The interplay of global standards and EU pharmaceutical regulation

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Abstract

The PhD research 'The Interplay of Global Standards and EU Pharmaceutical Regulation' discusses the EU implementation of pharmaceutical standards set by the International Council for Harmonisation (ICH). It is argued that the process of standard-setting in the ICH does not adhere to the same level of participation, transparency and independence of expertise as would be ensured through administrative procedure in the Union. This leads to legitimacy flaws of the ICH standards. With the implementation of ICH standards in the Union, its flaws are imported as well. These legitimacy flaws are not compensated through the Union's implementation procedure.