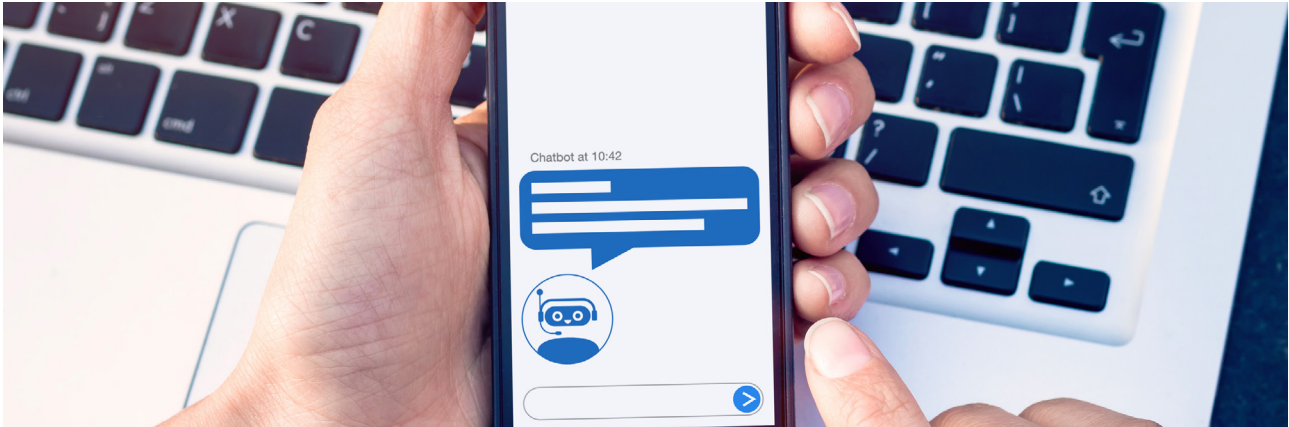# THE EU **AI LIABILITY DIRECTIVE** AND **PRODUCT LIABILITY DIRECTIVE**

Crucial updates to liability which aim to protect fundamental rights in the digital age.

INTRODUCTION

On 28 September 2022, the European Union (EU) Commission published two new proposals to make liability rules suitable for the digital age, in which Artificial Intelligence (AI) systems will have a common place in society. Through the proposed amendments to the Product Liability Directive (PLD)[1], and the new AI Liability Directive (AILD)[2], the Commission aims to update the laws governing manufacturers' strict liability for defective goods (from medical devices to smart technologies). The revised rules aim to provide businesses with greater legal security so they can invest in developing new, cutting-edge products. At the same time the Commission aims to strengthen the position of people to receive just compensation when faulty goods, including digital goods, cause them harm. Both these proposals aim to harmonise and strengthen the product liability regime, filling the gap left by the Product Liability Directive adopted in 1985 that currently still regulates AI system liability. Under the current regime, it is difficult to get compensation for harm caused by faulty AI systems because of the way the law is phrased. For this reason, the PLD Proposal and the AILD establish two much needed new liability regimes.

DEFINITION OF 'A PRODUCT'

The old Product Liability Directive is not fit-for-purpose when it comes to AI system liability, as it has a problematic definition of a 'product'. In its article 2, it defines a product as "all movables, with the exception of primary agricultural products and game, even though incorporated into another movable or into an immovable". This definition does not specify whether it includes just tangible or also intangible products, which leads to uncertainty as to whether the definition also includes autonomous AI and software. This uncertainty has a strong impact on EU Member States' regulations on AI systems because, as they embedded the PLD into their national law[3], they have incorporated this uncertainty in their legal systems that govern AI. For example, in Sweden damages caused by defective products are regulated under the Product Liability Act (Produktansvarslagen). Most of the time, AI technology is not covered by the latter because, according to Swedish legislation, software is not a product. However, the Product Liability Act may apply to the AI system if it is integrated into a product.[4] The same applies in Belgium, where the 1991 Product Liability Act seems to be restrictive.

It enables software to be classified as a product when it is embodied in a physical item, but again, the classification is unclear when the software is considered stand alone, and is not integrated into hardware, such as a computer.[5]

The newly proposed PLD, among other things, will amend the current definition of product to include software, including AI systems, in the definition. This means that an injured person can claim compensation for damage caused by AI.[6] This makes it possible to harmonise laws of the various Member States, which, until now, have classified software differently. Although there is some opposition to the necessity of these clarifications from the side of medical technology industry[7], we believe that they are essential to ensure better protection of people's fundamental rights. In addition, the old regime of the PLD is aimed only at "finished products". This is no longer sufficient considering that some products are now still developing after being brought to market, as for instance is the case with software updates and self-learning algorithms.[8] By including software, as well as software updates[9] in the definition of a product, the revised PLD covers all software. This is relevant for the healthcare sector, since some technologies and applications used in healthcare are only virtual. Under the new regimes, if an AI medical device erroneously fails to notify the doctor when a patient is having a heart attack, the patient is certain they can hold the manufacturer liable.[10]

PROVING A CAUSAL LINK

Under the PLD Proposal the individual must prove a causal link between the product defect and the damage suffered. While proving this can be difficult, the good thing is that the defendant will be held liable regardless of fault (called 'strict liability'). In other words, the manufacturer always carries full responsibility for its products. With the AILD, the Commission, for the first time, proposed a harmonisation of national liability rules for AI, in order to simplify compensation for persons who suffer damage as a result of AI.[11] The new AILD establishes a 'presumption of causality'[6], in order to alleviate the burden of proof for victims.[5] They will still need to prove that the product was malfunctioning, and that they were harmed. However, a causal link between the malfunctioning and damage doesn't have to be proved, but under certain conditions is assumed.

These new rules are necessary to facilitate access to justice for persons harmed by AI systems which are not embedded in a material object. These two proposals also acknowledge some issues related to the specific characteristics of AI, such as its complexity, autonomous operating, and opacity. These factors make it difficult for patients to succeed in a lawsuit against a physician or the manufacturer of the AI medical device. In fact, these devices can cause harm that cannot be linked to the fault of the manufacturer or health care provider under national law, for instance, because the patient is unable to show they breached their duty of care.[12]

Although there is still uncertainty on whether the new proposals fill all the gaps in medical AI liability, it is a step forward in the harmonisation of the subject at EU level.

"Under the new regimes, if an AI medical device erroneously fails to notify the doctor when a patient is having a heart attack, the patient is certain they can hold the manufacturer liable."

ENDNOTES

1. Proposal for a Directive of the European Parliament and of the Council on Liability for Defective Products, 28 September 2022.

2. Proposal for a Directive of the European Parliament and of the Council on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive), 2022.

3. Article 288 TFEU.

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6. Marianna Drake Peets Jiayen Ong, Marty Hansen, Lisa, (Inside Tech Media, 2 February 2023). Accessed 8 May 2023.

7. https://www.medtecheurope.org/wp-content/uploads/2022/09/20220712_one-pager.pdf 'MedTech Europe Position Paper on the Revision of the Product Liability Directive' (MedTech Europe). Accessed 8 May 2023.

8. 'Commission non-paper on digital elements of the proposal for a new Product Liability Directive', (European Commission), 8 February 2023. Accessed 19 June 2023.

9. Stefano de Luca, "New Product Liability Directive", Briefing EU Legislation in Progress, European Parliament. https://www.europarl.europa.eu/RegData/etudes/BRIE/2023/739341/EPRS_BRI(2023)739341_EN.pdf

10. Idem.

11. New Liability Rules on Products and AI to Protect Consumers (European Commission - European Commission). Accessed 24 April 2023.

12. Duffourc, M.N., Gerke, S. The proposed EU Directives for AI liability leave worrying gaps likely to impact medical AI. npj Digit. Med. 6, 77 (2023). https://doi.org/10.1038/s41746-023-00823-w

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