Client Briefing: Commission proposal for a new Directive of the European Parliament and of the Council on liability for defective products ("Product Liability Directive")

On 28 September 2022, the Commission has published its proposal for a revised Product Liability Directive, and, for the first time a targeted harmonization of national liability rules for AI (see link).

In a nutshell, the Commission´s proposal of a new **Product Liability Directive** implements rather **extensive rules presuming defectiveness** of the product **and/or the causal link** between its defectiveness and the damage for the benefit of the claimants. In addition, **disclosure obligations** for defendants are implemented to ease the position of the claimant, however, without considering a similar claim of the defendant against the claimant (e.g. in relation to medical records). For determining whether a **product is defective**, factors such as "product safety requirements" or "interventions by a regulatory authority or by an economic operator relating to product safety" have been added to the list of factors to be considered by courts when assessing defectiveness. This will become particularly relevant in the event a medical device has been recalled or was otherwise subject to a Field Safety Action.

At first glance, the new Product Liability Directive, will expose manufacturers of medical devices to **significantly higher liability risks** and has potential **to hamper innovation**, leading also to **potentially higher product prices** and **reduced access to innovative medical devices**.

The Commission proposal must now be adopted by the European Parliament and the Council. It remains to be seen when and to what extent a political consensus will be found on all of the Commission's proposals. As a rule, the Commission's legislative proposals are expected to be adopted within 2 years, even if no deadlines are set in the legislative procedure. Member States must transpose the Directive 12 months after it enters into force and communicate the national execution measures to the Commission.

Below, we have summarized some key aspects of the proposed **Product Liability Directive** that may become relevant for medical device manufactures in Europe:

1. **Concerned products (Art. 4 (1)):** The definition of a product shall respond to the reality of products in the digital age, in a technology-neutral manner, by including software and digital manufacturing files within the definition of product and by clarifying when a related service is to be treated as a component of a product. It also expands the notion of compensable damage to include the loss or corruption of data. This revision may be relevant, e.g. for medical devices including software applications or medical apps.

2. **Product defect (Art. 6):** The test for determining whether a product is defective – i.e. whether the product provided the safety which the public at large is entitled to expect – is substantively the same as under the old regime. However, in order to reflect the changing nature of products in the digital age, and to reflect case law of the European Court of Justice (e.g. relating to pacemakers, ICDs with a potential defect), factors such as "product safety requirements" or "interventions by a regulatory authority or by an economic operator relating to product safety" have been added to the non-exhaustive list of factors to be taken into account by courts when assessing defectiveness. Such product safety measures could cover, e.g. Field Safety Notices / Actions as per Medical Device Regulations.

3. **Potential defendants (Art. 7):** The range of economic operators that can be held liable for defective products has been extended. This shall consider the growing significance of products manufactured outside the EU that are placed on the Union market. Where the manufacturer of the defective product is established outside the Union, the importer of the defective product and the authorised representative of the manufacturer can be held liable for damage caused by that product. Considering multi-national medical device companies, the Authorized Representative as per Art. 11 MDR to be appointed and labeled on the device can now be held liable under the Product Liability Directive (though the MDR already had a similar regulation in Art. 11 Nr. 5 MDR for the Authorized Representative). To allow a proper defense, the Authorized Representative would require access to product related information and documentation (see also next bullet regarding "Burden of Proof").

4. **Disclosure of evidence (Art. 8):** National courts shall be empowered, upon request of an injured person claiming compensation for damage caused by a defective product who has presented facts and evidence sufficient to support the plausibility of the claim for compensation, to order the defendant to disclose relevant evidence that is at its disposal (measures to protect trade secrets must be implemented).

    - It remains to be seen, whether this will be considered as a **separate information claim**. At least in Germany, a similar concept has been introduced in the German Drug Act for product liability cases relation to medicinal products.

    - The obligation to disclose information related to a medical device will certainly increase. Non-compliance with a disclosure obligation will lead to a procedural situation in which the **defectiveness** of the product shall be **presumed** (cf. Art. 9 No 2 (a) of the new Product Liability Directive).

- A **similar claim of the defendant** against the claimant (e.g. in relation to medical records) has **not been implemented**, which does not comply with the principle of "equality of arms" in civil litigation proceedings.

5. **Burden of Proof (Art. 9):** The burden of proof is on injured persons, who must prove the damage they have suffered, the defectiveness of the product and the causal link between the two. However, considering challenges faced by injured persons, especially in complex cases, the burden of proof shall be eased.

    - The defectiveness of the product shall be presumed, where any of the following conditions are met:

        - the defendant has failed to comply with an obligation to disclose relevant evidence at its disposal pursuant to Art. 8(1) of the new Product Liability Directive;

        - the claimant establishes that the product does not comply with mandatory safety requirements laid down in Union law or national law that are intended to protect against the risk of the damage that has occurred; or

        - the claimant establishes that the damage was caused by an obvious malfunction of the product during normal use or under ordinary circumstances.

    - The causal link between the defectiveness of the product and the damage shall be presumed, where it has been established that the product is defective, and the damage caused is of a kind typically consistent with the defect in question.

    - Should the claimant faces excessive difficulties, due to technical or scientific complexity to prove the defectiveness of the product or the causal link between its defectiveness and the damage, or both the defectiveness of the product or causal link between its defectiveness and the damage, or both, shall be presumed where the claimant has demonstrated, on the basis of sufficiently relevant evidence, that: (a) the product contributed to the damage; and (b) it is likely that the product was defective or that its defectiveness is a likely cause of the damage, or both.

    - The defendant shall have the right to contest the existence of excessive difficulties or the likelihood, however, without a claim against the defendant to disclose certain relevant information (e.g. medical records).

- Technical or scientific complexity should be determined by national courts on a case-by-case basis, considering various factors. Those factors should include the complex nature of the product, such as an innovative medical device; the complex nature of the technology used, such as machine learning; the complex nature of the information and data to be analyzed by the claimant; and the complex nature of the causal link, such as a link between a pharmaceutical or food product and the onset of a health condition, or a link that, in order to be proven, would require the claimant to explain the inner workings of an AI system.

6. **Exemption from liability (Art. 10):** Economic operators are entitled, as under the current regime, to be exempted from liability on certain conditions for which they carry the burden of proof. However, past court cases in the medical device industry – at least in Germany – have shown that an exemption afforded to manufacturers for scientifically and technically undiscoverable defects is hardly to demonstrate.

7. **Limitation periods (Art. 14):** The 3-year time limit for initiating proceedings remains unchanged compared to the current regime. Economic operators are liable for defective products for a 10-year period after placing the product on the market, but claimants will enjoy an additional 5-year period in cases where the symptoms of personal injury are slow to emerge, for example following ingestion of a defective chemical or food product. Depending on the product, also medical devices may provide for symptoms of personal injury that are slow to emerge (e.g. implantable medical devices).

Combined with the Directive (EU) 2020/1828 of the European Parliament and the Council of November of 25 November 2020 on **representative actions for the protection of the collective interests of consumers a**nd repealing Directive 2009/22/EC (to be transported into national law by December 25, 2022), the new Product Liability Directive will most likely have an impact on the litigation landscape in Europe. A German draft bill has been published by the German government in September 2022.

For more information, please contact our Partner Marc Oeben.

Düsseldorf, 29 September 2022

* * * *