EUROPEAN COMMISSION PROPOSED PRODUCT LIABILITY DIRECTIVE
EFPIA POSITION PAPER

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I. EXECUTIVE SUMMARY

(1) On 28 September, the European Commission (**Commission**) published its proposed Product Liability Directive (the **Proposal**) which would, if adopted, replace and modernise the existing Product Liability Directive (the **Directive**), adopted in 1985.

(2) The Proposal is part of the Commission's overall plan to adapt product liability rules for the digital age. The Proposal sets out rules on the strict liability of manufacturers for defective products, including for damage caused by software. It has been issued alongside the Commission's proposed AI Liability Directive (**Proposed AILD**), which aims to harmonise certain aspects of national fault-based liability regimes relating to damage caused by AI systems specifically[i].

(3) Since its adoption nearly 40 years ago, the Directive has largely proved effective in achieving its main objective of "*ensuring a fair balance of the interests of consumers and producers*"[ii]. In considering adaptations, it is vital to maintain this balance. Specifically, in order to fully benefit from technological developments and promote the EU's transition to the digital economy, the EU's product liability framework must strike an appropriate balance between consumer protection and innovation, while ensuring that the regime is predictable and legally certain.

(4) This is particularly so in R&D-intensive industries such as pharmaceuticals. Recent technological developments, particularly AI, are of particular importance for the pharmaceutical industry and have the potential to contribute significantly to improved patient care and the safety of medicinal products.

(5) However, the Proposal risks undermining both this balance of interests and legal certainty, in turn hindering investment in new technologies to the disadvantage of patients and consumers. In order to protect themselves against unnecessary speculative litigation risks, producers[1] will likely have to spend more on insurance premiums and legal fees, as well as devoting time to defensive market strategies, instead of innovating. This will ultimately be reflected in consumer prices and the availability of products on the market, and may even require producers to pull out of certain markets altogether.

(6) This paper makes the following points:

a. The Proposal conflates product safety and product liability rules, going beyond its necessary scope and placing an undue burden on producers. See *Section II* below.

b. The Proposal leads to a *de facto* reversal of the burden of proof that will deter innovation by exposing producers to a constant threat of unnecessary litigation. See *Section III* below.

[1] For the purposes of this paper, 'producer' refers to the manufacturer of a product or component, the provider of a related service, the authorised representative, the importer, the fulfilment service provider or the distributor.

c. The Proposal imposes disproportionate disclosure requirements on producers, unnecessarily compounding the liability risk faced by producers and further disincentivising innovation. See *Section IV* below.

d. The Proposal is unnecessarily broad in scope, disrupting the careful balance of interests under the existing Directive. See *Section V* below.

e. The Proposal fails to provide appropriate claims thresholds, further undermining legal certainty and increasing the threat of unnecessary litigation. See *Section VI* below.

II. THE PROPOSAL CONFLATES PRODUCT SAFETY AND PRODUCT LIABILITY RULES

(7) The Proposal conflates product safety and product liability rules. Under the Proposal, a product will automatically be presumed to be defective if it does not comply with relevant product safety rules under EU or national law[iii].

(8) The EU's product safety framework provides for a sophisticated regime to guarantee a high level of consumer protection. In relation to pharmaceuticals, this includes some of the world's most exigent and extensive product and human safety requirements. Further, the relevant regulators have extensive tools at their disposal to monitor continuously the efficacy and risk profile of pharmaceutical products.

(9) It is common for pharmaceutical producers to be in continuous dialogue with regulators regarding product safety, particularly with respect to the multitudinous pharmacovigilance obligations imposed such as updates to labelling and the supply of data on suspected adverse reactions, all of which must be supplied within specific deadlines and in specific forms, etc. With such extensive requirements in place, it can happen that a producer may find themselves in technical breach of an obligation (e.g., the late submission of some necessary data). Regulators have the tools to ensure compliance, including tools to find that a breach of a technical obligation has occurred. However, the finding of such a breach in no way amounts to a regulatory determination that a product is unsafe for use or is "defective". Under the current Proposal, even a minor technical breach of a pharmacovigilance obligation may be sufficient to allow a product to be presumed defective, even if the competent regulatory body had made no such determination.

(10) Such a possibility usurps the regulatory function, and can lead to conflicting outcomes: even though a competent product safety authority has no issue with a product's risk profile, or with it continuing to be available on the market, the civil liability regime would *presume* the product to be defective, with all of the consequences this entails.

(11) Next, the Proposal provides that "*(t)he 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*"[iv].

(12) The Proposal rightly requires that liability should rest upon a claimant establishing (a) defect, (b) harm, and (c) a causal link between the two. However, the Proposal provides

that two of the three essential requirements (defect and causation) can simply be presumed, meaning that in law it may be sufficient for a claimant only to show harm and legal presumptions alone will be sufficient to find a producer liable from that point.

(13) It takes $2.6 billion and 12-13 years[v] on average for a pharmaceutical company to bring a product to the market. Considerable time and resources are devoted to complying with relevant product safety regulations and obtaining the necessary marketing authorisations. In addition to the significant and increasing costs of pharmaceutical R&D, companies spend extensive time and resources to undergo the detailed scientific assessment process needed to ensure that products meet relevant safety standards before they are commercialised. Even once approved, pharmaceutical producers are required to comply with regular scientific reviews (reflecting the most up-to-date state of scientific and technical knowledge) and rigorous safety monitoring rules. The Proposal should not usurp the power of competent regulatory authorities to determine the safety and efficacy of such regulated products by *presuming* that a product is defective in the civil liability sense, where the competent authority itself has not made any such determination.

III. THE PROPOSAL LEADS TO A *DE FACTO* REVERSAL OF THE BURDEN OF PROOF

(14) The Proposal provides for rebuttable presumptions that a product is defective and its defectiveness caused the alleged damage[vi].

(15) The defectiveness of the product shall be presumed where:

a. the defendant fails to comply with a court order to disclose relevant evidence (as described in *Section IV* below);

b. the claimant has established that the product does not comply with relevant safety requirements under EU or national law;

c. the claimant has established that the damage was caused by an obvious malfunction of the product during normal use or under ordinary circumstances, or

d. the claimant faces excessive difficulties in proving the defectiveness of a product due to its technical or scientific complexity and the claimant has demonstrated that (i) the product contributed to the damage and (ii) it is likely that the product was defective.

(16) The causal link between the defectiveness of the product and any damage caused shall be presumed where:

a. the claimant has established that the product is defective and the damage caused is of a kind typically consistent with the defect in question, or

b. the claimant faces excessive difficulties in proving the causal link due to the technical or scientific complexity of the product and the claimant has demonstrated that (i) the product contributed to the damage and (ii) its defectiveness is a likely cause of the damage.

(17) The practical effect of these presumptions is to reverse the burden of proof from claimant to defendant: where a presumption applies, the defendant is required to "prove a negative" by demonstrating that the product is not defective or the lack of a causal link.

(18) An appropriate allocation of the burden of proof, founded on causation and fair apportionment of risk, is the cornerstone of a balanced product liability regime. Of particular importance is the requirement for a claimant to prove causation as it is fundamental to maintaining an adequate balance between the interests of consumers and producers. This balance is especially important in fast-paced and innovative industries such as pharmaceuticals, which require significant time and resources to develop new technologies. To be able to invest and innovate, producers must have sufficient certainty that they will be provided with minimum protections from unnecessary litigation, including litigation which is frivolous or vexatious, or simply speculative or opportunistic. In particular, where the burden of proof is so materially changed, it may be that producers have little or no alternative but to pay-out on claims that should not – without the benefit of presumptions to tip the scales – succeed.

(19) This is particularly so given the possibility to bring representative actions under the Proposal, thereby potentially swelling the size and scope of claims. To introduce this possibility alongside far-reaching alleviations to the burden of proof requirements will likely embolden those who may wish to initiate opportunistic litigation primarily for their own ends.

(20) So as to shield themselves against the costs of unnecessary litigation, producers will have to spend more on insurance premiums and legal fees, as well as devoting time to defensive market strategies, instead of innovating. This will in turn likely be reflected in higher prices and the availability (potentially even shortages) of products on the market. Indeed, if forced to account for and accept materially different risk of liability and financial burdens (even where that liability is not based on proven fault), producers might become reluctant to invest and innovate in the first place, which risks obstructing many potentially significant societal and economic benefits from the development of new technologies.

(21) Rather than encouraging more litigation, the EU product liability framework should in any case facilitate alternative dispute resolution mechanisms. The Commission has itself found that litigation is a less effective, less equitable and more expensive means to obtain compensation[vii]. In this respect, the Proposal represents a missed opportunity to promote more appropriate means of redress for injured parties.

(22) As such, in order to protect consumers from these consequences, and to ensure a balanced and fair legal system that provides for the appropriate apportionment of risk, the Proposal should maintain the fundamental procedural safeguards that require claimants to demonstrate fault and causation in order to obtain compensation. If the presumptions are introduced, the EU should provide clearer guidance on the circumstances in which they would apply, underpinned by clear and objective criteria.

IV. THE PROPOSAL IMPOSES DISPROPORTIONATE DISCLOSURE REQUIREMENTS

(23) The Proposal provides that courts are able to require producers to disclose relevant evidence at their disposal in order to support a claimant's action[viii].

(24) The concept of "relevant" evidence has not been defined and risks being overly subjective, failing to provide sufficient legal certainty. The concept also appears to be at odds with the requirement that such disclosure should be limited to that which is necessary and proportionate[ix], which naturally narrows the scope of the obligation.

(25) If, in the future, a defendant's liability will be determined by whether they are in a position to produce evidence and data to prove the *absence* of their responsibility for unknown future harms, this will have real-world implications on how they must conduct their activities today. As it cannot be known what claims might arise, a cautious producer may need to log and record every development step and all relevant data specifically with future litigation defense in mind, and in ways that would be required by no regulatory system. This risks placing an immense and disproportionate burden on producers, particularly for SMEs and start-ups who often will have more limited resources.

(26) As a result of this burden, for certain claims it will likely be easier for producers to pay-out or settle the claim rather than comply with the disclosure obligations. This opens the door for opportunistic claimants to seek compensation of speculative bases, using the threat and cost of disclosure as a means to extract settlements. Such tactics are commonly referred to as pursuing "blackmail settlements", and are common in litigation where appropriate safeguards are not in place.

(27) In practical terms, the introduction of such broad disclosure requirements will likely represent significant challenges for the legal procedures and jurisprudence of EU Member States. It may also be unworkable for parties to conclude contractual terms that would adequately offset the associated liability risks.

(28) As such, the requirement for a claimant to produce their own evidence to establish their claim should serve as a minimum necessary threshold to protect producers from opportunistic litigation. Removing such well-established guarantees would result in unduly heavy liability burdens on producers, undermining their incentives to innovate to the ultimate disadvantage of consumers and wider society. At the very least, any disclosure obligations should be limited to simply that which is necessary and proportionate. In particular, producers should only be required to disclose information that is readily available to them (e.g., information that the producer has already provided to a notified body during a conformity assessment), rather than having to produce new evidence in order to defend themselves against potentially speculative and opportunistic claims.

(29) In addition, the evidence disclosure and preservation obligations compound the risks identified under *Section III* above, further exposing producers to the constant threat of unnecessary litigation.

V. THE PROPOSAL IS UNNECESSARILY BROAD IN SCOPE

(30) In order to ensure a balanced liability regime, any adjustments to the definitions under the existing Directive must also be balanced and proportionate. To date, these definitions have been effective and remain largely fit for purpose. While small refinements may be required to adjust the definitions for the digital age, an overly broad approach should be avoided. In the Commission's own words, any revisions must be careful not to "*upset this balance* [i.e., the balance between consumer protection and innovation] *leading to adverse economic effect and diminishing the level of consumer protection*" [x].

a) *Definition of 'Product'*

(31) The definition of 'product' has been expanded under the Proposal to include, among other things, electricity, digital manufacturing files and software[xi].

(32) This definition is overly broad and fails to account for important nuance. The resulting lack of clarity may risk undermining the effective application of the Proposal.

(33) While software that controls how a device operates should constitute a 'product', ancillary software (such as a gaming app or a digital map) that does not control how the device functions should not be included. In addition, the definition of 'product' should differentiate between various categories of products and applications, for instance between complex AI systems and less sophisticated algorithms that have been in safe use for decades.

(34) It is also not appropriate for blanket strict liability to be imposed for all types of software. For most AI systems, by their very nature, the outcomes produced cannot be foreseen at the time of development and commercialisation. As such, strict liability for AI systems should be limited to exceptional and clearly defined high risk circumstances.

b) *Definition of 'Damage'*

(35) The definition of 'damage' has been expanded under the Proposal to include psychological harm and the loss or corruption of certain types of data[xii].

(36) There is no need to expand this definition to include nebulous concepts of non-material damage – indeed, it would be inappropriate to impose strict liability in these circumstances. To permit certainty and avoid encouraging speculative claims, damage should be provable, foreseeable and scientifically quantifiable. Without such certainty, there is a real risk that a claim will escalate into punitive levels of damages. Imposing penalties is the function of the EU's regulatory regime, and should not form part of any system to award compensation for actual damage suffered.

(37) In any event, claimants may already seek compensation for these types of damage under national fault-based product liability regimes and may seek recourse for data-related infringements at EU-level through the GDPR. To include data infringements at EU level under the Proposal further undermines legal certainty and gives rise to the risk of inconsistent or conflicting enforcement with the GDPR.

(38) Furthermore, insurers have great difficulty quantifying non-material damage risks, which gives rise to the risk that premiums would rise materially if these types of damage are included, a cost that would ultimately be reflected in consumer prices.

(39) As such, the current definition of 'damage' under the existing Directive should be retained as it is already effective and adequately broad.

a) Definition of 'Defect'

(40) The list of circumstances that should be taken into account to determine whether a produce is 'defective' has been expanded under the Proposal to include, among other things, (i) the reasonably foreseeable misuse of a product; and (ii) the effect on the product's ability to learn after deployment[xiii] (according to the Commission, "*to reflect the legitimate expectation that a product's software and underlying algorithms are designed […] to prevent hazardous behaviour*"[xiv]).

(41) Firstly, to include 'misuse' in the list of relevant circumstances considerably expands the application of the existing Directive, further undermining legal certainty and placing a material burden on companies to anticipate and mitigate their liability risk in the event of misuse of their products. This risks adopting the overly-inclusive approach to product liability. At the very least, if the concept of 'misuse' is adopted, the Proposal should carefully delineate its scope. Importantly, liability should not be presumed in the circumstances where the producer has provided the necessary product instructions and warnings.

(42) Secondly, to include a product's self-learning function as a factor for assessing its defectiveness is likely to further deter AI software developers from installing autonomous decision-making capabilities. They will be reluctant to enable this function where there is a risk that they will be held liable for outcomes that are unforeseeable and outside of their control.

c) *Definition of 'Economic Operator'*

(43) The term 'producer' has been replaced under the Proposal by the term 'economic operator', which includes the manufacturer of a product or component, provider of a related service, authorised representative, importer, fulfilment service provider or distributor[xv]. Each of these operators may be held liable for damage caused by a defective product where the operator preceding them in the supply chain does not have an established base in the EU[xvi]. Liability may also extend to online marketplaces in certain circumstances[xvii].

(44) Crucially, producers should not be required to account for, and accept, liability in circumstances where they are not in control of the risk or where the risk should be properly allocated to another party.

(45) While it is important that the Directive provides efficient and effective redress for injured parties, it is equally essential to ensure that certain limits are in place to provide legal certainty for businesses. The current concept of 'producer' in the existing Directive is sufficiently broad, already including other parties in the supply chain e.g.,

manufacturers of components, raw materials and importers. To further broaden the scope would risk discouraging EU-based operators to facilitate the import of products into the EU, ultimately resulting in reduced choice for consumers.

VI. THE PROPOSAL FAILS TO PROVIDE APPROPRIATE CLAIMS THRESHOLDS

(46) Since it entered into force in 1985, the Directive has provided for certain temporal and monetary minimum thresholds "*in order to avoid litigation in an excessive number of cases*"[xviii]. This rationale still holds true today.

(47) However, the Proposal has weakened the existing claims thresholds, further undermining legal certainty and exposing producers to an increased threat of unnecessary and opportunistic litigation.

a) *Weakened limitation period*

(48) The Proposal extends the time limit for claimants to bring a claim from 10 to 15 years in circumstances where the symptoms of personal injury are slow to emerge, e.g., following ingestion of a defective chemical or food product[xix].

(49) As the Commission indicated in its appraisal of the Directive, "*the time-limits aim at creating a balance between the interests of producers and those of injured parties … to give legal certainty and reduce financial burdens for producers*"[xx]. Indeed, the existing time limits strike an appropriate balance between providing potential claimants with adequate time within which to launch a claim and persevering legal certainty for producers.

(50) To weaken the limitation period would be disproportionate, fail to provide sufficient legal certainty for producers and may create issues relating to data processing and retention for certain industries, including pharmaceutical companies that operate with the 10-year time limit. Such a time limit extension may have implications for data retention practices and may clash with GDPR requirements, which states that personal data should not be kept "*longer than necessary*"[xxi].

b) *Removal of minimum claims value*

(51) The Proposal has removed the EUR 500 minimum value threshold for claims.

(52) This change is also disproportionate, failing to adequately protect producers from frivolous and vexatious litigation. If anything, the minimum value threshold should be adjusted upwards for inflation since it has not been updated since the existing Directive was introduced in 1985.

(53) In any event, as explained in *Section III* above, alternatives to court-based litigation should be prioritised for product liability claims, particularly for claims of lower value, in the interests of the efficient administration of justice.

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[i] EFPIA has provided comments on the Proposed AILD in a separate submission.

[ii] COM (2018) 246 Final, *Report From The Commission To The European Parliament, The Council And The European Economic And Social Committee on the Application of the Council Directive on the approximation of the laws, regulations, and administrative provisions of the Member States concerning liability for defective products (85/374/EEC)*, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2018:246:FIN.

[iii] Article 9(2)(a) of the Proposal.

iv Article 9(3) of the Proposal.

[v] EFPIA, *The Pharmaceutical Industry in Figures*, available at:

https://www.efpia.eu/media/602709/the-pharmaceutical-industry-in-figures-2021.pdf, pp. 6 and 9.

[vi] Article 9 of the Proposal.

[vii] European Commission, *Alternative Dispute Resolution for Consumers*, available at: https://ec.europa.eu/info/live-work-travel-eu/consumer-rights-and-complaints/resolve-your-consumer-complaint/alternative-dispute-resolution-consumers_en.

[viii] Article 8 of the Proposal.

[ix] Article 8(2) of the Proposal.

[x] COM (2006) 496 Final, *Third report on the application of Council Directive on the approximation of laws, regulations and administrative provisions of the Member States concerning liability for defective products (85/374/EEC of 25 July 1985, amended by Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999)*, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52006DC0496&from=EN, p. 8.

[xi] Article 4(1) of the Proposal.

[xii] Article 4(6) of the Proposal.

[xiii] Article 6 of the Proposal.

[xiv] Recital 23 to the Proposal.

[xv] Article 4(16) of the Proposal.

[xvi] Article 7 of the Proposal.

[xvii] Ibid.

[xviii] Recital 9 to the Directive.

[xix] Article 14(3) of the Proposal.

[xx] SWD (2018) 157 Final, *Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee on the Application of the Council Directive on the approximation of the laws, regulations, and administrative provisions of the Member States concerning liability for defective products (85/374/EEC)*, available at:

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=SWD:2018:157:FIN, p. 9.

[xxi] Regulation (EU) 2016/679 of the European Parliament and the Council *on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation*), available at: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679&from=EN#d1e40-1-1, recital 39.