EU Commission proposes AI Liability Directive

Damage caused by AI: Practitioners' liability

The European Commission published its "Proposal for a Directive on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive)" 2022/0303/COD on 28 September 2022. It includes liability rules for damage caused by AI.

The proposal should be seen in the context of the "Proposal for a Regulation laying down harmonised rules on artificial intelligence (Artificial Intelligence Act)" through which the EU intends to take an international lead with regard to holistic regulation of AI. Against the background of the growing use of AI in medicine, this article, in addition to describing the planned regulations, addresses the resulting liability consequences for dentists/physicians who use AI systems in the context of their treatments in particular.

I. Proposal for a Directive on AI liability

1. Background and objectives

Under current law, there are no liability regimes in the member states that explicitly cover damage caused by AI systems. Rather, all liability regimes refer to damage caused by human action or omission.

The Commission states in the explanatory memorandum to the proposal that, in particular, the existing fault-based liability rules are inappropriate for handling liability claims for damage caused by AI-enabled products and services, and notes that it is currently difficult for companies to predict how the existing liability rules will be applied by the courts. Assessing and insuring one's own liability risks is therefore currently an almost impossible task for providers and users of AI systems. It is therefore no surprise that liability is one of the top three obstacles to the use of AI by European companies and thus represents a real obstacle to innovation.

On the other hand, potential victims of AI-related damage, especially against the background of the so-called "black box" effect, are currently faced with the problem of having to prove fault and causality in liability proceedings.

Taking into account these diverging interests, the European Commission intends its proposal for an AI Liability Directive to achieve the following objectives:

- Promotion of the rollout of trustworthy AI to harvest its full benefits for the internal market
- Equivalent protection for victims of damage caused by AI as for victims of damage caused by products in general
- Reduction of legal uncertainty of companies developing or using AI regarding their potential exposure to liability
- Prevention of the emergence of fragmented AI-specific adaptations of national civil liability laws.

2. Regulatory content

The published proposal was originally based on three policy options, which the Commission compared in a multi-criteria analysis, taking into account their effectiveness, efficiency, coherence and proportionality.

Policy option 1 provided "three measures to ease the burden of proof for victims seeking to prove their liability claims." Policy option 2 went beyond option 1 by providing for "harmonising strict liability rules for AI use cases with a particular risk profile, coupled with mandatory insurance" in addition to the measures in option 1.

Ultimately, the phased approach of option 3 was chosen, combining the first two options. This option now provides that measures to ease the burden of proof for victims seeking to prove their liability claims will be introduced first (option 1). After five years, a review of the impact of the measures on the achievement of the objectives pursued by the directive is then to be carried out (Article 5). If, in the opinion of the European Commission, these objectives are not achieved, the additional measures of option 2, i.e. the introduction of strict liability and compulsory insurance, are to be implemented in a further step if necessary.

Thus, the proposed directive in its current version does not define any separate liability claims. Instead, it contents itself with regulations on the disclosure of evidence as well as presumptions of fault and causality in order to make it easier for the (potential) claimant to provide evidence when asserting a claim for damages under national law.

Due to the extensive scope of the proposed directive, only the most important regulations will be presented below.

Pursuant to Article 1 (2), the proposed directive claims to apply to non-contractual fault-based civil law claims for damages in respect of harm caused by an AI system. Thus, neither contractual nor strict liability claims for damages nor, for example, criminal liability are covered. In addition, the damage must have been caused directly by an AI system or its output.

Article 3 (1) provides for a claim for information by the (potential) claimant, in particular against the provider or the user, for disclosure of relevant evidence concerning a specific high-risk AI system suspected of having caused damage.

The consequences of refusal to disclose the evidence are far-reaching.

Thus, according to Article 3 (5), breach of the duty of care and thus a fault of the provider or user is automatically (rebuttably) presumed. However, this breach of the duty of care (which may be presumed pursuant to Article 3 [5]) is also the first prerequisite for the (rebuttable) presumption of causality between the fault (= breach of the duty of care) of the provider/user and the output of the AI system as per Article 4 (1), so that the non-disclosure of the evidence triggers or at least favours a chain reaction of legal consequences. Further requirements for the presumption of causality of Article 4 include that the fault has influenced the AI result or its absence as well as the causality (to be proven by the claimant) between the output of the AI system and the damage.

The breach of the duty of care required for the presumption of causality under Article 4 (1) is specified in paragraphs 2 and 3 for providers and users of high-risk AI systems by establishing a link to the obligations of these addressees under the planned Artificial Intelligence Act.

Accordingly, in accordance with Article 4 (3), users must fulfil their obligation to use or monitor the AI system in accordance with the attached instructions for use or, if necessary, to suspend or interrupt its use (according to Article 29 of the AI Act) and/or apply to the AI system only input data that are subject to their control and that correspond to the intended purpose of the system [according to Article 29 (3) of the Artificial Intelligence Act]. In this way, the proposed directive creates incentives to comply with the due diligence obligations provided for in the Artificial Intelligence Act.

II. Implications for the dental and medical professions

So what are the specific consequences of the proposed directive for practitioners who use AI systems in the course of treatment?

The good news first: The proposed directive in its current version does not (yet) provide for strict liability regardless of fault, so that damage caused by an AI system does not automatically lead to liability on the part of the practitioner. In addition, liability continues to be gov-

erned, in principle, by the national law of the respective member state.

Nevertheless, practitioners may in principle be covered by the scope of the planned directive, with the result that potentially injured patients may demand the disclosure of evidence in order to be able to substantiate a claim for damages. Furthermore, the above-mentioned presumptions of fault and causality may apply, which the practitioner can and must refute to avoid being exposed to a claim for damages.

The primary addressees of the proposed directive are providers and users of high-risk AI systems. Article 2 (3) of the proposed directive refers to Article 3 (4) of the Artificial Intelligence Act for the definition of "user". Here, the term "user" means "any natural or legal person, public authority, agency or other body using an AI system under its authority, except where the AI system is used in the course of a personal non-professional activity." Physicians, but also hospitals, are thus to be regarded as users within the meaning of the proposed directive. Also, with regard to the definition of high-risk AI systems, Article 2 (2) of the proposed directive refers to Article 6 of the Artificial Intelligence Law, which contains the requirements for classifying AI systems as high-risk. This Article refers to Annex II of the Artificial Intelligence Act, whose No. 11 in turn refers to Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices. Accordingly, AI medical devices are likely to be classified as high-risk AI systems within the meaning of the proposed directive.

However, this fundamental applicability of the directive to dental/medical treatments using AI medical devices is subject to a significant restriction in Article 1 (2) and Article 2 No. 5, in that it is a prerequisite that the relevant harm must be caused by the AI system. Recital 15 of the proposed directive specifies that "there is no need to cover liability claims when the damage is caused by a human assessment followed by a human act or omission, while the AI system only provided information or advice which was taken into account by the relevant human actor. In the latter case, it is possible to trace back the damage to a human act or omission [...], and thereby establishing causality is not more difficult than in situations where an AI system is not involved."

If the AI system only provides the practitioner with information regarding a possible diagnosis/treatment, on which the practitioner still has to make an independent decision, the directive does not apply. Since there are hardly any AI medical devices in use at present that could directly cause harm, the significance of the guideline for the dental/medical professions would be quite low, at least at present.

However, even in the case of future use of AI-capable medical devices that directly cause damage, at least the presumption of causality in Article 4 (1) is unlikely to be of decisive importance, since the user's duties of care are not as extensive as those of the provider. Thus, practitioners who use an AI system in accordance with its instructions for use and only provide it with data in accordance with the system's intended purpose will largely escape liability due to the lack of a breach of the duty of care (cf. Article 4 [3]).

III. Conclusion

In conclusion, the proposed directive on AI liability in its current version does not imply any groundbreaking changes for the practitioners' liability, as no new liability claims are defined. Rather the proposal is concerned with alleviating the burden of proof for potential claimants, who are invariably likely to face (evidentiary) difficulties when attempting to enforce a claim for damages, given the lack of transparency of AI systems. To remedy the problem, the draft provides for a right to information and presumptions of fault and causation against the user of a high-risk AI system. A dental/medical practitioner may therefore well become an addressee. However, a prerequisite would be that the damage was directly caused by an autonomous AI result or its absence. However, at present AI medical devices hardly cause any direct damage; rather, practitioners would regularly make decisions on their own responsibility based on the output of an AI, so there is little change for the time being in terms of the practitioner's liability for any breach of duty of care. In this way, the situation is comparable to the use of classic medical devices.

The outcome of the planned review of the effectiveness of the directive five years after its introduction will be eagerly awaited. Failure to achieve the objectives of the directive (in particular when it comes to closing liability gaps) could result in strict liability for operators of AI systems, which would of course have far-reaching consequences for the dental and medical professions. Even though the directive will probably not be transposed into national law in the member states until 2026 at the earliest (cf. Article 7 [1]), it is advisable to keep a critical eye on the legislative process.

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