

PANEL 3

Encouraging Appropriate Business Practices in the Pharmaceutical Sector: What Role do Regulation and Self-Regulation play?

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1. Overview

The forthcoming panel raises the question of the roles regulation and self-regulation play for encouraging appropriate business practices in the pharmaceutical sector. For two reasons, this question is of an enormous importance. First of all and most obviously, the healthcare sector has a vital significance for anyone of us; it hence has become one of the biggest economic markets during the last fifty years. Let me give some examples: According to data generated by the OECD, Germany pumps more than 11% of its Gross Domestic Product into the healthcare sector, while the spending in the US even exceed 16%. With only 5% of the GDP, Turkey ranks at the end of OECD-list, but this means, by absolute numbers, that 40 billion dollars circulate in the Turkish healthcare sector – each year. The pharmaceutical sector accounts for a significant portion of health budgets globally. Almost a fifth of the entire healthcare budget across OECD countries is spent on medicines.

A global market of such an extent attracts corruption, in particular since only few gatekeepers decide, which medicinal products are prescribed to patients or bought by hospitals. I will come back to this point later. But before I do so, I would like to sketch the second reason for the general importance of the following panel. This reason does not relate to corruption as the problem, but rather to the way how this problem can be tackled: not by means of regulation and law enforcement, and certainly not alone by the “markets” and the actors on the markets. Instead, state regulation and self-regulation must mutually refer to each other. This strategy of using a “responsive law”, which combines state regulation with private self-regulation, can be transferred from the pharmaceutical sector to other corruption-infected areas. For that reason, the discussion on the roles of regulation and self-regulation in the pharmaceutical sector stands *pars*

pro toto, as one part for the whole – that means: for the whole promising approach how to combat corruption in general.

2. Corruption in healthcare sector

Combatting corruption in the healthcare and pharmaceutical sector is an important issue in many parts of the world. A risk-based approach reveals the reasons. Most distinctive for the pharmaceutical sector is the fact that only a few gatekeepers determine the spending of a huge amount of money. In some part of the world, a handful of government officials decide, which products are being granted access to the national healthcare market; doctors prescribe, which drug a patient shall use or which drug a pharmacy shall hand out to the patient; managers of hospitals have the power to choose particular drugs or medical devices among rival products. In the process of decision-making, both the pharmaceutical companies from the supply side of the market as well as buyers from the demand side like hospitals pursue economic interests.

When the pursuit of economic interests suppresses the interests of the patients and the common good, one can speak of corruption. Examples for corruptive relationships between pharmaceutical companies and doctors or government officials are manifold. Cases in which companies have tried to influence doctor's prescriptions by hiring them for so-called surveillance-studies or by inviting them to conferences in luxury hotels have been widely discussed in Germany. Such practices do not only hamper the competition between companies; more importantly, they can harm the public trust in the functioning of one of its most important institutions: the healthcare sector. In other parts of the world, government employees have even facilitated the infiltration of substandard medicines into the distribution systems. Such forms of corruption do not only undermine rules of competition and the functioning of institutions, it threatens the life of many. For these reasons, corruption in the pharmaceutical sector needs to be fought.

3. Examples for regulation

In a report published last year, Transparency International (TI) stated that world governments and big pharma-companies are "turning a blind eye" to bribery and

corruption. TI proves these findings with impressive data and examples. But this is only one truth. Another truth is the wave of regulation, which has circled the globe. In the last years, several countries around the world have tightened their regulation and improved their enforcement. The People's Republic of China enacted "Nine Prohibitions for Strengthening Ethical Conduct in the Healthcare Industry", which inter alia prohibit the accepting of kick-backs or other undue advantages by healthcare professionals. Moreover, the law provides for the possibility of blacklisting enterprises. According to professional observers, the Chinese government has also improved their law enforcement. In the recent past, for example, a company has been sanctioned with a fine of 440 million euro. Traditionally, the US anti-corruption law is among the most extensive and effective one. In the last years, the U.S. Securities and Exchange Commission (SEC) focussed on the healthcare sector and will continue to do so, according to a statement issued by *Andrew Ceresney*, the director of enforcement.

Moreover, the US Department of Justice founded the "Health Care Fraud Prevention and Enforcement Action Team", that shall coordinate the fight against and the prevention of corruption. It is fairly telling, that Donald Trump explicitly mentioned the "pharma lobby" in his first press conference after his election as a group that has caught his attention. Without doubt: This is an alarming statement. In Europe, France and several other countries have enacted laws that oblige pharmaceutical companies to reveal their devotions granted to healthcare professionals. Most of these follow the base lines of the US Sunshine Act.

Last but not least, the German Federal government has enacted two criminal law provisions exclusively addressing active and passive bribery of doctors and other healthcare professionals. A legal loophole initially caused this legislation. The loophole became apparent after the German Supreme Court held that freelance doctors working in their own medical office are neither covered by the statutes on bribery of public officials nor by the provision on bribery in the private sector. The new laws, however, do not only cover these types of doctors but address a wider range of healthcare professionals. A criminal law statute that exclusively addresses one sector – the healthcare sector – is of an enormous symbolic importance and generates a huge practical impact. In the last month, many doctors, hospitals and pharma companies have revised their contracts and collaborations and adjusted their compliance rules.

Moreover, professional chambers and associations have started to discuss, whether to specify their professional rules.

4. Responsive law

As we see, the actors on the German pharmaceutical market have already responded to the new law by adjusting their self-regulation. State regulation has triggered self-regulation. But the concept of responsive law is more complex, as it does not only comprise the mentioned top-down effect. It also has a reverse effect, since state law, even criminal law, can absorb the private rules established in the process of self-regulation. For example: When it comes to the interpretation of a criminal law provision, one needs to decide, for example, whether the advantage is undue or not or whether the procurement decision has been made in an objective and due manner or not. All these questions can neither be answered by criminal law codes nor by case law alone, for the first is too abstract, the latter too concrete. The interpreter of law hence needs additional orientation. For this purpose, it makes sense to incorporate the rules of self-regulation in the process of specifying state law.

We see that in the concept of responsive law both regulation and self-regulation have corresponding roles. One cannot be potent without the other. Only together they can tackle corruption effectively – in the pharmaceutical sector and beyond.