

Confronting theories of European integration: A comparative congruence analysis of veterinary drugs regulations in five countries

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Abstract

This study moves beyond current perspectives of European Union (EU) implementation research to paint a comprehensive picture of the fine-tuning of domestic regulations beyond compliance. We compare the hitherto unexplored veterinary drugs regulations of four member states, France, Germany, Austria, and the United Kingdom, with those of the non-member Switzerland. We link causal mechanisms back to three differing theoretical assumptions about European integration. These theories are confronted using congruence analysis in a comparative case study design. We find evidence for historical institutionalism and for the domestic politics hypothesis. The assumption of a neo-functionalist development of regulations is only weakly supported.

Keywords: European integration, historical institutionalism, neo-functionalism, domestic politics, congruence analysis, comparative case study design, veterinary drugs regulations

Similar solutions to transboundary problems?

The European Union (EU) evolved in response to increasing transboundary challenges to secure the efficient functioning of markets through regulation (Majone 1996). While a broad body of knowledge on compliance with EU law exists (e.g., Falkner et al. 2005, Mastenbroek and Kaeding 2006, Perkins and Neumayer 2007), the question of the actual fine-tuning of domestic policies remains largely unexamined. Even if correctly transposed, community law still allows member states considerable space for interpretation, leading to differences in the application of EU rules that were originally intended to be uniform (Falkner et al. 2005, Knill and Tosun 2012: 242). Indeed, the European experience illustrates how far-reaching economic integration can be reconciled with legitimate differences in national preferences (Majone 1999, Schmidt 2008). An impressive range of explanatory factors have been identified for the adoption of EU law. We argue together with Treib (2008: 18) that “for the progress of EU implementation research as a whole, however, it would be even more desirable to link these results back to theoretical arguments”. To address this gap, we ask: Do compliant countries really have similar regulations? What underlying theoretical assumption about integration serves best to explain the emergence of domestic regulations?

This paper provides a systematic empirical analysis of the regulations which govern the dispensing of veterinary drugs for livestock; these play a major role in securing animal health and food safety and have hitherto been understudied (Treib 2008: 16; for pharmaceutical marketing authorizations, see Vogel 1998, Krapohl 2007). The study compares four EU member states with a non-member state. We investigate to what extent the regulations of Germany, Austria, France, the United Kingdom (UK) and Switzerland resemble each other. Our aim is infer the appropriateness of three theoretical assumptions about the evolution of

international institutions (Starke et al. 2008: 978), which are applied to analyse the implementation of regulations at the national level.

A first, functionalist hypothesis has been advanced by Vogel (1998: 18), who argues that “political pressures for more rapid drug approval in both Europe and the United States, and the experience of international co-operation itself” lead to the globalisation of pharmaceutical regulation. In this case, all countries should apply similar solutions to shared problems, whether they are members of the EU or not. A second, historical-institutionalist hypothesis proposes a path-dependent development of supranational regulatory regimes (Krapohl 2007), which would imply greater variation between EU members and non-members than among EU member states. A third hypothesis encapsulates Majone’s (1996) argument that domestic politics are the most decisive factor for policy outcomes (Mastenbroek and Kaeding 2006); as a result, there should be a tendency for regulations to diverge in line with domestic preferences.

In the next section, the theoretical assumptions are presented and hypotheses are derived. The presentation of the method and research design in section three is followed by the two-tiered empirical assessment. The concluding section discusses the findings and answers the research questions.

Three theories about European integration

The expectation that the EU would facilitate similar solutions to common problems rests upon a basic assumption about the nature of integration. Until the 1970s, neo-functionalism was the predominant view. However, as the course of events challenged neo-functionalism assumptions, alternative integration theories took over, amongst them supranationalism, intergovernmentalism, historical institutionalism and the domestic politics approach (Keohane

and Hoffmann 1991, Corbey 1995: 254-258, Pierson 1996, Puchala 1999, Aspinwall and Schneider 2000, Peterson 2001).

Various conceptually related processes may lead to similar policies (Knill 2005: 765-768, Starke et al. 2008) (see Table 1). International factors tend to foster convergence, such as policy problems that exceed national boundaries (for example, Armingeon and Bonoli 2006), policy learning processes (Zito and Schout 2009), and regulatory competition (Starke et al. 2008: 979). The transfer of policies can also be fostered by joint affiliation in international institutions or even be non-voluntary by means of legal harmonisation (Knill 2005, Scharpf 2010). Conversely, domestic political and institutional factors can lead to divergent regulations (for example, Falkner et al. 2005, Krapohl 2007). We argue below that these mechanisms can be attributed to three basic theoretical currents about integration: neo-functionalism, historical institutionalism, and domestic politics.

“Insert Table 1 about here”

Competing theories agree upon basic concepts but disagree about the causal connections between them (Blatter and Haverland 2012: 156). Unlike supranationalism or intergovernmentalism, the three theories assessed here are not merely concerned with “history-making decisions” at the supranational level (Peterson 2001: 294). By making different assumptions about the main driving factors behind the emergence of national institutions,¹ they disagree about the relative importance of these factors for the emergence of similar domestic regulations (that is, integration).

These theories are not mutually exclusive, but they do emphasize the different causal

¹ Institutions are defined as the “(...) formal or informal procedures, routines, norms and conventions embedded in the organisational structure of the polity (...)” (Hall and Taylor 1996: 938).

mechanisms that they find decisive. Neo-functionalists do not deny a causal role of institutions or harmonisation (Puchala 1999: 319), nor does the domestic politics approach preclude the influence of functional pressures. Although basic differences exist between the teleologies of institutionalist and neo-functionalist theories (Aspinwall and Schneider 2000, Peterson 2001: 297), Peterson (2001) notes a lack of theories of EU governance which are true rivals. Rather, existing models explain different outcomes at different levels of the EU multi-tiered system. Since there is no unified meta-theory of European integration, it should be specified what different approaches do or do not explain (Puchala 1999). We aim to do precisely this, by assessing the relative strength of these three theories to explain the (dis)similarity of regulations in the cases under investigation.

We present these approaches in the following sections. We derive basic assumptions about the pattern of similarity they lead us to expect. Our expectations focus only on the core assumptions of each theory about the decisive causal mechanisms, which necessarily implies some degree of oversimplification.

Neo-functionalism: form follows function

Neo-functionalism conceives integration as a mainly apolitical effect of economic-functional requirements and technical interdependences between states and policy areas. An alignment of policies can be expected between all countries where these functional pressures prevail (Armingeon and Bonoli 2006). The idea of functional spillover implies that co-operation in one field leads to integration in adjoining fields. If integration in one policy sector is hampered by non-integration in functionally linked areas, then efforts to overcome these problems will lead to further integration (Corbey 1995: 254-258, Renner 2009). The idea of spillover effects is linked to policy learning in an increasingly interconnected world (Knill

2005: 766, Zito and Schout 2009). Spillover occurs when policy actors strongly commit themselves to integration (Tranholm and Mikkelsen 1991: 4–6, cited in Macmillan 2009: 791): “*Political spillover* encompasses the integrative pressures exerted by national élites, who realize that problems of substantial interest cannot be satisfactorily solved at the domestic level” (Niemann 1998: 430). Such integrative processes tend to happen “in sectors where the intensity and value of cross-national transactions” are already relatively high (Sandholtz and Sweet 2010: 11). Thus, by way of the spillover, “policy integration would intensify and expand through the policy process” (Stephenson 2012: 801). For veterinary drugs regulations, spillover effects can be expected from or to the European single market for food products and the regulations of feedstuffs (Ugland and Veggeland 2006: 612).

If form follows function, then all countries affected by a problem have a similar incentive to react, independently of their institutional affiliation. Therefore, we ought to find similarity between the regulations of all countries, whether they are members of the EU or not. Co-operation at the supranational level creates spillover effects over time. Hence, a neo-functional perspective grants importance to EU membership as leading to similar regulations. The decisive observation is the behaviour of the non-member who shares similar functional problems, especially if some form of co-operation occurs.

Historical institutionalism: no institution emerges from a *tabula rasa*

Amongst new institutionalist theories, rational choice institutionalism stresses the role of actors, whereas sociological institutionalism states that institutions influence actors’ preferences and perceptions, leading to institutional isomorphism. Historical institutionalism argues that institutions and history matter. Regulations emerge in a path-dependent way; past policies and the polity’s institutional organisation structure subsequent policy choices.

Context matters; the same operative forces will not generate the same result everywhere. Moreover, institutions privilege some interests while constraining others, which leads to distinct national outcomes (Hall and Taylor 1996: 937, 941-942, Haverland 2000, Lodge 2007: 279).

Historical institutionalism divides the flow of historical events into periods of continuity punctuated by *critical junctures*, which open windows of opportunity for substantial institutional changes. However, the political opportunity structure determines whether this window is exploited by political actors. If this does not occur, institutions are conceived as remaining very stable and resistant to change (“sticky”) (Pierson 1996, Krapohl 2007: 28-29). Institutional change happens gradually as the result of a long-term incremental process (Pierson 2004: 82, Streeck and Thelen 2005, Steunenberg and Kaeding 2009). In this research tradition, it is the interplay of path dependency, domestic politics, and country-specific problem pressures that accounts for policy variation (Starke et al. 2005: 979, for example, Aspinwall and Schneider 2000, Maggetti et al. 2011).

Some institutionalist arguments focus on the role of legal harmonisation and legal-administrative factors in the EU as leading to positive or negative integration (Schmidt 2008, Steunenberg and Toshkov 2009, Scharpf 2010). Member states have historically and incrementally developed similar regulations due to their obligation to follow community orders. EU commission directives influence domestic policy choices in the aftermath of crises. Policy actors are organized and lobby in Brussels. Even if countries face similar challenges, then these elements are missing in non-member states; the pre-existing institutions differ following EU membership and prominently explain policy choices (Knill and Tosun 2012: 81). To support the historical-institutionalist hypothesis, we should observe greater variation of policies between EU members and non-members than among EU member states.²

² While this outcome would also be expected according to institutional isomorphism, our argument is crucially

Although the domestic policies are still filtered through distinct national institutions during implementation, EU members have a common institutional basis upon which new regulations are built. Our conception of the outcome allows the domestic regulations to differ, so long as they have at least some commonalities.

Domestic politics: the actor-centered perspective

Functionalist and institutionalist theories are challenged by a third perspective, according to which domestic politics are decisive for policy outcomes (Falkner et al. 2005, Mastenbroek and Kaeding 2006). Without denying the importance of institutions (Knill and Tosun 2012: 91ff), the domestic politics approach focuses on actors and their preferences. In this view, national policy making is mainly influenced by domestic political processes and power structures (Treib 2003: 509).

A transnational alignment of policies faces difficulties for two reasons. First, each government acts as a defender of the national status quo during transposition. Second, political party constellations, the resulting preferences, and veto powers predominate in determining policy outcomes (Treib 2003, Oosterwaal and Torenvlied 2012). If we assume that these political-institutional factors are unique for each country, then so will be the policy outcomes. Thus, the domestic politics perspective expects little similarity between the countries' regulations, regardless of the existence of EU directives.

We can now formulate assumptions about the kind of observations that can be expected or not, according to the core assumptions of these three theories (Table 2).

based on the idea of path-dependency.

“Insert Table 2 about here”

Research design

We test these three differing expectations by analysing regulations of the dispensing of veterinary drugs for livestock in Europe. We thereby follow calls in EU implementation research to include policy sectors that have hitherto attracted only scant attention (Treib 2008: 16). Dispensing denotes the process by which a veterinary drug reaches the end user who administers it to the animal. As Figure 1 illustrates, this process has no direct transboundary dimension, which grants countries relatively extensive legislative leeway. This makes dispensing policies a particularly rigorous touchstone on which to test assumptions about the conditions under which similar regulations arise.

“ Insert Figure 1 about here”

We focus on four sub-aspects. First, general dispensing policies regulate the access to and the distribution of veterinary drugs for livestock. Second, we analyse the regulations of medicated feedstuffs, a mixture of a veterinary drug with feed. Third, the requirements for documentation of the dispensing process enable the authorities to control compliance and to trace the sources of animal diseases or contaminated food across borders. Finally, EU law prescribes frequent controls of compliance with the dispensing rules, while their further enforcement falls to the member states. Country case studies are provided in the online appendix. These policies are operationalized according to 29 indicators, which were chosen for their direct comparability and clear distinguishability from other processes in the lifecycle

of a veterinary drug (Table B online appendix). Data were collected through expert interviews with agents of the central administration and stakeholder groups and an analysis of legal bases, policy documents, and secondary literature (see Sager et al. 2011 for case studies and a list of all legal sources).

Congruence analysis and case selection

Due to the theoretical and empirical complexity of our research object, we conducted a qualitative in-depth analysis of theoretically interesting cases. Since we seek congruence between our theoretical assumptions and the empirical information, we applied congruence analysis (Blatter and Haverland 2012). This method focuses on observations that discriminate between rival theories by providing evidence for the correctness of one theory and the incorrectness of another theory at the same time. Congruence analysis implies that concepts can have different meanings depending on their theoretical embedding (see Table 2). For example, the expression of domestic actors' interests reveals the political opportunity structure within historical institutionalism, but also domestic pressures in the domestic politics approach. Thus, one should rely not only on single observations, but on clusters of observations to obtain a picture which is meaningful in the light of the theoretical framework. This picture is then contrasted with the meanings within the other theoretical frameworks (Blatter and Blume 2008: 332, 343) to reduce the risk of a "confirmation bias" (Blatter and Haverland 2012: 174).

We proceeded in two stages. By means of descriptive statistics, we first tested whether the countries' regulations resemble each other. The regulations of the 29 policy aspects in each country were compared with those of every other country according to whether they are fully, partially or not at all similar (see Table C online appendix). This allows an indicative

assessment of the congruence of the three theoretical expectations with the observations.

Holzinger and Knill (2005) warn of the pitfall of inferring from the similarity of policies to the explanation at work. Thus, in a second step, we undertook a qualitative in-depth examination of selected policy aspects to explain how the regulations emerged (Howlett and Newman 2013). Each hypothesis was examined in this way. Alternative explanations and puzzling observations identified in the quantitative overview were discussed.

During the first analytical step, our cases were the regulations for the dispensing of veterinary drugs in France, Germany, Austria, the UK and Switzerland. A most-similar-cases design was employed to preclude the risk that contextual features explain the observed differences (Blatter and Haverland 2012: 42). Because livestock farming has a similar relevance for agriculture (Sager et al. 2011: 301), the countries face comparable regulatory requirements. The four EU members have been members ever since the first veterinary drugs regulations were issued in the early 1990s, and they share a tendency toward low compliance (Falkner et al. 2005). The second analytical step focused on specific policies as cases that represent “most likely cases”, meaning that the theory in question has a high probability of explaining the case (Blatter and Blume 2008: 347, Blatter and Haverland 2012: 167-178). Accordingly, the causal factors proposed by the theory which is tested by the case were present and could be expected to be at work.

Considering a non-member state enables us to assess the role of EU membership for integration, while the context should ensure the cases’ comparability as being “crucial” for the theories tested (Blatter and Haverland 2012: 177ff). Functionally, the European non-EU member’s similar agricultural sectors should have a comparable significance; a high significance of fishery, for instance, would create entirely different regulatory requirements. Relative democratic and political stability since the early 1990s when the first EU regulations emerged should ensure the country’s comparable regulatory capacity. Although covering a

variety of non-EU member countries might enhance the results' analytical leverage, Switzerland is the only European non-EU member that complies with our "most similar" assumptions (see Table A online appendix).

Since 1 January 2009, Switzerland has a contractual obligation for equivalence to relevant EU rules (veterinary agreement). As a consequence, its legislation is checked for Euro-compatibility (Linder 2011: 46). This can lead to the transposition of EU law into Swiss law, however often subject to the regular legislative and democratic processes (Maggetti et al. 2011). The Swiss administration tends only to identify a need for revision if a rule directly contradicts the EU provision. From a neo-functionalist perspective, this institutionalized co-operation of Switzerland with the EU should have fostered spillover effects. The historical institutionalist perspective would view the veterinary agreement as opening a window of opportunity for adapting to EU rules, provided that the political opportunity structure is given. The domestic politics argument would assume domestic interest constellations to be decisive, regardless of the presence of co-operation with the EU.

Ordinary veterinary drugs are usually regulated in Directive 2001/82/EC, and medicated feedstuffs in Council Directive 90/167/EEC (see Table B online appendix). That the policies were subject to transposition processes is crucial to testing the domestic politics assumption. The EU rules had generally been adopted by all five countries by 2011 (Sager et al. 2011). There is one policy aspect in which Switzerland has not established full equivalence yet, and roughly one third of the analysed variables are not regulated in community law at all. Our case selection enables us to assess the relevance of both the existence of EU legislation and the non-member's institutionalized co-operation with the EU for policy integration.

Confronting theories of integration

Same-same but different?

To paint a comprehensive picture of the policies' (dis)similarity, cases of partial and full similarity are merged, and their number is expressed as a percentage of all policies for each comparison of two countries. This facilitates calculating the average similarity of policies between all countries, between Switzerland and the EU members, and between the EU members. Table 3 distinguishes between policies that are regulated by an EU directive and those that are not. It reveals that the countries do use the leeway left by the EU directives. Despite the fact that Switzerland has been subject to the EU standards since 2009, its rules are considerably more distinct from the EU member countries' regulations than the member states' regulations from each other. Table 4 below, which differentiates between the four aspects of dispensing, shows that this holds both for those aspects that have been transposed by Switzerland, and for the documentation requirements where it has not.

“Insert Table 3 about here”

“Insert Table 4 about here”

Most interestingly, Switzerland resembles the other countries equally or even more in the absence of EU standards (regulations of inspections) than in aspects regulated by community law. Apparently, that Switzerland has been committed to these directives since 2009 has not been decisive for its policy choices. By contrast, for EU members, the existence of EU directives does make a remarkable difference. Member states pursue individual solutions if they can: there is a stronger similarity on average if an EU directive exists than if there are no common standards. If the latter is the case, the extent of dissimilarity no longer varies with

EU membership. These findings point to the importance of domestic politics as soon as there is enough scope for action.

This is clearly the pattern we would expect according to historical-institutionalist assumptions, stressing the importance of path dependencies and pre-existing institutions. In turn, we find surprisingly little evidence for neo-functionalism assumptions, according to which EU-membership would be largely irrelevant for the emergence of similar policies. Nor do we find strong evidence for the domestic politics hypothesis at first glance: under certain circumstances, policies do resemble each other to a great extent.

Is it about problems, actors, or institutions?

Each hypothesis is now tested based on a selected policy aspect. We assess whether the evolution of the domestic regulations corresponds to the theoretical expectations, which are further specified beforehand. We also discuss whether two alternative explanations have been at work (Blatter and Haverland 2012).

The neo-functional hypothesis

Neo-functionalism expects the regulations of the non-member to be similar to the other countries when a) similar problem pressures lead to similar solutions, regardless of existing institutions, and b) close co-operation in related policy fields creates spillover effects over time as political élites exercise integrative pressures. Such mechanisms are likely to happen with the regulations of supply shortfalls of veterinary medicines.

When no registered veterinary drug is available for rare species and maladies, drugs not authorized for the specific use can be dispensed instead. The European Cascade rule allows

the veterinarian to dispense a) a veterinary drug authorized in the country for use with another animal species, or for another condition in the same species; b) either a human medicinal product authorized in the country, or a veterinary drug not authorized in the country but authorized in another member state; or c) a drug prepared according to *formula magistralis* (see online appendix). The irregular use of medicines raises the issue of drug residues in food products. The dispensing rules for supply shortages need to ensure both the proper treatment of animals and the safety of the end product – ultimately, consumer health in a European single market. They have a direct effect on the safety and exportability of animal food products. The EU is the main export destination for Swiss animal food products. Hence, there are strong shared functional requirements, and we can expect close collaboration in the trade in agrarian products to lead to integration in this intertwined aspect.

Indeed, the EU Cascade rule has been implemented in all five countries. It has been binding for EU members since 2001. Yet it took Switzerland another nine years to adopt the Cascade rule in 2010 during a minor revision of the *Tierarzneimittelverordnung* (Sager et al. 2011). Although functional pressures to ensure the exportability of Swiss food products and the competitiveness of Swiss livestock farmers already existed after 2001, the Swiss rules resisted change. Functional requirements were not decisive for the adoption of the European rule, but the legal obligation for equivalence in the year 2009. The veterinary agreement opened a window of opportunity for the policy's revision which was exploited proactively by the administration.

In line with the historical institutionalist expectations in Table 2, the EU members implemented the EU template, while the Swiss regulations remained unchanged in this respect until the institutionalized co-operation with the EU facilitated change. The neo-functional explanation of functional spillover and the predominant relevance of functional pressures for integration hardly applies even to this most likely case. Domestic politics may have

influenced the delay in establishing equivalence. In Switzerland, veterinarians influence policy making more actively than the agricultural producers' associations. Veterinarians find the Cascade rule too restrictive, whereas producers are more interested in the exportability of their products (Sager et al. 2011: 379). Yet these interest constellations were ultimately not decisive (see Table 2). The historical sequence by which Switzerland finally adopted the EU rules is most congruent with a historical institutionalist explanation.

The domestic politics hypothesis

The expectation that national regulations tend to differ from each other rests upon the assumption that there are a) strong domestic interest constellations defended by the actors concerned by the regulations and b) domestic political processes that are c) very specific to countries, leading to diverse policy outcomes. This could be the case for the regulations of medicated feedstuffs.

Feedstuffs are the most common route of application for antibiotics, and often used excessively to compensate for the negative health effects of intensive livestock farming. This may lead to antibiotic resistances, which can be passed on to human consumers. Whereas farmers tend to emphasize their individual responsibility, veterinarians and regulatory bodies call for more restrictive rules (Sager et al. 2011: 375). This has led to particularly strict EU requirements for the manufacturing of medicated feedstuffs, both by feed mills and through on-farm manufacturing (OFM). Nonetheless, EU law leaves some leeway, as the countries are free to define specific conditions for OFM. Since these rules can represent a significant hurdle for the producers, they are likely to be disputed, with the livestock owners trying to defend their freedom for OFM, and veterinarians calling for better animal health. The reactions of the national regulators will depend on their specific regulatory priorities.

Indeed, the solutions in the countries are multi-faceted and independent of their EU membership. Germany has completely prohibited OFM and seriously complicated the business for feed mills. This highly contested procedure was in line with a broader regulatory strategy for preventing antibiotic resistances. France allows OFM; however, since 2004 it has been bound to such numerous administrative hurdles and restrictions that it is virtually never practised. This strategy was motivated by a consensus that OFM increases the risk of an unsafe use of veterinary drugs. Industrially manufactured medicated feedstuffs prevail. By contrast, the UK's liberal rules for OFM stress the livestock owners' individual responsibility. While the blending must be supervised by "qualified persons", there are no legal requirements as to their qualification. British policy makers deliberately focus on non-binding codes of conduct. The support for this strategy from both livestock owners and veterinarians is reflected in their membership in the Responsible Use of Medicines in Agriculture Alliance. In Switzerland, OFM since 2004 has only been allowed where necessary for two days if the process is supervised by a specially qualified veterinarian (Sager et al. 2014). The Swiss regulations resisted change until the institutionalized co-operation with the EU facilitated policy change. Typical for the Swiss consensus style, the policy makers sought to maintain the liberty of livestock owners while ensuring the controllability of the process. The quite influential veterinarians who regularly urge more restrictions on the use for antibiotics (Sager et al. 2011: 375) were considered suitable for ensuring the correct procedure.

In Austria, OFM is highly but rather liberally regulated. Within the private *Tiergesundheitsdienste* (TGD), farmers are permitted to undertake OFM in unrestricted amounts, provided they undergo the obligatory training for this and are accompanied by a veterinarian. The voluntary TGD were created in 2003 as part of a governmental strategy to reduce the use of veterinary drugs and enhance legal certainty for users. OFM has a high practical relevance in Austria. Thus, the regulations meet the needs of Austrian farmers particularly well.

These national solutions differ quite substantially, as expected by the domestic politics hypothesis (see Table 2). They reflect domestic regulatory strategies and the interests of the actors involved. An important factor limiting integration between EU member states was the leeway left by the EU minimal standards, which made their effective adoption and interpretation a political question.

As for the neo-functional hypothesis, the issue of resistances to antibiotics among consumers is highly salient in all countries, and the sector is closely integrated with the regulations of animal feed. Nonetheless, neither were there spillover effects nor did functional problem pressures foster similar solutions, which is not congruent with the expectations in Table 2. Similarly, pre-existing institutions cannot explain the different outcomes. The use of medicated feed and OFM used to be common practice in all countries prior to and even after the issuing of Directive 90/167/EEC; historical institutionalism would hence have expected more similar regulations.

The historical-institutionalist hypothesis

The assumption that the regulations of EU countries resemble each other more than Swiss regulations resemble them rests upon the idea that there are a) rules in form and/or in use which b) EU member states (used to) share but Switzerland does not so that c) their “stickiness” and path-dependent development over time has not yet led to an equal level of similarity, although Switzerland is bound to EU standards. The documentation requirements for veterinary drugs dispensing provide the prerequisites for such a development.

Documentation rules significantly affect the actors’ everyday professional lives. They are disputed; compliance is an omnipresent issue (Sager et al. 2014). The EU documentation requirements date back to 2001; they were adopted by its members subsequently. Switzerland,

too, issued documentation regulations three years later, five years before the veterinary agreement. Yet, the Swiss rules are more liberal than the EU standards and even today have not been adjusted to the EU norms.

Thus, contrary to the Cascade rule example, the bilateral agreement of 2009 has not played the role of a critical juncture here: the political opportunity structure did not enable a change in the Swiss documentation system. The widespread opposition against more restrictive documentation rules amongst the Swiss policy addressees and even among national regulators is not caused by strong functional interests. Most respondents indicate that the costs of such an adaptation are very low. The main argument is simply that one has gotten used to doing it this way. This is a typical example of the “stickiness” of an institution.

Whereas this could also be a case of domestic politics, strong opposition equally existed in the other countries, which, however, did adopt the EU norms. Therefore, the motives behind this opposition are not political, but simple inertia (Table 2). Common problem pressures as assumed by neo-functionalism exist: transboundary traceability when food scandals occur is essential in a single market. In principle, the Swiss documentation rules are sufficient to ensure traceability. Yet, functional requirements were not the main motive for the voluntary adoption of these rules. In Switzerland, a series of scandals about drug residues co-occurred with first reports about food-related resistances to antibiotics around the year 2000. A small group of influential officials and representatives of the veterinarians’ association then urged the Swiss Federal Office for Public Health to regulate the target groups. Thus, these scandals opened a window of opportunity that was exploited. Neo-functionalism cannot explain the remaining differences to the EU; similar problems and the institutionalized co-operation since 2009 should have led to similar solutions (cf. Table 2). The EU countries’ rules were based on the EU directive from the outset. The rules in Switzerland, however, are based on a contrasting regime and have survived despite co-operation in related areas. This is a clear-cut

case of the path-dependent, persistent institutions predicted by historical institutionalism (cf. Table 2).

Discussion

At first glance, the emergence of veterinary drugs regulations in the five countries appears to correspond most closely to neo-functionalist expectations. Transboundary problems related to animal diseases, residues of veterinary drugs in food products, and resistances to antibiotics created a demand for regulation that was satisfied by the European Veterinary Medicines Directive and national regulations. Switzerland, embedded in the European single market for agricultural products, concluded a bilateral veterinary agreement in order to remain competitive.

However, a closer analysis of the domestic regulations reveals that the neo-functionalist theory can neither account for the remaining differences nor provide an adequate explanation for their emergence. Policy changes required more than functional pressures: a combination of critical events with an appropriate political opportunity structure. The pattern of resemblance of the national regulations and their emergence mostly correspond to the expectation of path dependency of historical institutionalism. Moreover, even EU countries used their scope of action whenever community law or its absence left them some leeway, which is when domestic politics became decisive for policy outcomes. Notwithstanding this, two aspects of Table 3 require further discussion.

Integration and regulation

Why do the EU countries' regulations not resemble each other more than they resemble the

Swiss rules in aspects not regulated by EU law? Apparently, it was the existence of EU requirements that was decisive for integration and not institutional affiliation to the EU (Table 2). In the absence of a *concrete* common institution, no path-dependent development toward similar regulations took place. This provides quite strong evidence against the idea of spillover effects. Such a concrete institution may be an EU rule, but it does not have to be.

One instance is the rules regarding the actors who are authorized to prescribe and dispense veterinary drugs for livestock. EU law sets a general prescription requirement without specifying actors. It sets a duty to obtain an authorisation and registration for dispensing actors; internet retail is unregulated. The countries' regulations share the common characteristic that registered veterinarians may prescribe the medicines, and pharmacies can dispense them. This pattern is rooted in the institutional organisation of the pharmaceutical sector *per se* that prevails everywhere.

Going beyond that, France has defined unique additional dispensing frameworks due to political pressures of French farmers and practitioners. The British Competition Commission found market distortions in the supply of prescription-only medicines in 2003. This led to the UK being the only country that extends prescription and dispensing rights to suitably qualified persons, and generally allows internet retail of prescription drugs. Switzerland has not complied with the general prescription requirement yet because it contradicts established practices (Sager et al. 2011). Thus, without concrete community rules, domestic political pressures, practical needs and national institutions accounted for differences in the regulations. Similarities can be attributed to institutional features other than EU membership.

Integration and time

Why has Switzerland's adaptation to the other EU countries apparently not primarily been

affected by the existence of EU standards, despite its legal obligations since 2009? The adoption of EU rules regarding documentation and supply shortfalls by Switzerland followed a historical institutionalist logic in that it required the coincidence of both a window of opportunity and the political opportunity structure for change. Historically grown institutions such as documentation procedures are particularly rooted. The respective legislative processes are still ongoing. These findings are therefore congruent with the assumptions of historical institutionalism outlined in Table 2: while EU directives or co-operation may provide a window of opportunity for institutional change, they do not suffice. The path-dependent development of similar regulations takes time. However, our historical institutionalist assumption about the role of EU membership needs refinement. Instead, our observations suggest that what facilitated integration was the existence of common binding standards or other institutional features combined with sufficient time and the political conditions for their adoption.

Settling the battle of theories

This study has analysed the fine-tuning of domestic policies of the dispensing of veterinary drugs in five Western European countries. By reassessing EU integration theories, the study addresses the “lack of cumulativeness that has marked some of the literature so far” (Treib 2008: 17). It contributes to existing research on integration by considering the role of institutional affiliation and the existence of EU law in an unexplored policy field. However, our causal analysis remains indicative, as we lack complete information about the emergence of the regulations.

We discussed the relative validity of the simplified core assumptions of three dominant theories about the decisive driving forces behind integration: neo-functionalism, historical

institutionalism and the domestic politics approach. Our findings are not congruent with the neo-functionalist assumptions of form following function (for example, Armingeon and Bonoli 2006) and spillover processes (for example, Tranholm and Mikkelsen 1991, Niemann 1998, Vogel 1998, Renner 2009, Sandholtz and Sweet 2010, Stephenson 2012); the approach has difficulties explaining both the remaining differences between the domestic regulations and their historical development (Risse 2005). Our observations correspond best to the historical institutionalist expectation of a path-dependent, incremental evolution of institutions (for example, Aspinwall and Schneider 2000, Haverland 2000, Krapohl 2007). The analysis of aspects not regulated by EU law highlights that it is not the institutional affiliation in terms of EU membership that accounts for similar regulations, but most importantly legal harmonisation (Scharpf 2010). Yet it was only in combination with sufficient time and the appropriate political opportunity structure that integration also occurred in the non-EU member state (Steunenberg and Kaeding 2009, Maggetti et al. 2011). In the absence of these features, the development of the national regulations was subject to domestic political processes, as assumed by the domestic politics approach (Falkner et al. 2005, Mastenbroek and Kaeding 2006, Oosterwaal and Torenvlied 2012). In summary, our findings suggest that integration may be the complex result of legal harmonisation from above, time, and political will (Perkins and Neumayer 2007).

Instead of aiming at statistical generalisation, this research contributes to the battle of theories over European integration by drawing inferences on their relative explanatory validity to explain the cases under investigation (Blatter and Blume 2008: 349). Rather than being mutually exclusive, the three theories which were examined each have their particular explanatory strengths and weaknesses. Our results support Peterson's (2001) thesis that neo-functionalism works best at the super-systemic level of "history-making", whereas institutionalism can better explain how policies are adopted at the systemic level. However, a close look at the complex interplay of path dependencies and political processes is needed to

understand the fine-grained patterns of the (dis)similarity of *domestic* policies in Europe.

References

- Armingeon, K. and Bonoli, G. (Eds), 2006, *The Politics of Post-Industrial Welfare States. Adopting Post-War Social Policies to New Social Risks* (London/New York: Routledge).
- Aspinwall, M. and Schneider, G., 2000, Same menu, separate tables: The institutionalist turn in political science and the study of European integration. *European Journal of Political Research*, 38(1), pp. 1-36.
- Blatter, J. and Blume, T., 2008, In search of co-variance, causal mechanisms or congruence? Towards a plural understanding of case studies. *Swiss Political Science Review*, 14(2), pp. 315-356.
- Blatter, J. and Haverland, M., 2012, *Designing Case Studies: Explanatory Approaches in Small-N Research* (Basingstoke: Palgrave Macmillan).
- Corbey, D., 1995, Dialectical functionalism: Stagnation as a booster of European integration. *International Organization*, 49(2), pp. 253-284.
- Falkner, G., Treib, O., Hartlapp, M. and Leiber, S., 2005, *Complying with Europe: EU Harmonisation and Soft Law in the Member States* (New York: Cambridge University Press).
- Hall, P. A. and Taylor, R., 1996, Political science and the three new institutionalisms. *Political Studies*, 44(5), pp. 936-957.
- Haverland, M., 2000, National adaptation to European integration: The importance of institutional veto points. *Journal of Public Policy*, 20(1), pp. 83-103.
- Holzinger, K. and Knill, C., 2005, Causes and conditions of cross-national policy convergence. *Journal of European Public Policy*, 12(5), pp. 775-796.
- Howlett, M. and Newman, J., 2013, After “the regulatory moment” in comparative regulatory studies: Modeling the early stages of regulatory life cycles. *Journal of Comparative Policy*

Analysis: Research and Practice, 15(2), pp. 1-15.

Keohane, R. O. and Hoffmann, S., 1991, Institutional change in Europe in the 1980s, in: R. O. Keohane and S. Hoffmann (Eds) *The New European Community. Decisionmaking and Institutional Change*, (Boulder, Colorado: Westview), pp. 1-39.

Knill, C., 2005, Introduction: Cross-national policy convergence: Concepts, approaches and explanatory factors. *Journal of European Public Policy*, 12(5), pp. 764-774.

Knill, C. and Tosun, J., 2012, *Public Policy. A New Introduction* (London: Palgrave Macmillan).

Krapohl, S., 2007, Thalomid, BSE and the single market: An historical-institutionalist approach to regulatory regimes in the European Union. *European Journal of Political Research*, 46(1), pp. 25-46.

Linder, W., 2011, Europe and Switzerland: Europeanization without EU membership, in: C. Trampusch and A. Mach (Eds) *Switzerland in Europe. Continuity and Change in the Swiss Political Economy*, (Abingdon/New York: Routledge), pp. 43-60.

Lodge, M., 2007, Comparative public policy, in: F. Fischer, G. J. Miller and M. S. Sidney (Eds) *Handbook of Public Policy Analysis, Theory, Politics and Methods*, (Boca Raton: CRC Press, Taylor and Francis Group), pp. 273-288.

Macmillan, C., 2009, The application of neofunctionalism to the enlargement process: The case of Turkey. *Journal of Common Market Studies*, 47(4), pp. 789-809.

Maggetti, M., Afonso, A. and Fontana, M., 2011, The more it changes, the more it stays the same? Swiss liberalization and regulatory policies in comparative perspective, in: C.

Trampusch and A. Mach (Eds) *Switzerland in Europe. Continuity and Change in the Swiss Political Economy*, (Abingdon/New York: Routledge), pp. 205-223.

Majone, G., 1996, *Regulating Europe* (London: Routledge).

- Majone, G., 1999, Regulation in comparative perspective. *Journal of Comparative Policy Analysis: Research and Practice*, 1(3), pp. 309-324.
- Mastenbroek, E. and Kaeding, M., 2006, Europeanization beyond the goodness of fit: Domestic politics in the forefront. *Comparative European Politics*, 4(4), pp. 331-354.
- Niemann, A., 1998, The PHARE programme and the concept of spillover: Neofunctionalism in the making. *Journal of European Public Policy*, 5(3), pp. 428-446.
- Oosterwaal, A. and Torenvlied, R., 2012, Policy divergence in implementation: How conflict among decisive legislators reinforces the effect of agency preferences. *Journal of Public Administration Research and Theory*, 22(2), pp. 195-217.
- Perkins, R. and Neumayer, E., 2007, Implementing multilateral environmental agreements: An analysis of EU directives. *Global Environmental Politics*, 7(3), pp. 13-41.
- Peterson, J., 2001, The choice for EU theorists: Establishing a common framework for analysis. *European Journal of Political Research*, 39(3), pp. 289-318.
- Pierson, P., 1996, The path to European integration: A historical-institutionalist analysis. *Comparative Political Studies*, 29(2), pp. 123-163.
- Pierson, P., 2004, *Politics in Time: History, Institutions, and Social Analysis* (Princeton: Princeton University Press).
- Puchala, D., 1999, Institutionalism, intergovernmentalism and European integration: A review article. *Journal of Common Market Studies*, 37(2), pp. 317-331.
- Renner, S., 2009, The Energy Community of Southeast Europe: A neo-functionalist project of regional integration. *European Integration online Papers (EIoP)*, 13.
- Risse, T., 2005, Neo-functionalism, European identity, and the puzzles of European integration. *Journal of European Public Policy*, 12(2), pp. 291-309.

Sandholtz, W. and Sweet, A. S., 2010, Neo-functionalism and Supranational governance.

Forthcoming in the *Oxford Handbook of the European Union*. Available at

<http://dx.doi.org/10.2139/ssrn.1585123>.

Scharpf, F. W., 2010, The asymmetry of European integration, or why the EU cannot be a “social market economy”. *Socio-Economic Review*, 8(2), pp. 211-250.

Schmidt, S. K., 2008, Beyond compliance: The Europeanization of member states through negative integration and legal uncertainty. *Journal of Comparative Policy Analysis: Research and Practice*, 10(3), pp. 299-308.

Starke, P., Obinger, H. and Castles, F. G., 2008, Convergence towards where: In what ways, if any, are welfare states becoming more similar?. *Journal of European Public Policy*, 15(7), pp. 975-1000.

Stephenson, P. J., 2012, Image and venue as factors mediating latent spillover pressure for agenda-setting change. *Journal of European Public Policy*, 19(6), pp. 796-816.

Streeck, W. and Thelen, K., 2005, *Beyond Continuity: Institutional Change in Advanced Political Economies*, (Oxford: Oxford University Press).

Steunenberg, B. and Kaeding, M., 2009, “As time goes by”: Explaining the transposition of maritime directives. *European Journal of Political Research*, 48(3), pp. 432-454.

Steunenberg, B. and Toshkov, D., 2009, Comparing transposition in the 27 member states of the EU: The impact of discretion and legal fit. *Journal of European Public Policy*, 16(7), pp. 951-970.

Treib, O., 2003, Die Umsetzung von EU-Richtlinien im Zeichen der Parteipolitik. Eine akteurszentrierte Antwort auf die Misfit-These. *Politische Vierteljahresschrift*, 44(4), pp. 506-528.

Treib, O., 2008, Implementing and complying with EU governance outputs. *Living Reviews*

in European Governance, 3(5).

Ugland, T. and Veggeland, F., 2006, Experiments in food safety policy integration in the European Union. *Journal of Common Market Studies*, 44(3), pp. 607-624.

Vogel, D., 1998, The globalization of pharmaceutical regulation. *Governance: An International Journal of Policy and Administration*, 11(1), pp. 1-22.

Sager, F., Thomann, E., Zollinger, C. and Mavrot, C., 2011, *Tierarzneimittelregulierung in Europa*, Study mandated by the Swiss Federal Office of Public Health (Bern: Center of Competence for Public Management).

Sager, F., Thomann, E. Zollinger, C., van der Heiden, N. and Mavrot, C., 2014, Street-level bureaucrats and New Modes of Governance – How Conflicting Roles Affect the Implementation of the Swiss Ordinance on Veterinary Medicinal Products. *Public Management Review*, 16(4), pp. 481-502.

Zito, A. R. and Schout, A., 2009, Learning theory reconsidered: EU integration theories and learning. *Journal of European Public Policy*, 16(8), pp. 1103-1123.

Tables and Figures

Table 1: Scenarios, causal factors and theoretical classification

| <i>Theory about integration</i> | <i>Causes</i> | <i>Process</i> | <i>Result</i> |
|---------------------------------|---|----------------|---------------|
| Neo-functionalism | Similar problem pressure Imitation and policy learning Regulatory competition | | |
| | Legal harmonisation | | |
| | | | |
| Domestic politics approach | Domestic political-institutional factors | | |

Sources: Starke et al. (2008: 978); authors' own illustration.

Aspect (partly) observable by the available evidence

Table 2: Theoretically expected observations

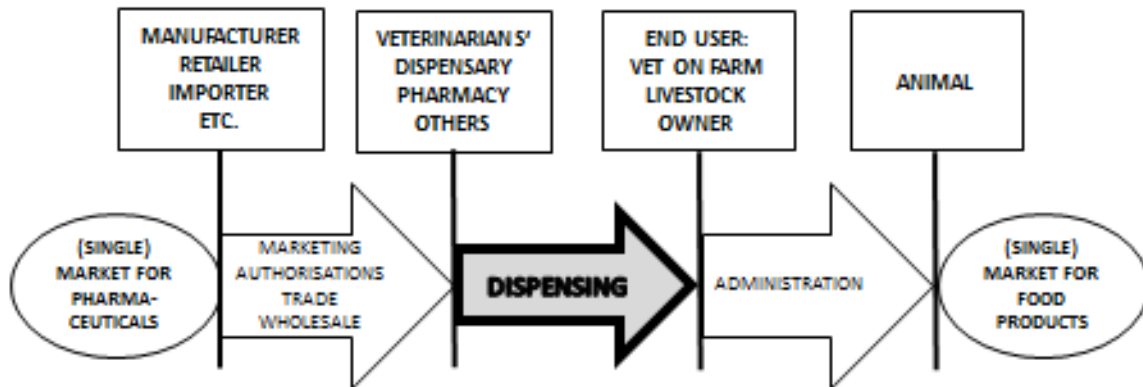
| <i>Causal Factor</i> | <i>Theory</i> | <i>Expected</i> | <i>Not expected</i> |
|----------------------|---------------|---|--|
| | <i>NF</i> | Primary driving force If shared: similar solutions regardless of existing institutions | Other factors are decisive |
| | <i>HI</i> | Play a role besides other factors, for example by influencing the political opportunity structure | Lead to policy change despite the absence of a window of opportunity and the political opportunity structure |
| | <i>DP</i> | Structure political interest constellation and discussion | Will automatically lead to integration if shared |
| | <i>NF</i> | Spillover effects | No spillover over a longer period of time |
| | <i>HI</i> | Can create a window of opportunity for integration | Leads to integration regardless of existing institutions and political opportunity structure |
| | <i>DP</i> | Not decisive | Leads to integration although domestic politics are unfavorable |
| | <i>NF</i> | Domestic institutions: not decisive EU membership fosters co-operation | Inhibit integration despite similar functional problems and co-operation |
| | <i>HI</i> | Resist change; basis upon which new regulations are built Domestic institutions: inertia EU membership: integration | Irrelevance |
| | <i>DP</i> | Structure domestic politics (for example veto points) | EU membership leads to integration although domestic politics are unfavorable |
| | <i>NF</i> | Can create functional problem pressure | Policy change is contingent on critical junctures |
| | <i>HI</i> | Create a window of opportunity for integration | Policy change in the absence of a window of opportunity |
| | <i>DP</i> | Structure domestic politics | Lead to integration although domestic politics are unfavorable |
| | <i>NF</i> | Importance of elites' behavior | Decisive for non-change despite functional problem pressures |
| | <i>HI</i> | Provide political opportunity structure for policy change | Irrelevance Leads to policy change in the absence of some window of opportunity |
| | <i>DP</i> | Decisive, usually different between countries | Irrelevance |

NF = Neo-functionalism

HI = Historical institutionalism

DP = Domestic politics

Figure 1: The “life cycle” of a veterinary drug



Source: authors' own illustration.

Boxes represent actors and arrows stand for processes.

Table 3: Similarity of policies according to existence of EU norm

| <i>Variables</i> | <i>Pattern of Similarity</i> | <i>...between all countries</i> | <i>...between Switzerland and EU countries</i> | <i>...between EU countries</i> | <i>Range (Standard deviation)</i> |
|---|-----------------------------------|---------------------------------|--|--------------------------------|-----------------------------------|
| <i>All policy aspects 29 variables</i> | <i>Partial or full Similarity</i> | 76.9 | 65.5 | 84.5 | 34.5 (11.2) |
| <i>EU directive exists 18 variables</i> | <i>Partial or full Similarity</i> | 81.1 | 62.5 | 93.5 | 44.4 (16.6) |
| <i>No EU law exists 11 variables</i> | <i>Partial or full Similarity</i> | 70 | 70.5 | 69.7 | 36.4 (13.6) |

Number of observations: 290.

EU = European Union.

Average similarity was obtained by first calculating the share of bilateral policy similarity (full or partial) between all possible combinations of two countries in per cent of all respective policy aspects, and then aggregating these bilateral values according to the rules specified in the first row.

Table 4: Similarity of policies according to policy aspect

| <i>Variables</i> | <i>Pattern of similarity</i> | <i>...between all countries</i> | <i>...between Switzerland and EU countries</i> | <i>...between EU countries</i> | <i>Range (Standard deviation)</i> |
|---|-----------------------------------|---------------------------------|--|--------------------------------|-----------------------------------|
| <i>Regulation of dispensing of VMPs 11 variables</i> | <i>Partial or full Similarity</i> | 78.2 | 70.5 | 83.3 | 27.3 (9.8) |
| <i>Regulation of dispensing of MFS 4 variables</i> | <i>Partial or full Similarity</i> | 80.0 | 68.8 | 87.5 | 50.0 (15.8) |
| <i>Documentation requirements for dispensing* 8 variables</i> | <i>Partial or full Similarity</i> | 80.0 | 50.0 | 100.0 | 50.0 (25.8) |
| <i>Controls of dispensing** 6 variables</i> | <i>Partial or full Similarity</i> | 68.3 | 75.0 | 63.9 | 50.0 (16.6) |

Number of observations: 290

EU = European Union

VMP = Veterinary medicinal product

MFS = Medicated feedstuff

*More than one EU standards have not been transposed by Switzerland

**Aspect not regulated by EU

Average similarity was obtained by first calculating the share of bilateral policy similarity (full or partial) between all possible combinations of two countries in per cent of all respective policy aspects, and then aggregating these bilateral values according to the rules specified in the first row.