

BETWEEN CRIMINAL LAW AND CORPORATE SOCIAL RESPONSIBILITY - DRUG DONATIONS TO HCPS AND HCIS IN THE AGE OF THE CORONAVIRUS

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AKG e.V. stands for Arzneimittel und Kooperation im Gesundheitswesen e.V. (Association for Drugs and Cooperation in Healthcare). The AKG was founded in November 2007 and is the organization with the largest number of members in the area of voluntary self-regulation of the pharmaceutical industry in Germany. The AKG gives top priority to compliance with codified rules on competition and conduct according to the practice-based principle of "prevention before sanction". As a body involved in self-regulation of the pharmaceutical industry, the AKG supports its members in ensuring transparent and fair corporate conduct in the cooperation between the pharmaceutical industry and the medical profession. The AKG has a Code of Conduct which contains regulations for the cooperation of member companies with doctors, hospitals and other health care institutions and which is binding for member companies

Federal Finance Minister Olaf Scholz wants to give tax concessions to companies that donate disinfectants, protective masks and other medical goods during the coronavirus crisis. The minister was quoted by the news agency Reuters on April 3, 2020 as follows: “Many donations are being made to hospitals, medical practices and nursing homes. This should be encouraged. Medical donations in kind are now exempt from VAT.” Such donations are not only politically desirable, but also an expression of corporate social responsibility, i.e. the voluntary contribution of a company to overcoming the current social and economic problems and a way of assuming a corresponding share of responsibility. However, these good intentions alone do not override the compliance rules and limits of criminal law on permissible benefits to healthcare professionals (HCPs) and healthcare institutions (HCIs). Under German criminal law on corruption, such donations constitute “benefits” or “third-party benefits”, which can fall under §§ 299, 299a, 299b, 331 ff. of the German Criminal Code. The following limits must be observed:

1. The AKG Code of Conduct covers donations, which include monetary donations and the donations in kind concerned here, in § 22. § 22 (1), (3) AKG Code of Conduct limits the permissible recipients of donations in accordance with tax law (§ 10b of the German Income Tax Act (EStG) and § 9 of the German Corporation Tax Act (KStG)). Accordingly, donations may not be made to individuals belonging to professional groups (§ 22 (3) AKG Code of Conduct), but only to institutions, organizations or associations of members of professional groups. In this context, the Code mentions hospitals, university clinics and medical-scientific professional associations as examples, which as a rule fall under § 10b (1) sentence 2 no. 1 EStG, § 9 (1) sentence 2 letter a KStG (legal entity under public law, e.g. university clinic operated in the legal form of an AöR) or under § 10b (1) sentence 2 no. 2 EStG, § 9 (1) sentence 2 letter b KStG, in each case in conjunction with § 5 (1) no. 9 KStG. Further conditions include the fact that the donation is made voluntarily and free of charge in order to promote tax benefits that help others. In this context it is not the internal motives that matter, but the external circumstances. A donation may therefore still have marketing objectives, for example, in addition to charitable and altruistic purposes. In connection with the principles of separation and documentation, § 22 (1) AKG Code of Conduct contains the restriction that “on objective assessment of the circumstances under which they are made, donations cannot be understood as influencing therapeutic, regulation or procurement decisions and shall be properly documented for a period of at least five years after they have been made”. If drug donations are related to the additional demand caused by the crisis, this suggests that there is no possible intention to exercise such influence. Insofar as donations are made to HCIs and not to individual HCPs under the above conditions, drug donations are in compliance with the Code and will not be subject to criminal prosecution. Unless there is evidence to the contrary which suggests that there is an intention to influence decisions regarding procurement or regulations, the prerequisites of an unjust agreement that would constitute a criminal offense as described above are not met.

Medical device manufacturers are taking a somewhat different approach on the basis of the MedTech Europe Code of Ethical Business Practice of December 2015, section IV of which stipulates that grants to hospitals are generally not permitted. However, in connec-

tion with the coronavirus crisis, the committee has allowed member companies to support hospitals to overcome the crisis under certain conditions (see “Donation and Free of charge loans”) by means of an additional internal guideline (MedTech Europe Code Committee Guidance, March 27, 2020). Donations can be made in the form of funds, capital goods, products, consumables, services or software (see “Types of emergency support/requests”). The donation should be related to immediate needs in connection with and for the duration of the coronavirus crisis (see “Donation and Free of charge loans”).

3. On the other hand, donations are not permissible if the drugs are given to individual doctors or other HCPs. According to the AKG Code of Conduct, such donations are excluded. They fall under the prohibition of individual donations according to § 22 (3) AKG Code of Conduct and do not constitute permissible gifts according to § 21 AKG Code of Conduct. Firstly, the benefit is not granted for a reason that is explicitly covered by § 21 (2) AKG Code of Conduct. Secondly, the prohibition of individual donations in § 22 (3) AKG Code of Conduct may not be circumvented by a broad interpretation of § 21 (2) AKG Code of Conduct (see also the interpretation principle in § 4 (1) AKG Code of Conduct); and thirdly, in the case of donations to individual doctors, the recipient does not enjoy non-profit status, which is a prerequisite for a donation as defined under tax law and according to § 22 AKG Code of Conduct (more detailed information: AKG (ed.), At a glance, 3rd edition 2018, keyword “donation”). Finally, it should be noted that doctors do not dispense or use medicines, but only prescribe them. Except in certain exceptional cases, dispensing by doctors is precluded by the prohibition in § 43 (1) of the German Drugs Act (AMG) and § 17 (1a) of the German Pharmacy Operation Ordinance (Ap-BetrO). If it becomes apparent that these limits have been exceeded, the objectives pursued by the provision of the medicinal products to individual doctors may be examined. This can at least result in the risk of investigation for an offence involving corruption. Of course, this is not the case if no drugs are donated, but disinfectants, breathing masks or protective clothing, which doctors and dentists in practices urgently need.

4. Finally, the prohibition on benefits under § 7 (1) of the German Advertising of Medications Act (HWG), which also applies to HCIs pursuant to § 2 HWG, must be observed. In the above case of donation of, for example, disinfectants or respiratory masks, there is no cause for concern that § 7 (1) HWG may have been infringed, because the donations are not considered to be product-related sales advertising for a specific medication within the meaning of § 1 (1) no. 1 (unless the products in question are printed with a drug name, for example). Accordingly, the HWG does not apply. The situation may be different if the drug donation is used to advertise the use of the drug in therapy. In this case, the advertising material is identical to the advertised product. This entails the risk that the donation may be unlawful pursuant to § 7 (1) HWG. A violation of § 7 (1) HWG constitutes an administrative offense pursuant to § 7 (1) no. 4 HWG. Since § 7 (1) HWG is a market conduct standard, infringement of that provision also suggests the existence of an agreement which is unlawful under §§ 299, 299a, 299b and 331 et seq. of the German Criminal Code.

5. Caution is also required if the donation of a drug is accompanied by an implied invitation to off-label use. At present, various active ingredients are being used which are said

to be effective against coronavirus or at least have a function that supports the recovery process. If this relates to products that are used or are intended to be used outside of approval, the advertising ban of § 3a sentence 2 HWG applies, which is also covered by § 9 sentence 2 AKG Code of Conduct. If it is possible to interpret the donation as advertisement of off-label use, this can also be regarded as an intention to influence the donor and may entail the corresponding risks of prosecution under criminal law for an offence of corruption.

In summary, donations of medications should therefore only be made to hospitals or their pharmacies and not to individual medical bodies or individual doctors. Professional medical bodies may be institutions that enjoy tax benefits and are in principle legitimate recipients of donations in kind. However, professional bodies do not treat patients, with the result that the legitimate purpose of the drugs is questionable and would have to be defined more precisely in the context of earmarking the donation. There is no risk of conflict with the law if the benefits cannot also be regarded as product-related sales advertising and do not entail an invitation to off-label use.