

# COMPLIANCE, WHITE COLLAR CRIME

## Newsletter

### Healthcare and pharmaceutical industry are falling into a “corruption trap”: The Bundestag passed a law combating corruption in the healthcare sector.

**Physicians or alternative practitioners, pharmacists or pharmaceutical representatives:** Members of the entire healthcare sector are risking and threatened by lengthy prison sentences in case of corrupt conduct. The law adopted on 14 April 2016 combating corruption contributes two new (special) criminal offences by introducing section 299a and section 299b Penal Code. These provisions are very broadly defined ensuing that with regard to hitherto legitimate cooperation inquiries can now be conducted in case of suspected corruption. Therefore, distribution and sales channels, observational and other studies, author and cooperation contracts have to be checked immediately for compliance with the new regulations and have to be adjusted, if required. Furthermore, medical practices, pharmacies and pharmaceutical companies have to adjust their compliance management accordingly.

Competition as well as the confidence of the patients in the independence of medical decisions is dented and eroded by corruption and corruptibility (active and passive bribery). The annual damage caused by corruption in the healthcare sector is said to amount to up to EUR 10 billion. Due to a legal loophole in many cases medical professionals were only threatened by a fine or consequences under professional law when they accepted being bribed. This loophole already reminded and addressed to by the Grand Criminal Panel with the Federal Supreme Court in 2012 is now closed by the frequently discussed law combating corruption – subject to its signing by the Federal President.

#### **New (special) criminal offences combating corruption in the healthcare sector**

The adoption of the law on 14 April 2016 came as a surprise to many. Experts expected that the law would be adopted only in summer 2016. The adoption was preceded by a compromise of the Grand Coalition: The express reference to professional law in the new (special) criminal offences of active and passive bribery

in the healthcare sector (section 299a and section 299b Penal Code), which still existed in the draft bill, has been deleted in the version now adopted.

The law was originally designed to make violations of duties under professional law concerning the preservation of independence of healthcare professions against the granting of advantages punishable. With a view to the principle of legal certainty on the basis of different professional regulations for physicians the relevant medical chambers of individual federal states expressed constitutional reservations in this respect. Now competition law is meant to serve as connecting factor. Unfair preference in competition will be punishable. However, by means of the feature of unfairness the professional law and the obligation to medical independence are still (also) included indirectly in the new provisions. If it is to read frequently that reference to professional law has been deleted from the new provisions, this is not the entire truth. Furthermore, reference is made to the fact that the term “competition” has to be interpreted broadly. The new provisions shall also apply to alleged monopoly situations.

The second central amendment to the original draft bill relates to the treatment of pharmacists who, in principle, are covered by the scope of application of the new regulations. The sale and purchase of pharmaceuticals, however, were almost completely deleted. Thus, any allowance or discount received by pharmacists upon the purchase of pharmaceuticals are (no longer) covered by the new provisions. The legislator wants to exclude the purchase of pharmaceuticals so that politically desired discounts will not be under suspicion of corruption. On the donor side, pharmacists, however, are still covered. For example, in the future the bribing of physicians for the allocation of prescriptions will be punishable.

Another essential modification of the original draft bill refers to the waiver of a requirement to lodge a criminal complaint. The provisions now adopted are designed as *ex officio* crimes and, therefore, have to be prosecuted *ex officio* in case of suspected corruption.

#### **Addressees – Everybody may be on the part of the donor**

The new provisions refer to professions in the healthcare sector with regard to which state-regulated vocational trainings are required for the exercise of the profession or the bearing of the professional title. On the receiver side, in particular, physicians, den-



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tists, veterinarians and psychotherapists as well as members of the so-called paramedical professions, such as e.g. occupational therapists, speech therapists and psychotherapists are included.

However, everybody may be on the donor side, in particular, pharmaceutical representatives, lab technicians and pharmacists who are specialized in the trade and distribution of pharmaceuticals, auxiliary tools or medical products and maintain close contacts to the "receiving side".

### Far-reaching new provision

In particular, premium and discount models, which are granted, for example, by pharmaceutical companies to reward physicians for prescribing certain pharmaceuticals, are covered by the new provisions. If appropriate discounts and other advantages are not transferred to patients or competent cost units, this will be punishable.

Furthermore, so-called "sponsored" supply decisions will be punishable if and to the extent that they refer to certain pharmaceuticals, auxiliary tools or medical products. Therefore, in particular, with regard to the purchase and supply of implants and prosthetic devices which are typically distributed by sales representatives attention must be paid to not exposing themselves to the reproach of corruption.

Attention will have to be paid to the assignment of patients or test material. The legislator expressly intended to punish the unnecessary "passing round" of (private) patients who are referred by physicians to other specialists although this is not medically indicated.

Moreover, penal liability may also arise from participation in training sessions financed by pharmaceutical companies with quite considerable leisure time involved.

Also in the field of observational studies applicability of the new penal provisions is looming: If observational studies mainly serve the purpose of preferably prescribing certain drugs in order to receive a premium, then the public prosecutor will certainly conduct inquiries, if required, even with key departments to be established. Appropriate grounds for suspicion are quickly found which could only be refuted by a provably valid scientific background of the observational or other study.

### Admissible actions

It is clear that numerous actions, which had not been triable within the scope of the former legislation, are now punishable under the new provisions.

However, also in the future cooperation in the healthcare sector should be admissible. In the end, the healthcare sector should not be deprived of the advantages following from such cooperation. General grooming without direct reference to a concrete

action shall remain non-punishable. Furthermore, socially normal actions, such as e.g. the giving of advertising gadgets (promotional gifts), will also not be prohibited. Moreover, only future unfair preference will be punishable. Decisions which are made without counter-performance and are based on the physician's own conviction, such as prescribing a drug with regard to which he is convinced of its effect, or the regular reference to an experienced colleague remain admissible.

### High risk of detection and prosecution

Based on the genesis of the new regulation, in particular, the judicial and historical decision of the Grand Criminal Panel we expect public prosecutors to show an increased sensibility regarding corruption in the healthcare sector.

The fact that external examinations by public authorities exactly analyse cooperation agreements and discount arrangements involves a high risk of detection. If suspicion of corruption emerges within the scope of such examination, the files will be handed over to the public prosecutor.

### Consequences for the practice

The law adopted will enter into force one day after its promulgation by the Federal President. The challenge in the practice will now be to define and differentiate the still permissible cooperation between the parties involved in the healthcare sector from punishable behaviours. Insofar also in the healthcare sector it will be decisive whether advantages can still be classified as reasonable. Fixed value limitations do not exist in this respect. The detailed expertise acquired so far in other fields could be of assistance.

In particular, major events and congresses sponsored by pharmaceutical companies will attract the interest of the public prosecutor to conduct detailed inquiries. It remains to be seen how events of said kind could be arranged and designed in detail in the future without the new provisions being applicable. It will still take some time until clarifying higher-court decisions have been passed. Therefore, relatively extensive leisure-time programmes or comprehensive sponsoring activities should be dispensed with in the future, thus, not exposing oneself to the charge of corruption.

The observational studies frequently mentioned in the media recently might also constitute a weak point for public prosecutors who are obliged to investigate and inquire due to the fact that the new provisions are designed as *ex officio* crimes if they are aware of suspicious facts, for example, through the daily press.

### Attention: Corporate fines!

Reference has to be made to the fact that the new provisions could quickly become a (direct) conduit for a corporate fine pur-



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suant to section 30 Administrative Offences Act. Insofar a “round-about approach” through a violation of supervisory duties pursuant to section 130 Administrative Offences Act is not required. Since corruption must not be committed from within the company, the scope of application for a corporate fine pursuant to section 30 Administrative Offences Act is already given if the accusation (allegation) of bribery in the healthcare sector relates to an executive of the company.

Not only pharmaceutical companies but also pharmacies or joint practices are risking fines. In view of the enormous level of fines amounting to EUR 10 million per case this risk should be taken seriously in any event.

Therefore, it is urgently recommended to immediately review existing “cooperation agreements” and distribution channels as to their compliance with the new provisions, thus, avoiding to expose oneself to any suspicion and investigations.

In so doing, detailed expertise in the practice of public prosecution will be decisive for a proper compliance management. Present experience shows that not only “big” pharmaceutical companies but – entirely within the meaning of the reasonableness of a CMS – also “small” practices are obliged to deal with compliance unless they want to expose themselves to the suspicion of corruption and, simultaneously, to the risk of substantial corporate fines.



Jörg Bielefeld,  
Lawyer,  
BEITEN BURKHARDT  
Rechtsanwaltsgesellschaft mbH,  
Munich



Dr. Lenard Wengenroth,  
Lawyer,  
BEITEN BURKHARDT  
Rechtsanwaltsgesellschaft mbH,  
Munich

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### Editor in charge

Jörg Bielefeld



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BEITEN BURKHARDT · RECHTSANWALTSGESELLSCHAFT MBH

MUNICH · GANGHOFERSTRASSE 33 · 80339 MUNICH · TEL.: +49 89 35065-1393 · FAX: +49 89 35065-2122  
JÖRG BIELEFELD · [JOERG.BIELEFELD@BBLAW.COM](mailto:JOERG.BIELEFELD@BBLAW.COM)



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### At a glance: The new provisions combating corruption in the healthcare sector.

#### Section 299a Penal Code

##### Passive corruption (taking bribes) in the healthcare sector

Whosoever as a member of a healing profession, with regard to which state-regulated vocational trainings are required for the exercise of the profession or the bearing of the professional title, in connection with the exercise of his profession demands, has himself promised or accepts an advantage for himself or a third party as counter-performance that he

1. upon the prescription of drugs, remedies or auxiliary tools or medical products,
2. upon the purchase of drugs or auxiliary tools or medical products, which are determined for direct application by the member of the healing profession or one of his professional assistants, or
3. upon the assignment of patients or test material

unfairly prefers another in domestic or foreign competition, shall be liable to imprisonment not exceeding three years or a fine.

#### Section 299b Penal Code

##### Active corruption (giving bribes) in the healthcare sector

Whosoever offers, promises or grants to a member of a healing profession within the meaning of section 299a in connection with the latter's exercise of profession an advantage for him or a third party as counter-performance that he

1. upon the prescription of drugs, remedies or auxiliary tools or medical products,
2. upon the purchase of drugs or auxiliary tools or medical products, which are determined for direct application by the member of the healing profession or one of his professional assistants, or
3. upon the assignment of patients or test material

unfairly prefers him or another in domestic or foreign competition, shall be liable to imprisonment not exceeding three years or a fine.

#### Section 300 Penal Code

##### Aggravated cases of taking and giving bribes in commercial practice

In especially serious cases an offender under sections 299, 299a and 299b shall be liable to imprisonment from three months to five years. An especially serious case typically occurs if

1. the offence relates to a major benefit, or
2. the offender acts on a commercial basis or as a member of a gang whose purpose is the continued commission of such offences.