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Limits of Law in the Multilevel System: Explaining the European Commission's Toleration of Noncompliance Concerning Pharmaceutical Parallel Trade*

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Abstract

This article aims to explain the under-researched phenomenon of why the European Commission (the Commission), as 'guardian of the Treaties', tolerates member states' noncompliance with the EU law. While major accounts of selective enforcement depict the Commission as a self-serving political entrepreneur, this paper assumes that it is a trustee guardian of EU treaties that aims to safeguard the stability and integrity of the EU legal order. For this purpose, the Commission is theorized to strategically utilize toleration of noncompliance to evade jurisdiction overlap and norm collision. Relying on the detailed tracing of the Commission's enforcement leniency towards Slovakia regarding pharmaceutical parallel trade, this illustrative case study indicates that toleration of noncompliance is a necessary evil for the Commission and other stakeholders to navigate through a legal and political impasse. And it simultaneously preserves the delicate integrity of the existing legal order of EU free movement law.

Keywords: European Commission; toleration of noncompliance; jurisdiction overlap; norm collision; pharmaceutical parallel trade

Introduction

Noncompliance is commonly believed to be a legal disease that compromises the effectiveness of governance and erodes commitment to collective rules. Naturally, it needs to be eradicated by rigorous surveillance and stringent enforcement. But when it comes to the EU, it is no news that the Commission pursues legal infractions selectively and strategically (Conant, 2002; Hartlapp and Falkner, 2009). This article aims to explain why the Commission on some occasions tolerates member states' noncompliance.

From a strictly legal perspective, infringements of EU law can only be verified through adjudications by the Court of Justice of the EU (the Court). But given the fact that the majority of infringement cases are settled at the pre-litigation stage, toleration of noncompliance would remain an inscrutable phenomenon by the application of this strict legal standard. In addition, the aim of this article is not to assess the actual legality of contested national measures. It is of little relevance whether or not the Court actually perceives

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contested national measures as breaches of EU law. Rather, this article aims to investigate the enforcement strategy of the Commission. Thus, toleration of noncompliance is defined as instances where the Commission consciously turns a blind eye to contested national measures, even though said measures are considered illegal by the Commission and remain unrectified.[1]

The core theoretical argument of this research is that toleration of noncompliance could provide the Commission with the flexibility needed to evade the functional limits of law within the EU multilevel system. Specifically, by assuming that the Commission's enforcement decisions aim to safeguard EU legal order, the author contends that toleration of noncompliance could help to evade jurisdiction overlap and norm collision and could thus maintain the stability and integrity of EU law.

This research does not intend to provide a covering-law theory that claims a general applicability to all instances of toleration of noncompliance. Rather, the main objectives are to open up new research avenues on tolerated noncompliance, and to demonstrate the theoretical feasibility of the proposed argument. To pursue these objectives, this research focuses on a typical policy issue, pharmaceutical parallel export (Toshkov, 2016, p. 294). This business model perfectly embodies the jurisdiction overlap and norm collision that are inherent in the European pharmaceutical regulatory system. Furthermore, among the three cases of tolerated noncompliance concerning this specific policy issue, I further zoom in on the infringement proceeding against Slovakia due to its representativeness and due to the availability of comprehensive empirical evidence.

The enquiry into the infringement proceeding against Slovakia relies upon the within-case process tracing, which examines the congruence between the theorized enforcement rationale of the Commission and the actual enforcement motivations that played out in the Slovak case. Empirical materials are collected from three sources: (1) internal infringement documents of the Commission, to which the author has been granted access; (2) eyewitness accounts by six Commission officials from four departments, who were directly involved in the related enforcement process; (3) supplementary policy papers from EU institutions, and governmental data from Slovakia.

The findings of the case study make both conceptual and theoretical contributions. By showing the role of enforcement leniency in evading functional limits of the multilevel legal system, this case study indicates that noncompliance is not *per se* a malady of the rule of law. On the contrary, toleration of noncompliance under certain conditions might be a necessary evil for the stability and integrity of a multilevel legal order. Moreover, the seemingly contradictory combination of the centralized legal monitoring system and unfettered enforcement discretion carried out by the Commission is also evocative of the notion of institutional equilibrium, argued by comparative federalists.

I. Toleration of Noncompliance: A Phenomenon Stays under the Academic Radar

As an important aspect of compliance research, toleration of noncompliance surprisingly receives scant academic attention. Among the small number of works on the subject, most

[1]In contrast, amicable settlements of the infringement cases usually entail some degree of behavioural changes from the member state in question, for example, a partial rectification of noncompliance (Andersen, 2012, p. 18).

of them interpret the Commission as a political entrepreneur or an administrative agency and presume that its enforcement decisions predominantly aim to respond to preferences of member states, or to maximize self-interests.

The first group of literature shows by using game-theoretical models that the Commission's enforcement decisions are determined by cost–benefit calculation of a group of factors (for example Steunenberg, 2010). Specifically, König and Mäder (2014) find that the Commission is more willing to pursue cases that have higher chances of enforcement success. Based on these findings, the Commission is more likely to ignore noncompliance when there is only a slim chance of bringing the member state into compliance.

Scholars also point out that the Commission strategically uses infringement procedure to advance its legislative agenda in related issue areas. In this regard, Schmidt (2000) in her seminal study puts forward the argument that the Commission uses litigation to coax member states to abandon their objections to specific legislative proposals in the Council. By analogy, the Commission's leniency could also be recognized as a 'reward' for an offending member state for its legislative support in the Council.

As a rational actor, the Commission is also believed to be more cautious when dealing with powerful member states or with an alliance of member states. In this regard, early studies show that the Commission is reluctant to pursue member states who contribute significantly to the EU budget and possess considerable voting power (Jordan, 1999). Inspired by the study of the judicial politics of the Court, analysts also point out the possibility that the Commission, similar to the Court, is vulnerable to the threat of legislative override (Fjelstul and Carrubba, 2018). In other words, the Commission is more likely to turn a blind eye when a dominant member state or the majority of member states oppose strict enforcement of a specific case.

Domestic factors have also been raised to explain the Commission's enforcement inaction. According to the management school of compliance, enforcement is a resource-consuming process. For member states with inadequate implementation capacity, ruthless enforcement makes little sense when compared to capacity building (Falkner *et al*., 2004, pp. 459–61). Moreover, research on political sanctions brings another domestic factor to our attention, namely the risk of backfire. For instance, the Commission is said to be unwilling to prosecute Eurosceptic countries for fear of adding fuel to the fire (Jordan, 1999) – although other scholars dispute this judgement (for example Closa, 2018).

Regardless of the specific explanatory variables listed above, the common denominator of most existing explanations is the assumption that the Commission, as the supranational prosecutor, is an enforcement agent of member states. Thus, the Commission's enforcement motives are either driven by the preferences of member states (the principal's control), or by its self-interest as a political entrepreneur (agency slack). However, the agency perspective is inherently inappropriate to the conceptualization of the Commission's role as the 'guardian of the Treaties' as Article 17 TEU explicitly prohibits it from subordinating to the instructions of any member state. On this note, considering that the behavioural logic of the Commission is widely recognized as being multidimensional (for example Hartlapp *et al*., 2014, pp. 294–303), the Commission, especially as a law enforcer, is better to be observed through a new lens, rather than viewing it merely as a responsive agent or as an opportunistic entrepreneur.

II. Theorizing Toleration of Noncompliance

To supplement the conventional agency perspective, this article introduces an alternative approach which recognizes the Commission as a trustee when monitoring the application of EU law (Majone, 2001). A trustee is irreversibly delegated a complete decision-making power by the trustor and is required to act in the sole interests of its beneficiary (Lettanie, 2019, p. 321). By analogy, the Commission's enforcement competence is conferred by member states for the interests of the Union. Inferentially, the Union's interests concerning legal enforcement could be concretized, based on Article 17 TEU, as the stability and integrity of EU law. After all, it is through the smooth functioning of EU legal order that disputes are adjudicated and settled, that transnational activities are guaranteed and catalyzed and that cooperative benefits are materialized and distributed.

Toleration of Noncompliance in the Multilevel System: Cushioning the Functional Limits of Law

If the Commission is assumed to safeguard the stability and integrity of EU legal order, it is counterintuitive to think that selective enforcement of EU law has any role to play in fulfilling this mandate. This confusion is not groundless because some legal scholars have long appealed that the Commission should vigorously enforce EU law and eliminate legal breaches by all means (for example Munoz, 2006, p. 418). But this view of law's functions might be oversimplified and even unrealistic.

Firstly, the law is not omnipotent in adjudicating all disputes, and it has functional limits regarding what it can achieve (Lowe, 2015, p. 123). In this regard, Fuller and Winston (1978, pp. 395, 397) posit that adjudication is inherently unsuited to settling disputes with a polycentric feature. By 'polycentric' Fuller and Winston refer to issues with interacting points of influence which involve many affected parties and a somewhat fluid state of affairs. The main reason behind this is the unpredictably complex repercussions of judicial interventions. A typical example here would be that wages or prices should not be decided through adjudication due to its complex repercussions on the economy and society.

Moreover, functional limits of law are further exacerbated by inherent deficiencies of the political system where the law operates. No legal rule is implemented in institutional voids and the effectiveness of law is shaped by itsinstitutional setting (Keohane *et al*., 2000). For example, a multilevel system like the EU is notable for its instability caused by institutionalized tensions between unity and diversity, and between rigidity and flexibility (Benz, 2016, p. 9). Vertically, authority migrations between central and sub-unit levels would destabilize the spatial balance of power (Bednar, 2004). Horizontally, substantive tensions between social, ideational and institutional dimensions mean that multilevel systems are exposed to constant pressure for change (Benz, 2016, p. 14; Jachtenfuchs and Kasack, 2017, pp. 599–600). Thus, within a multilevel system which is dynamic and conflictual, it is no surprise that the corresponding legal order is also volatile and prone to frictions.

Due to the functional limits of law, rigorous enforcement might not only contribute little towards materializing the expected benefits of a multilevel system but might even

exacerbate its intrinsic tensions. By contrast, a flexible approach to enforcement could be the necessary evil of lubricating the multilevel system so as to avoid some pressing inherent frictions.

Toleration of Noncompliance in the EU: Evading Jurisdiction Overlap and Norm Collision

With an unusually complex governing structure and a highly legalized but malleable constitution, the EU is a multilevel system where we would expect most strongly to see the functional limits of law and which is also the most fertile soil for toleration of noncompliance.

Functional limits of the law in the EU are firstly demonstrated by jurisdiction overlap between Union law and national law. By jurisdiction overlap, this article refers to the situation where certain legal controversies are inextricably linked to both national and EU jurisdictions. Firstly, it is unclear in practice where national jurisdiction ends and where Union jurisdiction begins, despite the formal principle of competence conferral (Schmidt, 2018, p. 11). Secondly, policy problems which derive from distinct national regulatory structures can exert unexpected pressures and repercussions on the application of EU law. Therefore, what is seemingly an infringement of EU law could actually have its roots in the unsynchronized policies among member states. Thus, the blind enforcement of EU law not only misconceives the root cause of infringement but even aggravates the existing policy problem. As a good illustration, defence and security policy is normally a national prerogative of member states. In the EU, the defence market is nationally fragmented, asymmetric, and dominated by a limited number of companies from the UK, France, Italy, and Germany. To support domestic industries, small member states usually adopt protectionist procurement policies, which demands compensations from non-national bidders (Weiss and Blauberger, 2016). Clearly, this compensation obligation goes against principles of free movement and non-discrimination enshrined in the EU treaties. But the blind enforcement of EU law would only imprudently disguise the real problem of industrial imbalance as an issue of lax compliance. Eventually, it contributes almost nothing while encroaching upon the defence sovereignty of small member states, and further exacerbates the already existing asymmetry of the European defence market.

Functional limits of law in the EU are further exemplified by the norm collision inherent to the integration project. Norm collision occurs when actors disagree on which policy goals should be prioritized and how said conflicting goals should be balanced. Over the decades of European integration, market freedom as the fundamental value of the internal market is without question the most prioritized policy goal in the Court's jurisprudence (Garben, 2017; Scharpf, 2010). At the same time, it has to be acknowledged that the Court is not a single-minded defender of market freedom. A group of policy goals such as public security, public order, environmental protection, and so on, have been increasingly recognized by case law as justifiable grounds for restricting market freedom. However, even if listed policy goals (for example, public health) have gradually developed autonomous and distinct legal identities, which are recognized by the Court and are no longer merely exceptions to legal provisions on internal market and economic policies, it is still a challenging task for the Court and the Commission to sufficiently accommodate these policy goals in every specific instance, especially when these goals are balanced against the

long-established principles of free movement and fair competition (Hervey, 2017, p. 359; de Ruijter, 2019, p. 842). In such circumstances, if the Commission enforces EU law in the way that upholds the conventional market paradigm, it restricts member states' actions in policy areas such as public health, which entails ethical and legitimacy consequences. On the other hand, if the Commission fully acquiesces to national policies based on other norm claims, it risks fragmenting the EU internal market (Alemanno and Garde, 2015).

For both jurisdiction overlap and norm collision, the shared underlying concern is that supranational enforcement by the Commission is not an ideal way to settle these controversies (Dawson, 2013, p. 24). For lawyers, these two controversies are clearly beyond the mission of law. Dawson and De Witte (2016), p. 221) argue 'law itself does not serve to answer the question of what the 'good life' presupposes but instead acts as a vehicle within which deliberation about these goals can take place'. For the law it is better, in other words, that these controversies be settled at political forums. For political scientists, legitimacy and democratic accountability would be at stake if norm conflict and jurisdiction overlap were to be settled solely through enforcement and sanction, and not also through institutional flexibility or political deliberation (for example, Börzel, 2016; Kreuder-Sonnen, 2018, p. 455).

The foregoing has explained *why* selective leniency in enforcement might be necessary to evade jurisdiction overlap and norm collision in EU multilevel system. The following will briefly postulate *how* toleration of compliance could help to evade these two problems.

1 Toleration of noncompliance directly suppresses 'symptoms' of political and legal contentions. As explained above, one-track-minded enforcement of EU law against policy issues with overlapping jurisdiction could easily oversimplify them as occurrences of compliance deficiency and could thus misperceive their root causes. In extreme cases, it would even aggravate rather than alleviate the existing contentions. In this regard, enforcement leniency could prevent the present contentions from being exacerbated by judicial coercion.
2 Toleration of noncompliance creates the opportunity to address the root cause of policy problems. By replacing the eye-catching litigation process with enforcement leniency, the Commission could signal to the offending government its sincerity for a thoroughly political settlement so as to completely remedy the institutionalized deficiency. In this way, flexible enforcement brings about favourable conditions for a comprehensive political solution. Despite its potential, enforcement leniency should still be seen as a catalyst rather than a guarantee for such definitive political solutions.

Scope Conditions of Toleration of Noncompliance

This article does not want to suggest that the Commission is unconstrained in granting leniency in cases of any noncompliance. Driven by the proposed theory, this research suggests three conditions under which lenient enforcement is most likely to occur.

Firstly, EU jurisdiction in the policy area concerned needs to be very intrusive. If lenient enforcement is theorized as a functional response to issues caused by jurisdiction overlap and norm collision, it is reasonable to expect that toleration of noncompliance is more likely to occur where EU jurisdiction heavily interferes with the governing

autonomy of member states. The conditions of intrusive EU jurisdiction also clarify that not every policy area falling into the category of 'shared competence' is automatically prone to lenient enforcement. Similarly, the exclusive competence of member states is not completely immune to selective enforcement either. As the case of defence procurement demonstrates, the constitutionalized market freedoms encroach on the national defence competences, and transforms certain elements into de facto 'shared competences'.

Secondly, the infringement issue in the member state concerned needs to be salient. The intrusive EU jurisdiction largely precludes stringent enforcement by the Commission. However, it does not prevent the Commission and noncomplying member state from finding an amicable agreement which would allow for the partial ratification of the alleged noncompliance. It is in this regard that a high level of issue salience significantly constrains the policy options of both the Commission and the member state concerned. Together with the first condition, the attention of public audiences pushes both the Commission and the member state into a fix, wherein neither stringent enforcement by the Commission nor concessions made on compliance from the member state are politically feasible.

Thirdly, the Court should have signalled that Union law is on the brink of becoming out-of-balance through less formalistic but more equivocal case law in the contentious policy area. Having argued that enforcement leniency is to prevent the law from being pushed over its limit, there is no evidence more credible than the Court's difficult legal balance. Given that individual case law mostly touches upon quite idiosyncratic matters, equivocal case law only indicates the wicked nature of a policy area in general rather than of its substantial elements. Thus, it is also important to reiterate here that equivocal case law concerning a general policy area does not preclude the Commission from expressly establishing the illegality of a specific infringement based on the well-defined proportionality test.

III | The European Regulatory System for Medicines and Pharmaceutical Parallel Trade

Briefly speaking, the EU's competence in health is relatively limited and ambiguous. Its main legal basis, Article 168 TFEU, is weak by design. By specifying that 'the Union shall respect the responsibilities of the member states for the definition of their health policy and for the organization and delivery of health services and medical care', Article 168 empowers EU institutions to take only supportive measures within its jurisdiction and to promote coordination among member states (Greer, 2014, p. 15). On the other hand, most of the existing EU health-related regulations have a market connection as their legal basis (Greer, 2021, p. 93). In essence, EU health policy has long been recognized as a side issue or by-product of the internal market and it is largely a means to re-regulate the EU market in areas where national regulatory barriers to trade have been removed (de Ruijter, 2019, p. 176).

The weak mandate of the EU health policy coupled with its inherent link with the internal market legal bases jointly generate two distinct features of the European pharmaceutical regulatory framework. Firstly, member states firmly control the core elements of pharmaceutical policy. For instance, pharmaceutical pricing and reimbursement rules fall under the exclusive national competence (European Medicines

Agency (EMA), 2016). In comparison, the Commission is only involved when granting EU-wide marketing authorizations of medicines based on recommendations of the EMA. As for the European department of health, DG SANTE mostly acts as the information and coordination hub which facilitates exchanges of national policy ideas and practices. (de Ruijter, 2019).

Secondly, trade and marketing of pharmaceuticals in the EU are still governed by free movement law and competition law at the Union level. Even with potential causes of derogations like the protection of health and human life, pharmaceutical policy can hardly be completely exempt from the deregulation biases of the EU internal market, including the preference for promoting cross-border mobility and for prohibiting discrimination on grounds of national origin. For this reason, infringement investigations on pharmaceutical parallel trade within the Commission are led by the internal market department DG GROW rather than DG SANTE.

Pharmaceutical Parallel Trade Epitomizes Jurisdiction Overlap and Norms Collision

It is the distinct European regulatory system that nurtures pharmaceutical parallel trade in the EU internal market. Basically, parallel trade in medicines occurs when a disparity in price exists between markets, which makes it profitable to export medicines from a low-price market to a high-price market. As noted above, the pricing of medicines, different from ordinary goods, is largely a national regulatory process which takes into account factors such as the type of healthcare (insurance) system and budget constraints (Navarro Varona and Caballero Cabdelario, 2019, p. 410). As a result, prices of medicines vary significantly across member states. Simultaneously, trade and marketing of medicines is governed by free movement law and competition law at the Union level. Thus, pharmaceutical parallel trade is a typical business model subject to overlapping jurisdiction between segregated national pricing policies and a harmonized free movement and competition law.

Parallel trade in medicine also manifests the fundamental collision of norms between market freedom and protection of human lives (Navarro Varona and Caballero Cabdelario, 2019, p. 430). For patients in importing countries such as Germany and Denmark, their welfare is enhanced by an abundant supply of medicines facilitated by free trade, whereas patients in exporting countries like Greece and Slovakia where prices of drugs are set at a low level usually suffer from periodic shortage of medicines. Likewise, governments of high-price countries could get sizable budgetary savings for their health insurance systems through the parallel import of cheap medicines. But governments of low-price countries are forced to raise prices of reimbursable medicines in order to compensate drug producers' profit-loss and then to prevent these medicines being withdrawn from the market in those states.

Pharmaceutical Parallel Trade Pushes the Established Legal Order to the Limit

For decades the Court has been known for using its expansive interpretation of free movement law to strike down national barriers (Maduro, 1998, pp. 61–102). When applying this market-based formula in parallel trade in medicines, however, the Court's determination towards defending market freedom oscillates significantly. On the one hand, EU judges acknowledge that special attention should be given to the distinct nature of

medical products whose therapeutic effects distinguish them from other goods.[2] Moreover, the Court agrees that 'health ranks foremost among the interests protected by the Treaty … member state should be allowed a measure of discretion'.[3] On the other hand, the Court equivalently emphasizes that pharmaceutical sector cannot be exonerated from the application of free movement law entirely, especially the proportionality test.[4]

The Court's slightly schizophrenic approach is not confined to free movement law but is manifested in competition law as well. Through a series of prominent cases, EU judges have highlighted that the unique regulatory framework of the pharmaceutical industry is highly relevant to competition law analysis (Völcker, 2011). But in a subsequent legal battle, the Court demonstrated that its flexible application of competition law would not drift from the formalistic interpretation to an extent that erodes the overall integrity of established legal formulation.[5]

All these equivocal, even contradictory, case laws manifest that when adjudicating on parallel trade cases involving overlapping jurisdictions and conflicting norms, the Court is forced to strike an almost impossible balance between market freedom and public health. In this regard, the long-established aim and scope of EU's free movement law and competition law have reached their functional limits (Hervey and McHale, 2015, pp. 288–91).

IV | The Commission's Lenient Enforcement Concerning Restrictive Measures against Pharmaceutical Parallel Export

Suffering from reoccurrences of medicine shortages in the domestic market, EU member states have erected various forms of restrictive measures against medicine exports, ranging from temporary export bans to prior export notification procedures.[6]

However, the Commission took issue with these national measures, on the grounds that they hindered the intra-community trade and could not be justified by treaty exemptions. Since 2015, the Commission had launched four enforcement investigations against Slovakia, Portugal, Poland, and Romania respectively. The enforcement against Slovakia and Portugal took the form of formal infringement proceedings, whereas the enforcement investigations concerning Poland and Romania were pre-infringement EU Pilot cases. Eventually, apart from Portugal, who largely remedied the alleged infringements in accordance with the policy prescriptions of the Commission, the contested national measures of the other three member states remained unrectified (Interview 3). Yet, the Commission still terminated the three enforcement cases, all on 17 May 2018. Thus, the Commission's enforcement decisions against Slovakia, Poland, and Romania amounted to toleration of noncompliance as defined in this research.[7]

While administrating all four cases, the Commission largely followed the same enforcement rationale. From the perspective of legal substance, the Commission put

[2]Case C-531/06 *Commission v Italy*, 2009, para 55.
[3]Case C-198/14 *Visnapuu*, 2015, para 118.
[4]Case C-141/07 *Commission v Germany (Pharmacies for hospitals)*, 2008.
[5]Joint Cases C-501/06 P, C-515/06 P and C-519/06 P, *GlaxoSmithKline Service (GSK) v Commission*, 2009; Joint Cases, C-468/06 to C-478/06 *Sot. Lélos kai Sia EE v Glaxowellcome*, 2008.
[6]For a snapshot of restrictive measures adopted by various member states between 2012 and 2013, see: https://efpia.eu/media/15427/policy-proposals-to-minimise-medicine-supply-shortages-in-europe-march-2014.pdf. Accessed 11 June 2021.
[7]The detailed information of restrictive measures of four member states and of the Commission's enforcement assessments is provided in the supplementary material.

forward almost identical legal analyses. As an illustrative example, the Commission raised the same concerns in its reasoned opinions against Slovakia and Portugal over 'the excessive scope of the procedure', 'the absence of clear criteria for determination of medicine shortage', and 'the existence of less restrictive measures' (European Commission, 2016a, 2016b). Furthermore, from the perspective of enforcement procedures, reasoned opinions to Slovakia and Portugal were sent by the Commission on the very same day, and the four enforcement cases were also collectively terminated by the Commission. Most importantly, when justifying its selective leniency towards Slovakia, Poland, and Romania, the Commission offered the same reasoning of highlighting 'the need to find ways other than infringements to adequately solve the complex situation'.[8]

Considering that the Commission's enforcement rationale and subject-matters of three cases of tolerated noncompliance were almost identical, this research zooms in on the infringement case against Slovakia. This is firstly because the within-case analysis of a typical case could bring in more in-depth evidence without compromising the validity of the proposed argument for the other two cases. Additionally, compared to EU Pilot cases against Poland and Romania, the infringement proceeding against Slovakia was more formal and transparent in procedure, which ultimately grants a more favourable accessibility of evidence.

The Noncompliance that Is Difficult to Be Overlooked

While initiating the infringement procedure against Slovakia, the Commission was well aware of the oscillated case law over pharmaceutical parallel trade. As the Slovak government specifically reminded the Commission of the particular nature of medicines and the paramount importance of public health, the Commission reassured its counterpart in the reasoned opinion that the distinct feature of drugs had been taken and would continuously be taken into account in its investigating assessment (European Commission, 2016a, p. 6).

But what made the Commission determined to initiate and escalate this case was that Slovakia's restrictive measures had apparently gone beyond the necessary and appropriate limit. Firstly, according to the *ex post* survey conducted by DG SANTE, only 11 out of 27 member states have erected export restriction measures in cases of medicine shortage (DG SANTE, 2018b, p. 14). When comparing Slovakia with those countries that have similar restrictive measures, it is notable that no country imposes restrictions on such a scale as Slovakia does (European Commission, 2016a, p. 7). For example, only 27 out of 1,096 medical products subject to restrictive measures were in actual shortage. The post-enforcement export authorization procedure even expanded the already overbroad scope to cover all 4,471 categorized medicines (Ministerstvo zdravotníctva, 2015).

In addition to the exorbitantly broad scope of the procedure, Slovakia's contested measures also had a deterring effect on parallel exports, which is strictly prohibited by EU law. Based on data from the State Institute for Drug Control (ŠÚKL), the number of types of exported drugs had plummeted from 1,216 in 2015 to 36 in 2017. This number further

[8]Press release of the Commission: https://ec.europa.eu/commission/presscorner/detail/en/IP_18_3459. Accessed 11 June 2021.

shrunk to 30 and then 21 in 2018 and 2019 respectively.[9] In other words, trade restrictive measures of Slovakia almost brought the entire parallel export business to a halt.

The Noncompliance that Is Hard to Be Litigated

Notwithstanding the clarity of Slovakia's infringement, the Commission's investigation was by no means smooth and trouble-free. Throughout the infringement proceeding, the Slovak government voiced its concerns and discontent to the Commission from both Bratislava and Brussels (Interview 3).

Slovakia's government is crystal clear on the significant salience of medicinal shortages. Faced with mounting complaints from both patients and pharmacists, Bratislava had imposed severe punishments on pharmaceutical companies who were liable for the unavailability of drugs. Even after being challenged by the Commission in 2015, Slovakia's government did not in any way loosen its virulent policy on parallel exports. In 2015, ŠÚKL issued 622 bans on medicine exports, which remained almost the same as the pre-infringement years.[10]

Slovakia also took the opportunity of holding the rotating presidency of the Council to elevate the salience of this issue among other member states. In its Priorities of Presidency, the Slovak government highlighted that it would build upon work done by the previous presidency regarding the availability of medicines in the context of parallel export (Government of Slovakia, 2016, p. 24). In 2016, Slovakia convened two Council meetings to discuss issues in the pharmaceutical systems, *inter alia*, the shortage of medicines. In the Council conclusion, Bratislava successfully brought all member states on board in emphasising that special attention should be given to the matter of access to medicines for patients in small member states (EU Council, 2016).

The Noncompliance that Places the Commission in a Dilemma

Considering the severity of Slovakia's infringement and the determination of Bratislava to stick to its path, the Commission had clearly been caught in an enforcement dilemma. In the end, whatever decision the Commission made on this case would lead to a political and legal dead end. Thus, toleration of Slovakia's infringement was the only feasible and probably the most satisfactory way to muddle through this political and legal impasse.

In the first hypothetical scenario, a successful litigation by the Commission in the Court is tantamount to judicial harmonization of national health policies, which would provoke Eurosceptic backlash from national capitals. Given the unnecessarily broad scope of contested measures and their deterrent effect on parallel export, it is highly likely that the Court would outlaw these restrictions due to their evidently disproportionate nature. Considering that free trade in the pharmaceutical sector is 'inextricably intertwined with national prerogatives of health policy' (Interview 3), such a ruling is equivalent to a judicial process of generalizing low prices of medicines across the Union through parallel exports. Regarding the potential risks of a successful litigation, the official from the

[9]Export notification platform for medicines (ŠÚKL), https://portal.sukl.sk/vyvozpublic/?act=VyvozMainPublic&mId=1. Accessed 20 June 2020.

[10]List of medicines banned from export by ŠÚKL, https://www.sukl.sk/en/inspection/post-authorisation-quality-control/export-of-medicinal-products/list-of-medicinal-products-for-which-they-were-issued-decisions-not-to-allow-the-export-from-slovak-republic?page_id=4006. Accessed 5 July 2020.

Commission's Legal Service explicitly pointed out that '[the Legal Service] was in a difficult position to delineate the proper boundary between internal market and public health in the present case'. And if the Legal Service took the position consistent with existing case law, 'it would for sure have political repercussions for national health policies' (Interview 5).

Same as the potential risk of a blind enforcement theorized above, a successful litigation in the Court would grant a long cheer to European parallel traders and it will most certainly aggravate the existing shortages in the markets of small member states. Even if the export of medicine remains at the pre-adjudication level, patients suffering from medical shortages would still blame the EU for rescinding their national shields against arbitrage and for prioritizing commercial interests over saving lives. With regard to this, the Commission officials emphasized that 'it is also a matter of public opinion' (Interview 1). After all, 'the whole purpose of internal market is to bring benefits to citizens rather than aggravating the shortage of medicines in some member states' (Interview 2).

In the second but less likely scenario, if the Court were to tilt the legal balance further towards Slovakia, it may risk compromising the integrity of EU free movement and competition law. In the current case, if the Court acquitted Slovakia of export restriction, this result could indeed significantly alleviate the sheer pressure on governments of exporting countries. But by stretching its lenience to the extent that even covering the quasi-ban on exports as in the Slovakia case, the Court will signal that the pharmaceutical market is so distinct that its legal analysis has *de facto* broken away from the bounds of the existing legal dogma. Then an obvious question left open by the Court would be whether this deviation from the prevailing legal formula could be applied by analogy to other industries which are subject to similar state intervention, such as telecommunication and energy (Kingston, 2009, p. 694). Therefore, this ingrained tendency of expansionary tolerations of restrictive measures by the Court risks the integrity of the interpretation of EU law, and more importantly it risks reversing the market integration into market partition based on sectors. As a result, DG SANTE, a passionate advocate in the Commission of the priority of medicine accessibility, had to stick to the underpinning principle of market freedom by iterating that restrictive measures adopted by member states must be 'justifiable as appropriate, necessary and proportionate' (DG SANTE, 2018a). Similarly, DG GROW, the leading department for the present enforcement cases, emphasized that the argument of public health should neither be abused, nor over-prioritized to an extent which would compromise the current legal order of free movement laws (Interview 5).

Looking at both scenarios together, despite the seeming difference, both represent the same situation where supranational institutions are forced to make an impossible choice on the normative underpinning of the internal market. Even if the normative trade-off is an integral part of judicial function, the court room is definitely not an ideal forum to settle such a highly controversial balance without any political consequence. Thus, the Commission concluded upon the need to look for other ways than infringements to solve this complex situation (European Commission, 2019, p. 14; Interview 3).

The Toleration of Noncompliance that Only Suppresses 'Symptoms'

The Commission's enforcement leniency in this case is a satisfactory result for multiple stakeholders. Firstly, discretionary enforcement insulates the Commission and the Court

from deciding upon a politically explosive case. During the inter-services consultation, 'this infringement case was recognized by the Commission services as politically very sensitive'. Especially given that 'no case law has yet touched upon the exporting aspect of pharmaceutical parallel trade', the Commission evaluated the potential adjudicating challenge for the Court as well (Interview 6). For the Slovak government, the Commission's let-it-go decision grants it desperately needed flexibility to pacify the mounting criticism from patients and pharmacists. Lastly, for the Commission, which selectively loosens its legal grip on Slovakia, its reputation as 'guardian of the Treaties' is not necessarily tarnished, as medicine shortages are a widely recognized problem faced by most of member states. This is also part of the reason why 'the Commission was confident to issue [a] press release on this case rather than [to] covertly terminate the investigation' (Interview 1).

If toleration of noncompliance in the present case has successfully suppressed the 'symptoms' of the shortage of medicine caused by parallel trade, is it able to address the cause as well? It has been illustrated above that the economic root of parallel trade lies in the disparate pricing of drugs across member states. As prices of medicines are largely determined by the social-economic status of each member state, pharmaceutical arbitrages can only be eliminated when national healthcare (insurance) systems are relatively equal. Theoretically, enforcement leniency could indeed create an amicable atmosphere for the Commission to broker a political compromise, but the fundamental divide on health policies among member states leaves almost no political space for the Commission to manoeuvre. In this regard, DG SANTE bluntly stated that 'the Commission does not have any plan to take further action to address drug shortage besides what has already been done' (Paun, 2019).

V. Evaluation of Alternative Explanations

With regard to the explanation of enforcement success, it could be further broken down into prospects of litigation success and the risk of overt resistance to adverse rulings. The first argument expects the Commission to tolerate noncompliance when the enforcement grounds are not firm enough or the probability of a litigation success is not reassuring. But this consideration does not explain the Commission's lenient enforcement against the Slovakia case. The Commission, in its reasoned opinion, assuredly stated that trade restrictive measures introduced by Slovakia were far beyond what is necessary and appropriate to alleviate medicine shortages (European Commission, 2016a). Therefore, they would be almost certain to fail the proportionality test, the indispensable nature of which has been emphasized by the Court in all relevant case laws.

The second argument expects the Commission's lenient enforcement to avoid enforcement failures caused by protracted recalcitrance of noncomplying member states (Falkner, 2018). However, evidence drawn from the parallel enforcement cases lends little support of this argument. For instance, the infringement case against Portugal clearly indicates that it was entirely feasible to bring member state into voluntary compliance through persistent enforcement pressure. In addition, if lenient enforcement is to avoid enforcement failure, we would expect the Commission to take any and all chances to fully exploit all procedural room for manoeuvre before terminating the enforcement case. Specifically, concerning EU Pilot cases against Poland and Romania, the Commission was perfectly

capable of pushing up the costs of noncompliance by initiating formal infringement proceedings, so as to seize every opportunity of achieving voluntary compliance. But in reality, the Commission forwent these options and dropped these two cases at a rather early stage, together with the Slovak case. Taking all factors together, the rationale behind the Commission enforcement decisions was less likely to be about avoiding the enforcement failure of a *specific* case but, more about addressing a *systemic* problem manifested in a series of infringements.

When it comes to the explanation that the Commission's opportunistic enforcement is used to advance its legislative agenda in a related policy area, this claim could be directly refuted by the unequivocal statement from the Commission that it had no additional plan to tackle medicine shortages besides what had been done through law enforcement (Paun, 2019).

The available evidence also does not support explanations based on member states' power status or the threat of legislative override. Although the rotating presidency of the Council could amplify Bratislava's political influence, Council resolution has no binding effect on the Commission's enforcement decisions, not to mention that the Council did not specifically ask the Commission to re-examine the Slovakia case. Moreover, considering that national interests are deeply divided on parallel trade between low-price markets and high-price markets, it is extremely unlikely that member states are willing to forge a political alliance to overhaul the existing pharmaceutical regulatory framework.

Conclusion

This paper argues that toleration of noncompliance, under certain conditions, is a necessary evil to suppress the symptoms of systematic dysfunction and thus temporarily maintain the stability of the multilevel legal system. However, to address the root causes of noncompliance, such as the instance concerning pharmaceutical parallel export, flexible enforcement is insufficient and must be accompanied with other political means, such as the transformation of unsynchronized regulatory frameworks between the EU and member states.

Findings of this research provide another lens to understand institutional stability/dynamics. Federalists have long argued that an equilibrium between 'shared rule' and 'self-rule' is critical to the stability of a multilevel system. This is even more true in the case of the EU, as its multilevel system is a 'halfway house' and continues evolving. Thus, the supranational oversight by the Commission combined with the enforcement flexibility strike a balance between maintaining member state's commitment to EU legal order and palliating their fear of losing legitimately sovereign claims (Andersen, 2012, pp. 28–9). In simple words, toleration of noncompliance works like a safety valve to depressurize the multilevel system when it is plagued by inherent deficiencies.

Virtues aside, the theorization of toleration of noncompliance in this article also warrants some caution. Firstly, as a preliminary attempt to theorize the Commission's selective leniency in enforcing EU law, case studies of this research predominantly demonstrated the theoretical relevance of the proposed explanation. To accurately de-limit the scope of the theoretical proposition, evidence of other policy sectors or of cross-sector analysis is needed. For instance, social policy might be another promising area where free movement law, the principle of non-discrimination, and national welfare

policies are inextricably intertwined (Schmidt *et al*., 2018). Secondly, the trustee view brings additional insights into enforcement incentives of the supranational prosecutor. Yet, the introduction of the new perspective by no means implies that the enforcement rationale of the Commission is in reality confined to a simple dichotomy between an agent and a trustee. It is highly likely that toleration of noncompliance may take different causal paths as a result of a complex configuration of enforcement incentives. In other words, the theoretical proposition in this research may only represent one of many potential typological explanations. Thus, alternative explanations that do not find success in the Slovak case could still be pertinent in other typological explanations. Thirdly, the argument of functional limits mainly aims to explain flexible enforcement in the EU. However, it is theoretically plausible that toleration of noncompliance also works in other highly legalized organizations (for example, WTO) (Zimmerman, 2011) or federal states. But it is advisable to note that differences in organizational features of dispute settlement mechanisms, as well as the actual situations pertaining to constitutional balance, are all important factors which could affect the manifestations of enforcement leniency in other political entities.

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List of Interviews

Interview 1: *Official of Secretariat-General* (Brussels: European Commission) November 2019.
Interview 2: *Official of Secretariat-General* (Brussels: European Commission) November 2019.
Interview 3: *Official of DG GROW* (European Commission) Online, November 2019.
Interview 4: *Official of DG SANTE* (European Commission) Online, August 2020.
Interview 5: *Official of Legal Service* (European Commission) Online, March 2021.
Interview 6: Official of Legal Service, European Commission, Online, March 2021

Supporting Information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Data S1. Supporting Information.