Whitepaper

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Digital Health Telemedicine

20 Questions and Answers on Regulatory Affairs & Medical Law, Drug Advertising Law & Liability, Data Protection & AI

Digital Health - Telemedicine

20 Questions and Answers on Regulatory Affairs & Medical Law, Drug Advertising Law & Liability, Data Protection & AI

1. Can any physician in Germany provide telemedical treatment? What are the medical and regulatory requirements?

2. Can foreign physicians examine and treat patients in Germany via telemedicine?

3. Under what conditions can drugs be prescribed after a telemedical examination?

4. Where does telemedicine reach its (legal) limits? When is „conventional“ face-to-face treatment necessary?

5. Are app operators or internet platforms allowed to offer or arrange telemedicine services from domestic or foreign physicians?

6. Under what conditions do health insurance funds pay for telemedical treatments?

7. Where and how is advertising for telemedicine permitted?

8. What legal restrictions apply to advertising if a telemedicine treatment concept also includes the prescription of medicinal products?

9. What other restrictions apply under the HWG to advertising for telemedicine?

10. Is health influencer marketing permissible for telemedicine? What restrictions apply to social media marketing?

11. Can telemedicine services be advertised with gifts, discounts, vouchers, or other benefits?

12. How are physicians who offer telemedicine liable? How are platform operators liable?

13. Does the use of telemedicine always require the explicit consent of the patient?

14. How can medical confidentiality be maintained when telemedicine platforms or IT service providers are involved in treatment? What are the requirements with regard to Section 203 StGB?

15. What data security requirements must be observed when using telemedicine? Are there certain certifications that can or must be relied upon?

16. Does a data protection impact assessment have to be carried out before using telemedicine?

17. To what extent does the AI Act influence the use of AI in telemedicine?

18. Is an AI in telemedicine always a „high risk“ AI system?

19. What compliance obligations does the AI Act stipulate for the use of AI in telemedicine?

20. How can transparency and human oversight be maintained when using AI in telemedicine?

Contents

Part I: Overview

The use of telemedicine in healthcare is an important part of the further development of medical care. It has gained in importance due to the shortage of physicians, especially in rural areas and during the coronavirus pandemic. Telemedicine raises many legal questions, particularly in the areas of regulatory affairs and medical law, drug advertising law and liability, as well as data protection and AI, which are answered below.

Telemedicine refers to the provision of healthcare services where the service provider (e.g., physician) and the service recipient (patient) are not physically present at the same place at the same time, but where treatment is provided via telecommunications media. Telemedicine can also be provided across borders. The European Court of Justice (ECJ) defines it as healthcare services provided to a patient by a healthcare provider established in a Member State other than the Member State of affiliation, using information and communication technologies, without the simultaneous physical presence of the patient and the service provider.[1] Telemedicine thus makes it possible to offer patients medical advice and treatment via means of communication despite physical separation.

Part II: Telemedicine, Regulatory Affairs and Medical Law

1. Can any physician in Germany provide telemedical treatment? What are the medical and regulatory requirements?

Yes, in principle, any physician with a valid German license to practice medicine may provide telemedical treatment. Since 2018, according to Section 7 (4) of the (Model) Professional Code for Physicians in Germany (MBO-Ä) and the corresponding state professional codes that have adopted this clause, exclusive distance treatment has been permitted under professional law, provided that it is medically justifiable in individual cases and the necessary medical care is guaranteed. This must be taken into account in particular regarding the manner of diagnosis, consultation, treatment, and documentation. In addition, the patient must be informed about the special features of exclusive consultation and treatment via communication media. All professional obligations – from compliance with the standards of medical treatment to confidentiality and data protection – also apply without restriction in telemedicine.

[1] ECJ, judgment of September 11, 2025 – C-115/24 – Österreichische Zahnärztekammer, para. 90.

2. Can foreign physicians examine and treat patients in Germany via telemedicine?

Telemedicine is not a „special legal area“ but a normal form of medical treatment. The same licensing, professional and liability regulations apply as for in-person treatment. In principle, the telemedical treatment of patients in Germany without a German license would constitute a violation of Section 2 (1) of the Federal Medical Practitioners Act (BÄO), according to which anyone who wishes to practice medicine must be licensed as a physician.

However, due to the physical separation between physicians and patient, telemedicine also enables cross-border treatment. This raises the question of whether and under what conditions foreign physicians are allowed to treat patients in Germany via telemedicine. A distinction must be made between physicians from EU/EEA countries and those from third countries:

a) Physicians from EU and EEA countries

Directive 2011/24/EU of the European Parliament and of the Council of March 9, 2011, on the application of patients‘ rights in cross-border healthcare (the so-called „Patient Mobility Directive“) defines in Art. 3 (d) Sentence 2 the so-called „Member State of treatment“: „In the case of telemedicine, healthcare is considered to be provided in the Member State where the healthcare provider is established.“ „Healthcare“ within the meaning of the Directive is defined in Art. 3 (a) as „health services provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices.“

It is controversial whether Art. 3 (d) of the Directive only regulates issues of reimbursement within the meaning of Art. 7 of the Directive or whether it establishes a general country of origin principle to the effect that, in the case of cross-border telemedicine, the law (and thus also the medical licensing and professional law) of the country from which the physician provides the telemedical healthcare services always applies.

The ECJ answered this question in its decision in the case of the Austrian Dental Association (judgment of September 11, 2025 – C-115/24). According to the ECJ, Art. 3 (d) of the Directive is an exception that must be interpreted narrowly. According to this, each healthcare service must be considered individually, and only those services that are provided exclusively by means of telemedicine as defined in Part I are subject to the provisions of the Directive of the country in which the physician is based – and not to the professional law of the country in which the patient is located.[2] According

[2] ECJ, judgment of September 11, 2025 – C-115/24 – Österreichische Zahnärztekammer, para. 93.

to the ECJ, these provisions regulated by the Directive include the legal provisions of that Member State, the standards and guidelines of that Member State for quality and safety, and EU legislation on safety standards.[3] This also includes the requirements relating to qualifications and licenses for practicing the profession.[4]

In short: if physicians based in other EU countries are authorized to practice medicine and treat patients (including via telemedicine) in accordance with local licensing and professional law, they may also treat patients in other EU Member States, such as Germany, **provided that the healthcare service is provided exclusively via telemedicine.**

b) Physicians from third countries

Physicians from third countries cannot, in principle, invoke the Patient Mobility Directive and the above-mentioned judgement of the ECJ because neither is applicable outside the EU. Usually, therefore, the law of the country in which the patient is resident remains applicable.

Therefore, physicians **from third countries** are generally only allowed to treat patients in Germany if they have a German license to practice medicine or a professional license. Their foreign qualifications must be assessed as equivalent in the recognition procedure. Since 2012, the Recognition Act has allowed licenses to be granted regardless of nationality, subject to successful examination of the applicant‘s knowledge.

[3] ECJ, judgment of September 11, 2025 – C115/24 – Österreichische Zahnärztekammer, para. 102.
[4] ECJ, judgment of September 11, 2025 – C-115/24 – Österreichische Zahnärztekammer, para. 103 et seq.

3. Under what conditions can drugs be prescribed after a telemedical examination?

After a purely telemedical examination, medication may only be prescribed if the medical history and findings obtained by video or telephone allow for a sufficiently reliable diagnosis. The physician must therefore be able to take professional responsibility for ensuring that the remote examination is sufficient for the indication. If this is the case, a prescription can be issued – usually electronic – and redeemed at a pharmacy.

If the prescription is to be issued by physicians based in other EU countries – as is the case with many online health platforms – the latest judgement of the ECJ of September 11, 2025, states that this is again subject to the legal provisions, standards, and guidelines of the Member State in which the physician is based (see also Art. 3 (d) and Art. 4 (1) of Directive 2011/24/EU). The reason for this is that regulations, standards, and guidelines on the prescription of medicines affect the quality and safety of treatment. Since these are covered by the Patient Mobility Directive and, in the case of purely telemedical healthcare services, the law of the country in which the physician is located applies in this respect,[5] the legal issues relating to the prescription as such are also subject to the law of that Member State. If the telemedicine service provided and prescription issued are among the services to which the patient is entitled in their Member State of insurance, they are generally also entitled to reimbursement from their health insurance fund.[6]

However, where German law applies, the following must be observed: When prescribing medicines to persons who have statutory health insurance, special restrictions apply in accordance with the Federal Framework Agreement for Medical Practitioners (BMV-Ä): Narcotics and other addictive substances may not be prescribed to previously unknown patients during a video consultation (Section 11 (1) of Annex 31 (c) to the BMV-Ä). Apart from such exceptions, every prescription of drugs must be based on a careful telemedical examination, be properly documented and comply with all drug regulations. In particular, physicians must check interactions, adequately inform patients, and securely transmit the prescription.

[5] ECJ, judgment of September 11, 2025 – C-115/24 – Österreichische Zahnärztekammer, para. 102.
[6] See Art. 7 et seq. of the Patient Mobility Directive and the corresponding transpositions into national law.

4. Where does telemedicine reach its (legal) limits? When is „conventional“ face-to-face treatment necessary?

The limits of telemedicine are reached when a physical examination or treatment is essential. If a reliable diagnosis or therapy cannot be guaranteed by camera and telephone alone, the physician must refer the patient for a face-to-face consultation. For example, a physician´s own assessment often requires palpation, tapping or auscultation of the patient – activities that require physical presence and are not possible in a video consultation. Guidelines from the relevant scientific medical societies can provide important guidance here.[7] Under professional law, physicians are obliged to decide on a case-by-case basis whether distance treatment is compatible with the recognized state of medical science. If this is not the case – for example, in the event of unclear, severe symptoms or an urgent need for intervention – telemedicine may not replace conventional treatment. In such cases, a personal examination and treatment on site is necessary to protect the patient.

Based on the provisions of Art. 3 (d) and Art. 4 (1) of the Patient Mobility Directive and in accordance with the above-mentioned judgement of the ECJ of September 11, 2025, telemedicine healthcare services provided by physicians from other EU Member States are subject to the provisions of those countries (country of origin principle, for details, see questions 2 and 3 above). In this context, particular attention should be paid to the ECJ‘s statement that there are no „hybrid forms“ between telemedical treatment and face-to-face treatment, as even in the context of complex overall treatments, each service must be considered individually. If, for example, the initial medical history of a German patient is taken in person by a German physician and the follow-up treatment is provided by an Irish physician via telemedicine, then the in-person treatment is subject to German standards and only the follow-up treatment is subject to Irish law in accordance with the country of origin principle for telemedicine. The focus of the treatment is not relevant in this context.[8] Rather, the overall treatment must then be divided as described above.

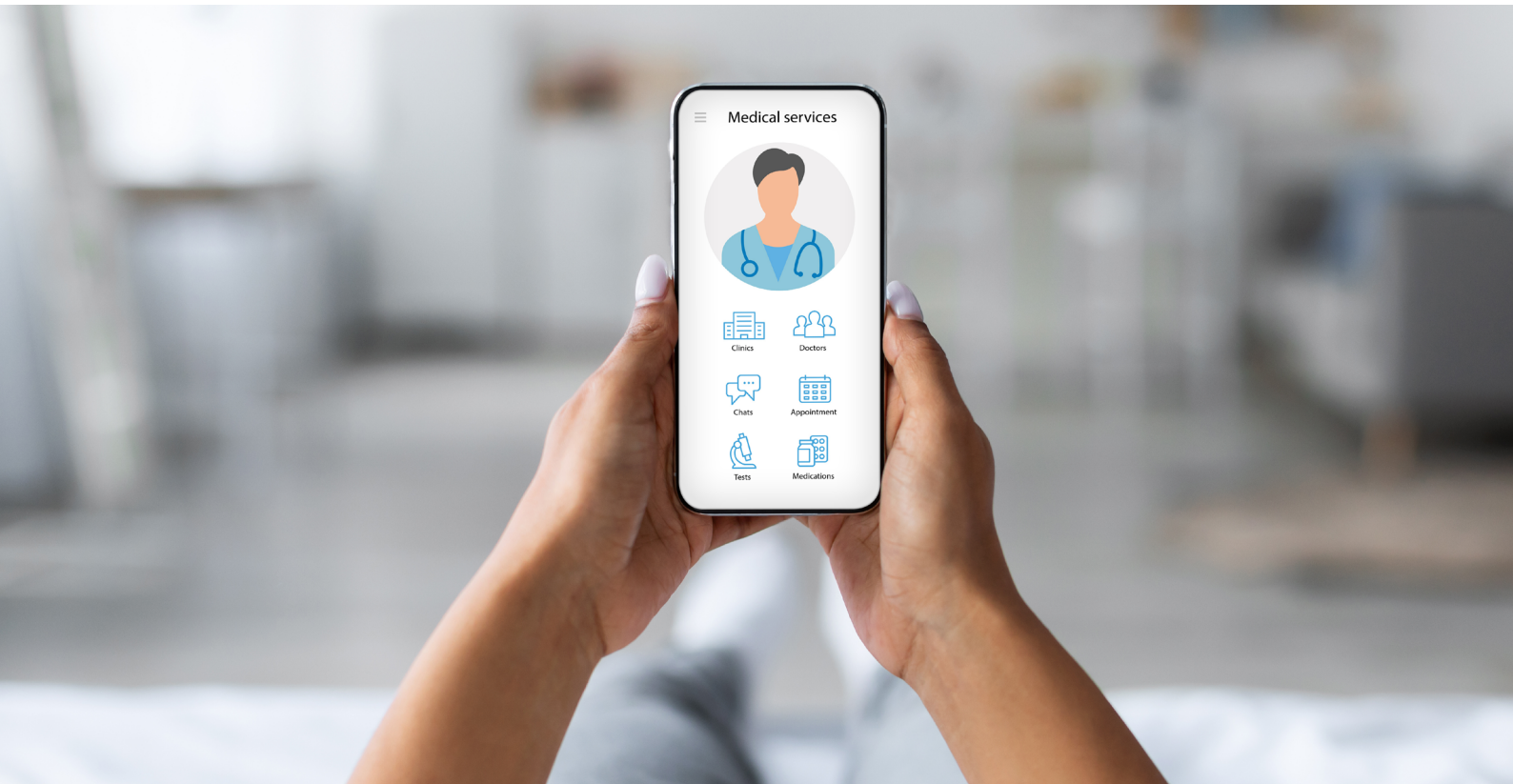
[7] See, for example, the overview of guidelines at https://register.awmf.org/de/leitlinien/aktuelle-leitlinien.
[8] ECJ, judgment of September 11, 2025 – C-115/24 – Österreichische Zahnärztekammer, para. 90 et seq.

5. Are app operators or internet platforms allowed to offer or arrange telemedicine services from domestic or foreign physicians?

In principle, yes. Telemedicine services can be provided via digital platforms. However, they must comply with the legal requirements. As explained above, healthcare services provided purely via telemedicine are generally subject to the law of the country of origin. This applies in all cases where the law falls under the Patient Mobility Directive or the E-Commerce Directive.[9]

Unless the law of the EU Member State in which they are based provides otherwise, platform operators may not offer medical treatment themselves but may only act as technical service provider (e.g. by providing a certified infrastructure for video consultations). Interference with medical freedom of choice is generally prohibited: for example, the platform may not keep patient records on its own authority or restrict patients‘ freedom to choose their physician.[10] Performance-based commission models or exclusive ties (e.g. to certain pharmacies) are also problematic, as they generally violate professional and competition law requirements, at least in Germany. However, as mentioned above, due to the country of origin principle recently confirmed by the ECJ, the law of the Member State in which the physicians are based may apply instead of the above principles, which must then be examined on a case-by-case basis.

[9] ECJ, judgment of September 11, 2025 – C-115/24 – Österreichische Zahnärztekammer, para. 100 ff.
[10] Munich Social Court, judgment of April 29, 2025 – S 56 KA 325/22.



However, the question of whether the country of origin principle also applies to advertising for telemedicine remains open and has not yet been explicitly decided. This is supported by the fact that, from a German perspective, the regulations on advertising of medicinal products primarily serve to protect the health of individuals in the public interest, to prevent the misuse and abuse of medicinal products, self-treatment by lay persons and inappropriate advertising claims in the health sector, and to protect consumers in specific health matters. It can be argued that this constitutes „legal provisions of the Member State of treatment“ (in the case of cross-border telemedicine, the Member State of the physician is the Member State of treatment, Art. 3 (d) Sentence 2 of Directive 2011/24/EU) within the meaning of Art. 4 (1) (a) of Directive 2011/24/EU, so that the law on advertising for telemedicine is also subject to the country of origin principle. However, this is contradicted by the fact that, according to general principles of international competition law, the market location principle normally applies in advertising law – i.e. the advertising law of the country in which the market is to be influenced. This would usually be the law of the country in which the patient being courted is located. The judgement of the ECJ of September 11, 2025 (C-115/24) does not comment on this. It remains to be seen how case law will develop in this area.

6. Under what conditions do health insurance funds pay for telemedical treatments?

Telemedicine treatments are now an integral part of statutory healthcare and are reimbursed by health insurance funds under certain conditions. Firstly, the treatment must be carried out by a contracted physician, i.e. a service provider approved by the statutory health insurance system.

Since the „Digitalization Push 2020+“ – the accelerated use of digital technologies and processes triggered by the COVID-19 pandemic – the National Association of Statutory Health Insurance Physicians (KBV) and the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) have created framework regulations that integrate video consultations and other telemedicine services into standard care. Contract physicians are permitted to offer telemedicine services if this is medically appropriate and they meet the quality requirements. This includes the use of approved technical services (e.g. a video service provider certified by the KBV) and compliance with the requirements of Annex 31(c) to the BMV-Ä – such as a properly equipped teleworking station, documentation in the electronic patient file and prioritization according to urgency. If these requirements are met, telemedicine services can be billed using the appropriate tariff items and are therefore reimbursable by health insurance funds. In summary, statutory health insurance covers telemedicine examinations and treatments if they are provided by authorized service providers in accordance with the applicable regulations.

For telemedical health services provided from other EU Member States, the provisions of Chapter III of the Patient Mobility Directive (Directive 2011/24/EU) on the reimbursement of costs for cross-border healthcare and its national implementing regulations apply.[11] In principle, patients can also apply for reimbursement from their health insurance funds when using healthcare providers in other EU countries if the healthcare service in question is one of the services to which the insured person is entitled in the Member State of insurance.

Part III: Telemedicine, Healthcare Advertising Law and Liability

7. Where and how is advertising for telemedicine permitted?

Providers are only allowed to advertise distance treatments within very narrow limits – which contradicts the legislative goal of promoting digitization in healthcare and telemedicine. It makes no sense that physicians are allowed and even encouraged to provide telemedicine services on the one hand, but are not allowed to advertise them, or only to a very limited extent, on the other. The advertising restrictions have an even more serious impact on healthcare platforms on the internet, which are legally permitted to broker and, in some cases, provide telemedicine services, but are then subject to considerable legal restrictions when it comes to advertising these services. Unfortunately, the legislator is undermining its own promotion of telemedicine through overly restrictive overregulation at the advertising level.

Only if compliance with recognized professional standards is guaranteed, i.e. if, according to the recognized state of medical science, proper treatment and consultation using means of communication is fundamentally possible, these services may be advertised. If this is not the case, advertising for telemedicine services is prohibited in Germany (Section 9 (1) German Healthcare Advertising Act (HWG)).

[11] In Germany, implementation took place primarily in Section 13 (3) and (5) SGB V and in Section 219d SGB V concerning the national contact point. In addition, various federal states have enacted state laws to implement Directive 2011/24/EU.

Distance treatment may therefore be advertised if

- → they using communication media and
- → according to generally recognized professional standards, personal medical contact with the person being treated is not necessary (Section 9 (2) HWG).

The first requirement for the admissibility of advertising for telemedicine is generally unproblematic: all means of communication that can be used for treatment without the patient and physician being physically present at the same time may be used for distance treatment. These include, for example, telephone, email, video telephony and apps.

The second criterion is more difficult and usually involves considerable uncertainty: when interpreting the exemption provision in Section 9 (2) HWG, an abstract, generalized approach is required, as advertising is aimed at a large number of unspecified individuals, regardless of the specific treatment situation and the specific patient. When, according to generally accepted professional standards, personal medical contact with the person to be treated is not necessary depends primarily on the respective illness. The decisive factor is not whether an advertised distance treatment would be permissible under medical professional law. The term „generally accepted professional standards“ is not defined in the HWG. It must therefore be interpreted with reference to Section 630a (2) of the German Civil Code (BGB)[12] and the principles developed from the obligations to be fulfilled by the physician under a medical treatment contract[13] and is subject to constant further development. If guidelines or recommendations from professional associations are available, the state of medical science contained therein must be taken into account.[14] If these are not available, the applicable standards must be applied, taking into account medical experience and available scientific knowledge. The burden of proof for the existence of generally recognized professional standards lies with the advertiser.

A professional standard represents the action that can be expected from an attentive and conscientious physician in the respective treatment situation from the professional point of view of the specialist field at the time of treatment.

[12] Section 630a (2) BGB states (translation into English): „Treatment must be carried out in accordance with the generally accepted professional standards existing at the time of treatment, unless otherwise agreed.“
[13] Federal Court of Justice, judgment of December 9, 2021 – I ZR 146/20.
[14] See the AWMF Guidelines Register: https://register.awmf.org/de/leitlinien/aktuelle-leitlinien.

However, case law applies strict standards to the advertising and implementation of distance treatments and is generally very restrictive. Here are a few examples:

- Telemedicine treatments must be advertised in such a way that patients are aware that distance treatments are subject to restrictions and are not suitable for every diagnosis or treatment. Advertising with the offer „Initial consultation with a physician on site or digitally“ was therefore classified as a violation of Section 9 HWG for treatment with medical cannabis.[15]

- Advertising for the prescription of obesity medication based solely on questionnaires was deemed inadmissible, as further tests are necessary for a sound diagnosis and therapy in order to meet the recognized professional standard.[16]

- Advertising for the issuance of certificates of incapacity for work via remote diagnosis, which are issued solely based on questionnaires and do not ensure that the need for personal contact with the patient has been verified, is also inadmissible.[17]

- The diagnosis and prescription of medication based solely on a completed online questionnaire does not meet general professional standards and is inadmissible.[18]

- The treatment of malocclusion exclusively through telemedicine is not permitted.[19]

- Advertising for an internet platform where customers can obtain a prescription for medication to treat erectile dysfunction based solely on an online questionnaire is not permitted. The generally accepted professional standard requires direct medical contact with the patient for the diagnosis and treatment of erectile dysfunction.[20]

- Advertising for distance treatments in which patients living in Germany are offered diagnoses, therapy recommendations and sick notes for unspecified treatment cases via an app from physicians based abroad is inadmissible.[21]

[15] Higher Regional Court of Frankfurt am Main, judgment of March 6, 2025 – 6 U 74/24.
[16] Munich District Court I, judgment of March 3, 2025 – 4 HK O 15458/24.
[17] Higher Regional Court of Hamburg, judgment of November 5, 2020 – 5 U 175/19.
[18] Higher Regional Court of Cologne, judgment of June 10, 2022 – 6 U 204/21.
[19] Berlin District Court, judgment of August 18, 2021 – 101 O 76/20.
[20] Higher Regional Court of Munich, judgment of April 18, 2024 – 29 U 1824/23.
[21] Federal Court of Justice, judgment of December 9, 2021 – ZR 146/20.

→ Advertising on an internet platform with the slogan „Goodbye waiting room. Hello online doctor – doctor's consultation, private prescription and sick note in just a few minutes" infringes Section 9 HWG, as the platform is thereby advertising a comprehensive digital primary care model that is not limited to specific clinical pictures. The combination of „Goodbye waiting room" and „Hello online doctor" conveys the message that medical care is possible without a physical visit to the doctor.[22]

However, case law makes it clear that advertising for distance treatment is considered permissible if it is not misleading, clearly states the limitations of remote care and is restricted to specific, medically justifiable applications. For example, a digital follow-up appointment after an initial physical examination for treatment with medical cannabis has been deemed permissible and, according to the court, may also be advertised accordingly.[23]

Finally, it should be noted that the provision of Section 9 HWG only applies if the HWG is applicable at all. Outside the scope of sales promotion for medicinal products already discussed, this is only the case if the advertising specifically refers to certain remedies, procedures, treatments or objects within the meaning of Section 1 (1) No. 2 HWG. However, it is not advertising if a telemedicine company merely advertises itself or its services in general without referring to the diagnosis or treatment of specific diseases, even if these are only indirectly recognizable.

[22] Munich Social Court, judgment of April 29, 2025 – S 56 KA 325/22.
[23] Higher Regional Court of Frankfurt am Main, judgment of March 6, 2025 – 6 U 74/24.

8. What legal restrictions apply to advertising if a telemedicine treatment concept also includes the prescription of medicinal products?

Prescription drugs may not be advertised to medical laypersons (Section 10 (1) HWG). Only physicians, dentists, veterinarians, pharmacists, and persons who are legally authorized to trade these drugs are permitted to do so. This also applies to telemedical treatment concepts. The prohibition aims to limit the risk of self-medication and to prevent consumers from being encouraged to consume these medicinal products.

Medicinal products may therefore not be mentioned by name on telemedicine platforms if the intention is to promote their sales. However, the prohibition in Section 10 (1) HWG does not extend to corporate advertising (company and image advertising) that promotes the reputation and performance of the company in general without referring to specific medicinal products.

Platforms must therefore carefully differentiate between purely informational content or mere corporate advertising and advertising for prescription drugs. Providing information about an illness is permissible. However, specific recommendations for prescription drugs are a different matter. The use of images or names of such medicinal products should therefore be avoided. Even describing a diagnosis in connection with a medicinal product offer can constitute indirect advertising and infringe Section 10 (1) HWG if the context creates an association with a specific drug. It is completely irrelevant whether the advertiser has a direct interest in the distribution of the advertised drug. The mere intention to promote the prescription and sale of the medicinal product through advertising is sufficient.

9. What other restrictions apply under the HWG to advertising for telemedicine?

Advertising for telemedicine outside of medical circles is subject to the same restrictions as other advertising for medicinal products.

Section 10 (1) HWG is often of great practical importance here. This provision states that prescription drugs may only be advertised to physicians, dentists, veterinarians, pharmacists and persons who are legally permitted to trade in these drugs. This means that advertising for prescription drugs outside the of these professional circles is generally prohibited. This applies, for example, to product-related advertising for specific, named or at least identifiable drugs on weight loss platforms or in the field of medical cannabis. Whether advertising constitutes product-related sales promotion for medicinal products or, for example, only provides medical and scientific information

about them, which is then not covered by Section 1 HWG and is therefore permissible even for consumers, must always be carefully examined and assessed on a case-by-case basis.

Another important standard for consumer advertising is Section 11 HWG. This prohibits a variety of specific misleading and inappropriate advertising measures for medicinal products, procedures, treatments, objects, or other means. The provision serves to protect the health of consumers. Consumers generally lack the necessary expertise to properly assess advertising claims and to form a clear understanding of the consequences of individual use in connection with a specific illness.

According to Section 11 HWG, it is not permitted to advertise medicinal products, procedures, treatments, products or other remedies outside of professional circles, for example

- with information or representations that refer to a recommendation by scientists, healthcare professionals, veterinary health professionals, or other persons who, due to their prominence, may encourage the use of medicinal products (para. 1 no. 2),

- using the reproduction of medical case histories or references thereto, if this is done in an abusive, repulsive, or misleading manner or if it could lead to a false self-diagnosis through a detailed description or representation (para. 1 no. 3),

- by displaying abusive, offensive, or misleading pictorial representations of changes in the human body caused by disease or injury or the effect of a medicinal product on the human body or parts thereof (para. 1 no. 5),

- using advertising claims inferring that a person´s health could be impaired by not using the medicinal product or that the use of the medicinal product could enhance a person´s health (para. 1 no. 7),

- using statements made by third parties, especially letters of thanks, recognition, or recommendation, or with references to such statements, if these are made in an abusive, offensive, or misleading manner (para. 1 no. 11).

Section 11 HWG aims to prevent advertising that typically has a rapid and inappropriate influence on consumers, causing them to use the products incorrectly or even misuse them. Section 11 HWG therefore prohibits advertising that is likely to cause consumers to form false impressions of the advertised product or means. However, it is important to note that the advertising prohibitions in Section 11 (1) HWG are stricter for medicinal products, procedures, treatments, and items than for medical devices: For medical devices, only the advertising prohibitions in Section 11 (1) No. 7 to 9, 11, and 12 HWG apply accordingly; the advertising prohibitions in Section 11 (1) No. 1 to 6, 10, and 13 to 15 HWG do not apply to medical devices.

Furthermore, Section 12 HWG must be observed when advertising for certain diseases, which supplements Sections 10 and 11 HWG. Section 12 (1) HWG prohibits advertising outside professional circles for the detection, prevention, elimination, or alleviation of certain serious diseases or conditions. The purpose of this prohibition is to protect the health interests of individuals and the general public from inappropriate self-treatment. Section 12 (2) HWG extends the prohibition to all other products, procedures and items (including cosmetic products and consumer goods), with the exception of advertising for the prevention or treatment of abortions, as well as for treatments in spas, health resorts, and sanatoriums.

Finally, advertising for telemedicine must not be misleading. In addition to the general provisions of competition law, in particular Sections 5 and 5a of the Unfair Competition Act (UWG), the special standard in Section 3 HWG must be observed. In addition, as is generally the case in therapeutic products advertising law, the so-called strict principle applies to advertising for telemedicine, whereby particularly strict requirements must be placed on the accuracy, unambiguity, and clarity of health-related advertising. Accordingly, health-related claims must correspond to reliable scientific knowledge. Here, too, the burden of proof lies with the advertiser.[24]

[24] Comprehensive: Federal Court of Justice, judgment of March 6, 2013 – I ZR 62/11; Holtorf/Reese, in: Dieners/Reese, Handbuch des Pharmarechts, Section 11 HWG para. 140; established case law, cf. e.g. Federal Court of Justice, judgment of June 17, 1992 – I ZR 221/90 – Hyanit.

10. Is health influencer marketing permissible for telemedicine? What restrictions apply to social media marketing?

Influencer marketing is attractive to companies because the perceived authenticity of many influencers maintains the interest and engagement of their audience, even with promotional content. A characteristic feature is that a person perceived as a role model presents products or companies in their accounts in an apparently private manner – for example, through „tagging“ or „linking“ – in return for payment or other benefits. In this way, they strategically influence their followers‘ willingness to buy.

As already explained in question 7 telemedical treatment may be advertised using communication media if, according to generally accepted professional standards, personal medical contact with the person being treated is not necessary (Section 9 Sentence 2 HWG). This also applies to the promotion of telemedical treatment by influencers. In other words, if distance treatment itself is permissible according to generally accepted professional standards, then its advertising is also permissible.

Section 11 (1) No. 2 Alternative 4 HWG prohibits the use of celebrities to advertise medicinal products. The question of whether influencers are considered celebrities within the meaning of this provision is currently the subject of intense debate. The decisive factor in determining whether a person is a well-known figure within the meaning of the standard is whether the target audience – i.e. the influencer‘s followers – perceive the person as well-known and could be encouraged to consume the medicinal product by their portrayal. Absolute celebrity status or a certain number of followers is not relevant in the context of influencers.[25]

In principle, influencers must always label advertising measures in their posts transparently and appropriately as advertisement. The labeling should be easily recognizable and clearly understandable for everyone, so that the advertisement can be identified as such. This general principle is also explicitly addressed in Section 11 (1) No. 9 HWG. Furthermore, the legal notice must also be complete and easy to find.

If an advertising measure is unlawful, both the influencer and the company behind them can be held liable or responsible, particularly under the HWG, the UWG, and the German Administrative Offenses Act (OWiG).

For so-called medfluencers, who are licensed physicians, the stricter professional regulations from the MBO-Ä and the respective state professional codes based on it apply in addition to the provisions of the HWG and UWG. According to Section 27 (3) Sentence 2 MBO- Ä, advertising that is particularly promotional, misleading, or comparative is unprofessional and therefore prohibited. Furthermore, advertising for one‘s own

[25] Higher Regional Court of Cologne, judgment of September 11, 2025 – 6 U 118/24.

or third-party commercial activities or products in connection with medical practice is not permitted, Section 27 (3) Sentence 4 MBO-Ä. Physicians may only provide „objective, profession-related information," but may not engage in „profit-oriented behavior." The ban on third-party advertising serves to maintain the neutrality and integrity of the profession. As „persons working in the healthcare sector," physicians are also not permitted to make recommendations in advertisements for medicinal products (Section 11 (1) No. 2 HWG).

11. Can telemedicine services be advertised with gifts, discounts, vouchers, or other benefits?

In principle, no, unless one of the exceptions specified by law applies.

Telemedicine services are subject to the same legal requirements as other medical or health-related services. According to Section 7 (1) HWG, benefits and promotional gifts in the form of free goods or services are generally prohibited in product-related advertising for medicinal products, medical devices, and certain medical procedures and treatments (Section 1 (1) HWG) – with certain exceptions, which are regulated in Section 7 (1) Sentence 1 clause 2 No. 1 to 5, (2) HWG. This regulation applies to advertising both within and outside professional circles and aims to exclude any undue influence through promotional gifts in the field of advertising for medicinal products. One of these exceptions is „small items of negligible value" (Section 7 (1) Sentence 1 clause 2 No. 1 HWG). A small gift of negligible value exists if any relevant undue influence on the target group appears to be ruled out and the gift serves to express general customer friendliness. The value limit for this is only 1 EUR – at least for so-called public advertising, i.e. advertising outside medical circles.[26]

The ECJ confirmed the strict requirements of the HWG in a recent ruling.[27] The Federal Court of Justice (BGH) referred questions to the ECJ for a preliminary ruling on the conformity of Section 7 HWG with European law. In the proceedings in question, the BGH dealt with a legal dispute between the mail-order pharmacy DocMorris and the Apothekerkammer Nordrhein (North Rhine Chamber of Pharmacists) (Germany). DocMorris had been prohibited from various advertising measures due to violations of the uniform pharmacy retail price for price-controlled medicines in Germany.

[26] Federal Court of Justice, judgment of July 17, 2025 – I ZR 43/24 – PAYBACK.
[27] ECJ, judgment of February 27, 2025 – C-517/23 – Apothekerkammer Nordrhein v. DocMorris NV.

In its decision, the ECJ differentiated between non-prescription and prescription drugs. According to Directive 2001/83/EC, which fully harmonizes the HWG, granting advantages is not permitted if the financial incentive for prescription drugs can also promote the purchase of non-prescription drugs. This is the case, for example, when vouchers are issued for the redemption of a prescription that can also be redeemed for subsequent orders of non-prescription drugs. The ECJ further ruled that a Member State may prohibit a financial incentive for prescription-only medicines on grounds of consumer protection, even if it does not simultaneously promote the purchase of non-prescription medicines, if its exact amount is not apparent to the customer in advance.

In addition, the ECJ states in its judgement that not every discount campaign for a prescription drug falls under the advertising term of Directive 2001/83/EC and thus under the absolute ban on advertising to the general public. The discount promotion does not promote the sale of the medicinal product if, when prescriptions are dispensed, price reductions or bonuses are granted immediately in the amount of a previously specified amount. Such discount promotions do not promote the sale of the medicinal product in question but only relate to the decision in favor of the pharmacy.

12. How are physicians who offer telemedicine liable? How are platform operators liable?

a) Liability of physicians

Physicians who offer telemedicine may be liable under contract pursuant to Section 280 (1) of the German Civil Code (BGB) in conjunction with the treatment contract and under tort law pursuant to Section 823 (1) BGB. The applicable standard of care for distance treatment must be specified objectively and individually for each case. Physicians providing distance treatment must inform their patients about the restrictions and limitations of exclusive distance treatment and must ensure throughout the diagnosis and treatment that their medical knowledge and skills are sufficient to provide adequate care for their patients. If the treatment requires special medical knowledge, possibly from a specialist, the patient must be referred to a suitable clinic. A breach of duty of care due to negligence occurs, for example, if it is not sufficiently checked whether all the information required for the diagnosis or treatment can really be obtained via telemedicine. To avoid liability risks, physicians should always request in-person treatment when in doubt. If the duties of care is observed, physicians providing distance treatment cannot be accused retrospectively of having been able to avoid damage to health by providing physical treatment.

[26] BGH, Urteil vom 17.07.2025 – I ZR 43/24 – PAYBACK.
[27] EuGH, Urteil vom 27.02.2025 – C-517/23 – Apothekerkammer Nordrhein./. DocMorris NV.

b) Liability of telemedicine platform operators

The **liability of platform** operators offering telemedicine is subject to a complex legal framework that includes both general liability principles for platforms and specific medical law requirements.

Platform operators offering telemedicine are generally subject to the regulations for information society service providers. The central liability privilege is found in Art. 6 of Regulation (EU) 2022/2065 (Digital Services Act – DSA). According to this, a hosting service provider is not liable for information stored on behalf of a user if:

- it has no actual knowledge of illegal activity or illegal content and, with regard to claims for damages, is not aware of any facts or circumstances from which illegal activity or illegal content is apparent, or

- as soon as it obtains such knowledge or awareness, it acts expeditiously to block access to the illegal content or to remove it.

The liability privilege does not apply if the user is subordinate to or supervised by the service provider. The exception in Art. 6 (3) DSA is particularly relevant for the consumer protection liability of online platforms which enable consumers to conclude distance contracts with entrepreneurs, if the platform displays the specific individual information or enables the transaction in such a way that an average consumer can assume that the information or service is provided by the platform itself or by a user under its supervision.

In contrast to general platforms, telemedicine platforms are subject to increased duties of care because they operate in the sensitive area of healthcare. The Higher Regional Court of Karlsruhe has clarified that electronic marketplace operators for pharmacies who are responsible for the homepage in accordance with Section 5 of the German Telemedia Act (TMG) may be liable for injunctive relief in accordance with Sections 3, 3a, 8 (1) UWG in conjunction with Section 9 HWG.[28]

[28] Higher Regional Court of Karlsruhe, judgment of December 22, 2022 – 4 U 262/22.

Telemedicine platforms also have special **traffic obligations** that go beyond the general requirements for platform operators. This includes in particular:

- **Verification obligations when accepting physicians:** The platform must ensure that only licensed physicians with the appropriate authorization are active on the platform.[29]

- **Monitoring compliance with professional regulations:** The platform must ensure that the physicians working through it comply with professional regulations, in particular the regulations on distance treatment pursuant to Section 7 MBO-Ä.[30]

- **Ensuring data integrity and security:** Special requirements for the protection of sensitive health data.[31]

Platform operators can reduce their liability by:

- carefully checking the medical licenses and approvals of physicians,

- regularly monitoring compliance with professional regulations, and

- establishing clear delegation agreements that preserve the responsibility of physicians.

To reduce liability, it is important that:

- the platform makes it clear that it only offers technical intermediary services,

- physicians are clearly identifiable as independent service providers, and

- the limits of telemedicine are communicated transparently.

The burden of proof for the existence of the conditions for liability privilege lies with the platform operator. It must prove that it had no knowledge of illegal content and acted immediately upon becoming aware of it.

If telemedical treatment is provided by a physician via a third-party digital platform, the platform operator may, in principle, be subject to contractual liability pursuant to Section 280 (1) BGB. However, this requires an independent contractual relationship between

[29] Munich Social Court, judgment of April 29, 2025 – S 56 KA 325/22.
[30] Munich Social Court, judgment of April 29, 2025 – S 56 KA 325/22.
[31] BeckOK SozR/Scholz, SGB V, Section 307, para. 11.

the platform operator and the patient. Whether such a contractual relationship exists is a question of the individual case and depends largely on the external appearance of the platform operator. If the platform operator does not appear externally at all, but only the physician, and the platform operator merely provides the digital infrastructure, the contractual relationship exists exclusively between the physician and the patient.

If there is an independent contractual relationship between the patient and the platform operator, a clear demarcation of responsibilities between the platform operator and the physician is necessary: The platform operator is not liable for medical malpractice unless the specific contractual agreements stipulate otherwise. However, the platform operator‘s liability extends to the proper provision and maintenance of the functionality of the digital infrastructure. If there is a technical error in the infrastructure that leads to damage to health, patients can assert claims for damages against the operator. Any liability exemptions in the terms and conditions for damage to health are generally invalid.

As mentioned above, the platform operator is also responsible for carefully selecting the physicians who want to offer their telemedical treatment on its platform. This duty of care includes taking into account their professional qualifications and the fulfillment of technical requirements by the physicians providing distance treatment. In addition, platform operators must follow up on reports of professional or criminal violations by physicians and, if necessary, exclude physicians from further use of the platform after a fruitless warning. However, ongoing monitoring of the physicians working on the platform cannot be imposed on the platform operator due to a lack of actual control options.

Part IV: Telemedicine and Data Protection

13. Does the use of telemedicine always require the explicit consent of the patient?

No. Healthcare treatment is not subject to consent simply because it is provided using telemedicine methods. For physicians and hospitals, the processing of health data in the context of medical treatment is regularly legitimized by the broadly defined legal permissions of Art. 9 (2) (h) General Data Protection Regulation (GDPR) in conjunction with Section 22 (1) No. 1 (b) German Federal Data Protection Act (BDSG). This also includes telemedicine services such as telemonitoring, teleconsultation, or teleconsultation, in which several physicians may be involved. Separate consent under data protection law is not required for this (unless consent is required for certain data transfers anyway, see, for example, Section 140a (5) German Social Security Code, Book V (SGB V)).

There is a special regulation for video consultations. Section 4 (2) of Annex 31b BMV-Ä (Federal Framework Agreement for Physicians) obliges the attending physician to obtain the patient‘s consent to the data processing of the video service provider used for a video consultation. This must meet the requirements of Art. 7, 9 (2) lit. a GDPR. Further requirements beyond the provisions of the GDPR also arise from Annex 31b BMV-Ä. For example, the video service provider must be certified and data processing may only take place within the EU or a country for which an adequacy decision pursuant to Art. 45 (3) GDPR exists.

If distance treatment is carried out via an online platform, all parties involved must always check whether the platform operator acts as a processor (Art. 28 GDPR) or whether joint controllership (Art. 26 GDPR) applies. In the case of processing, the data protection obligations apply solely to the (distance) physician. No separate legal basis (in particular no consent) is required for the transfer to and data processing by the platform operator (provided that the data processing remains within the scope of the processing and no processing for the platform operator‘s own purposes takes place). The situation is different in the case of joint controllership: here, the transfer and processing of treatment data by the platform operator requires the patient‘s consent. All parties involved must also conclude a joint controllership agreement that meets the requirements of Art. 26 GDPR. The distinction between order processing and joint controllership is sometimes difficult and requires consideration and examination on a case-by-case basis. The attending physician or healthcare facility must do this before introducing a specific telemedicine solution or platform, if only for criminal law

reasons (cf. Section 203 of the German Criminal Code (StGB), see below). However, the provider also has a vested interest in ensuring that the circumstances are legally clear and transparent, on the one hand because it too has obligations under Art. 26 and 28 GDPR, among others, and on the other hand because a clear data protection structure is a prerequisite for the successful distribution of its own product.

14. How can medical confidentiality be maintained when telemedicine platforms or IT service providers are involved in treatment? What are the requirements with regard to Section 203 StGB?

According to Section 203 (1) No. 1 StGB, physicians are subject to confidentiality, which means that they may not disclose patient secrets without authorization. This includes, in particular, health data, diagnoses, and treatment information. Confidentiality protects the relationship of trust between physician and patient.

According to Section 203 (3) Sentence 1 StGB, persons bound by professional secrecy may only pass on information to so-called „professional assistants“ without this constituting a breach of confidentiality. This includes persons who work closely with the physician and are bound by instructions, such as medical assistants or nurses. External telemedicine platforms or IT service providers are not included.

To enable professionals such as physicians to legally involve such external service providers, Section 203 (3) Sentence 2 StGB allows cooperation with „other persons involved.“ However, strict requirements must be met for this. According to Section 203 (4) No. 1 StGB, the platform operator/IT service provider must be bound to secrecy. Due to Section 203 (4) No. 2 StGB, the platform operator/IT service provider should also be obliged to require its employees and subcontractors to maintain confidentiality and to instruct them about the possible criminal liability under Section 203 (4) StGB. The relationship between Section 203 StGB and Article 28(3) (b) GDPR is controversial. If a contract for order processing – as is often the case in practice – does not expressly contain the obligations required by Section 203 StGB and the contract does not specifically refer to Section 203 StGB, the question arises as to whether a clause that meets the requirements of Art. 28 (3) (b) GDPR also fulfills the requirements for due diligence under Section 203 StGB. Foreign platform operators and IT service providers in particular are often unfamiliar with Section 203 StGB, and in some cases there is also a reluctance to include an explicit clause on Section 203 StGB in the contract. In our opinion, a clause that complies with Art. 28 (3) (b) GDPR essentially covers the requirements of Section 203 StGB. Nevertheless, we recommend including an explicit clause on Section 203 StGB in contracts. If the contractual partner is not willing to do so, this, however, would not constitute a „showstopper“ with regard to the conclusion of the contract, but in any way requires a case-by-case risk assessment.

15. What data security requirements must be observed when using telemedicine? Are there certain certifications that can or must be relied upon?

When using telemedicine, specific data protection requirements must be observed, whereby a distinction must be made in this context depending on whether the telemedicine application is operated within or outside the telematics infrastructure (TI).

The telematics infrastructure is the secure digital network for the German healthcare system, which is centrally controlled by the federal government and gematik. This security infrastructure is organized centrally. Users of the TI, i.e., physicians, hospitals, and other healthcare providers, are obliged to use certified TI components and comply with security requirements. However, they do not have to produce the basic security technology themselves, but rely on the infrastructure provided by the federal government and gematik.

Telemedicine services outside the TI are fully responsible for ensuring data security. The entity responsible under the GDPR – usually the physician or hospital – is obliged to implement the technical and organizational measures (TOM) in accordance with Art. 32 GDPR. These measures must be state of the art and appropriate to the risk of processing. These include in particular:

- → End-to-end encryption for data transmission and storage
- → Secure server infrastructure with access restrictions,
- → Multi-factor authentication for identity verification,
- → Complete logging of accesses to protect against misuse.

To meet these requirements, actors can refer to established standards and certifications. The ISO standards 27001 and 27799 are particularly relevant here. While ISO 27001 defines general requirements for an information security management system (ISMS), ISO 27799 is specifically aimed at organizations in the healthcare sector and provides concrete recommendations for the protection of sensitive health data.

16. Does a data protection impact assessment have to be carried out before using telemedicine?

According to Art. 35 (1) GDPR, if a form of processing, in particular when using new technologies, is likely to result in a high risk to the rights and freedoms of natural persons due to the nature, scope, circumstances, and purposes of the processing, the controller shall carry out a data protection impact assessment in advance. The regulatory example in Art. 35 (3) (b) GDPR provides for the obligation to carry out a data protection impact assessment, in particular in the case of „extensive“ processing of personal health data. Irrespective of this, the need for a data protection impact assessment for telemedical treatments also arises from the positive list in accordance with Art. 35 (4) GDPR. According to point 16 of this list (https://www.lda.bayern.de/media/dsfa_muss_liste_dsk_de.pdf), a data protection impact assessment must be carried out for the „use of telemedicine solutions for the detailed processing of health data“ even if the data processing is not considered „extensive“ within the meaning of Art. 35 (3) (b) GDPR. It is required „if data processing using sensors or mobile applications is not a one-off event and the data is received and processed by a central location.“ An example given is a physician who „uses a web portal or (...) an app to communicate with patients via video telephony and to collect and process health data in detail and systematically using sensors on the patient (...). By means of a so-called threshold analysis, it must be examined and documented in each individual case on the basis of the above-mentioned parameters (cf. Art. 5 (2) GDPR) whether a data protection impact assessment must be carried out. The obligation to carry out a data protection impact assessment lies with the data controller. From the perspective of a telemedicine platform acting as a processor, it may nevertheless be useful for marketing purposes to provide its own customers with a template or framework for a data protection impact assessment.

Part V: Telemedicine and AI

17. To what extent does the AI Act influence the use of AI in telemedicine?

Artificial intelligence (AI) is also playing an increasingly important role in the context of telemedicine. It is no longer science fiction that AI-supported applications are used to make the diagnosis, treatment, and care of patients more efficient and precise. They can analyze medical data such as images and laboratory values and assist physicians in detecting diseases. Telemedicine also enables medical care and consultation across geographical distances, so that diagnoses can be made regardless of location. Intelligent chatbots and virtual assistants enable round-the-clock consultation, while vital parameters can be evaluated continuously and automatically. AI is therefore already contributing to a significant increase in the quality and accessibility of telemedicine.

The AI Act (Regulation (EU) 2024/1689; „AI Act“) now creates, for the first time, a comprehensive, uniform set of rules across the EU for the development, marketing, and commissioning of AI. It pursues a risk-based approach and links obligations and legal consequences for violations directly to the risk class of an AI system and the role of the respective actor in the value chain.

The central point of reference is the so-called „AI system,“ which is defined in Art. 3 No. 1 AI Act.[32] According to this, an AI system is „a machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments.“ In contrast to classic „if-then“ programmed systems, AI systems are trained using machine learning methods and develop their decision-making logic based on patterns and correlations that they independently recognize from extensive data sets. If an „AI system“ is present in a specific individual case, the requirements of the AI Act must be observed.[33]

The scope of compliance obligations then depends on the role a company plays in the development and/or use of AI. For the purposes of this white paper, the focus will be solely on providers and deployer of AI systems:

[32] This white paper does not address so-called general purpose AI models. The white paper focuses solely on AI systems and the compliance obligations that companies must observe in this regard. If, in individual cases, the placing on the market of a general purpose AI model is (also) under consideration, the relevant legal requirements must be assessed separately.

[33] It should be noted that the requirements of the AI Act will be applied in stages. While transparency requirements pursuant to Art. 50 AI Act will apply from August 2, 2026, requirements for high-risk AI systems pursuant to Annex I of the AI Act will not have to be implemented until August 2, 2027. However, in our opinion, thorough preparation requires that the respective topics be addressed now.

According to Art. 3 No. 3 AI Act, a provider means „a natural or legal person, public authority, agency, or other body that develops an AI system or a general-purpose AI model or that has an AI System or a general-purpose AI model developed and places it on the market or puts the AI system into service under its own name or trademark, whether for payment or free of charge.“ In the context of telemedicine, these are typically software manufacturers or medtech companies that develop an AI-supported application and then offer it to customers (e.g., medical practices) on the European market.

A deployer within the meaning of Art. 3 No. 4 AI Act, on the other hand, means „a natural or legal person, public authority, agency or other body using an AI system under its authority except where the AI system is used in the course of a personal and non-professional activity.“ In telemedicine, this could be a physician´s office or a digital healthcare provider that uses the AI-based application in the treatment process.

Once the role has been clarified from the perspective of the company using AI, the next step is to carry out a risk classification.

18. Is an AI in telemedicine always a „high risk“ AI system?

No, risk classification must always be assessed on a case-by-case basis and based on the actual circumstances. The AI Act distinguishes between four risk classes:

- Prohibited AI practices (Art. 5 AI Act): These include AI systems that manipulate people, make socially harmful assessments, or systematically violate fundamental rights. They do not generally play a role in telemedicine, as telemedicine applications are typically geared toward medical support rather than manipulation or social scoring.

- High-risk AI systems (Art. 6 AI Act in conjunction with Annex I/III): According to the AI Act, high-risk AI systems are defined as systems that may have a significant impact on health, safety, or fundamental rights. Annex I of the AI Act is particularly relevant to the field of telemedicine. The regulation refers to AI systems that are already subject to specific sectoral regulation, such as the Medical Device Regulation (MDR) or the In Vitro Diagnostic Medical Devices Regulation (IVDR), and which are additionally subject to a conformity assessment procedure by third parties. Medical devices are a practical example: If an AI system is a safety component of a medical device or is itself classified as a medical device, it is considered a high-risk AI system under the conditions mentioned above. In addition, Annex III of the AI Act lists further use cases of high-risk AI systems that are geared toward specific purposes, such as in the field of human resources or critical infrastructures. However, these are generally of secondary importance for telemedicine.

- AI systems with limited risk (Art. 50 AI Act): AI systems with limited risk are subject to specific transparency requirements under Art. 50 AI Act, which result from the nature of their use. These include, for example, AI-supported chatbots or certain recommendation systems where users must be informed that they are interacting with AI or that the respective output was generated by AI. In the field of telemedicine, such systems are particularly relevant when there is direct interaction between patients and AI, for example, in the automated answering of health questions or the provision of recommendations. In these cases, it must be ensured, among other things, that the AI character is clearly recognizable to users.

- Minimal risk: AI systems without relevant risks, for which the application of voluntary codes of conduct is sufficient. The AI Act does not provide for any further obligations for such AI systems, which is why they will not be discussed further here.

In telemedicine practice, several case groups can be distinguished that can lead to different risk classes.

a) Diagnostic and therapeutic AI systems

These include, in particular, applications that use patient data – such as image, speech, or laboratory data – to prepare medical diagnoses, suggest treatment options, or predict disease progression. These systems often fulfill the characteristics of a medical device within the meaning of Art. 2 No. 1 MDR, as they are intended as/in software for the detection, prediction, monitoring, or treatment of diseases.

If the AI system is a safety component of a medical device (and it is not only a Class I device) or is even considered a medical device itself, Annex III of the AI Act applies directly: The AI system is classified as a high-risk AI system because the medical device has to go through a conformity assessment procedure by a notified body, as required by the MDR.

b) Administrative or communicative AI systems

AI systems that perform exclusively organizational or communicative tasks in telemedicine – such as scheduling appointments or chatbots for general patient information without a medical decision-making component – do not directly affect the health or safety of patients. They are generally not covered by the MDR and are not included in the high-risk categories of Annex III. They are only subject to the general transparency requirements of Art. 50 of the AI Act, in particular the obligation to provide information about the interaction with AI.

c) Conclusion

The use of AI in telemedicine can lead to classification as a high-risk AI system, especially in diagnostic or therapeutic applications. However, risk classification must always be assessed on a case-by-case basis. Borderline cases can arise in particular with „hybrid“ applications that control both organizational and medically relevant processes.

19. What compliance obligations does the AI Act stipulate for the use of AI in telemedicine?

The AI Act distinguishes between compliance obligations according to the risk of the respective application. This means that high-risk AI systems are subject to more extensive obligations than AI systems that only pose transparency risks.

a) High-risk AI systems

Providers of high-risk AI systems are required by the AI Act to establish a continuous risk management system (Art. 9 AI Act), use high-quality, error-free, and representative data for training, validation, and testing (Art. 10 AI Act), and create comprehensive technical documentation (Art. 11 ff. AI Act). They must ensure that appropriate human oversight is possible at all times (Art. 14 AI Act) and take appropriate measures to ensure the cybersecurity and robustness of the system (Art. 15 AI Act). In addition, there is an obligation to report serious incidents to the competent authorities without delay (Art. 73 AI Act) and to provide clear instructions for use and transparency information (Art. 13 AI Act).

Note:

The AI Act also provides for a conformity assessment procedure for high-risk AI systems in accordance with Art. 16 lit. f) and g) in conjunction with Art. 43 ff. AI Act, which is intended to ensure that requirements for safety, quality, and transparency are met. For suppliers of medical devices that are already certified under the MDR, there is close regulatory integration: if an AI system itself is a medical device or its safety component, the existing MDR conformity procedure can be supplemented by the additional obligations of the AI Act. This means that a separate procedure is generally not necessary, but rather an integrated assessment is possible, provided that the AI-specific requirements-such as those relating to data governance, transparency, risk management, and human oversight-are embedded in the existing quality management system. This avoids duplication of work and facilitates the implementation of the new requirements into existing compliance structures.

Deployers of high-risk AI systems, such as clinics or medical practices, are obliged under Art. 26 AI Act to use the system exclusively in accordance with the instructions provided by the supplier and for the intended purpose, to continuously monitor ongoing operations and to document any malfunctions or deviations, and to report these immediately to the supplier and, in the event of serious incidents, to the competent authorities. In addition, they must ensure that the personnel employed are trained in the proper use of the AI system, take into account the information provided by the supplier on performance, limitations, and risks, and take appropriate measures to protect patient safety and personal data.

b) AI systems with transparency obligations

Providers of AI systems intended for direct interaction with patients – such as chatbots or digital assistance systems in telemedicine – must ensure, in accordance with Art. 50 (1) AI Act, that users are clearly and unambiguously informed that they are interacting with an AI system, unless this is already obvious. This information must be provided in a clear and understandable manner at the latest at the beginning of the first interaction and must comply with the applicable accessibility requirements (Art. 50 (5) AI Act). If the AI system also generates synthetic content, such as automated texts, Art. 50 (2) AI Act requires that this content be marked as artificially generated or manipulated in a machine-readable format. **Deployers** should then ensure in practical operation that the references to the use of AI are clear, understandable, and easily accessible to users. In addition, the personnel employed must be trained in the proper use of AI-based tools (cf. Art. 4 AI Act).

Note: Deployers of AI systems with transparency obligations may be subject to further obligations under the provisions of the AI Act – e.g., the obligation to label so-called deepfakes. However, as this white paper addresses exclusively the field of telemedicine, these obligations are of secondary importance and are therefore not discussed in detail.

c) Conclusion

The compliance obligations under the AI Act depend on the risk profile of the respective AI system. High-risk AI systems require comprehensive technical and organizational measures, while systems with transparency obligations focus on providing clear and comprehensible information to users. Providers and deployers are each independently responsible for compliance with the requirements and must work closely together to fully meet the legal requirements.

20. How can transparency and human oversight be maintained when using AI in telemedicine?

The use of telemedicine requires a high degree of trust on the part of patients, as personal physician-patient interaction is reduced and digital systems – especially those using AI – increasingly operate independently. To meet this need for trust, maximum transparency about the technologies used and clear human control and responsibility are essential. Only in this way can automated decision-making processes remain comprehensible and patient safety be guaranteed.

The AI Act addresses these requirements with binding provisions on transparency (Art. 13 AI Act) and human oversight (Art. 14 AI Act) for high-risk AI systems. Both principles are core components of the „human in the loop“ approach: AI should support medical decisions, but not replace medical responsibility.

Transparency means that the functioning, limitations, and decision-making logic of AI are comprehensible to operators and affected individuals. Providers of high-risk AI systems must therefore provide technical documentation, instructions for use, and information on performance, limitations, and data sources (Art. 13 AI Act). This information enables deployers to fulfill their own obligations and ensure safe use.

> **Note:** From the deployer‘s point of view, clear information about the use of AI and data processing in accordance with Art. 13 and Art. 14 GDPR must also be provided to patients.

Human oversight requires that high-risk AI systems be designed in such a way that they can be monitored, reviewed, and overridden by medical personnel at any time (Art. 14 AI Act). In telemedicine, this is essential to ensure that physicians retain ultimate responsibility (Section 630a BGB). Physicians must be able to review AI-based suggestions and reject them if necessary.

Practical implementation in telemedicine:

- **Explainability:** AI must disclose its decision-making processes, e.g., through visual markings in image analysis or clinical plausibility reports.
- **Documentation and logging:** All inputs, system decisions, and changes must be documented in a traceable manner.
- **Human override:** Functions must be available to manually stop or correct the system in case of doubt.

Implementation by deployers:

- Ensuring clear processes for human control, e.g., dual control principle for critical diagnoses.
- Training of medical staff in dealing with AI results.
- Documentation of medical reviews to preserve the burden of proof (Section 630h BGB).

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