

ANTI-CORRUPTION COMPLIANCE IN TIMES OF THE COVID-19 PANDEMIC

Criminal law risks and incentives for compliance-mangement-systems in the healthcare sector

Elias Schönborn

AUTHOR

Dr. Elias Schönborn is a Senior Associate at DORDA Rechtsanwälte GmbH in Vienna and member of the law firm's Dispute Resolution/White Collar Crime team. He specializes in anti-corruption law, white collar crime, compliance as well as civil procedural law matters. He passed the Austrian bar exam in 2020 with distinction and advises and defends clients in complex and cross-border business cases. Furthermore, he represents aggrieved parties in criminal proceedings in asserting their civil claims by way of joining the proceedings as a private party. Elias is the author of numerous publications and articles on all areas of white collar crime, corruption law and compliance. In 2020, his monograph on the topic of anti-corruption in the health sector was published by Linde. DORDA Rechtsanwälte GmbH ranks among the leading law firms in Austria and advises domestic and international clients in all areas of business law. Currently, Legal 500 ranks the law firm in Tier 1 for White Collar Crime (including fraud). For further information, visit <https://www.dorda.at/en>.

ABSTRACT

In addition to a global endurance test for the health system, the Corona pandemic triggered a tremendous social and economic crisis. Health professionals as well as politicians and business managers have to make decisions with considerable consequences under great time pressure. In this context, numerous international organizations - including Transparency International, GRECO and IACA - point out that the Corona crisis can be a breeding ground not only for conflicts of interest, but also for corruption.¹ Even though quick decisions have to be made at present,

¹ Cf. Transparency International Deutschland, *Die Corona-Krise - ein Katalysator für Korruption?* Positionspapier (June 2020), https://www.transparency.de/fileadmin/Redaktion/Publikationen/2020/Positionspapier_Korruptionspraevention_Corona_Juni_2020.pdf (last visited Jan. 31, 2021); Daniel Bischof, *Corona-Krise als Nährboden für Korruption*, interview with Thomas Stelzer, Wiener Zeitung, (Apr. 27,

it is clear that the strict prohibitions on corruption must be fully observed also in times of the Corona crisis. In order to avoid violations from the outset, existing compliance systems should continuously be updated and adapted to the current situation. This article begins with a description of possible forms of corruption in the health care sector that are particularly relevant in the current times of crisis. Finally, the article offers ideas for updates on the company's internal healthcare compliance system with regard to anti-corruption.

2020), <https://www.wienerzeitung.at/nachrichten/politik/oesterreich/2058429-Corona-Krise-als-Naehrboden-fuer-Korruption.html> (last visited Jan. 31, 2021); GRECO, *Corruption Risks and Useful Legal References in the context of COVID-19* (Apr. 15, 2020), <https://rm.coe.int/corruption-risks-and-useful-legal-references-in-the-context-of-covid-1/16809e33e1> (last visited Jan. 31, 2021).

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I. INTRODUCTION

Fighting corruption is not only an important topic in public discourse in times of crisis. In recent years, prosecution offices and courts have had to deal with an increasing number of different forms of corruption. In times of the corona crisis, in addition to the need for medications and vaccines, the demand for numerous medical products, such as respirators, disposable gloves, protective masks, disinfectants or COVID-19-tests has increased drastically. Involved persons often have to provide and procure large quantities of these products under considerable time pressure. Thomas Stelzer, head of the International Anti-Corruption Academy (IACA) recently stated in this context (translated from German original): "*States around the world are suddenly investing an enormous amount of money to support the economy and the health system. This can enable corruption, if sufficient control structures are not created at the same time. [...] The boundaries between legitimate commissions and other 'payments' are often very thin.*"²

Many legal laypersons are not aware of how narrow this range is. After all, getting a commission can be a normal business process in one case, and a violation of criminal law punishable by several years of imprisonment in the other case.

The actors in the health sector are facing the challenge of providing effective therapies, tests and vaccines for patients within a short time for the COVID-19-virus that has not been known for long and mutations of that virus that have been known for even less time. In this context, there is a considerable risk of facilitation payments, for example to gain preferential access to certain medical services in an overburdened health system. GRECO points out that in times of crisis, this form of corruption (which is commonplace in some states) appears even in states where it is otherwise rare.³

In addition, another potential gateway for corruption is the danger of conflicts of interest and (partly inadmissible forms of) lobbying. Transparency International shows that, for example, during the swine flu pandemic, scientific advisors to the WHO were simultaneously employed by pharmaceutical companies that earned money from the pandemic. In order to avoid conflicts of interest, WHO advisors must therefore now disclose their income and (financial) connections. The fact that the government is granted an extraordinary amount of power in times of crisis, while restricting traditional parliamentary structures, is also cited as a potential threat for corruption and abuse of power.⁴

This article cannot describe all forms of corrupt behavior in the health sector.⁵ In the following, the corruption risks that are currently relevant for the economic sector, and there especially for the health industry, are presented. This concerns payments/commissions on the medical procurement market,

² Daniel Bischof, *Corona-Krise als Nährboden für Korruption*, interview with Thomas Stelzer, Wiener Zeitung, (Apr. 27, 2020), <https://www.wienerzeitung.at/nachrichten/politik/oesterreich/2058429-Corona-Krise-als-Naehboden-fuer-Korruption.html> (last visited Jan. 31, 2021).

³ GRECO, *Corruption Risks and Useful Legal References in the context of COVID-19*, 3, (Apr. 15, 2020), <https://rm.coe.int/corruption-risks-and-useful-legal-references-in-the-context-of-covid-1/16809e33e1> (last visited Jan. 31, 2021).

⁴ Transparency International Deutschland, *Die Corona-Krise - ein Katalysator für Korruption?* Positionspapier, 2, (June 2020), https://www.transparency.de/fileadmin/Redaktion/Publikationen/2020/Positionspapier_Korruptionspraevention_Corona_Juni_2020.pdf (last visited Jan. 31, 2021).

⁵ For an in-depth analysis of the topic, cf. Elias Schönborn: *Korruption im Gesundheitswesen*, 45 et seq. (2020).

sponsoring of hospitals as well as donations and gifts to hospital staff. In addition to the relevant provisions of the Austrian Medicines Law (*Arzneimittelgesetz*, "AMG"), the Law on Medical Products (*Medizinproduktegesetz*, "MPG"), the limits of judicial criminal law in accordance with the Criminal Code (*Strafgesetzbuch*, "StGB") must be followed in particular.

II. MEDICAL PROCUREMENT MARKET

The healthcare market is highly competitive, which has even increased since the outbreak of the pandemic in the beginning of 2020. It does not take too much imagination to assume that the manufacturers of medical products, medicines and vaccines have a considerable incentive to convince patients or end users, physicians, pharmacists, intermediaries, hospitals, local authorities and entire confederations to buy exactly their products. Especially in the hospital sector, there is a large procurement market with many suppliers and care providers, which is a playground for purposeful influence and informal control mechanisms.⁶

A. Procurement by public institutions

If Austrian public hospitals procure medical products, medical devices and vaccines (hereinafter referred to as "medical goods"), the hospital employees are mostly employees of the Austrian hospital operating companies, which are mostly limited liability companies in accordance with Austrian corporate law. The shares of those companies are held by a regional authority (mostly one of the nine Austrian federal states). They are therefore office bearers (*Amtsträger*) and thus subjects to the anti-corruption provisions of the Austrian StGB.⁷

If a company in the healthcare sector tries to influence an office bearer to order medical goods for a public hospital by means of financial incentives (e.g. by granting commissions to him personally), this gives rise to criminal liability in accordance with the anti-corruption provisions in accordance with Sec 304 – 308 StGB.

Furthermore, physicians and other employees who have the power to dispose of the hospital's assets are persons in authority within the meaning of Sec 153, 153a StGB.⁸ Hospitals are generally entitled to any provisions their employees receive for their professional activities. A breach of this principle can therefore also constitute the offence of embezzlement or forbidden acceptance of gifts under Sec 153 et seq StGB.⁹

The above mentioned principles also apply when the European Commission procures medical goods for its Member States, which was for example the case when the European Commission ordered COVID-19 vaccines.¹⁰ The acting decision-makers of the European Commission are office bearers in

⁶ Grimm, *Korruption im stationären Sektor*, in: Walter Pfeil & Michael Prantner, *Sozialbetrug und Korruption im Gesundheitswesen*, 87 (2013).

⁷ Elias Schönborn: *Korruption im Gesundheitswesen*, 101 et seq. (2020); Grimm, *Korruption im stationären Sektor*, in: Walter Pfeil & Michael Prantner, *Sozialbetrug und Korruption im Gesundheitswesen*, 105 (2013).

⁸ Elias Schönborn: *Korruption im Gesundheitswesen*, 167 et seq. (2020).

⁹ RIS-Justiz RS0095569; Kirchbacher/Sadoghi, in: Höpfel/Ratz, *WK² StGB § 153 mn.* 31, 47.

¹⁰ Cf. MedMedia, *Erster Corona-Deal: Österreich fixiert 6 Millionen Impfdosen* (Aug. 27, 2020), <https://www.medmedia.at/relatus-med/erster-corona-deal-oesterreich-fixiert-6-millionen-impfdosen/> (last visited Jan. 31, 2021).

accordance with the Austrian StGB. Corruptive conduct in this context is punishable under Sec 304, 305, 307 and 307a StGB if the deciding EU office bearer acts with the intent that the financial interests of the EU are thereby harmed or likely to be harmed.¹¹

B. Procurement by private institutions

Employees and agents of private hospitals and other private medical institutions generally do not fall under the definition of office bearers and are therefore not subjects of corruption offences in the public sector. However, in the case of a commission granted to the decision-maker, they may be liable to prosecution under Sec 153 et seq StGB according to the principles described above.

In addition, employees and agents of private medical institutions can fulfil Sec 309 StGB. In summary, this offence requires the granting of a benefit in the course of business to a staff member or agent for a legal act in breach of duty. If a staff member of a private hospital purchases medical goods from a certain supplier because he receives a benefit (e.g. a commission) for it, although there are cheaper suppliers for the same or a comparable product on the market, this order (as a legal transaction) is in breach of duty and therefore punishable under Sec 309 para 1 StGB.¹² The person who offers, promises or provides such a commission is liable to prosecution according to Sec 309 para 2 StGB.

III. SPONSORSHIP OF PUBLIC HOSPITALS

Contributions from manufacturers to hospitals generally fall under the regulations for sponsoring. The term sponsoring covers any material or immaterial benefit in which the "donor" seeks a return, essentially in the form of advertising effects. This distinguishes sponsoring from traditional (gratuitous) donations or gifts.¹³ An essential criterion of sponsoring is therefore the exchange relationship between the sponsor and the sponsored.¹⁴

Sponsoring is commonplace in the medical sector and serves in particular to promote the image of pharmaceutical companies and medical device manufacturers. In concrete terms, conferences, congresses or other events are usually "sponsored", where the aforementioned companies are offered the opportunity to present their products. However, sponsoring can also be provided without an (openly expressed) advertising effect, for example in the case of borrow agreements for medical equipment with hospitals.¹⁵

According to the criteria of the Austrian Supreme Court, sponsoring is permissible if the sponsoring service is based on a contract for pecuniary interest that is valid under civil law.¹⁶ If the specific sponsoring is not opposed by any legal regulations and if there is no sham contract, benefits in the course

¹¹ On the related criticism of the limited criminal liability under corruption law of "EU officials", cf. Stefan Huber, *Neueste Änderungen im Korruptionsstrafrecht durch BGBl I 2019/III*, JSt 2020, 111 (114 et seq).

¹² Nordmeyer/Stricker, in: Höpfel/Ratz, WK² StGB § 309 mn 33.

¹³ Koblizek, *Verwaltungssponsoring*, in Wieselthaler: Korruptionsprävention in Theorie und Praxis, 57 (2015).

¹⁴ Cf. Clara Ifsits: *Strafrechtliche Risiken des Sponsoring. Zur Strafbarkeit von Sponsor und Gesponsertem wegen Untreue und Korruption*, 3 with further references (2017).

¹⁵ Elias Schönborn: *Korruption im Gesundheitswesen*, 53 with further references (2020).

¹⁶ OGH, June 6, 2016, 17 Os 8/16d.

of sponsoring are therefore excluded from criminal corruption law.¹⁷ If, for example, a physician concludes a third-party funding contract with a pharmaceutical company on behalf of the hospital he works for, the financial benefits are matched by the contractually agreed research project. Due to the legally justified claim from the exchange relationship, there is therefore no "benefit" relevant to corruption criminal law.¹⁸

Generally, also pandemic-related gifts from companies to hospitals also fall under the sponsorship regulations. This concerns, for example, providing (free of charge) protective masks, disinfectants, protective equipment, respirators, etc. Since such benefits regularly have at least an advertising effect for the company, there is usually an (implied) sponsoring relationship, so that the provisions of corruption law generally do not apply due to the lack of a "benefit".

If, on the other hand, direct benefits are granted to physicians or other hospital employees in the course of sponsoring, it depends on the question whether the individual person is in a contractual relationship with the sponsor. If this is not the case, there is also no service and consideration between the individual and the sponsor that excludes a benefit under corruption criminal law.¹⁹ Such benefits are analyzed in more detail below.

IV. GIFTS TO HOSPITAL STAFF

Corrupt agreements between healthcare professionals (especially physicians) and companies are hardly ever practiced openly, but "hidden" in legal cooperation agreements. For healthcare compliance, it is therefore important, especially in times of the Covid pandemic, to check the plausibility of cooperation relationships with physicians and to document the cooperation agreements in detail.²⁰ Existing cooperations must also be checked for validity, plausibility and whether they are likely to create the appearance of justifying or concealing an unlawful act. In addition to the relationship between physicians with hospitals, this applies in particular to cooperations and consultancy agreements with pharmaceutical and medical device manufacturers as well as financial participations in these companies. As stated above, in the case of a contract for pecuniary interest that is valid under civil law, a "benefit" under corruption law is excluded and therefore not punishable. Therefore, in the following, only those cases in which the individual does not have a contractual relationship with the "sponsoring" company are assessed.

Recital 50 of the European Union's Directive on the Community code relating to medicinal products for human use²¹ reads as follows: "*Persons qualified to prescribe medicinal products must be able to carry out these functions objectively without being influenced by direct or indirect financial inducements.*" Gifts to hospital staff must therefore be viewed in a differentiated manner. In general, the special relationship of trust between physician/pharmacist and patient requires that physicians and phar-

¹⁷ See also Huber: *Das Korruptionsstrafrecht 2013 – alte Probleme, neue Regelungen, offene Fragen*, 71 (2017).

¹⁸ Alois Birklbauer, *Die Anwendbarkeit der Korruptionsbestimmungen auf Ärzte*, RdM 2013, 223 (226).

¹⁹ Elias Schönborn: *Korruption im Gesundheitswesen*, 53 with further references (2020).

²⁰ Cf, also on the topic in Germany: Daniel Geiger, *Das Gesetz zur Bekämpfung von Korruption im Gesundheitswesen und seine Auswirkungen auf Strafverfolgung und Healthcare-Compliance*, CCZ 2016, 172 (177 et seq).

²¹ Directive 2001/83/EC.

macists, when recommending or prescribing drugs or medical products, are guided solely by the patient's well-being and interests and not by the question whether they have received or are to receive personal benefits in this process.

According to Sec 55a AMG, it is prohibited to grant, offer or promise a premium, financial or material advantage to physicians or pharmacists in the context of sales promotion of medicinal products/drugs. The cost absorption of reasonable travel and accommodation expenses and participation fees at scientific events exclusively related to the profession are excluded from the prohibition as well as appropriate representation expenses (Sec 55a paras 2 and 3 AMG). Furthermore, benefits of low value that are relevant to medical or pharmaceutical practice are also not covered by the above-mentioned prohibition under Sec 55a AMG. This generally includes items with a value of less than EUR 100, such as small amounts of benefits like disinfectants, respiratory masks, disposable gloves etc.²²

The equivalent for medical device advertising is regulated in Sec 108 MPG. The same regulations and prohibitions apply *mutatis mutandis* as for the promotion of medicinal products.

It must be pointed out that in all these regulations there is no "relief" whatsoever in the event of a crisis and/or pandemic. The limits outlined must therefore be strictly adhered to even in times of the current Corona crisis.

In the absence of a special authorization, a failure to transfer a benefit with a value of more than EUR 100 to the employer (such as the hospital) may also constitute a criminal offence under Sec 153a StGB. This is the case, for example, if a representative of a pharmaceutical company visits a physician in the hospital and gives him a gift, if the physician does not pass the gift over to the hospital.

Cases in which there is a connection between a benefit and a concrete activity or future activity of the hospital employee have to be assessed particularly critically and may, under certain conditions, be punished under the corruption provisions of StGB. This concerns, for example, the prescription of a drug/medical product that is made on the basis of a financial benefit, for example within the framework of a commission agreement with a physician, who receives a certain percentage of the sales price for each product prescribed. The corresponding offences are, depending on the specific form of corrupt behavior, to be assessed under Sec 153, 153a StGB as well as Sec 304 - 309 StGB and are punishable by prison sentences of several years.

V. COMPLIANCE

The purpose of anti-corruption compliance is not merely to prevent penalties, but – above all – to protect patients as well as business partners and employees. Healthcare compliance also serves the reputation of the company and the public's trust in the healthcare system.²³

For anti-corruption compliance in the medical sector, precise knowledge of medical law and criminal law contexts is indispensable. From a certain company size onwards, companies in the health sector

²² Cf. Elias Schönborn: *Korruption im Gesundheitswesen*, p. 235 et seq (2020).

²³ Cf. Alexander Petsche/ Daniel Larcher, *Von Geschenken und anderen die Freundschaft erhaltenden Vorteilen: Korruptionsprävention im Gesundheitswesen*, JMG 2016 H 0, 40 (42).

employ their own "compliance officers" as (legal) generalists to ensure compliance with all legal norms relevant to the specific company. If necessary - especially in difficult or special cases - they also engage external specialists in certain areas of law. This regularly also includes the particularly sensitive area of anti-corruption.

Especially smaller and medium-sized companies that are active in the health sector and do not have a compliance department that is specialized down to the last detail have their compliance system put together and regularly reviewed by external experts, especially attorneys, and benefit from the attorney's strict duty of confidentiality. This involves in particular the elaboration of a compliance guideline or a code of conduct which analyses the concrete risks of the company in order to raise the problem awareness of the employees on the one hand and to work out concrete instructions for action for employees on the other hand. An important principle in this context is the documentation and written form principle for (cooperation) contracts with physicians.²⁴

Since every company is different, healthcare compliance must specifically address the concrete corruption risks and (medical) facilities as well as problem areas of the respective company. In this context, compliance guidelines and codes of conduct have to be adapted to new circumstances in the company and - due to frequent amendments to the law - have to be updated regularly.

In practice, it has also proven useful to hold regular employee training sessions on these topics, in which employees also have the opportunity to enter into a dialogue with experts and receive answers to compliance-relevant questions that affect their daily work. In this context, areas that tend to be vulnerable to corruption, such as sales/distribution or procurement can also be addressed in detail. In addition, internal whistleblowing systems that maintain confidentiality as well as concrete amnesty programmes can be a perfect rounding of a company's compliance management system.²⁵

If a suspicion of corruption arises within the company, internal investigations by external advisors such as attorneys and/or auditors can help to uncover potential misconduct while maintaining absolute confidentiality.

VI. CONCLUSION

In addition to individual punishment of the decision-makers or employees involved, companies operating in the health care sector may also be imposed with considerable fines under the Austrian Act on responsibility of legal entities (*Verbandsverantwortlichkeitsgesetz*, "VbVG"). In accordance with the quote by US lawyer Paul McNulty "*If you think compliance is expensive, try non-compliance*", some health care companies have already established special compliance precautions for anti-corruption, while for others this process is still pending. The Covid pandemic is an opportunity to catch up on this long overdue homework. The examples presented above concern only the most obvious forms of corruption in the health sector in times of the Corona crisis. Overall, the topic is complex and includes not only an assessment under criminal and administrative law, but also civil and corporate law issues.

²⁴ Alexander Petsche/ Daniel Larcher, *Von Geschenken und anderen die Freundschaft erhaltenden Vorteilen: Korruptionsprävention im Gesundheitswesen*, JMG 2016 H 0, 40 (42 et seq).

²⁵ Alexander Petsche/ Daniel Larcher, *Von Geschenken und anderen die Freundschaft erhaltenden Vorteilen: Korruptionsprävention im Gesundheitswesen*, JMG 2016 H 0, 40 (43).

Moreover, since there are hardly any court decisions on this topic in Austria, there is a growing need for legal certainty among companies operating in the medical sector. The first step towards this is a comprehensive analysis of the corruption risks in one's own company. To conclude the topic with the words of Transparency International (translated from German original): *"We can understand the Corona crisis as setting the course for a comprehensive social transformation. [...] This new challenge offers a window of opportunity for changes that are of fundamental importance for trust in politics and administration, for decency and fairness in business and for the cohesion of society as a whole"*²⁶

²⁶ Transparency International Deutschland, *Die Corona-Krise - ein Katalysator für Korruption?* Positionspapier, 5, (June 2020), https://www.transparency.de/fileadmin/Redaktion/Publikationen/2020/Positionspapier_Korruptionspraevention_Corona_Juni_2020.pdf (last visited Jan. 31, 2021).