

On 29 July 2015, the German government introduced a legislative initiative with the aim of fighting corruption in the healthcare sector.

With effect from 4 June 2016, the German Act on Fighting Corruption in the Healthcare Sector (*Gesetz zur Bekämpfung der Korruption im Gesundheitswesen* – Act) entered the German Criminal Code (*Strafgesetzbuch*) in its sections 299a and 299b. From now on, it is a criminal offence to take and receive bribes in the healthcare sector. These new regulations could have a substantial impact on companies, as giving bribes to self-employed healthcare professionals is now considered a criminal corruption offence.

Background

The main reason for the new Act was the decision of the German Federal Court of Justice (*Bundesgerichtshof*) on 29 March 2012. The findings of this verdict demonstrated that Sections 299 et seqq. and section 331 of the German Criminal Code (*Strafgesetzbuch*) dealing with Bribery and Corruption in commercial transactions and in the public sector respectively did not apply for resident medical practitioners such as doctors, alternative practitioners and pharmacists with a public education. In regard to section 331 of the German Criminal Code (*Strafgesetzbuch*), the German Federal Court of Justice (*Bundesgerichtshof*) clearly pointed out that a private medical practitioner, who is admitted for statutory healthcare supply, in exercising such duties, does not fall under the group of possible offenders which would require a public official or a person entrusted with special public service functions and who, therefore, would have to be, for example, an authorized representative of the statutory healthcare insurance scheme. As a consequence, it was not unlawful for a private medical practitioner to allow himself or herself to be promised or accept a benefit in return for the prescription of certain pharmaceuticals. Thereby, “prescription” (*Verordnung*) has a wide interpretation and entails pharmaceuticals as well as further medical products such as adjuvants. In this context, the new Act tries to “fill the gap” by extending Bribery and Corruption charges to physicians and other individuals in healthcare-affiliated professions.

Current Legal Situation

Criminal penalties for bribery and corruption are mainly regulated in the German Criminal Code (*Strafgesetzbuch*) and address offences in public office, commercial business transactions and the manipulation of voters. Ultimately, the aim of the new Act is to fill the aforementioned criminal gap in regard to taking and giving bribes in the healthcare sector and for that purpose, the Act intends to comprehensively include professionals in this sector regardless of their employment status. Therefore, Sections 299a and 299b of the German Criminal Code (*Strafgesetzbuch*) are exclusively designed for this sector of the economy. In short, Section 299a rules on the act of demanding, receiving and even allowing the promise to receive (passive bribery), whereas Section 299b penalizes the counterpart and hence to act of offering, promising or granting an incentive (active bribery). It needs to be stressed that both provisions extend to extraterritorial competition and are not restricted to the German domestic market.

Both provisions – as laid out before - are now applicable to employed and self-employed healthcare professionals. In contrast to Section 299b, where any person can be the offender, Section 299a limits the criminal liability to persons belonging to the group of people defined in the rule as follows: healthcare professionals who require a state-regulated education for the exercise of their profession or the right to bear their professional title. Besides, the new rules only include the (domestic and extraterritorial) competition model (benefit in return for an indented unfair preference in competition). In this regard, the legislator turned against another partly favored model that was linked to professional ethics (benefit in return for an indented breach of professional ethics, in particular an infringement of the healthcare professional’s independence). However, the legislator pointed out in the preparatory work that the protection of the integrity of the medical profession was aimed, at the same time, regardless of the main focus, to guarantee free competition.

Practical Consequences

The new legal situation will change the healthcare sector fast and dramatically; thereby, introducing penalties in a market that constitutes a considerable share of the German economy. The implementation of the new provisions of the German Criminal Code (*Strafgesetzbuch*) are likely to have a substantial impact on healthcare-related companies, since offering and granting incentives are widely restricted now and will change the traditional conduct in this respect.

It may be suggested that criminal investigations soon will affect pharmaceutical and other companies, as well as self-employed healthcare professionals. The aim especially for any company – which are usually under intense public scrutiny - should be to prevent initial suspicion and possible investigations generating media attention and possible sanctions for their agents, as well as for the company itself. This is why adherence of the new provisions and tightly knitted internal compliance systems are preferable.

Hence, companies in the life sciences and healthcare sector - not limited to pharmaceuticals - are well advised to examine existing contracts and practices and to document them precisely. Moreover, compliance systems should be put in place. It is urgently recommended to initiate risk-mitigating measures, such as compatibility with the regulations of the FSA Code of Conduct for healthcare professionals and replacing missing transparency measures for self-employed healthcare professionals.

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