Comments uploaded by GDV on 11.12.2022 to the European Commission's "Stakeholder Feedback Process" on "Product Liability Directive - Adapting liability rules to the digital age, circular economy and global value chains".

"GDV appreciates the opportunity to comment on the proposals for a new Product Liability Directive and a AI Liability Directive. The following remarks address key aspects of the proposals from the perspective of the German insurance industry.

1. Revision of the Product Liability Directive

The Product Liability Directive 85/374/EEC (PLD) is a balanced system that offers a high level of protection to persons sustaining damage by a defective product, while at the same time taking into account the legitimate interests of producers and thus promoting technological innovation and economic growth. This also applies in principle to innovative digital technologies such as artificial intelligence (AI) or the Internet of Things (IoT). We therefore welcome the fact that the Commission's proposal to revise the PLD (PLD-P) maintains the tried and tested basic principles of the PLD. However, some of the proposed new provisions would place an excessive, unwarranted burden on manufacturers. Other proposed provisions should be specified or concretised in order to prevent undesired and counter-productive legal uncertainty. These would lead to an increase in litigation and ultimately to higher costs for consumers, as well as harm the expressly promoted technical innovation capacity of the affected economic sectors. Furthermore, they could negatively impact the current availability of comprehensive insurance cover for manufacturers in product liability insurance, as insurers would be hampered in their ability to assess and calculate risks.

1.1 Burden of proof, obligations to disclose evidence (Art. 8, 9 PLD-V)

As a matter of principle, changes to existing liability regimes should only be considered if systematic gaps in protection can be empirically demonstrated. The explanatory memorandum and recitals 3, 30 and 34 state that claimants face unjustified difficulties in meeting burden of proof requirements in "complex cases", but without any detailed assessment of where these difficulties lie. However, Articles 8 and 9 PLD-T provide for far-reaching facilitations of the burden of proof for injured parties, which would apply to all products and all cases. Only Art. 9(4) contains a provision according to which, in cases where national courts consider that injured parties are exposed to "excessive difficulties" due to technical or scientific complexity, further facilitations would apply.

In our view, such far-reaching changes to the rules on burden of proof should only be contemplated for specific constellations or cases for which systematic gaps in protection can be demonstrated. Should the provision in Art. 9(4) be maintained, we believe that the terms "technical or scientific complexity" and "excessive difficulties" need to be defined in the PLD. Leaving their definition to the discretion of the national courts would result in undesirable legal uncertainty due to conflicting case law in the member states, which could jeopardise the insurability of product liability risks and should also be avoided from the point of view of full harmonisation.

The disclosure obligations provided for in Art. 8 PLD-P are a novelty in German law. Where they exist in isolated cases, for example in section 33g of the Act against Restraints of Competition (Gesetz gegen Wettbewerbsbeschränkungen, GWB), they have rightly been described as a paradigm shift. Their blanket application to product liability cases of all kinds does not appear justified: We recognize that the Proposal endeavours to limit disclosure by requiring the claimant to submit facts and evidence supporting the plausibility of the compensation claim and to protect trade secrets (Art. 8(3) and (4)). However, there is a risk that Art. 8 PLD-P could be construed as a first step towards establishing an undesirable "pre-

trial discovery" such as exists in US law, because the interpretation of these restrictions is largely left to the national courts. Allowing claimants to enforce disclosure of documents from defendants purely to further their own cases would also require far-reaching changes to German civil law. From an insurance point of view, it is also problematic that a disclosure request that merely serves the purpose of finding out whether a claim exists, but no actual claim has been made, would not trigger insurance cover. However, the insured defendant will expect coverage from his insurer in this case as well.

1.2 Defences (Art. 10 PLD-P)

We welcome that the existing exceptions from liability are to be maintained - albeit in a modified form. These represent a necessary correlation to producers' strict liability and as such enable a comprehensive level of product liability insurance protection. In particular, the development risk defence (i.e. the product defect was objectively undetectable according to the state of science and technology - the strictest standard known to technology law - at the time it was placed on the market) is indispensable to enable technological innovation. Innovation would be inhibited if manufacturers could be held liable for defects that were objectively undiscoverable at the time of marketing.

1.3 Scope of application of the PLD-P

1.3.1 German Pharmaceutical liability (sections 84ff. of the German Pharmaceuticals Act – Arzneimittelgesetz, AMG)

According to recital 10 PLD-P, consumers are adequately protected where specific national liability provisions exist for persons injured by pharmaceutical products exist in some Member States; the right to bring such claims is to remain unaffected by the PLD-P. In Germany, this concerns the special liability of the pharmaceutical entrepreneur according to sections 84ff. AMG. Art. 2 PLD-P provides in para. 3(c) and (d) that claims under national law remain unaffected, which either do not require a product defect or were already in force before 30 July 1985. Both of these criteria apply to liability under sections 84ff. AMG. However, the wording in Art. 2 PLD-D is not clear. In this respect, it should be clarified that liability under sections 84ff. AMG (and under similar provisions in the law of the Member States) remains excluded from the scope of application of the PLD, so that the provisions of the PLD do not affect these national liability situations. Otherwise, the insurability of the AMG liability, which is subject to mandatory financial security, and which is currently insured by an insurer pool (the so-called Pharma Pool), could be called into question.

1.3.2 Priority of specific liability provisions in other Union legislation

For reasons of legal certainty and to avoid contradictory provisions, it should be made clear that specific liability provisions in Union legislation other than the PLD, e.g. under the GDPR or the Medical Devices Regulation, take precedence over the PLD and supersede it ("lex specialis").

1.3.3 Clinical studies and trials

It should be clarified that medical and pharmaceutical products used in the context of clinical trials or studies have not been "placed/made available on the market" or "put into service" within the meaning of the PLD-P and are thus excluded from the scope of the PLD-P.

1.3.4 Hospital as producer

In 2015, the Higher Regional Court of Koblenz ruled that a hospital can be considered a producer in the sense of the PLD if a surgeon combines a hip prosthesis stem with a joint head to form a complete hip prosthesis. We suggest to use the opportunity of the PLD recast

to exclude this - surely unintended - interpretation by adding suitable wording to Art. 4(8)-(10) PLD-P.

1.4 Updates

The PLD-P introduces a de-facto obligation for the provision of safety-relevant updates. This "update obligation" should be time-limited in order to prevent “everlasting” liability. The proposal for a "Cyber Resilience Act", to which the PLD-P makes explicit reference, limits it to 5 years.

The provision of updates could be considered a "substantial modification" of a product within the meaning of Art. 7(4) PLD-P. In this case, the 10-year limitation period according to Art. 14(2) would be restarted with each provision of an update. In this respect, a clarification should be included as to the point in time at which claims finally expire.

Finally, with regard to Art. 2(1), it is not clear how products are treated that were placed on the market before the PLD-P comes into force, but which receive an update after that time. Here, too, clarification would be useful.

Generally, overlapping or contradictory requirements in different legislative acts, such as the Medical Devices Regulation or the proposed Cyber Resilience Act, should be avoided in the interest of legal certainty.

2 Proposal for a Directive on AI Liability (AILD-P)

The AILD-P provides for harmonised evidentiary relief to be implemented in national non-contractual fault-based liability legislation. Its key terms and concepts reference the proposed Artificial Intelligence Act (AI Act). The AI Act itself is currently still hotly discussed. A detailed assessment of the concrete effects of the AILD-P therefore only appears possible once the AI Act has been finalised.

We welcome the fact that the AILD-P does not propose a new, distinct harmonised liability regime for damage sustained in connection with AI. Seeing that economic actors covered by the PLD-P can also fall under the scope of the AILD-P, we further welcome the fact that an accumulation of the various reliefs foreseen under the PLD-P with those proposed under the AILD-P is to be ruled out.

However, we doubt that such far-reaching interventions in the distribution of the burden of proof are necessary for AI systems of all kinds (albeit with stricter provisions for high-risk AI systems than for other AI systems). In addition, a review is foreseen after 5 years to establish whether a harmonised specific strict liability regime for AI systems should be introduced, possibly flanked by mandatory financial security.

The term "AI system" refers to a large number of different applications with quite heterogeneous potential for causing damage. For those AI applications that are especially relevant at this point in time - autonomous motor vehicles and aircraft - adequate liability rules (predominantly in the form of strict liability) already exist at national level – as well as harmonised insurance obligations under Union law in the form of the MID and Regulation 785/2004. We see no need for additional liability legislation in this respect. In order not to anticipate future technical developments in liability law with the danger of introducing unsuitable rules, we suggest first to identify additional AI applications that potentially require additional dedicated liability provisions. In case systematic deficits in the existing liability regimes can be demonstrated, specific remedies to these deficits should be considered.

The proposed provisions on disclosure obligations and easing the burden of proof are similar to the corresponding provisions of the PLD-P. In this respect, we refer to our basic assessment above under 1.1.