The interplay of global standards and EU pharmaceutical regulation

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Valorisation Addendum

The social relevance of this research

This research examines the influence of global risk regulation standards on EU pharmaceutical regulation and it questions the legitimacy of the implementation of these standards in the EU risk regulation framework. The societal relevance of the legitimacy of risk regulation standards, especially where they aim to promote and protect public health is evident. For instance, several incidents of regulatory failures in the history of the EU – the most vivid memory is certainly left by the BSE crisis – have shown that risk regulation processes should be subjected to critical legal examination especially with regard to procedural aspects with the aim to improve the quality of the measures taken as well as the public trust in such risk regulation measures.

The value of critically examining global standards does not only hold true in the health related area of pharmaceutical regulation, but the societal relevance of examining the legitimacy of global standards is broader. A 2016 study by the Bertelsmann Stiftung “Globalisierungsangst oder Wertekonflikt?” (Fear of globalization or conflict of values?) identified a direct link between fears of the general public related to globalization and the recent electoral successes of populist parties. This demonstrates that it is essential to obtain an in-depth understanding of the legal and regulatory consequences of globalization, to identify and address the situations in which such fears may be valid and to de-mystify incorrect claims. This research wants to contribute to this debate, by providing a better understanding of the effects of global standard-setting – a regulatory response to globalization – on risk regulation in the Union and by making suggestions on how to improve global standard-setting processes.

More in detail, this research contributes to analysing the impact of global pharmaceutical standards on the regulation of medicinal products in the EU. A discussion of global standards in the regulation of pharmaceuticals in this regard is especially important, as also in the area of pharmaceuticals public trust in regulatory capacity has been shaken by the ‘Mediator Scandal’ as well as the withdrawal of the anti-diabetes drug Avandia as addressed in the Introduction of this research. The research at hand shows that the global standard-setting processes of the International Council for Harmonisation (ICH) – when compared to EU procedural norms of transparency, participation and independence of expertise – is indeed flawed. These procedural defects negatively affect the legitimacy of their implementation in the Unions regulatory framework for pharmaceuticals. The research also identified a political and judicial accountability gap for the implementation of these standards in the EU. However, the study also suggests that ‘uploading’ of procedural benchmarks from the EU to the global level can improve the ICH standard-setting process.

In addition, the identification of such procedural norms can also contribute to the forming of a body of administrative law on the global level. This research aims to contribute to the societal debate on a shift from government to governance, including the shift of decision-making from the national to the global level. Regulating global standard-setting processes can contribute to addressing the legal challenges posed by abandoning traditional forms of legitimization and accountability in the national states.

From a EU perspective this research is important, as it identified an incoherent approach to the participation of EU bodies in global standard-setting initiatives. It also showed that the subsequent implementation of such standards in the EU is subject to fragmented, policy-specific processes. The EU functions as a ‘gatekeeper’ for these standards as they are regulating the internal market, where they affect not only EU but also national regulators, the companies producing the regulated products and also the consumer that buys

the regulated product. Therefore, it is necessary that the Union develops a better understanding of the impact of global standards and coherently regulates them.

The beneficiaries of this research

In addition to the academic audience, this research is mainly addressed to the regulators and policy-makers responsible for pharmaceuticals but also to regulatory authorities involved in global standard-setting in other regulatory areas. It is primarily concerned with regulatory bodies in the EU, but is also relevant to non-EU participators in global standard-setting. Moreover, it is of relevance for global standard-setting bodies, such as the ICH. It aims to improve the regulatory process of standard-setting in terms of its participatory openness, transparency and independence of expertise, though concrete recommendations. However, the findings may also contribute to the more general public debate on how to carry out regulatory standard-setting processes on the global level.

Also, public interest representatives will benefit from the findings and recommendations of this research as it identifies the main hurdles to participation and transparency as well as offering suggestions to overcome such hurdles. It ultimately leads to suggestions of how to improve global standard-setting in the area of risk regulation, which is beneficial for society as a whole.

Furthermore, this research challenges the presumption of risk regulation standards as merely technical and scientific voluntary measures by showing their *de facto* capability to affect the legal situation of regulators (in the EU and in the Member States) as well as the regulated companies and consumers. Besides their implementation in the form of non-binding measures, global pharmaceutical standards influence legally binding measures and are used as interpretative tools in courts. This research thereby addresses the regulators, legislators and courts, in calling for a more critical handling of these regulatory measures. The research also suggests to the EU legislator to introduce a more coherent framework for the EU's participation in global standard-setting processes and the implementation of these standard. The current framework is fragmented along different policy areas and does not contain clear accountability structures.

Translating the results into activities and products

Next to the thesis itself, which I plan to publish in the form of a monograph, the research has and will continue to form the subject of academic publications in chapters of edited volumes and journal articles. These publications are contributing to the debate in the EU law scholarship as well as in the academic debates addressing administrative bodies on the global level, such as the global administrative law and international administrative law scholarship. Moreover, in order to enhance the visibility of the questions raised by this research in civil society, I have already and will continue to address aspects of this research in blog posts. In addition to this I have already taken the opportunity during the interviews conducted for this research and during stakeholder dialogues in the framework of the Academic Research Network on Agencification of EU Executive Governance (TARN), to discuss the findings of this research with stakeholders such as representatives of EU regulatory bodies involved in global standard-setting.

Innovation

Although this research builds on the existing literature in the field of Global Administrative Law, European administrative law and European institutional law, it adds an in-depth understanding of the influence of global risk regulation standards on the European

regulation of pharmaceuticals that was lacking previously. This research also identifies in-depth the effects of these standards on different actors, such as the EU bodies implementing them as well as the Member States, and the regulated companies. Moreover, this deeper understanding of the role of these standards in the risk regulation of pharmaceuticals in the EU permitted the identification of various gaps with regard to the political and judicial accountability for the implementation of such standards in the EU.

Moreover, the detailed examination of the practices with regard to transparency, participation and independence of expertise that have been identified in this thesis contribute to the existing scholarship analysing global administrative bodies. The detailed comparison of such practices on the global level with the procedural rules applicable in the EU allowed to derive useful practices from the EU level which can be transferred to the global level. This can contribute to enhancing the legitimacy of the standard-setting process.

Implementation

The findings in academic journals and a monograph published on the basis of this research will be presented not only to the academic community but also to stakeholders in the regulatory process. Through blog posts I will also provide concise information about the core arguments of this research concerning procedural standards in the standard-setting process in a way that is accessible to the general public. Moreover, copies of this thesis will be sent to the European regulatory bodies involved in the ICH, the European Commission and the European Medicines Agency, which already during the interviews conducted for this research emphasised their interest in the final thesis and the policy recommendations it contains.

With regard to the European Commission and the European Medicines Agency, which take part in the ICH process, they can use the findings in Chapter 6 regarding procedural benchmarks for participation, transparency and independence of expertise to ignite an improvement of the ICH standard-setting process. Moreover, as it became clear in Chapter 1 and 2, that the rules with regard to the EU participation in global standard-setting and the implementation of these standards are diverging between the different policy areas, lacking coherence, the research proposed also address the global administrative activities of EU bodies in a European administrative procedures act. As the adoption of a European administrative procedures act has been called for by the academic scholarship as well as the Ombudsman and European Parliament, this provides an opportunity to also advocate more coherence in the approach of the EU to global standards.