Governing ex-post drug risk surveillance: linking different epistemic cultures

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The need for fast drug innovation and the public demand for risk-free drugs create a dilemma for regulatory authorities: rapid market access conflicts with uncertainty about benefit/risk profiles of new drugs. When drugs are approved, risk is monitored and regulated through pharmacovigilance activities, such as spontaneous reporting. These efforts are additional to the ex-ante risk regulation that is performed in the context of clinical trials. Pharmacovigilance becomes increasingly important when, in order to stimulate innovation, ex-ante risk regulation is relaxed, e.g. through earlier, conditionally approving new drugs.
The aim of this paper is to increase the understanding of pharmacovigilance governance arrangements in the light of an increasing array of different stakeholders that are involved. STS literature learns us that involvement of actors coming from multiple backgrounds can be beneficial to make risk regulation more effective and legitimised. At the same time, distinct epistemic communities – or cultures – need to be aligned to have an impact.
To understand these multi-actor governance constellations in risk regulation we draw on two theoretical strands. Firstly, the conceptualisation of post-marketing surveillance and risk assessment as a crucial element in the process of innovation is based upon theories in the field of science and technology studies that stress the involvement of multiple stakeholders in technological development. Secondly, ideas about new forms of regulation are adapted from the growing field of governance studies.
The empirical emphasis of this study is on the governance of pharmacovigilance in conditionally-approved medicines. Results from two case studies are presented that come from the qualitative analysis of the governance of pharmacovigilance, based on interviews and extensive desk research, complemented with the results of expert workshops. The case studies are about conditional approvals in the fields of HIV/AIDS and pandemic influenza.
In the context of the two case studies different patterns of interaction, exchange of information, power relations, network rules, role perceptions, incentives, and interests were observed. This leads to the identification of modes of governance of pharmacovigilance for the two disease areas that, for example, differ in the way users are involved in risk definition and decision-making. Special attention is paid to aligning four epistemic cultures, i.e. those of medical professionals (physicians, pharmacists), industry, regulators, and patients (through experiential knowledge).
Ex-post risk evaluation becomes more prominent in favour of ex-ante risk profiling, which means an increasing involvement of different types of actors and knowledge backgrounds. This paper explores new and innovative modes of risk governance which takes these distinct epistemic cultures into account, differing over disease areas.