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TABLE OF CONTENTS

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EDITORIAL

COMPLIANCE IN HEATH CARE AND ENVIRONMENT

Apart from typical compliance issues this edition revolves around two primary themes: Health Care and Ecology, providing insights into compliance challenges along with solutions and answers.

Christoph Renk investigates the duties and legal parameters surrounding the Person Responsible for Regulatory Compliance (PRRC) in companies that manufacture medical devices, highlighting the responsibilities and legal exposure of these roles.

Viktoria Neubert sheds light on recent advancements in the European Health Data Space, characterized as a "health-specific ecosystem", which establishes uniform standards and procedures for handling personal data.

Juliane Dost and Ina Schmidbauer delve into the complexities of compliance related health care law and focus on inpatient and outpatient activities by the same Physician.

Furthermore, Luminita Diaconu, a scholar in environmental law, explores how compliance is managed within the ecological domain, particularly through governmental environmental reviews that are crucial for company approvals regarding new waste recycling methods and technologies. She also compares environmental impact assessments on an international scale and relates these insights to the situation in the Republic of Moldova.

With our best regards,

Michele DeStefano, Konstantina Papathanasiou & Hendrik Schneider
Content Curators of CEJ

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THE PERSON RESPONSIBLE FOR REGULATORY COMPLIANCE IN THE MEDICAL DEVICE LAW AND ITS LIABILITY

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TABLE OF CONTENTS

The following article shall – after a quick introduction into the European Medial Device Regulation – examine the duties of the so called „person responsible for regulatory compliance" of medical device manufacturers.

I. BASICS OF MEDICAL DEVICE REGULATION

Since May 26, 2021, medical device law has been directly regulated in the European Union by the Medical Device Regulation (EU) 2017/745 (MDR). The national medical device laws that implemented the previous European Directives no longer apply. The term „medical device" is defined in Art. 2 Nb. 1 MDR as any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more specific medical purposes, like diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease. In contrast to medicinal products, medical devices do not achieve their principal intended action by pharmacological, immunological or metabolic means.

The MDR lays down rules concerning the placing on the market, making available on the market or putting into service of medical devices for human use and accessories for such devices in the EU (Art. 1 (1) S. 1 MDR). With the MDR, the EU wants to ensure a high level of protection of health for patients and users and at the same time, set high standards of quality and safety for medical devices in order to meet common safety concerns (see recital (2) of the MDR). Therefore, a manufacturer is only allowed to place a device on the market, if the device has been designed and manufactured in accordance with the requirements of the MDR (Art. 5 MDR). To prove this, the MDR requires a conformity assessment procedure. The scope the conformity assessment procedure depends primarily on the risk class of the medical device (s. Art. 52 MDR). Except for products in risk class I, manufacturers must involve a notified body like TÜV in the conformity assessment procedure. The notified body controls especially the technical documentation and/or the quality management system of the manufacturer. The assessment is completed by affixing a CE marking of conformity on the device (Art. 20 MDR).

II. PERSON RESPONSIBLE FOR REGULATORY COMPLIANCE (PRRC)

One major innovation of the MDR was the introduction of the person responsible regulatory compliance ("PRRC", or Article-15-Person). This is regulated in Art. 15 MDR: Manufacturers shall have available within their organisation at least one[1] PRRC who possesses the required expertise in the field of medical devices. In regard of these qualifications, see Art. 15 (1) (a) to (b).

Out of the formulation "within their organisation" it can be discussed whether a freelancer can be appointed as PRRC or if the PRRC has to be an employee of the manufacturer. Art. 15 (2) MDR, which only allows micro and small enterprises to not have the person responsible for regulatory compliance within their organisation but allows them to have such person permanently and continuously at their disposal, suggests that all other manufacturers must appoint an employee as PRRC. This is also the

[1] If the manufacturer appoints more than one, see Art. 15 (4) MDR.

recommendation of the guideline by the Medical Device Coordination Group of the European Commission.[2]

According to Art. 15 (3) MDR, the PRRC shall at least be responsible for ensuring that (a) the conformity of the devices is appropriately checked, in accordance with the quality management system under which the devices are manufactured, before a device is released; (b) the technical documentation and the EU declaration of conformity are drawn up and kept up-to-date; (c) the post-market surveillance obligations are complied with in accordance with Art. 10 (10) MDR; (d) the reporting obligations referred to in Art. 87 to 91 MDR are fulfilled; (e) in the case of investigational devices, the statement referred to in Section 4.1 of Chapter II of Annex XV MDR is issued. This means, that the manufacturer needs to appoint (at least) one of its employees as an PRRC and that he has to give the PRRC at least (!) the responsibilities in Art. 15 (3) (a) to (e). The manufacturer is free to give the PRRC more responsibilities if he wants to. The scope of this should be defined in the employment contract. Furthermore, the MDR demands that the PRRC shall suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his or her duties (Art. 15 (5) MDR). The manufacturer therefore needs to ensure this via contractual agreements with the PRRC and through SOPs in regard of its other employees. The manufacturer must give the PRRC the authority to enforce the regulatory compliance in its organisation. If the PRRC is unable to meet its obligations, the PRRC should inform the manufacturer about it.[3]

The PRRC has a relevant position in the manufacturers' organization. The PRRC is the needle eye for the regulatory duties: Especially, each release of products must be approved by the PRRC. With other words, every medical device placed on the market needs the approval of the PRRC. As an employee of the manufacturer, the PRRC has the obligation to denounce nonconformities – for example, if nonsterile devices are to be released – and shall suffer no disadvantages out of such.

III. LIABILITY OF THE PRRC

In the following, we want to focus on Art. 15 (3) (a) MDR and the possible liability of the PRRC for breaching these duties: The PRRC must ensure, that each released device is in accordance the quality management system under which the device is manufactured. This duty refers to Art. 10 (9) S. 3 MDR. According to this, manufacturers of devices must establish, document, implement, maintain, keep up to date and continually improve a quality management system that shall ensure compliance with the MDR in the most effective manner and in a manner that is proportionate to the risk class and the type of device. Whereas the manufacturer is obliged to establish the quality management system to get the declaration of conformity for his devices, the PRRC is obliged to ensure that each device for release has followed the procedures established in the quality management system before being placed on the market.[4] The PRRC therefore must monitor and control the manufacturing process. The MDCG gives examples of how this can be done. Accordingly, the PRRC must audit or sample that all verifications, validations and other tests provided for in the quality management system have been carried out before devices are released. If – for example – a manufacturer places sterile devices on the market,

[2] MDCG 2019-07 Rev.1, p. 5 – these Documents are only interpretation aids for the industry, notified bodies and authorities, the ECJ alone has ultimate responsibility for interpreting the MDR. But nevertheless, these MDCG Documents have a high level of practical relevance.

[3] MDCG 2019-07 Rev. 1, p 8.

[4] MDCG 2019-07 Rev 1, p. 6.

like implants, the sterilisation process needs to fulfil the ISO-standards on sterilisation. In our example, the sterilisation process of the manufacturer does not fulfil these requirements, because the relevant SOP gave wrong instructions for the process. As a result, nonsterile products were placed on the market and resulted in harm to patients. It would have been possible to the PRRC to recognize the nonconformity of the implants before the release. Can the injured patients assert claims for damages against the PRRC? The question of the liability is still ruled in national law and can here only be discussed for German law.

IV. CIVIL LIABILITY

Under the German law a possible claim can result out of § 823 (2) BGB, if the violation of Art. 15 MDR is a protection law (Schutzgesetz[5]). The question, whether the medical device law aims to protect third parties is already answered for the liability of a notified body in regard of the so called PIP-Scandal[6]: The ECJ judged, that the medical device laws not only aim to abstractly protect the public health , but also each and every individual end user of medical devices.[7] The ECJ further says "that Directive 93/42 is to be interpreted as meaning that in the procedure relating to the EC declaration of conformity, the purpose of the notified body's involvement is to protect the end users of medical devices." This means, that a notified body can be hold responsible for not correctly auditing the quality management system of a manufacturer. The German Federal Courd (BGH) concluded, that the medical device laws are – in regard of the duties of a notified body – protection laws in the sense of § 823 (2) BGB and that patient can have a claim against a notified body.

These conclusions can be transmitted to the question on the liability of the PRRC, if Art. 15 MDR not only aims to protect the public, but also aims to protect each patient/user of the medical device for the risks of a nonconforming product. A personal responsibility of the PRRC can be based on the wording of Art. 15 (1) MDR, which hints that the PRRC is itself responsible and does not just have an accessory responsibility to the manufacturer's responsibility.[8] Especially the duty of Art. 15 (3) (a) MDR could demand the PRRC to prohibit the placing on the market of nonconforming devices. The MDR requires that the PRRC has appropriate powers to take such measures (Article 15 (5) MDR). If the PRRC fails to take such measures, it could be consequential, that he/she can be held responsible for his/her failure by the damaged patients. On the other hand, if the manufacturer does not secure the PRRC's powers or ignores the PRRC's recommendations, the manufacturer can be hold responsible for its organizational fault.[9] But strong counterarguments can also be made against the analogy to the judgement of the ECJ to the liability of a notified body: Notified bodies act as indirect state administration. They are appointed by an authority of an EU-member state to fulfil governmental task to audit that the manufacturers comply to the MDR. If there were no notified bodies, the conformity assessment would be a state task. This quasi-governmental task of the notified body could be the reason why the notified body's responsibility is to protect patients and end users. The obligations of the PRRC, however, arise from an employment contract with the manufacturer. The PRRC is only obliged to its employer, the manufacturer. Therefore, it could be concluded that Art. 15 MDR does not intend

[5] For the definition of a Schutzgesetz see BGH, Urteil vom 27.02.2020 - VII ZR 151/18, RN 40 with further sources.

[6] See https://www.aerzteblatt.de/archiv/124347/Skandal-um-Brustimplantate-Die-unsichtbare-Gefahr; https://edition.cnn.com/2012/01/27/world/europe/pip-breast-implant-scandal-explained/index.html.

[7] ECJ, Judgement of the 16 February 2017 – C-219/15, RN 50.

[8] *Hill/Schmitt,* WiKo Medizinprodukterecht, Lfg. 21 Oktober 2019, Art. 15 MDR, RN 49.

[9] *Hill/Schmitt,* WiKo Medizinprodukterecht, Lfg. 21 Oktober 2019, Art. 15 MDR, RN 49.

to protect patients or (end) users of medical devices, but only demands manufacturers to appoint a PRRC with (at least) the mentioned responsibilities and that the noncompliance with Art. 15 MDR only leads to an organizational fault of the manufacturer. *Rehmann* rightly emphasizes that liability of the PRRC beneath the manufacturers liability could also be inappropriate in the liability law system in view of the impending liability amounts.[10] Therefore, it can be argued that the patient's injury cannot be attributed to PRRC, but only to the manufacturer.

V. CRIMINAL LAW

However, if Art. 15 MDR is nonetheless a protection law for patients and end users, the criminal responsibility of the PRRC needs to be discussed. Under the German law, the PRRC's fault to prevent the placing on the market of non-sterile implants (see example above), could be a negligent assault (§ 229 StGB).

In German criminal law, the dependence of a criminal norm on a behavioural norm is discussed and whether the dependence is strictly accessory or limitedly accessory.[11] Particularly for elements of the criminal norm that would otherwise violate the principle of certainty (Art. 103 (2) GG), it is discussed to limit the liability to obvious breaches of duty.[12] Therefore, the non-criminal dereliction of duty in cases of infidelity (§ 266 StGB) is only relevant under criminal law if it is evident. It must be stated, that the PRRC's duties out of Art. 15 (3) MDR are relatively uncertain: The medical device law often uses vague legal terms, like "appropriately checked" (Art. 15 (3) (a)) and often refers to technical standards (like ISO-Norms) or the propriate risk class. Especially, there are currently no binding guidelines[13] as to when the PRRC has "appropriately checked" the device's conformity. With other words: No once can currently predict, when a PRRC fails to comply with its duty. Consequently, it could be argued that the PRRC is only criminal liable if he/she evidently fails to fulfil his/her duties. This could only be roughly outlined at this point and need to be examined in more detail.

VI. CONCLUSION

There are currently no known liability claims against PRRC. But it is to be feared that this will not remain the case for too long. The jurisprudence must, in advance of such cases, consider how liability of the PRRC can be legally justified or denied. Manufacturers shall insure their PRRC against the civil liability. Since the criminal liability can not be insured, it is the task of jurisprudence to find appropriate solutions, like a limited accessory interpretation of the criminal law to the medical device law.

[10] See also *Rehmann,* in: Rehmann/Wagner MP-VO, 4. Auflage 2023, Art. 15 Rn. 8.

[11] See e.g. *Rostalski,* Tatbegriff im Strafrecht 2019, p. 17 ff. with reply from *Herzberg*, ZIS 2021, 420 (420 ff.); *Rostalski*, GA 2016, 73 (73 ff.) with reply from *Herzberg*, GA 2016, 737 (737 ff.); *Lüderssen*, in: Festschrift Eser, 171; *ders*., in: FS Schroeder 2006, 570; *Borrmann,* Akzessorietät des Strafrechts zu §§ 1901a ff. BGB, 120.

[12] BVerfG, Beschluss vom 23.06.2010 – 2 BvR 2559/08, 2 BvR 105/09, 2 BvR 491/09.; BVerfG, Nichtannahmebeschluss vom 28.07.2015 – 2 BvR 2558/14, 2 BvR 2571/14, 2 BvR 2573/14, 1798 (Rn. 64); BVerfG, Beschluss vom 09.02.2022 – 2 BvL 1/20, 479 (Rn. 98); from the literature: Satzger, in: SSW-Strafgesetzbuch, § 1, Rn. 21; Basak, in: Matt/Renzikowski Strafgesetzbuch, § 1, Rn. 15a; Jahn/Ziemann, ZIS 2016, 552 (560); Kuhlen, JR 2011, 246 (249); Krüger, NStZ 2011, 369 (372); Saliger, ZIS 2011, 902 (903 f.); ders., NJW 2010, 3195 (3195); Landau, NStZ 2015, 665 (670); Hassemer/Kargl, in: Nomos-Kommentar StGB, § 1, Rn. 71; Kirsch, Gesetzlichkeitsprinzip im Allgemeinen Teil, 157.

[13] Even the MDCG Document seems vague on the PRRC's duties.

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SECONDARY USE OF DATA IN THE EHDS: ENSURING COMPLIANCE

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TABLE OF CONTENTS

The healthcare sector is undergoing a rapid transformation driven by digitalisation. This includes a wide range of advances such as electronic patient records, digital prescriptions, health apps, telemedicine, big data platforms and the creation of global research data hubs. Healthcare professionals regularly manage significant amounts of health data. To improve healthcare delivery, research capacity and overall infrastructure across the EU, digitalisation of the healthcare system is essential. A European Health Data Space (EHDS) is expected to be in place by 2025 at the latest, enabling standardised electronic exchange of health data across the EU.[1]

I. STEPS TOWARDS AN EHDS

The first steps to establish an EHDS were made in 2011, when the Patient Directive[2] was established. Its aim was enhancing cooperation and information exchange among member states within a voluntary network.[3] However, only about ten member states have implemented the infrastructure known as 'MyHealth@EU', which provides cross-border health services such as e-prescriptions and patient summaries.[4] The implementation of the General Data Protection Regulation (GDPR)[5] has not significantly improved access to and transmission of electronic health data. Limited interoperability among digital health service providers next to too little provided data remained an issue.[6] In 2020, the European data strategy[7] proposed the creation of European data spaces. The first sector-specific data space suggested was the EDHS.[8] In this context, the European Commission has proposed a draft regulation (EDHS-draft). End of 2023 the European Parliament voted on the draft regulation and accepted it with several amendments (EDHS-draft Parliament).[9]

The primary goal of the EDHS(-draft) is to provide EU citizens with better digital access to their electronic health data, empowering them to exercise more control. Furthermore, its objective is to improve the effectiveness of healthcare systems and advance health-related research, innovation, and policy-making by facilitating access to and sharing of electronic health data.[10]

[1] Draft European Parliament - Legislative Resolution on the proposal for a regulation of the European Parliament and of the Council on the European Health Data Space (COM(2022)0197 – C9-0167/2022 – 2022/0140(COD)), p.2.

[2] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare 2011.

[3] Moritz Hennemann and Björn Steinrötter, 'Hennemann/Steinrötter: Data Act – Fundament Des Neuen EU-Datenwirtschaftsrechts?' [2022] Neue Juristische Wochenschrift 1481.

[4] 'Electronic Cross-Border Health Services - European Commission' (9 January 2024) <https://health.ec.europa.eu/ehealth-digital-health-and-care/electronic-cross-border-health-services_en> accessed 17 February 2024; Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on measures for a high common level of cybersecurity across the Union, repealing Directive (EU) 2016/1148 2020.

[5] 'Regulation - 2016/679 - EN - Gdpr - EUR-Lex' <https://eur-lex.europa.eu/eli/reg/2016/679/oj?locale=en> accessed 17 February 2024.

[6] Written Johan Hansen and others, 'Assessment of the EU Member States' Rules on Health Data in the Light of GDPR'.

[7] 'European Data Strategy - European Commission' <https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/europe-fit-digital-age/european-data-strategy_en> accessed 17 February 2024.

[8] Draft European Parliament - Legislative Resolution on the proposal for a regulation of the European Parliament and of the Council on the European Health Data Space (COM(2022)0197 – C9-0167/2022 – 2022/0140(COD)), p.2.

[9] 'Texts Adopted - European Health Data Space - Wednesday, 13 December 2023' <https://www.europarl.europa.eu/doceo/document/TA-9-2023-0462_EN.html> accessed 17 February 2024. The article names just the EHDS-draft if no significant changes were made by the Parliament.

[10] Draft European Parliament - Legislative Resolution on the proposal for a regulation of the European Parliament and of the Council on the European Health Data Space (COM(2022)0197 – C9-0167/2022 – 2022/0140(COD)), p.2-4.

To achieve this goal data protection and compliance are crucial in the healthcare sector, particularly for the EHDS. They ensure the protection of sensitive healthcare data, compliance with legal regulations, and patient trust. By taking appropriate measures to secure and lawfully process data, risks can be minimized while supporting secure data exchange and trustworthy patient care. Overall, data protection and compliance are essential pillars to ensure the integrity and effectiveness of the EHDS.[11]

The EHDS-draft states that personal health data will be processed in compliance with stringent data protection regulations, such as the GDPR.[12] The directive mandates that personal data must be processed lawfully, fairly, and transparently, with measures in place to ensure confidentiality, integrity, and availability as can be seen in Art. 5 GDPR. However, there has already been criticism of its implementation, particularly in relation to the use of data.[13]

II. ENSURING COMPLIANCE - FORM OF DATA

In the EDHS-draft, personal health data undergo anonymization and subordinary pseudonymization processes to protect privacy, Art. 44 (2), (3) EDHS-draft. Anonymization removes or alters identifying information from data sets, making it impossible to link the data to an individual.[14] While pseudonymization replaces identifying information with pseudonyms that can only be linked back to individuals using additional information stored separately.[15]

Anonymisation and pseudonymisation are essential techniques used to minimise the risk of re-identification and unauthorised access to sensitive health information. The EDHS aims to strike a balance between facilitating valuable health research and innovation while protecting individuals' privacy rights by de-identifying personal health data. Furthermore, access controls and encryption may be implemented to further enhance the security of pseudonymised data within the EDHS ecosystem.

III. COMPLIANCE MEASURE - USE OF DATA

The EHDS-draft defines primary use as the use of electronic health data for the provision of healthcare services (e.g. to assess a patient's state of health or to prescribe medication). Primary use in the EHDS refers to the use of electronic health data for direct patient care purposes. This includes activities such as diagnosis, treatment of diseases, prescription of medicines and monitoring of a patient's health status. Primary use is intended to meet the immediate needs of patients and to ensure high quality healthcare.[16]

[11] ibid 39a; Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space 2022 2–4.

[12] Draft European Parliament - Legaislative Resolution on the proposal for a regulation of the European Parliament and of the Council on the European Health Data Space (COM(2022)0197 – C9-0167/2022 – 2022/0140(COD)) (n 6), p.3.

[13] E. g. https://www.aerztezeitung.de/Wirtschaft/Organisationen-aeussern-Kritik-am-Datenschutz-im-EU-Gesundheitsdatenraum-438319.html.

[14] 'Regulation - 2016/679 - EN - Gdpr - EUR-Lex' (n 4), CR (26); Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space, Recital (49).

[15] ibid. EuGH, 20012022 - C-165/20 [2022] EuGH C-165/20 [55]. The re-identification of pseudonymized data is forbidden. Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space, Recital (49). For the use of pseudonymized data, this must be requested separately, and reasons must be given as to why the provision of anonymized data is not sufficient in this case.

[16] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space, Art 12 ff.

Secondary use, on the other hand, concerns the processing of electronic health data for specific purposes in the public interest (including research, innovation, policy-making, regulation, patient safety and personalised medicine).[17] It also provides a reliable and efficient setup for the secondary use of health data. Thereby trust is essential for the success of the EHDS. It builds upon existing legal frameworks while addressing the unique sensitivity of health data.[18] The EHDS-draft defines types of data that can be used for secondary purposes.[19]

A. Players involved in secondary data use

In the context of the secondary use within the EHDS, there are three main players involved in the data access mechanism: data holders, health data access points, and data users. Data holders are natural or legal persons who are active in the health care sector or who conduct research in these areas and receive data from the patients/user. These can include hospitals, medical practices, health insurance companies, pharmaceutical companies, research institutes, EHR system manufacturers, controllers or processors based in the Union, and those in third countries who participate in the cross-border infrastructure for the primary use of health data and certain EU institutions authorized to provide health data.[20]

Health data access points are public bodies that provide access to electronic health data for secondary use. Member States may establish new public bodies or use existing ones. In Germany, the 'Health Research Data Centre' is expected to be the central access point for the EHDS. [21] Data users are individuals or organizations that have legal access to electronic health data for secondary use. Entities located within or outside the Union may receive electronic health data from data holders based in the Union.[22]

B. In need of a consent

The main legal challenge arises from the intended secondary use of the data by the data users. The obligation of the data holder to provide data applies to public, non-profit, or private health and care providers, organizations, and research institutions in the health or care sector. However, micro-enterprises with fewer than ten employees or less than 2 million in turnover are exempted from this obligation. These data holders must provide a description of their data sets, report their existence, and make them available upon request.[23]

[17] Draft European Parliament - Legislative Resolution on the proposal for a regulation of the European Parliament and of the Council on the European Health Data Space (COM(2022)0197 – C9-0167/2022 – 2022/0140(COD)), p.2-4.
[18] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space, p. 1, 5, 6.
[19] Draft European Parliament - Legaislative Resolution on the proposal for a regulation of the European Parliament and of the Council on the European Health Data Space (COM(2022)0197 – C9-0167/2022 – 2022/0140(COD)) (n 1).Art. 2 (2) d, e EDHS-draft.
[20] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space, Art. 1 (3) a, b; Art.2 (2) y.
[21] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space, Art. 36.
[22] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space, Art. 2 (2) z.
[23] Recital (41) EHDS-draft.

In the EHDS draft, it was not necessary to obtain consent for the secondary use of data, unless mandated by national law. The principle behind this is that data collected and processed using public funds should be made available for research purposes[24] and no individual interest should come across this aim.

Following the amendment by Parliament, a consent mechanism was included for secondary use. The reason for the change was to ensure the preservation of trust in doctor-patient relationships, it is imperative to uphold the principle of professional secrecy and the patient's entitlement to confidentiality when implementing digital healthcare services and to be compliant with the data security regulations within the EU.

Therefore, an opt-out mechanism should be established that is easily understandable and accessible in a user-friendly format (Art. 33 (5) EHDS-draft Parliament).[25] For the use of data from other applications such as biobanks and wellness applications, it may be appropriate to consider opt-in mechanisms (Art. 33 (5a) EHDS-draft Parliament).[26]

In EU countries, the processing of health data is dependent on the consent of data subjects already right now (Art. 6 (1) a GDPR). Any use of such data for secondary purposes without consent would be a significant departure from current data protection laws and could set a precedent for future legislation on the use of secondary data. Therefore, it is important to ensure the involvement of data subjects. The right to partial or full opt-out for some or all purposes of secondary use, while also ensuring the right to object under Article 21(6) of the GDPR, will be helpful.[27]

C. The data access process

The data access process in the EHDS is governed by the EHDS-draft, which outlines a decentralised system without a central database (Art. 44 et seq. EHDS-draft). Prior to the access procedure, data owners are required to provide information about their electronic health data to a data access point. The process is initiated by requests from data users, which must include details such as the purpose of processing, required data sets, and data protection policies (Art. 45 et seq. EHDS-draft). If approved, the data access point will confidently issue data authorisation and request data sets from owners, making them available to users in a secure environment (Art. 46 EHDS-draft). Access is typically granted in anonymised form, but may be granted in pseudonymised form in exceptional cases (Art. 44 (2) EHDS-draft), as described above. This approach enables researchers to apply for access to datasets for research purposes, with authorised access granted for a limited time (Art. 44 (1) EHDS-draft).

[24] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space (n 12) Recital 40.

[25] Draft European Parliament - Legaislative Resolution on the proposal for a regulation of the European Parliament and of the Council on the European Health Data Space (COM(2022)0197 – C9-0167/2022 – 2022/0140(COD)) (n 1), Recital 39a. An opt-out mechanism consent is fundamentally given unless the data subject expressly objects to it.

[26] Draft European Parliament - Legaislative Resolution on the proposal for a regulation of the European Parliament and of the Council on the European Health Data Space (COM(2022)0197 – C9-0167/2022 – 2022/0140(COD)) (n 1), Recital 39a.

[27] Draft European Parliament - Legaislative Resolution on the proposal for a regulation of the European Parliament and of the Council on the European Health Data Space (COM(2022)0197 – C9-0167/2022 – 2022/0140(COD)) (n 1). About the secondary use of data.

The EHDS draft clearly specifies that data must be used solely for specific purposes, such as healthcare, public health, research, innovation, policy-making, and patient safety (Art. 33(3) EHDS-draft). It is important to note that unauthorized use is strictly prohibited (Art. 35 EHDS-draft), and data holders are obligated to transmit data details to a designated data access point (Art. 36 EHDS-draft). Furthermore, Article 33 of the EHDS draft outlines 15 minimum categories of electronic health data, subject to possible exceptions. The Commission has the authority to modify the list to accommodate changing data. [28] It is important to note that personal health data is subject to strict safeguards under Article 44, which ensures compliance with principles such as purpose limitation and data minimization.[29]

With regards to the obligation to provide data in the EHDS, there is a practical concern regarding the inclusion of training data.[30] While training data is valuable for AI systems, it seems that those data are only required in exceptional cases for secondary use in the EHDS and only, if the "enriched datasets" which include the training data are enriched within the EHDS. Otherwise training data are not used as data here.[31] Providing clarification in this area would be beneficial, taking into account the economic interests of research-based companies. [32]

IV. RECOMMENDATION FOR ACTION

The process of amending the Directive to include an opt-out mechanism will help to process a large amount of data, thereby promoting research and innovation, as well as maintaining the trust of individuals. In terms of implementation, clear guidelines and standards need to be established and followed to ensure compliance. Interoperability with other sectors will also be important in the implementation, to ensure that the EHDS works legally and seamlessly with other sectors such as education, research and industry to foster innovation.

[28] Recital (38) f. EHDS-draft. Michael Denga, 'Die Nutzungsgovernance Im European Health Data Space Als Problem Eines Immaterialgütermarkts' [2023] Europäische Zeitschrift für Wirtschaftsrecht 25, 30: However, the broadly interpretable authorized purposes require a more precise definition. Maddaloni (n 29) 231: It is unclear whether the EHDS is intended to promote only scientific or also commercial health research (Art. 34 (1) f, g EHDS-draft). Although the text mentions both types of research purposes, it may seem that the recitals are contradictory. It is worth noting that profit-oriented research institutions are excluded as data users, possibly due to their lack of transparency and obligation to publish results.

[29] Philipp Roos John-Markus Maddaloni, 'Roos/Maddaloni: Regulierter Datenaustausch Zur Gesundheitsforschung' [2023] Recht Digital 225, 228.

[30] Philipp Roos John-Markus Maddaloni, 'Roos/Maddaloni: Regulierter Datenaustausch Zur Gesundheitsforschung' [2023] Recht Digital 225, 228; Herbert Zech, 'Zech: Haftung Für Trainingsdaten Künstlicher Intelligenz' [2022] Neue Juristische Wochenschrift 502, 503. Zech concerning the differences between training data, as opposed to raw data and pre-processed data. Training data is used to train AI systems or AI components and is usually pre-processed data that is specially enriched (e.g. through annotations).

[31] Sarah Bußmann and others, 'Die Schutzfähigkeit von KI-Trainingsdaten de Lege Lata' [2022] Recht Digital 391, 391. Enriched data are named in: Art. 37 (1) p, 41 (5), 42 (3) EHDS-draft.

[32] EPIC, 'DIGITALEUROPE's Position Paper on the European Health Data Space Proposal' (DIGITALEUROPE) <https://www.digitaleurope.org/resources/digitaleuropes-position-paper-on-the-european-health-data-space-proposal/> accessed 19 February 2024.

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CONSIDERATIONS ABOUT THE ECOLOGICAL EXPERTISE AND ENVIRONMENTAL IMPACT ASSESSMENT

Challenges, Similarities and Differences Between Countries

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ABSTRACT

In this article I have analyzed the world legislation that regulates the environmental impact assessment but also the attributions of the public authorities related to this topic. By researching the results obtained during the implementation of the legislation in this field, we can deduce that the existence of the legal framework does not fully guarantee the successful execution of a procedure, and in this case the implementation of environmental impact assessment. Environmental Impact Assessment (EIA) is a process that identifies, assesses and mitigates the environmental impacts of a proposed project. This article examines the challenges faced in carrying out EIAs, the similarities and differences between EIAs in different countries, and the evolution of EIA effectiveness over time. Although, the legislation of the Republic of Moldova regulates this process, in practice very few projects, whether public or private, are subject to environmental impact assessment. At the end of the article I have proposed some solutions to improve the performance of this large procedure.

TABLE OF CONTENTS

I. INTRODUCTION

The diversity and complexity of environmental problems require the use of a variety of methods to solve them. Eventually, a number of principles have emerged in the process of developing and implementing environmental protection regulations, including the principle of environmental degradation, which is based on the idea that preventing pollution is less expensive than repairing the damage and combating the destructive effects of pollution. For these reasons, the planning of certain activities that may have an impact on the environment, such as - industrial activities, draft laws that will allow the development of activities that present an increased risk of affecting the components of nature, are subject to certain initial assessments. However, taking into account the fact that not all activities present the same degree of risk, it has been found that the application of fair rules is only possible after some technical-scientific findings have been made in environmental matters, called **ecological expertise.**

So, in the context described above, we sometimes ask ourselves the questions: "What is ecological expertise? "and "What is environmental impact assessment?" since these 2 notions express similar activities.

II. ECOLOGICAL EXPERTISE AND ENVIRONMENTAL IMPACT ASSESSMENT: EVOLUTION AND CHALLENGES

According to Article 1 of Law 851/1996, ecological expertise is a type of activity in the field of environmental protection, consisting in the prior assessment of the expected economic impact on the state of the environment, the conformity of the parameters of these activities with the laws, regulations and standards in force. However, according to art. 1 of Law No. 86/2014,[1] by environmental impact assessment we mean the procedure carried out in accordance with this Law to assess the possible effects of the planned activity on the environment, as well as the elaboration of proposals for the prevention and minimization of the negative effects or, in case of violation of the requirements provided for, in this Law, for the prohibition of the commencement of the planned activity.

Obviously, these two concepts reflect similar content only in terms of the prior assessment of possible environmental impacts, but the concept of "**impact assessment"** also includes proposals for the prevention and minimization of negative impacts. Therefore, although the environmental impact assessment is a stage of the environmental expertise, its purpose is realized through a wider range of activities and tasks whose main objective is to prevent and minimize the negative impact.

Environmental Impact Assessment (EIA) is the process of identifying, assessing and mitigating the environmental impacts of a proposed project. The history of EIA can be traced back to the National Environmental Policy Act (NEPA) of 1969 in the United States, which required federal agencies to prepare Environmental Impact Statements (EISs) for proposed projects that would

[1] Law no. 86 of 2014 regarding environmental impact assessment. Official Monitor no. 174-177 of 04.07.2014, date of entry into force 04.01.2015.

have a significant impact on the environment. The success of NEPA led to the creation of the Environmental Protection Agency (EPA) in 1970.

In the UK, EIA was formally introduced in 1988 through its inclusion in the Town and Country Planning (Assessment of Environmental Effects) Regulations for England and Wales and the

Environmental Assessment Regulations for Scotland and Northern Ireland, based on European Directive 85/337/EC. India's experience with EIA began in 1976-77 when the Planning Commission asked the Department of Science and Technology to prepare guidelines for environmental clearance of river valley projects. Since then, EIA has evolved and expanded to include various forms of impact assessment, such as Health Impact Assessment (HIA) and Social Impact Assessment (SIA). The future of EIA is uncertain, with some countries shifting their focus from addressing environmental harm to ensuring specific environmental outcomes.

However, conducting an EIA can present a number of challenges[2], including:

1. *Obtaining reliable and relevant data*: Collecting accurate and relevant data on the baseline of environmental and social conditions, as well as the expected impacts of the project and mitigation measures, can be challenging.

2*. Inconsistent approach*: There is a significant barrier in the current environmental assessment regime due to the inconsistency of approach between EIA assessment and Strategic Environmental Assessment (SEA).

3. *Scope*: The scope of environmental assessment has become too broad and there is a need to refocus on the most relevant environmental impacts.

4. *Subjectivity:* The overall ethos of what environmental assessment is trying to achieve can be clouded by subjectivity.

5. *Choice of methods*: The choice of methods to assess the impacts of a project can range from qualitative to quantitative, from simple to complex, from generic to specific, and from deterministic to probabilistic. The choice of method depends on the objectives, scope and context of the EIA, as well as the availability, quality and uncertainty of the data.

6. *Stakeholder engagement*: Ensuring an open dialogue with affected communities and regulators is critical to successful EIA.

7. *Data collection:* Using state-of-the-art sensors and analytics can help minimise gaps and uncertainties in data collection.

8. *Mitigation and monitoring*: Implementing streamlined, cost-effective solutions that can adapt to unforeseen or long-term impacts is essential for effective EIA.

[2] ISO 14044: Environmental management—life cycle assessment—requirements and guidelines [S]. International Standard Organization, Geneva, 2006.

To address these challenges, guidance and support are needed to build confidence in the EIA process and ensure its effectiveness in achieving the desired environmental outcomes. However, the effectiveness and compatibility of EIA systems remain largely unknown, especially across the diverse ecological, social, and cultural contexts.[3]

III. EIA DIFFERENCES BETWEEN COUNTRIES

Environmental Impact Assessments (EIAs) differ between countries due to a number of factors, including legal frameworks, regulatory bodies, and cultural and socio-economic contexts. Some key differences in EIA processes between countries include:

Legal framework: Legal frameworks for EIAs vary widely between countries, with some countries having more stringent regulations and others having less developed systems.

Regulatory bodies: The agencies responsible for carrying out EIAs can vary from country to country, with some countries having dedicated environmental agencies and others relying on several agencies or departments.

Cultural and socio-economic contexts: The cultural and socio-economic contexts in which EIAs are carried out can influence the process, with some countries placing more emphasis on public participation and others focusing more on technical assessments.

Scope: The scope of EIAs can vary between countries, with some countries focusing on specific environmental impacts and others considering a wider range of impacts, including social and economic factors.

Stakeholder engagement: The level of stakeholder involvement in EIAs can vary between countries, with some countries prioritising public participation and others relying more on expert opinion.

Assessment methods: The methods used to conduct EIAs can vary between countries, with some countries using more quantitative approaches and others relying more on qualitative assessments.

Enforcement and compliance: Enforcement and compliance mechanisms for EIA can vary between countries, with some countries having more robust systems to ensure compliance with EIA requirements.

These differences in EIA processes can lead to different levels of effectiveness in addressing environmental concerns and achieving sustainable development goals.

All environmental impact assessment activities are carried out and guided by a set of principles that objectively reflect the need for training. Therefore, we distinguish the following principles that govern the realization of the environmental impact assessment.

[3] A Guide to approaches, experiences & information sources- Life Cycle Assessment.1997. European Environment Agency.

a) The presumption that any economic activity or other foreseeable material activity involving the use of natural resources may cause damage to the environment This principle recognizes that activities involving the use of natural resources can lead to an imbalance in nature. At the same time, it serves as a reason to carry out the entire impact assessment activity, in other words, it is like a justification of the mistrust given to the person who expects to carry out an economic activity or to capitalize on environmental factors.[4]

b) Obligation to carry out the state ecological expertise before taking decisions on the achievement of objectives. The principle in question supposes the obligation that any activity involving the use of environmental factors must be subject to the state ecological expertise, which at the same time constitutes a stage preceding the stage of realization of the project. At the same time, this principle implies the obligation to draw up the opinion of the ecological expertise.

c) Comprehensive assessment of the impact of the planned economic activity on the environment. The assessment of the possible impact on the environment takes into account the effect of all factors that may lead to a possible deterioration in the quality of the environment or, conversely, to an improvement in the quality of the environment.

d) Scientific substantiation, objectivity and legality of the opinion. According to these principles, all conclusions of the ecological report must be scientifically justified, based on the principles of environmental protection and justified in accordance with the ecological and economic interests of society.

e) Independence of state ecological experts and their responsibility and liability When making decisions on economic activities subject to ecological expertise, the state ecological expert shall not be influenced by anyone and shall be guided only by the legislation in force and his own convictions. The state ecological expert shall be responsible for the correctness of the assessment of the documents submitted for the expertise, the quality of the expertise, compliance with the conditions of the permit, compliance with the legislation on environmental protection, as well as for the protection of state, commercial and/or other secrets, legal instruments contained in the materials submitted for the state ecological expertise.

e) Participation of public health organizations and other subjects in the realization of ecological expertise. The exposed principle implies the realization of the possibility of carrying out the impact assessment activities by other subjects (departmental and public health) than the special body empowered by the state. Also, in case of necessity, public organizations can participate in the preparation of the ecological expertise.

f) Transparency and public consultation. It is particularly important to consult the public in the process of preparing projects concerning the development of the expected activities, and subsequently to ensure that the public has free access to information about the possible impacts following the implementation of these activities.[5]

[4] Mircea Dutu "Dreptul mediului "Editia 3, Bucuresti, 2010, p.188.

[5] Daniela Marinescu, Tratat de dreptul mediului, Editia a III-a, Bucuresti, 2008, p.417.

IV. THE ENVIRONMENTAL EXPERTISE SYSTEM

When we speak of the system of ecological expertise, we have in mind those components which, when correlated, solve the tasks set for this institution.[6]
Thus, the ecological expertise system includes two major categories of elements at the same time:

The types of ecological expertise and the functional structures for carrying out the expertise.

The types of ecological expertise and the structures responsible for their realization are respectively.

1. State Ecological Expertise - carried out by the Central Authority for the Environment, represented by the Directorate of Ecological Expertise and Environmental Permits within the State Ecological Inspectorate.

2. Departmental Ecological Expertise, carried out by the ministries and departments interested in the problem.

3. Community Ecological Expertise, carried out by public associations with an activity profile in the field of environmental protection.

Environmental expertise refers to the knowledge and skills required to assess and manage environmental issues.[7] It involves the application of scientific, technical, and social knowledge to address environmental challenges. Environmental expertise systems can take various forms, including expert panels, environmental impact assessments, and environmental management systems. These systems aim to provide guidance on how to tackle environmental challenges, equipping readers with tools to better understand the diversity of environmental knowledge and its implications. Environmental expertise systems can be used to identify and mitigate environmental hazards, assess the environmental impact of proposed projects, and develop strategies for sustainable environmental management. They are essential for ensuring that environmental issues are addressed in a systematic and effective manner, and for promoting sustainable development.

Measuring environmental literacy involves assessing various factors such as environmental attitudes, behavior and knowledge. Traditionally, environmental literacy has been measured using educational and psychological frameworks that may include dimensions such as system knowledge, action knowledge and efficacy knowledge. There is ongoing debate and research on best practices for measuring environmental knowledge, and several tools and technologies have been developed for this purpose. In addition, environmental literacy can be assessed through the impact of citizen science on environmental attitudes, behavior and knowledge. This multidimensional approach aims to provide a comprehensive understanding of environmental literacy and its implications. Each type of expertise has its role. For example, the State Ecological Expertise is the main link in the ecological expertise system because its opinion is binding, while the opinions of

[6] Legea nr. 86 din 29.05.2014 privind evaluarea impactului asupra mediului. În: Monitorul Oficial al Republicii Moldova, nr. 174-177, 04.07.2014.
[7] Igor trofimov, G.Ardelean, A .Cretu "Dreptul Mediului"Chisinau,2015, pp. 138.

the departmental and community experts are only advisory. In addition, the execution of the state ecological expertise is mandatory, while the departmental and community ecological expertise is optional.[8]

Some common tools used to measure environmental literacy include[9]:

a) The Three-Dimensional Theory of Environmental Knowledge: This framework divides environmental knowledge into system, action and effectiveness dimensions, providing a comprehensive approach to assessing environmental expertise.

b) The 19-item Environmental Knowledge Test (EKT-19): This test is a brief, psychometrically sound measure of environmental knowledge that has been validated by researchers.

c) Instrumental Framework for Measuring Environmental Awareness: This framework includes various factors such as environmental attitudes, behaviors and knowledge and has been developed to measure environmental awareness.

d) Citizen science projects: Citizen science projects can be used to measure the impact of environmental knowledge on attitudes, behavior and knowledge, and provide insights into the effectiveness of environmental expertise systems.

These tools and frameworks can be used to assess environmental literacy in different contexts, such as educational settings, workplace training and public awareness campaigns. They help to identify strengths and weaknesses in environmental literacy and provide guidance on how to improve environmental literacy.

V. THE EUROPEAN COMMISSION'S IMPACT ASSESSMENT TOOLS

The European Commission uses Impact Assessment (IA) in its policies to ensure that all major policy proposals include a Sustainability Impact Assessment (SIA) covering their potential economic, social and environmental impacts.

The IA process is based on integrated analyses of different policy concerns, such as the environment, the economy and society.

The Commission has introduced an internal system of Integrated Impact Assessment (IA) to address multiple policy concerns by assessing the likely environmental, economic and social impacts of all its major policies.
Key aspects of the European Commission's use of impact assessment in its policies include[10]:

1. *Integrated analysis*: The IA process is based on integrated analyses of different policy concerns, such as the environment, the economy and society.

[8] Igor trofimov, G.Ardelean, A. Cretu "Dreptul Mediului"Chisinau,2015, pp. 139.

[9] Esther Turnhout, Wageningen Universiteit, The Netherlands, Willemijn Tuinstra, Open Universiteit, Willem Halffman, Radboud Universiteit Nijmegen Cambridge University Press 2019.pp. 45.

[10] https://home-affairs.ec.europa.eu/whats-new/evaluations-and-impact-assessments_en .

2. *Sustainability Impact Assessment*: The European Commission has established rules to ensure that Member States assess the likely significant environmental effects of certain large infrastructure projects and public plans through environmental assessments, including the Environmental Impact Assessment (EIA) and Strategic Environmental Assessment (SEA) Directives.

3. *Better Regulation Agenda*: The Better Regulation Agenda is about designing and evaluating EU policies and legislation in a transparent way. Impact assessments are carried out by Commission services in accordance with the related Better Additional Guidelines on the Analysis of Human Rights Impacts in Impact Assessments of Trade-Related Policies.

4. *Public consultation*: Impact assessments include an online public consultation of interested parties to gather input and feedback.

5. *Quality assessment*: The results of the impact assessment process are summarised in an impact assessment report, which is reviewed and commented on by an independent body, the Regulatory Scrutiny Board.

6. *Proportionality analysis:* The Commission has introduced a new impact assessment tool that integrates, strengthens, streamlines and replaces all existing separate practices, helping decision-makers to take better-informed decisions.

VI. CONCLUSIONS

Evaluation of the quality of Environmental Impact Assessment (EIA) reports, changes to projects as a result of EIA and the impact of changes to EIA procedures in European countries such as the UK, Germany, Spain, Belgium, Denmark, Greece, Ireland and Portugal has shown promising results. The overall proportion of "satisfactory" EIA reports sampled in these countries increased from 50% to 71% between 1990-1991 and 1994-1996.

The European Union (EU) has established rules to ensure that Member States assess the likely significant environmental effects of certain large infrastructure projects and public plans through environmental assessments, including the Environmental Impact Assessment (EIA) and Strategic Environmental Assessment (SEA) Directives.

The European Commission has also applied impact assessment to its policies, aiming to consider simultaneously the economic, social and environmental impacts of proposals. The Commission has introduced an internal system of Integrated Impact Assessment (IA) to address multiple policy concerns by assessing the likely environmental, economic and social impacts of all its major policies Respectively, the evaluation of the performance of EIA systems in European countries and the EU's efforts to ensure environmental assessment are promising steps towards sustainable development and environmental protection.

In conclusion, the European Commission uses Impact Assessment in its policies to ensure that all major policy proposals include a sustainability impact assessment covering their potential economic, social, and environmental consequences. This integrated approach helps decision-makers make better-informed decisions and contributes to the overall goal of sustainable development.

EIA is a crucial tool for ensuring sustainable development and protecting the environment.[11] However, the challenges faced in conducting EIAs, the differences in EIA processes between countries, and the evolution of EIA effectiveness over time highlight the need for continuous improvement and adaptation of EIA practices to address the diverse ecological, social, and cultural contexts in which they are applied. The future of EIA is uncertain, with some countries shifting their focus away from addressing environmental harm to securing specified environmental outcomes.[12]

[11] Igor trofimov,G.Ardelean,A.Cretu "Dreptul Mediului"Chisinau,2015, pp.134.

[12] Rojanschi V., Braun F., Diaconu Gh., Economia şi protecţia mediului, Ed. Tribuna Economică, Bucureşti, 2000.

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REFLECTIONS ON ECOLOGICAL EXPERTISE AS AN INSTRUMENT OF ENVIRONMENTAL CONTROL

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ABSTRACT

This article provides reflections on the role of ecological expertise as a tool of environmental governance. It examines the importance of State Ecological Expertise (SEE) in maintaining the ecological balance and its influence on the decision-making process for various activities. The article examines the principles and considerations underlying SEE, its impact on sustainable development and the potential implications of its assessments. By examining the relationship between ecological expertise and environmental conservation, the article aims to contribute to a deeper understanding of the instrumental role of SEE in environmental governance and sustainable resource management. In this article we reflect on the concept, importance and functioning of the State Ecological Expertise (SEE) as an independent legal institution. SEE plays an important role in monitoring the preservation of the ecological balance of the environment and in providing preliminary state control to prevent potential negative impacts on the environment. We discuss the factors considered in SEE assessments, the activities subject to mandatory SEE and the implications of the opinions issued as a result of SEE. We also examine the procedural aspects of SEE, including the requirements for the composition of the documentation submitted for the State Environmental Impact Assessment. Through this reflection, we aim to improve the understanding of the role and importance of SEE in the system of expert activity of public authorities to prevent negative impacts on the environment. This abstract is based on the concept, meaning and functioning of State Ecological Expertise (SEE) as described in the provided search results.

TABLE OF CONTENTS

I. INTRODUCTION

State Ecological Expertise (SEE) plays a key role in environmental governance and sustainable resource management. Based on the principles of environmental needs, rational use of natural resources and sustainable development, SEE serves as a critical tool for monitoring the maintenance of the ecological balance of the environment. The opinions issued as a result of SEE assessments are an integral part of the decision-making process for the granting of environmental permits and the implementation of various activities, including land-use planning, industrial activities and the protection of natural resources[1]. This article aims to reflect on the importance of ecological expertise in environmental control, its implications for sustainable development and its influence on decision-making processes. By exploring the principles and considerations underlying SEE, the article seeks to provide insights into the instrumental role of ecological expertise in environmental governance and the pursuit of sustainable resource management. Environmental control is applied in various fields, encompassing industries, agricultural management, workplace design, and oil and gas exploration. The application of environmental control is diverse and essential for maintaining specific conditions and minimizing environmental impact. Here are the fields in which environmental control is applied:

Industries: Environmental control is utilized in industries such as agriculture, food production, medical and pharmaceutical, automotive, aeronautical, and testing. It involves the regulation and measurement of specific parameters to create controlled environments tailored to the requirements of each industry.

Agricultural Management: Environmental control is crucial in agricultural management, where it is used to regulate temperature, humidity, and light to create optimal growing conditions for plants and produce.

Workplace Design: In the context of workplace design, environmental control refers to the degree to which individuals, groups, or business units can modify and adapt features of their physical workplace to enhance work and business effectiveness. It involves optimizing workspaces, spatial adjacencies between buildings, and considering sustainability issues.

Oil and Gas Exploration: The petroleum industry places great emphasis on minimizing the environmental impact of its operations through the implementation of proper waste management plans and environmental principles. Environmental control is essential for mitigating the impact of exploration, production, and waste release on the environment.

These examples illustrate the wide-ranging application of environmental control across different sectors, highlighting its significance in maintaining controlled environments, minimizing environmental impact, and enhancing work effectiveness.

Some examples of environmental control measures used in agriculture include:

[1] Andreas Duit, Peter H. Feindt & James Meadowcroft (2016) Greening Leviathan: the rise of the environmental state?, Environmental Politics, 25:1, 1-23.

Air Quality Control: Environmental control measures are used to regulate the air quality in agricultural facilities, particularly in animal confinement areas. This involves the enclosure and ventilation of tractors, applying moisture to friable material, and the use of respirators to control aerosols.

Temperature and Humidity Control: Good environmental control in agricultural facilities requires sufficient air renewal, correct flow, adequate temperature without significant fluctuations, and adequate humidity. Farmers must take into account factors such as temperature, humidity, the path and speed of the air, the level of gases (such as carbon dioxide and ammonia), and light intensity to create optimal growing conditions for plants and produce.

Water Management: Water management is essential in agriculture to prevent soil erosion, nutrient depletion, and water pollution. Farmers can use precision irrigation techniques, such as drip irrigation, to minimize water usage and reduce runoff.

Organic Farming: The use of chemical-based fertilizers and pesticides in agriculture can lead to soil and water pollution. Organic farming practices, which avoid the use of synthetic chemicals, can help minimize the environmental impact of agriculture.

Land Use Management: Agriculture is responsible for the destruction of natural habitats and the degradation of land resources. Farmers can implement better land use practices, such as crop rotation, to prevent soil erosion and protect the Earth.

These examples illustrate the importance of environmental control measures in agriculture, which are essential for maintaining optimal growing conditions, minimizing environmental impact, and promoting sustainable practices.
Some ways to reduce water usage in agriculture through environmental control include:

High-Tech Irrigation Systems: The use of advanced irrigation systems, such as drip irrigation, can significantly reduce water consumption by delivering water directly to the plant's roots, minimizing evaporation that occurs with traditional spray watering systems.

Mulching: Mulching using plant-based material or biodegradable films plays an important role in water conservation by preventing evaporation, reducing weed growth, and maintaining soil moisture.

Capturing and Storing Water: Farmers can capture and store rainwater to reduce reliance on other water sources, such as municipal water or wells. Properly managed ponds can also create habitat for local wildlife while minimizing the impact on the surrounding watershed.

Optimizing Watering Times: Smart water management involves careful monitoring of weather forecasts, soil and plant moisture, and adapting irrigation schedules to current conditions to avoid under- or overwatering crops.

Drought-Tolerant Crops and Dry Farming: Growing drought-tolerant crops and practicing dry farming, which involves relying on soil moisture to produce crops during the dry season, can help conserve water resources.

Soil Conservation Practices: Implementing soil conservation practices such as cover cropping, minimal tillage, and rotational grazing can improve soil structure, increase water-holding capacity, and reduce water runoff.

These measures demonstrate the diverse strategies available to farmers for reducing water usage in agriculture, promoting sustainable water management, and minimizing the environmental impact of farming practices.

The State Ecological Expertise (SEE) is an independent legal institution that exists to control the preservation of the ecological balance of the environment, based on the principles of environmental needs, rational use of natural resources and sustainable development.[2] The purpose of the SEE is to provide preliminary state control to prevent potential ecological risks arising from certain activities. Activities subject to mandatory SEE include land use planning, port management, urban land planning, industrial activities, soil remediation for areas where an ecological disaster or epidemic has occurred, and plans for the protection, use or exploitation of water, forests, woods, soil, minerals and other natural resources. SEE assessments take into account the assessment of the potential environmental risks of certain activities, the comprehensive assessment of the possible environmental impact of the activity before it begins, environmental requirements and standards, the independence of experts in the free exercise of their duties, the reasoning and legality of the conclusions of the assessment, and public participation.

The State Ecological Expertise (SEE) is an independent legal institution that plays a crucial role in controlling the preservation of the ecological balance of the environment. Its purpose is to provide preliminary state control to prevent potential negative impacts on the environment. The SEE's opinion is an important factor in deciding whether to grant an environmental permit for various activities. SEE assessments take into account the assessment of potential environmental risks, the possible impact of activities on the environment, environmental requirements and standards, the independence of experts, the reasoning and legality of the assessment conclusion, and public participation. Activities subject to mandatory SEE include land use planning, port management, urban land use planning, industrial activities, soil remediation in areas affected by ecological disasters, and plans for the protection, use or exploitation of natural resources. Opinions issued as a result of EIA may be positive or negative, depending on various factors such as compliance with legislation, potential environmental impacts and measures to reduce or prevent environmental impacts.[3]

II. SUBJECTS OF ECOLOGICAL EXPERTISE

In the specialized legal literature, subject is considered to be the participant in this relationship, in the framework of which, by his own act, he has the prerogative to perform certain acts that would make possible the exercise of subjective rights in these relationships:

[2] D. M. Mishukov, 0. "The state ecological expertise: the concept, the location, the value of SER in the system of expert activity of public authorities to prevent negative impact on the environment," Entrepreneurâ€™s Guide, JSC â€œPublishing Agency â€œScience and Educationâ€, issue 30.

[3] Expertiză ecologică — gen de activitate îndomeniul protecţiei mediului înconjurător, constînd în aprecierea prealabilă a infl uenţei activităţilor economice preconizate asupra stării mediului, a corespunderii parametrilor acestor activităţi actelor legislative şi altor acte normative, normelor şi standardelor în vigoare; Legea privind expertiza ecologică, nr. 851 din 29.05.1996, publicat : 08.08.1996 în Monitorul Ofi cial Nr. 52–53 art Nr : 494, data intrării în vigoare : 08.08.1996.

a) the subjects initiating the expertise

b) the subjects of the expert's conduct

c) subjects who are beneficiaries of the environmental expertise

The **subjects** for the initiation of ecological expertise are:

State ecological expertise - considering that the State ecological expertise is the exclusive competence of the Central Environmental Authority, which orders its structural subdivisions to carry it out, we mention that this prerogative belongs to the Directorate of Ecological Expertise and the Environmental Authority .In this context, according to the legislation, the State Ecological Expertise is carried out by the ecological experts of the authorized directorates and sections of the Central Authority for Natural Resources and the Environment and its subdivisions, who have higher education, and a professional experience in the field of special ecological expertise.

Public expertise - officially registered public associations that have an activity profile in the field of the environment.

Departmental expertise - ministries and branch departments, whose activity involves the valorization of environmental components.

The subjects for carrying out the ecological expertise can be:

The Department of Ecological Expertise and Environmental Authorizations subordinated to the central authority for the environment, ministries and branch departments, scientific research institutes, the structural unit ecological expert or a direct specialist in the field subject to the expertise.
The beneficiaries of the ecological expertise are considered the authors of the projects and those who will benefit from the realization of the expected activity.

III. OBJECTS OF THE ECOLOGICAL EXPERTISE

The objects of the Ecological Expertise are the projects and documents related to the planned economic activities that may have an impact on the environment, the economic activities themselves and their results. For example, the Law on Environmental Protection of the Republic of Moldova provides that the activity that would be subject to the environmental impact assessment and the environmental impact assessment would be the use of environmental components, with the mention that they may damage the environment. Although this provision is of a general nature, the Law on Environmental Protection and the Law on Ecological Expertise contain separate provisions that require, as a matter of priority, that some activities be subject to the State Ecological Expertise.

Therefore, the state ecological expertise is mandatory for the project documentation and planning of objects and planned economic activities that affect or may affect the state of the environment and/or

provide for the use of natural resources, regardless of the purpose, location, type of property and subordination of these objects, the volume of capital investments, the source of financing and the method of execution of the construction works.[4]

The following shall be subject to mandatory state ecological expertise:

a) drafts of legal and other normative acts, instructions, norms and methods, regulations and standards concerning the state of the environment and/or regulating activities potentially dangerous for the environment, use of natural resources and protection of the environment,

b) drafts of international agreements, drafts of concession agreements regulating the use of natural resources of the Republic of Moldova,

c) new projects, programs, plans, schemes, strategies and concepts aimed at

- Economic and social development of the Republic of Moldova, certain regions, districts, municipalities, towns, villages;
- Protection of nature as a whole in the country and on separate territories;
- Reconstruction of municipalities, towns, villages;
- Supply of heat, water, gas, electricity;
- Construction of sewage systems of localities;
- Construction, expansion, reconstruction, reuse, modernization and re-profiling, conservation, demolition or liquidation of all economic and social objects that may affect the environment, as well as those that may affect the state of the environment in neighboring states, as defined by the International Convention on Impact Assessment Environment in Transboundary Context, to which the Republic of Moldova is a party.
- Construction of roads, railways, rivers, reconstruction of riverbeds, hydrotechnical constructions, irrigation and drainage systems, construction of systems to combat soil erosion and salinization;
- Exploration and exploitation of the subsoil, including in areas with a water protection regime;
- Planting of vineyards and orchards in areas with a water protection regime;
- Production and destruction of pesticides and other toxic substances;
- Location and arrangement of platforms for industrial, domestic and agricultural wastes and toxic residues, construction or location of processing facilities, neutralization or destruction of these wastes and residues.

IV. CONDITIONS AND FUNDING OF THE ECOLOGICAL EXPERTISE

The conditions and financing of SEE are usually governed by national laws and regulations.[5] The process of obtaining a positive conclusion of the state environmental review may involve the submission of project documentation for planned activities to the relevant environmental authorities, who will then

[4] Trofimov I.,Ardelean G.,Cretu A. Dreptul mediului, Chisinau ,2015 ,p.140

[5] Daniela Marinescu,Tratat de dreptul mediului,editia a III-a,Bucuresti,2008,p.417

conduct an assessment to determine compliance with environmental requirements. In terms of funding, the resources for carrying out a state environmental assessment are usually provided from the state budget or through environmental funds Depending on the complexity of the project, the state ecological assessment of the project and design documentation is carried out within up to 45 days from the date of submission of the required documentation. Design documentation for residential and utility buildings with centralized technical supervision is considered within 15 days. The Central Authority may prolong the term for conducting a state ecological assessment of documentation for complex and potentially environmentally hazardous facilities and activities, including documentation whose examination requires additional special scientific research, by an average of up to 3 months. In order to ensure the independence of ecological experts, the activities related to the performance of the state ecological expertise shall be financed from the state budget in the established manner. Expenses related to the performance of the state ecological expertise in competition with independent experts, project documentation and planning for complex and potentially environmentally hazardous facilities and economic activities, including documentation for facilities and activities requiring additional scientific research, shall be borne by the beneficiary.

What is the relationship between sustainable finance and environmental literacy?

Sustainable finance and environmental expertise are linked by their focus on environmental considerations and long-term sustainability. Sustainable finance involves the integration of environmental, social and governance (ESG) factors into investment decisions, leading to more long-term investment in sustainable economic activities and projects. This is in line with the objectives of environmental expertise, which aims to manage the preservation of the ecological balance of the environment and prevent potential negative impacts on the environment. By channeling capital into environmentally friendly projects, green finance, a component of sustainable finance, helps to combat climate change and protect ecosystems. The relationship between sustainable finance and environmental literacy lies in their common goal of promoting environmental protection, climate change mitigation and biodiversity conservation. Both sustainable finance and environmental expertise contribute to a more sustainable and resilient economy by taking environmental factors into account and promoting investments that support the transition to a low-carbon, climate-resilient and resource-efficient economy. Sustainable finance and environmental expertise are therefore complementary in their efforts to integrate environmental considerations into financial decision-making and to promote long-term environmental well-being.

Funding for carrying out state environmental assessments is usually provided from the state budget or through environmental funds. The process of obtaining funding for SEE may involve submitting proposals or applications to the relevant government agencies or environmental organizations responsible for overseeing ecological assessments. Expenses related to the performance of the repeated state ecological expertise are borne by the organization that prepared the documentation submitted for examination. The activity of carrying out the state ecological expertise is financed from the account of the public associations' own funds. According to art. 18 paragraph 8 of Act No. 851/1996, the beneficiaries of project and design documentation for objects financed from the state budget or local budgets are exempted from paying for the state ecological expertise.[6]

[6] Michel PRIEUR, DROIT INTERNATIONAL ET COMPARÉ DE L'ENVIRONNEMENT, Formation à distance, Campus Numérique "ENVIDROIT" TRONC COMMUN COURS n°5 LES PRINCIPES GÉNÉRAUX DU DROIT DE L'ENVIRONNEMENT, pag. 3.

V. CONCLUSIONS

State environmental expertise is an important procedure for companies that store, neutralize and dispose of waste. Without it, it is impossible to obtain or re-issue a license, introduce new technology, use new equipment or build a capital structure for disposal facilities.

If a company carries out its activities without a positive SER opinion at its own risk, it runs the risk of being fined by the Federal Service for Supervision of Environmental Management, ordered to eliminate violations, or refused to reissue a license.

Ecological expertise, as a critical instrument of environmental control, plays a key role in preserving the ecological balance and promoting sustainable development. The article highlights the following conclusions:

- Ecological expertise is rooted in the principles of environmental needs, rational use of natural resources and sustainable development.
- The opinions issued as a result of ecological expertise assessments are an integral part of the decision-making process for granting environmental permits and carrying out various activities.
- Environmental Impact Assessments shall take into account the assessment of potential environmental risks, the overall assessment of the potential environmental impact of the activity before it commences, environmental requirements and standards, the independence of experts, the justification and legality of the conclusions of the assessment and public participation.
- Activities subject to mandatory environmental impact assessment include land-use planning, port management, urban land-use planning, industrial activities, soil remediation and plans for the protection, use or exploitation of natural resources.
- An environmental impact assessment may be positive or negative, with a positive opinion being given if the supporting documentation complies with legislation and environmental standards, the implementation of the activity will not cause irreversible qualitative or quantitative changes in the state of the environment or natural resources, and the plan provides for measures to reduce or prevent environmental impact.
- The environmental impact assessment is an important procedure for companies that store, neutralize and dispose of waste, as it is necessary to obtain or re-issue a license, introduce new technology, use new equipment or build a capital structure for disposal facilities.
- The increasing sophistication of environmental management tools has led to further reflection on their relationship with environmental regulation.
- By exploring the principles and considerations underlying ecological expertise, the article seeks to provide insights into the instrumental role of ecological expertise in environmental governance and the pursuit of sustainable resource management.

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HEALTH CARE COMPLIANCE ISSUES WITH INPATIENT AND OUTPATIENT ACTIVITIES BY THE SAME PHYSICIAN

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TABLE OF CONTENTS

I. INTRODUCTION

The pleasure of humans seems to be often found in crossing boundaries. However, crossing legal boundaries provides a compliance violation that can lead to serious consequences – especially in the highly regulated German healthcare system. Due to the large number of regulations, economic competition is strictly limited in the German healthcare sector creating a considerable conflict between economic pressure, entrepreneurial visions and legal requirements. The identification of clear boundaries, the exploration of creative leeway and the crossing of compliance-related prohibition zones is oftentimes difficult due to the considerable legal 'grey area' between black and white, which has not yet been fully clarified by case law. The use of these grey areas as well as the crossing of permissible boundaries takes place in various forms in reality. Cooperations in which a physician crosses the so-called sectoral boundary (*Sektorengrenze*) in his own person, for example as an affiliated or fee-based physician (*Beleg- oder Honorararzt*), and provides both inpatient (*stationäre*) and outpatient (*ambulante*) medical services, are of particular relevance.

In this context, this article is intended to provide an overview of the most commonly used forms of combined outpatient and inpatient activities (intersectoral activities) by the same person and to highlight the associated compliance issues.

II. LEGAL FRAMEWORK

A. German healthcare system

Health is one of the most existential goods of human existence. Germany as welfare state recognised the need to provide everyone with the necessary healthcare services, regardless of their current financial circumstances, as early as the Bismarck era and erstablished compulsory health insurance already in the late 19th century. In terms of compulsory insurance, the German health insurance system is similar to the one in Liechtenstein and differs significantly from the system in the USA, for example.

From an economic point of view, the statutory health insurance functions via a so-called pay-as-you-go system (*Umlageverfahren*), i.e. the contributions of an individual do not have to cover their individual healthcare needs, but the total contributions of all insured people have to cover the funding requirements at the relevant time. In Germany, the state's duty to ensure that the medical infrastructure is sufficient to meet demand, is exercised on behalf of various self-governing bodies. The German healthcare system, thereby, does not follow pure market economy rules, but is highly regulated with regard to the accreditation of service providers and the billable remuneration. The accredited service providers are divided into two sectors – the practices as the outpatient sector and the hospitals as the inpatient sector, with a strict separation of the admitted service provision: Apart from emergencies and special, legally provided cases, in which hospitals are not only authorised but also obliged to provide initial outpatient treatment, in Germany (in contrast to various other countries) outpatient care generally takes precedence over inpatient care. This means that further inpatient treatment can only be considered if outpatient pre-treatment has exhausted its limits of possibilities and additional inpatient treatment is indicated. Generally, the system therefore requires a pre-treatment by an outpatient physician.

The outpatient physician will then determine the indication for inpatient follow-up treatment and initiate admission to an inpatient service provider. This dependence of inpatient service provision and inpatient service providers on the referral of patients by primary outpatient service providers has the following two consequences, among others:

The dependence harbours a particular risk of corrupt agreements between inpatient and outpatient service providers regarding the referral of patients.[1] In addition, this separation traditionally splits the service portfolio of each specialist area into the generally less complex, typically non-surgical and therefore less risky medical services that do not require overnight accommodation and are therefore have to be provided by outpatient service providers, and the surgical or more complex treatments that regularly require an inpatient stay and therefore have to be provided by hospitals. Those physicians interested in providing all services of their medical speciality are therefore often looking for possibilities to combine positions in both sectors. Those combinations are of particular interest for the hospitals as they allow to bind an outpatient colleague to a hospital through corresponding ancillary activities, thereby increasing the chances of attracting the outpatient colleague's patients. To ensure the best possible medical service provision for patients despite the outlined economic dependencies, the German anti-corruption regulations described below find their use.

B. Criminal anti-corruption law requirements

In the German healthcare system, the provision of inpatient medical services by physicians who originally work on an outpatient basis does not only theoretically exist in various forms, but it is also found in reality in many variations with considerably different regulatory requirements.

The German Criminal Code (*Strafgesetzbuch – StGB*) contains several legal requirements and prohibitions that must be complied with in case of intersectoral medical service provision by one and the same physician. Of particular relevance are the so-called 'anti-corruption offences' (Sections 299a and 299b StGB), which the federal legislator introduced in 2016 to protect fair competition in the German healthcare sector and the integrity of decisions and actions of healthcare service providers.[2]

According to Section 299a StGB, criminal offences are imposed for situations in which healthcare professionals such as physicians request, are promised or accept an advantage for themselves or a third party in the context of their professional practice in return for, for example, favouring a specific healthcare provider when providing or obtaining medical products or referring patients. While Section 299a StGB criminalises any passive corruption of physicians, among others, anyone who actively

[1] Ebermann/Schneider, Saalfrank – Handbuch des Medizin- und Gesundheitsrechts, Ed 10 (2022), Sec 135 mn with further explanations on numerous other relevant constellations.

[2] BT-Drs 18/6446, Entwurf eines Gesetzes zur Bekämpfung von Korruption im Gesundheitswesen; for an analysis of the legislative proposal see Schneider, Entwurf des Gesetzes zur Bekämpfung der Korruption im Gesundheitswesen (§§ 299a, b StGB-E): Lassen Sie sich nicht einschüchtern!, KH-J p 14 et seqq (1/2016).

corrupts a physician or another healthcare professional is liable to active corruption under Section 299b StGB.[3] Section 299b StGB primarily affects other, non-physician people like managing directors who are legally responsible for medical institutions. Both criminal liability of a physician for corruption under Section 299a StGB and criminal liability e.g. of a non-physician managing director for corruption under Section 299b StGB require economic benefits for preferential treatment.

Benefits' generally cover all grants that objectively improve the economic, legal or personal situation of the recipient. This includes both tangible benefits such as monetary payments, the free or uncommonly cheap provision of equipment, materials, premises or employees as well as intangible benefits such as honorary positions.[4]

However, the provision of benefits to a physician or a related third party only constitutes a criminal offence under Sections 299a and 299b StGB if it takes place in return for an inadmissible advantage in competition, for example for the referral of patients. This connection between benefit and medical reference behaviour, the so-called 'unlawful agreement', constitutes the core of the anti-corruption offences in the healthcare sector.[5]

Medical decisions must be based on the primary intention to ensure the patient's well-being and the best possible medical treatment and may only take economic and rational selection criteria into account as a secondary consideration. Medical decisions are therefore liable to prosecution if they are guided by improper primary considerations like monetary interests.[6]

C. Further compliance regulations

The anti-corruption provisions under criminal law described above are reinforced by further compliance regulations in the SHI Physicians' Law (*Vertragsarztrecht*) and professional law (*Berufsrecht*). Sections 128 para. 2 and 73 para. 7 Social Code Volume V (*Fünftes Sozialgesetzbuch – SGB V*) as well as Section 31 para. 1 of the respective Professional Code of Physicians (*Berufsordnung für Ärzte – BO*) essentially correspond to the previously outlined prohibitions according to Sections 299a and 299b StGB and prohibit any form of cooperation with and between physicians that, amongst others, includes the provision of benefits in return for the referral of patients. The general difference between the regulations is the group of people addressed and the potential sanctions in the event of compliance violations: While Sections 128 para. 2 and 73 para. 7 SGB V exclusively apply to SHI Physicians (*Vertragsärzte*), Section 31 para. 1 BO as a professional law provision applies to all physicians including those working in private practices or as employed physicians in hospitals. However, to this day, the licensing authorities

[3] E.g. Kubiciel, Bestechlichkeit und Bestechung im Gesundheitswesen – Grund und Grenze der §§ 299 a, 299 b StGB-E, MedR 1, 1 (2016); Dannecker/Schröder, Kindhäuser/Neumann/Paeffgen/Saliger – Kommentar zum StGB, Ed 6 (2023), Sec 299a StGB mn 20; Vasilikou/Grinblat, Gesetz zur Bekämpfung von Korruption im Gesundheitswesen und Compliance – Maßnahmen für Marktakteure, MPR 189, 189 (2016).

[4] For further examples see Eisele, Schönke/Schröder – StGB, Ed 30 (2019), Sec 299a StGB mn 12; Schuhr, Spickhoff – Medizinrecht, Sec 299a, 299b StGB mn 15 et seqq.

[5] Ebermann/Schneider, loc cit, Sec 14 mn 135; Dannecker/Schröder, loc cit, Sec 299a StGB mn 143; Dann/Scholz, Der Teufel steckt im Detail – Das neue Anti-Korruptionsgesetz für das Gesundheitswesen, NJW 2077, 2078 (2016).

[6] Krüger, Kooperation versus Korruption im Gesundheitswesen – Gedanken zu §§ 299a, 299b StGB, NZWiSt 129, 133 (2017).

(*Approbationsbehörden*) and Federal Medical Associations (*Landesärztekammern*) do not seem to be exercising their most effective measures not only to apply sanctions such as warnings and penalties, but also to withdraw SHI accreditations (*Vertragsarztzulassung*) and/or licences to practice medicine (*Approbation)*. In reality, the criminal sanctions of Sections 299a and 299b StGB therefore currently seem to be the sharpest weapon against violations of the applicable compliance regulations, which, however, is also still far from being fully utilized.

Some federal states, such as North Rhine-Westphalia, Bremen, Schleswig-Holstein and Thuringia, also have hospital regulations similar to Section 31 para. 1 BO that directly obliges hospitals to comply with corresponding corruption prohibitions.[7]

III. COMMON FORMS OF INTERSECTORAL ACTIVITIES

The following compilation is supposed to give an overview of the most commonly used forms to cross the boundaries between the two medical sectors by one and the same person and the corresponding compliance risks. All of those forms have in common, (i) that a physician who primarily works within the outpatient care obtains access to the typically more complex inpatient services within his/her medical speciality, (ii) that the hospital is able to compensate existing gaps in personnel and (iii) that the probability of the physician's patients seeking further inpatient treatments in the specific hospital is increased due to the comprehensible interest of the patient in 'treatment from a single source'. The last aspect will usually be the most attractive aspect from the hospital's point of view, but must not lead to unauthorised referral arrangements between the physician and the hospital.

A. Employed physicians (*angestellte Ärzte*)

To begin with, a physician who primarily works on an outpatient basis can also work in the hospital as an employed physician in the form of a secondary occupation (*Nebentätigkeit*). As an employed physician he is integrated into the organisational structures of the hospital during his inpatient activity, i.e. he is subjected to the instructions of the management, the medical director and the head physician of the respective medical department.

With regard to Section 17 para. 3 sentence 1 of the Hospital Remuneration Act (*Krankenhausentgeltgesetz – KHEntgG*), a secondary employment in a hospital has the advantage that – in contrast to the following forms of intersectoral activities – the physician can be included in the official chain of elective physicians (*Wahlarztkette*) and enjoys the benefit of a corresponding liquidation right (*Liquidationsrecht*).[8]

[7] E.g. Sec 35 Hospital Act of the Federal State of Bremen (Bremisches Krankenhausgesetz – BremKrhG) and Sec 31a Hospital Organization Act of North Rhine-Westphalia (Krankenhausgestaltungsgesetz des Landes Nordrhein-Westfalen – KHGG NRW).

[8] Starzer, Spickhoff – Medizinrecht, Sec 17 KHEntgG mn 6 et seq; Böhnke, BeckOK (as of 1 March 2024), Sec 17 KHEntgG mn 38 et seqq.

From a compliance law perspective, the secondary employment is particularly prone to compliance issues in two aspects and thus may lead to a prohibited referral of patients according to Sections 299a and 299b StGB:

As an employee of the hospital the physician actually has to treat all of the hospital's patients. However, oftentimes a high level of patient identity exists between the physician's outpatient patients and the hospital's patients treated by the physician. The greater the patient overlap, the more likely the agreements between the physician and the hospital are to be deemed corrupt. Particularly critical therefore are those constellations, in which the physician exclusively treats 'his own' patients in the hospital and thus effectively acts as an affiliated physician (in detail, see section III.B below).[9]

In addition, an appropriate level of reimbursement is relevant for the distinction between legal intersectoral activity and corruption that is subject to prosecution.[10] The reimbursement must not be inappropriately high in relation to salaries of physicians in comparable positions, neither must it represent a solely symbolic bonus. Both constellations of inappropriate reimbursement are an indication of prohibited benefits for the referral of patients from one sector to another. In practice, however, the evaluation of appropriate reimbursements regularly results in major challenges for physicians and hospitals, as concrete guidelines for the reimbursement of secondary medical activity can only be determined by an evaluation of comparable constellations, whereby the specific circumstances of the individual case, in particular the qualification and reputation of the physician, his experience and his position (assistant, specialist, senior or chief physician), play a key role.

B. Affiliated physicians (*Belegärzte*)

Another possibility for parallel outpatient and inpatient activity by the same physician, legally provided in Section 121 SGB V and Section 18 KHEntgG, is known as the service provision as affiliated physician in the original sense. This type of service provision is characterised by the fact that the physician, without being employed in the hospital, provides 'his own' patients with inpatient medical services by using the hospital's infrastructure. The affiliated physician is officially responsible for the medical services, while the hospital takes care of the accommodation and care services. In contrast to the employment constellation, the affiliated physician therefore concludes a separate treatment contract with the patient regarding the provision of the medical services in addition to the contractual relationship between the hospital and the patient regarding accommodation and care.[11] This structure, which originates from the SHI scheme, has also been acknowledged in the private medical sector (i.e. in private hospitals licensed in accordance with Section 30 of the Trade Regulation Code (*Gewerbeordnung – GewO*)).

[9] Kamann, Bleibt alles anders: Krankenhaussektor und Kooperationen im Lichte des Gesetzes zur Bekämpfung von Korruption im Gesundheitswesen, CB 136, 138 (2017); Tsambikakis, Saliger/Tsambikakis – Strafrecht der Medizin (2022), Sec 14 mn 81.

[10] According to a restrictive view, employed physicians should in principle (only) receive the same reimbursement as other employed physicians in the hospital with whom they are comparable regarding e.g. their special expertise see Tsambikakis, loc cit, Sec 14 mn 80.

[11] Federal Court of Justice, Judgement dated 19 February 1998, III ZR 169/97; Wagner, Münchener Kommentar zum BGB, Ed 9 (2023), Sec 630a BGB mn 40.

For the physician and the patient, the charm of this structure is that the physician can legitimately offer his patients a comprehensive range of services that includes both sectors, thereby significantly increasing his chances of competition. In addition – in contrast to employment in a hospital – the physician is not formally part of the organisational structures of the hospital and therefore determines the scope of his inpatient services himself. For the hospital, the advantage of affiliated physician structure is that it is not responsible for the provision of sufficient medical staff, because the medical service provision is entirely subject to the responsibility of the affiliated physician (see Section 121 para. 3 sentence 3 no. 1 SGB V, Section 18 para. 1 sentence 2 no. 2 KHEntgG). This means that the costs of retention finances (*Vorhaltekosten*) for physicians are reduced to zero on the hospital's side.

However, the disadvantages of the classic affiliated physician are the requirement of an authorisation as an affiliated physician (*Belegarztanerkennung*) from the responsible Association of SHI Physicians (*Kassenärztliche Vereinigung*) and the limitation to hospitals with an affiliated physician department (*Belegabteilung*) accredited by the hospital planning authority (*Krankenhausplanungsbehörde*). In addition, the reimbursement system currently in force for the classic service provision as an affiliated physician department is less favourable than the reimbursement system for the same service provision as a main department (*Hauptabteilung*): The sum of DRG (Diagnosis Related Groups) codes for accommodation and care and the EBM (*Einheitlicher Bewertungsmaßstab*) codes for medical services usually results in a lower total remuneration than the 'normal' DRG to be invoiced by a main department. In the case of private medical services, the affiliated physician must even reduce his own invoice by 15% in accordance with Section 6a para. 1 sentence 2 of the Ordinance on Medical Fees (*Gebührenordnung für Ärzte – GOÄ*) for the service provision outside the SHI scheme. In the special case of combined billing of inpatient services of the hospital and the affiliated physician by the hospital in accordance with Section 121 para. 5 SGB V and Section 18 para. 3 KHEntgG, the main department DRG code has to be reduced by 20%, making the financial disadvantage of affiliated physician departments even more tangible. For this reason, the extent of affiliated physician activities has declined significantly in the past.[12] It remains to be seen whether affiliated physician structures will survive the upcoming hospital reform in Germany at all.

From a compliance law perspective, affiliated physician structures have the advantage that they are a legally intended and therefore an officially permitted form of intersectoral cooperation. As long as the affiliated physician complies with the current legal requirements, particularly the reimbursement restrictions, this form of intersectoral activities does not face as many compliance risks as the other forms of intersectoral activities. In the explanatory statement to the anti-corruption criminal law for the healthcare sector, the legislator himself explicitly stated that legally permitted earning opportunities in the healthcare sector are not only intended by the legislator, but are also in the interest of the patient and therefore cannot constitute corrupt behaviour without any additional circumstances.[13]

This is not the case, however, if the affiliated physician makes use of supporting services of the hospital regarding original affiliated physician duties (e.g. on-call services (*Bereitschaftsdienste*)) and does not

[12] While the number of affiliated physicians was about 5.325 in 2014, it dropped to 4.332 in 2019 and has fallen to 3.799 in 2022, see Lamouri, BeckOGK (as of 1 September 2020), Sec 121 SGB V mn 4 with reference to statistical information from the federal register of the National Association of Statutory Health Insurance (Bundesarztregister der Kassenärztlichen Bundesvereinigung) 2022.
[13] BT-Drs 18/6446, p 18.

pay the hospital any or only an insufficient remuneration. As those services, would only be offered for an appropriate fee elsewhere in the market, such agreements give reason for the assumption, that the physician is illegally offered this benefit in return for the referral of his patients to the hospital and the resulting billing opportunities.

C. Fee-based physicians (*Honorarärzte*)

Physicians who are not employed by the hospital but are supposed to perform all medical services in a hospital as employed physicians are referred to as fee-based physicians.[14] However, they only provide their services in the case of availability and necessity (e.g. if the hospital's physicians are absent due to illness) and are therefore – in contrast to employed physicians – only reimbursed depending on the concrete engagement (often by hourly or daily flat rates). For the hospital, the fee-based physician therefore has the advantage of engagement according to demand without any upfront costs, although on-call engagement is usually associated with higher hourly/daily rates. This applies all the more if the placement of a fee-based physician is arranged through an agency that also charges brokerage. In order to avoid increased treatment liability risks, the short-term integration of fee-based physicians often also requires increased professional training and increased attention from the remaining hospital staff.

Ideally, the patient will not notice any difference between the provision of care by an employed physician and a fee-based physician. In both cases, the treatment contract is concluded with the hospital, which also receives the full reimbursement for the services provided, as the services of the fee-based physician are attributed to the hospital as part of the hospital's service (see Section 2 para. 1 sentence 1 KHEntgG).

The use of fee-based physicians is particularly problematic in connection with the provision of elective medical services (*Wahlleistungen*), as the fee-based physician is neither an employed physician nor a public servant according to Section 17 para. 3 sentence 1 KHEntgG and also does not perform his/her medical services on the basis of an explicit assignment in individual cases. The inclusion of fee-based physicians in the provision and invoicing of elective medical services therefore regularly causes legal problems.[15]

From a compliance law perspective, the existing pitfalls for fee-based physicians and for employed physicians are similar. The crucial factor is that the agreed fee is appropriate and does not represent a hidden bonus for the referral of patients (see section III.A above).[16]

In reality, the fee-based physicians and hospitals sometimes agree that the fee-based physician receives a percentage of the hospital's turnover and/or a higher reimbursement for those patients, he/she

[14] Federal Court of Justice, Judgement of 16 October 2014, III ZR 85/14; Rehborn, Huster/Kaltenborn – Krankenhausrecht, Ed 2 (2017), Sec 14 mn 117a.

[15] Rehborn, loc cit, Sec 14 mn 117b et seqq.

[16] With regard to the status determination procedures (Statusfeststellungsverfahren) pursuant to Sec 7a SGB IV to avoid the risk of criminal liability pursuant to Sec 266a StGB see Schneider/Reich, Welche Spielräume verbleiben zwischen §§ 299a, 299b und § 266a StGB?, medstra p 11 et seqq (2019).

has brought along to the hospital. In these cases, the turnover share (*Umsatzbeteiligung*) or the increased fees provide a benefit that could illegally incentivise the referral of patients. Such agreements therefore not only violate applicable regulations of SHI Physicians' Law and professional law, but can also be subject to prosecution under Sections 299a and 299b StGB.

Furthermore, in view of the Federal Social Court's (*Bundessozialgericht - BSG*) judgement regarding fee-based physicians (BSG, Judgement of 4 May 2019, B 12 R 11/18 R), the service provision of the fee-based physician must be considered as a self-employed activity, wherefore the simple label as a 'fee-based physician' is not sufficient. The crucial factor is the physician's freedom from instructions and – in contrast to the employed physician – the independence from the hospital's operations. Due to the commonly found integration of fee-based physicians into the hospital's organisation, the use of fee-based physicians has decreased significantly in recent years and has been progressively replaced by the employment of physicians.

D. Consultant physicians (*Konsiliarärzte*)

Consultant physicians, in the narrow sense, typically are external experts engaged in individual cases in the context of diagnosis and therapy determination as part of the hospital's general medical services in accordance with Section 2 para. 1 sentence 1 KHEntgG. The hospital invoices the consultant service itself – similar to the services of fee-based physicians – and reimburses the consultant physician. Billing between the hospital and the consultant physician is often based on the GOÄ, even if the GOÄ codes only directly apply for invoices towards patients.[17]

For the hospital, the retention of experts through consultant contracts (*Konsiliararztverträge*) has the advantage of expanding the hospital's expertise and thereby increasing competitiveness without having to employ the respective physician on a permanent basis.

In reality, consultant physician contracts often include significantly more tasks than characteristic for this type of service provision. As a result, the boundaries between consultant physicians and fee-based physicians are often blurred and the risk of pseudo self-employment (*Scheinselbständigkeit*) thus also arises for consultant physicians who are de facto integrated into the organisational structure of the hospital. From a compliance law perspective, the reimbursement must be appropriate for the services provided by the consultant physician (see section III.A above). The GOÄ does provide a helpful but not mandatory remuneration framework.[18]

E. Surgery centres (OP-Zentren)

The last frequently used form of intersectoral activities of one the same person is the operation of surgery centres in which the outpatient physicians either work as surgeons themselves or only provide the

[17] Quaas, Quaas/Zuck/Clemens – Medizinrecht, Ed 4 (2018), Sec 16 mn 144; Federal Court of Justice, Judgement of 12 November 2009, III ZR 110/09.

[18] Schneider/Boemke, Ein Honorar ist keine Fangprämie! Compliance-Fragen zwischen Krankenhaus und externem Arzt, KU Gesundheitsmanagement, p 64, 63 (6/2013) with guidelines for the implementation of a contract controlling system (Vertragscontrolling).

infrastructure for other surgeons on a fee-basis. Comparable to the other forms of intersectoral activities, the user fees (*Nutzungsentgelte*) must be appropriate and in line with market conditions also in this case, as the user fees could otherwise be considered as prohibited kickback payments for the referral of patients.

From a tax law perspective, two additional issues have to be considered: On the one hand, a tax advisor should assess, whether the provision of utilisation possibilities to third parties is excluded from VAT (*Umsatzsteuer*) in accordance with Section 4 of the German Value Added Tax Act (*Umsatzsteuergesetz – UstG*).[19] On the other hand, a so-called trade tax infection (*Gewerbesteuerinfizierung*) of the outpatient activities could take place in some cases. If the surgery centre is operated in the legal form of a limited liability company (*GmbH*), a trade tax infection usually does not pose an additional risk due to the obligation of a GmbH to pay trade taxes because of its legal form anyway.

IV.SUMMARY AND PROSPECTS

Based on the previous explanations, physicians and hospitals should be guided by the following key questions in order to achieve a suitable and compliant intersectoral cooperation structure:

A. Content

What are the services the physician is intended to perform in the hospital? Is he supposed to only treat his own patients or rather all patients of the hospital? Are the activities intended to cover all inpatient services or is the physician's work limited to a few consulting services for the inpatient service in individual cases?

The simple label of a contract as a 'fee-based', 'consultant' or 'affiliated physician' contract does not qualify the contract as such; the content is the relevant factor for its qualification. Oftentimes contracts 'sail under a wrong flag'. Particularly in those cases, the contracts face the risk of violating the legal requirements applicable to the respective form of activity.

B. Reimbursement

Are the provided service adequately reimbursed? Would other market participants pay a comparable remuneration? Please note that service provision with inadequate or even without reimbursement generally faces compliance issues. The level of reimbursement should therefore be in line with the market standard or be comprehensibly justifiable - e.g. based on the GOÄ, the EBM or the DRG.[20]

[19] Federal Fiscal Court, Judgement of 18 March 2015, XI R 15/11.

[20] For details on the question of adequacy of remuneration, especially for health care providers, see Schneider, Das Gesetz zur Bekämpfung der Korruption im Gesundheitswesen und die Angemessenheit der Vergütung von HCP – Wie viel Unsicherheit steckt im Vernunftstrafrecht?, medstra 195 et seqq (2016).

In addition to the correct regulatory configuration of intersectoral activities, physicians and hospitals should also seek tax advice in order to avoid any tax pitfalls. After all, the issue of potentially unauthorised personnel leasing (*Arbeitnehmerüberlassung*) can also become relevant in the context of service provision in hospitals by external physicians and can therefore cause considerable legal risks.

It is therefore recommended to conduct a proper legal review of the envisaged intersectoral activity before the actual commencement of activity.