industry (Junod 2009). Hence, potential conflicts of interest could be present.[7] A survey conducted in 2011 showed that about two-thirds of the external experts declared a relationship with the pharmaceutical industry, through professional mandates, membership on boards of directors, investments, and similar

matters, and as a consequence were required to recuse themselves from certain proceedings (Masmejan 2011).

The second type of intermediary is even more relevant for the regulation of pharmaceuticals than the first type. Foreign regulators act as externalized intermediaries for Swissmedic at the very core of the authorization process. According to the procedure in Article 13 of the Swiss Law on Therapeutic Products (the *LPTh*, SR 812.21), firms and laboratories that seek authorization for the marketing of pharmaceutical products in Switzerland may request that the results of clinical tests conducted under a foreign regulator, which led to an authorization abroad, be considered for granting an authorization in Switzerland, too. To implement this procedure, Swissmedic has entered into bilateral agreements on the mutual exchange of information with regulators in the United States, Canada, Australia, Taipei, Singapore, New Zealand, Japan, Ireland, Germany, Brazil, South Korea, Israel, South Africa, and China (in chronological order; Swissmedic 2016b).

Swissmedic unilaterally implemented this procedure for EMA, even without a bilateral agreement (between 2008 and 2015), and thus without access to confidential information from EMA (Conseil Fédéral 2012).[8] In other words, the Swiss agency renounced conducting its own examinations, instead relying on those executed by a foreign regulatory authority with which Swissmedic had no formal collaborative relationship. Generally, targets' use of foreign authorities as intermediaries for pharmaceutical authorization is increasing in Switzerland. Between 2009 and 2014, the proportion of authorization procedures concluded under Article 13 of the *LPTh* increased from 2.5 percent to 18.6 percent of the total (Canu 2015).

The implementation of this procedure clearly reflected the goals of the regulated industries: reducing the length, cost, and administrative burden of the authorization procedure. In practice, the industry exercised indirect political pressure via parliamentarians and the federal government to pass legislation that would speed up authorization by Swissmedic, especially if a product had already been admitted by a foreign regulator, such as the FDA.[9] As Ms. Ruth Humbel, a Swiss member of parliament who holds close relationships with the regulated industries as a board member (Conseil National 2016), wrote in a parliamentary interpellation before Article 13 of the *LPTh* was implemented: "Surveys conducted by the industry and small businesses, as well as recent statements by Swissmedic representatives about the ongoing procedures, call into question the reliability of the institute, required in Article 1 paragraph 3 of the LPTh. The authorization for therapeutic products is often delivered with major delays" (Conseil National 2008, 1, our translation). The procedure implemented since 2009 can be seen as an answer to these concerns, providing effective and accelerated procedures (Besson et al. 2015).

This state of affairs essentially confirms hypothesis 3. When regulators with weak organizational capacity are confronted with a target that has high capture potential, intermediaries are externalized, and partially selected and activated by the target.

The approval of medical devices in Switzerland

Medical devices do not undergo an official approval procedure in Switzerland. There are often no actual Swiss standards for admission and control. Switzerland follows international standards and relies on the international certification systems and CABs that are part of the EU Notified Bodies (Swissmedic 2016a; cf. Galland, this volume). Swissmedic provides a list of CABs located in Switzerland and abroad. International CABs include bodies in the EU, Australia, Canada, Israel, Japan, New Zealand, Switzerland, and the United States. The recognition of foreign bodies is based on treaties, which regulate the harmonization of Swiss procedures with international partners (Swissmedic 2016a; namely, SR 0.946.526.81). The EU hosts the Nando (New Approach Notified and Designated Organizations) Information System, which allows treaty partners—essentially the countries mentioned above—to register CABs that fulfill international norms and can thus be used by all treaty partners. In Switzerland, companies must request authorization by Swissmedic if they want to use a nonregistered body (Swissmedic 2016a).

To determine whether devices need to be certified, a classification system ranks medical products by risk. For products in the lowest risk category, for example, wheelchairs, the producer itself may evaluate and certify the product. In any other case, the producer must design its product according to international norms and guidelines. Further, depending on the product, clinical tests by the producer might be necessary. Such tests must be approved by Swissmedic or the cantonal ethics committee. Once data on a product are available, it must be certified by a CAB (procedure depends on the type of product). Successfully evaluated medical products receive the CE label, which signifies successful certification and allows for mass production and market introduction (Swissmedic 2016a).

Swissmedic is not directly involved in the certification process. It supervises the market and the CABs—for instance, by carrying out random checks of product certifications—located in Switzerland, but it does not certify medical devices; this process is entirely up to private CABs. If there were a problem with a given product, checks by the producer and recertification by a CAB may become necessary. This would entail reevaluation of the producer and its product by a CAB, including a new decision on certification (Swissmedic 2016a).

The regulatory practice in the certification of medical devices emphasizes external intermediaries, even more than in the pharmaceutical sector. The advantage of this system is its effectiveness.[10] Its disadvantage, however, is dependence on foreign regulators and intermediaries, which are beyond the control of Swissmedic. To deal with this problem, Swissmedic claims that it strives to improve coordination with foreign regulators. For example, it participates regularly in coordination meetings with agencies such as the FDA or EMA, to exchange information on procedures (Swissmedic 2007, 34) or to coordinate activities against counterfeit medicine and medical devices (Swissmedic 2009, 17).

To better regulate the approval of internationally certified drugs and medical devices, the Federal Council revised the Ordinance on Medical Devices (SR

812.213), including more specific conditions that must be fulfilled before foreign and third-party certified devices receive market approval in Switzerland. The initiative for this reform came in part from the changing requirements of EU law (Swissmedic 2010, 16; namely, EU 1235/2010). Finally, according to its own reports, Swissmedic increased its market surveillance and certification activities between 2009 and 2011 to deal with the problems of excessive reliance on external actors (Swissmedic 2010, 17; Swissmedic 2011, 51).

These self-reports indicate that Swissmedic aims to deal with regulatory capture due to its weak capacity to certify products. However, the available information does not allow us to determine conclusively whether the activities are actually solving this problem. However, the information does demonstrate the challenges that regulators face when relying on intermediaries from the private and international sectors.

Taken together, the findings from this case study lend support to our fourth hypothesis, suggesting that intermediaries will be externalized and independent where the organizational capacity of the regulator and the capture potential of the target are both low.

Discussion

The case studies presented here support our argument that a regulator with strong organizational capacity tends to develop more control over its intermediaries than does a regulator with fewer resources and less support from its principal. Furthermore, the analysis indicates that regulators with strong organizational capacity tend to keep intermediaries under their shadow, especially when the target has high capture potential. The Australian TGA has stronger organizational capacity, especially more human resources, than does Swissmedic. Swissmedic has fewer human resources, and lacks a coherent national regulatory framework, as cantonal governments still hold a share of regulatory power. In practice, both TGA and Swissmedic rely to some extent on external experts—a key requirement in regulation (Abbott, Levi-Faur, and Snidal, this volume). Since Swissmedic has relatively few resources, it must rely on external experts more, leading it to become partially dependent on them, even though some experts invited "from the field" have tight connections with the target.

We also found that the role of intermediaries in pharmaceuticals differs from that in medical devices. This is mainly because in pharmaceuticals the regulated sector has higher capture potential. A strong regulator (i.e., TGA) has the capacity to keep the intermediary under its shadow to shield it from capture by the target, and avoid "capture via intermediary" (Abbott, Levi-Faur, and Snidal, this volume). If, however, the regulator has fewer resources and cannot rely on the support of its principal (i.e., Swissmedic), the regulatory target can try to capture intermediaries by selecting and activating them.

With regard to medical devices, where the industry's capture potential is lower, the same regulators adopt a different approach: reliance on intermediaries

is more extensive, and intermediaries are more externalized. The case of medical devices in Australia shows that intermediaries can act quite autonomously, even when the target is more active than expected. This indicates that under some conditions—especially when the risk of capture by the target is considered low—reliance on external intermediaries can be regarded as particularly desirable by regulators, because such intermediaries can provide expertise and other resources efficiently. This situation also decreases the risk that the regulator will fully control the intermediary and dominate the regulatory regime (Abbott, Levi-Faur, and Snidal, this volume).

Our analysis has broad implications for understanding the roles of intermediaries in the regulatory process. First, the distinction between intermediaries working under the shadow of the regulator and those that are fully externalized deserves to be incorporated explicitly into the RIT framework (cf. Abbott, Levi-Faur, and Snidal, this volume). The former entail higher monitoring costs and may be less efficient than the latter, but they can be kept under the control of regulators, a feature that is particularly important when a strong risk of capture is anticipated. Fully externalized intermediaries—typically transnational organizations in charge of multiple regulatory issues across multiple jurisdictions (e.g., EMA)—are widely used to provide expertise, but their vulnerability to capture (and how to mitigate it) is an open question that deserves further research.

We suggest the extension of the typology of the different forms of globalization put forward by Drahos and Braithwaite (2001, 105), which underrates the role of transnational actors that may intervene as intermediaries in the regulation of domestic markets. The regulatory regime for therapeutic products, and pharmaceuticals in particular, involves the globalization of firms and the (partial) globalization of regulation, but without market globalization. However, externalized intermediaries can be used extensively to fill the regulatory gap between the global and domestic levels. Externalized intermediaries can act transnationally at the nexus between national and international levels, promoting policy convergence and harmonization (cf. Drezner 2001). Further, they can develop and diffuse norms and practices, even in a sector where markets remain strongly segmented and dependent on the domestic context (cf. Cloatre and Dingwell 2013).

We also highlight the role of the political principal in the RIT framework (cf. Abbott, Levi-Faur, and Snidal, this volume). Our analysis shows that the principal matters, because it provides support to the regulator. However, the principal-agent relationship portrayed in our case studies looks quite different from what one would expect from mainstream principal-agent models. Instead of being an advantage, the insulation of a regulator with few resources from the principal seems to increase its dependence on external intermediaries, which may occupy a dominant position in the regulatory regime, as does EMA in the case of Swissmedic.

We expect that these findings will hold for similar cases, that is, for intermediaries active in the regulation of complex and salient issues, where intermediaries can be created, selected, or activated by the regulators or by the target. However,

further research is needed to specify the scope and conditions and confirm our results in other cases.

Conclusion

This article has shown that the creation, selection, and activation of intermediaries vary between countries and sectors, depending on the organizational capacity of the regulator and the capture potential of the target industry. A strong regulator (such as the Australian one) tends to use its capacity to keep intermediaries under its shadow to avoid regulatory capture by a target industry with high capture potential (i.e., the pharmaceutical industry), while this is more difficult for a regulator with fewer resources (such as the Swiss one). Moreover, when the target industry has limited capture potential (i.e., in medical devices), regulators are more eager to rely on fully externalized intermediaries—independently of whether regulators themselves are well-funded and well-staffed—because this type of intermediation is usually perceived as an efficient way to provide unique expertise.

This article further contributes to the RIT framework by showing that political principal matters for the governance of intermediaries, especially in the case of support for the regulator. This support is important for weak regulators that must rely on the expertise of externalized intermediaries and are confronted with industries with high capture potential. Without such backing, a regulator might find its regulatory intermediaries threatened by capture. However, further research on the role of the principal is needed to include it systematically in the RIT framework. Further research should focus explicitly on the potential capture of intermediaries and, on the other hand, on the conditions for empowering regulatory intermediaries and keeping them accountable.

Notes

1. If, however, a captured regulator works with independent intermediaries, one would expect it to try to control the intermediation function as well.

2. Please note that intermediaries can also be created, selected, or activated under the impulsion of beneficiaries. The scope of our argument, however, is limited to intermediaries that are not created, selected, or activated by beneficiaries.

3. The International Federation of Pharmaceutical Manufacturers & Associations.

4. For example, MedTech Europe, International Medical Device Manufacturers Association, Advanced Medical Technology Association, International Association of Medical Equipment Remarketers and Servicers, and Global Medical Technology Alliance.

5. Interview with a researcher from the Australian National University, May 2011.

6. Interview with a researcher from the Victoria University, April 2011.

7. Interview with the head of the Swiss Medical Association, February 9, 2012.

8. Interview with a leading official in the Federal Office of Public Health, March 29, 2012.

9. Interview with the former head of the Cantonal Conference of Public Health Directors, January 26, 2012.

10. Interview with the former head of the Cantonal Conference of Public Health Directors, January 26, 2012.

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