

Abstract – Rasmus Borup

Pharmaceuticals are one of the most regulated industries. But who exactly decides what and where to regulate? As national pharmaceutical legislation is increasingly harmonised within the European Union (EU), what role do national authorities play? And how do private stakeholders participate? Just as the process of approving new medicines must balance the risk and benefit for the patients, so must the process of making new pharmaceutical legislation balance considerations for the patients and the industry. The thesis asks: how is EU pharmaceutical legislation shaped by national authorities and stakeholders? A case study of the making and implementation of the EU directive on falsified medicines (during the period around 2008-2013), forms the basis of the thesis which uses qualitative methods to study how national (Danish and Dutch) health authorities and interest groups have handled the Falsified Medicines Directive. Methods such as document analysis and qualitative interviews with policymakers, regulators and stakeholders were used to study how pharmaceutical legislation is made, focusing specifically on the role of national health authorities, private stakeholders, and the EU. Previous research on the EU regulatory landscape provided the theoretical inspiration of this thesis: neoliberalism and regulatory capture being two of the most dominant frameworks in this thesis.

The thesis consists of three studies. The first study situates the Falsified Medicines Directive in Danish pharmaceutical legislation, using a historic analysis of the role of EU harmonisation on Danish legislation governing the supply chain. The study shows that EU harmonisation has caused Danish legislation to become increasingly specific, and that recent legislation places importance on enforcing harmonisation, but seems to have put less emphasis on public health.

The second study examines the strategy of private stakeholders to influence the proposal to the EU Falsified Medicines Directive. The study shows how and why some stakeholders actively lobbied the European Commission to initiate legislation to combat falsified medicines. The analysis suggests that the effect of the directive may have been distorted by industry interest groups, who lobbied for policies that were more of a benefit for their business than for the public.

The third study examines the process of negotiating and implementing the directive from a national health authority perspective, focusing particularly on the involvement of national stakeholders and scientific experts. The analysis suggests that national authorities listen to stakeholders, but that they place

more focus on easing implementation than on changing the substance of legislation. National authorities do little to involve non-experts in the policy process and work under little public scrutiny.

In conclusion, this thesis shows how proposals for new legislative measures can originate from the regulated companies themselves through the EU legislative procedure. By highlighting public health benefits, new legislation will meet little resistance among authorities and stakeholders. Further, it appears that little effort is employed by national authorities to change the underlying content of EU directives. Rather, they appear to use the EU negotiating process to make directives easy to implement and enforce, paying little attention to the interest of patients and consumers.