

# Adapting liability rules to the digital age and Artificial Intelligence

Fields marked with \* are mandatory.

## Introduction

---

This public consultation aims to:

- confirm the relevance of the issues identified by the 2018 evaluation of the Product Liability Directive (e.g. how to apply the Directive to products in the digital and circular economy), and gather information and views on how to improve the Directive (Section I);
- collect information on the need and possible ways to address issues related specifically to damage caused by Artificial Intelligence systems, which concerns both the Product Liability Directive and national civil liability rules (Section II).

You can respond to both sections or just to Section I. It is not possible to respond only to Section II.

---

## About you

---

### \* Language of my contribution

- Bulgarian
- Croatian
- Czech
- Danish
- Dutch
- English
- Estonian
- Finnish
- French
- German
- Greek
- Hungarian

- Irish
- Italian
- Latvian
- Lithuanian
- Maltese
- Polish
- Portuguese
- Romanian
- Slovak
- Slovenian
- Spanish
- Swedish

\* I am giving my contribution as

- Academic/research institution
- Business association
- Company/business organisation
- Consumer organisation
- EU citizen
- Environmental organisation
- Non-EU citizen
- Non-governmental organisation (NGO)
- Public authority
- Trade union
- Other

\* First name

Victor

\* Surname

Stoimenov

\* Email (this won't be published)

V.Stoimenov@medtecheurope.org

\* Organisation name

255 character(s) maximum

MedTech Europe

\* Organisation size

- Micro (1 to 9 employees)
- Small (10 to 49 employees)
- Medium (50 to 249 employees)
- Large (250 or more)

Transparency register number

255 character(s) maximum

Check if your organisation is on the [transparency register](#). It's a voluntary database for organisations seeking to influence EU decision-making.

433743725252-26

\* Country of origin

Please add your country of origin, or that of your organisation.

- |   |  |  |  |
|---|--|--|--|
| <input type="radio"/> Afghanistan         | <input type="radio"/> Djibouti           | <input type="radio"/> Libya            | <input type="radio"/> Saint Martin                     |
| <input type="radio"/> Åland Islands       | <input type="radio"/> Dominica           | <input type="radio"/> Liechtenstein    | <input type="radio"/> Saint Pierre and Miquelon        |
| <input type="radio"/> Albania             | <input type="radio"/> Dominican Republic | <input type="radio"/> Lithuania        | <input type="radio"/> Saint Vincent and the Grenadines |
| <input type="radio"/> Algeria             | <input type="radio"/> Ecuador            | <input type="radio"/> Luxembourg       | <input type="radio"/> Samoa                            |
| <input type="radio"/> American Samoa      | <input type="radio"/> Egypt              | <input type="radio"/> Macau            | <input type="radio"/> San Marino                       |
| <input type="radio"/> Andorra             | <input type="radio"/> El Salvador        | <input type="radio"/> Madagascar       | <input type="radio"/> São Tomé and Príncipe            |
| <input type="radio"/> Angola              | <input type="radio"/> Equatorial Guinea  | <input type="radio"/> Malawi           | <input type="radio"/> Saudi Arabia                     |
| <input type="radio"/> Anguilla            | <input type="radio"/> Eritrea            | <input type="radio"/> Malaysia         | <input type="radio"/> Senegal                          |
| <input type="radio"/> Antarctica          | <input type="radio"/> Estonia            | <input type="radio"/> Maldives         | <input type="radio"/> Serbia                           |
| <input type="radio"/> Antigua and Barbuda | <input type="radio"/> Eswatini           | <input type="radio"/> Mali             | <input type="radio"/> Seychelles                       |
| <input type="radio"/> Argentina           | <input type="radio"/> Ethiopia           | <input type="radio"/> Malta            | <input type="radio"/> Sierra Leone                     |
| <input type="radio"/> Armenia             | <input type="radio"/> Falkland Islands   | <input type="radio"/> Marshall Islands | <input type="radio"/> Singapore                        |
| <input type="radio"/> Aruba               | <input type="radio"/> Faroe Islands      | <input type="radio"/> Martinique       | <input type="radio"/> Sint Maarten                     |

- Australia
- Austria
- Azerbaijan
- Bahamas
- Bahrain
- Bangladesh
- Barbados
- Belarus
- Belgium
- Belize
- Benin
- Bermuda
- Bhutan
- Bolivia
- Bonaire Saint Eustatius and Saba
- Bosnia and Herzegovina
- Botswana
- Bouvet Island
- Brazil
- British Indian Ocean Territory
- British Virgin Islands
- Brunei
- Bulgaria
- Burkina Faso
- Fiji
- Finland
- France
- French Guiana
- French Polynesia
- French Southern and Antarctic Lands
- Gabon
- Georgia
- Germany
- Ghana
- Gibraltar
- Greece
- Greenland
- Grenada
- Guadeloupe
- Guam
- Guatemala
- Guernsey
- Guinea
- Guinea-Bissau
- Guyana
- Haiti
- Heard Island and McDonald Islands
- Honduras
- Mauritania
- Mauritius
- Mayotte
- Mexico
- Micronesia
- Moldova
- Monaco
- Mongolia
- Montenegro
- Montserrat
- Morocco
- Mozambique
- Myanmar/Burma
- Namibia
- Nauru
- Nepal
- Netherlands
- New Caledonia
- New Zealand
- Nicaragua
- Niger
- Nigeria
- Niue
- Norfolk Island
- Slovakia
- Slovenia
- Solomon Islands
- Somalia
- South Africa
- South Georgia and the South Sandwich Islands
- South Korea
- South Sudan
- Spain
- Sri Lanka
- Sudan
- Suriname
- Svalbard and Jan Mayen
- Sweden
- Switzerland
- Syria
- Taiwan
- Tajikistan
- Tanzania
- Thailand
- The Gambia
- Timor-Leste
- Togo
- Tokelau

- Burundi
- Cambodia
- Cameroon
- Canada
- Cape Verde
- Cayman Islands
- Central African Republic
- Chad
- Chile
- China
- Christmas Island
- Clipperton
- Cocos (Keeling) Islands
- Colombia
- Comoros
- Congo
- Cook Islands
- Costa Rica
- Côte d'Ivoire
- Croatia
- Cuba
- Curaçao
- Cyprus
- Czechia
- Hong Kong
- Hungary
- Iceland
- India
- Indonesia
- Iran
- Iraq
- Ireland
- Isle of Man
- Israel
- Italy
- Jamaica
- Japan
- Jersey
- Jordan
- Kazakhstan
- Kenya
- Kiribati
- Kosovo
- Kuwait
- Kyrgyzstan
- Laos
- Latvia
- Lebanon
- Northern Mariana Islands
- North Korea
- North Macedonia
- Norway
- Oman
- Pakistan
- Palau
- Palestine
- Panama
- Papua New Guinea
- Paraguay
- Peru
- Philippines
- Pitcairn Islands
- Poland
- Portugal
- Puerto Rico
- Qatar
- Réunion
- Romania
- Russia
- Rwanda
- Saint Barthélemy
- Saint Helena  
Ascension and  
Tristan da Cunha
- Tonga
- Trinidad and Tobago
- Tunisia
- Turkey
- Turkmenistan
- Turks and Caicos Islands
- Tuvalu
- Uganda
- Ukraine
- United Arab Emirates
- United Kingdom
- United States
- United States  
Minor Outlying  
Islands
- Uruguay
- US Virgin Islands
- Uzbekistan
- Vanuatu
- Vatican City
- Venezuela
- Vietnam
- Wallis and Futuna
- Western Sahara
- Yemen
- Zambia

- Democratic Republic of the Congo
- Lesotho
- Saint Kitts and Nevis
- Zimbabwe
- Denmark
- Liberia
- Saint Lucia

The Commission will publish all contributions to this public consultation. You can choose whether you would prefer to have your details published or to remain anonymous when your contribution is published. **For the purpose of transparency, the type of respondent (for example, ‘business association’, ‘consumer association’, ‘EU citizen’) country of origin, organisation name and size, and its transparency register number, are always published. Your e-mail address will never be published.** Opt in to select the privacy option that best suits you. Privacy options default based on the type of respondent selected

### \* Contribution publication privacy settings

The Commission will publish the responses to this public consultation. You can choose whether you would like your details to be made public or to remain anonymous.

**Anonymous**

Only organisation details are published: The type of respondent that you responded to this consultation as, the name of the organisation on whose behalf you reply as well as its transparency number, its size, its country of origin and your contribution will be published as received. Your name will not be published. Please do not include any personal data in the contribution itself if you want to remain anonymous.

**Public**

Organisation details and respondent details are published: The type of respondent that you responded to this consultation as, the name of the organisation on whose behalf you reply as well as its transparency number, its size, its country of origin and your contribution will be published. Your name will also be published.

I agree with the [personal data protection provisions](#)

## Section I – Product Liability Directive

This section of the consultation concerns Council Directive 85/374/EEC on liability for defective products (“Product Liability Directive”), which applies to any product marketed in the European Economic Area (27 EU countries plus Iceland, Liechtenstein and Norway). See also Section II for more in-depth questions about the Directive and AI.

According to the Directive, if a defective product causes damage to consumers, the producer must pay compensation. The injured party must prove the product was defective, as well as the causal link between the defect and the damage. But the injured party does not have to prove that the producer was at fault or negligent ('strict liability'). In certain circumstances, producers are exempted from liability if they prove, e.g. that the product's defect was not discoverable based on the best scientific knowledge at the time it was placed on the market.

Injured parties can claim compensation for death, personal injury as well as property damage if the property is intended for private use and the damage exceeds EUR 500. The injured party has 3 years to seek compensation. In addition, the producer is freed from liability 10 years after the date the product was put into circulation.

The [Evaluation of the Directive](#) in 2018 found that it was effective overall, but difficult to apply to products in the digital and circular economy because of its outdated concepts. The [Commission's 2020 Report on Safety and Liability for AI, Internet of things \(IoT\) and robotics](#) also confirmed this.

The Evaluation also found that consumers faced obstacles to making compensation claims, due to thresholds and time limits, and obstacles to getting compensation, especially for complex products, due to the burden of proof.

---

### \* How familiar are you with the Directive?

- I have detailed knowledge of the Directive, its objectives, rules and application
  - I am aware of the Directive and some of its contents
  - I am not familiar with the Directive
  - No opinion
- 
- 

### Adapting the Directive to the digital age

Digital content such as software, algorithms and data are playing an increasingly crucial role in the safe functioning of many products, e.g. domestic appliances, vehicles, smart lawnmowers and surgical robots.

However, the Evaluation of the Directive found that the Directive was not easy to apply to digital technologies. Above all, it is not clear whether intangible items like digital content, software and data are covered, especially when supplied separately from a tangible product. Therefore, it is not clear whether consumers can get compensation under the Directive in the event that 'digital' defects lead to damage.

**Do you agree or disagree that consumers should get compensation under the Directive if the following intangible items are defective and cause physical /property damage?**

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion
Software embedded in a tangible product at the moment the tangible product is placed on the market	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Software made available separately via download for use on a tangible product (e.g. domestic robot) that has already been placed on the market	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Software upgrades and updates (e.g. to deliver new functionalities or fix a security flaw)	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Software that controls how a product operates (e.g. a car's engine control system, a robot's operating system)	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Software that is used on a device but does not drive the device (e.g. a gaming app on a computer or other device)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Bespoke software (e.g. software customised to control the production line in a factory)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Digital services that control how a product operates (e.g. cloud-based service for operating smart thermostat)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Data capable of influencing how a product operates (e.g. training data for an autonomous vehicle)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Data that comprises only information (e.g. a digital map, a menu)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Software that provides immediate decision-triggering information (e.g. blood glucose meter)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Software that provides only guidance or advice to an end user (e.g. software that interprets medical imaging and provides diagnoses)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
--	-----------------------	----------------------------------	-----------------------	-----------------------	-----------------------	-----------------------

The Directive holds importers strictly liable for damage caused by defective products when the producer is based outside the EU. Nowadays online marketplaces enable consumers to buy products from outside the EU without there being an importer.

Online marketplaces intermediate the sale of products between traders, including those established outside the EU, and consumers. Typically, they are not in contact with the products they intermediate and they frequently intermediate trade between many sellers and consumers.

Under the current rules, online marketplaces are covered by a conditional liability exemption (Article 14 of the e-Commerce Directive). The new proposal for a Digital Services Act includes obligations for online marketplaces to tackle illegal products online, e.g. gathering information on the identity of traders using their services. Moreover, the new proposal for a General Product Safety Regulation includes provisions for online marketplaces to tackle the sale of dangerous products online.

**Do you agree or disagree with the following statements?**

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion
The proposals for a Digital Services Act and General Product Safety Regulation are sufficient to ensure consumer protection as regards products bought through online marketplaces where there is no EU-based producer or importer.	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The Product Liability Directive needs to be adapted to ensure consumer protection if damage is caused by defective products	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

bought through online marketplaces where there is no EU-based producer or importer.						
---	--	--	--	--	--	--

**What do you think is the appropriate approach for consumers to claim compensation when damage is caused by a defective product bought through an online marketplace and there is no EU-based producer or importer?**

*2000 character(s) maximum*

For the medical technology (medtech) sector, the approach taken in the sectoral legislation regulates distance sales (Article 6 MDR/IVDR), and specifies that devices offered to natural and legal persons in the Union must comply with those regulations. The fulfilment service provider becomes responsible for the device when there is no representative in the EU (i.e. manufacturer, importer or authorized representative). For the sake of legal clarity, we would support alignment with those rules for other sectors.

Digital technologies may bring with them new risks and new kinds of damage.

- Regarding risks, it is not always clear whether cybersecurity vulnerabilities can be considered a defect under the Directive, particularly as cybersecurity risks evolve throughout a product’s lifetime.
- Regarding damage, the Directive harmonises the rights of consumers to claim compensation for physical injury and property damage, although it lets each Member State decide itself whether to compensate for non-material damage (e.g. privacy infringements, psychological harm). National rules on non-material damage differ widely. At EU level both material and non-material damage can be compensated under the General Data Protection Regulation (GDPR) when a data controller or processor infringes the GDPR, and the Environmental Liability Directive provides for the liability of companies for environmental damage.

**Do you agree or disagree with the following statements?**

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion
Producers should potentially be held strictly liable for damages caused as a result of failure to provide necessary security updates for smart products	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

The Directive should harmonise the right of consumers to claim compensation from producers who are not simultaneously data controllers or processors, for privacy or data protection infringements (e.g. a leak of personal data caused by a defect)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
The Directive should harmonise the right of consumers to claim compensation for damage to, or destruction of, data (e.g. data being wiped from a hard drive even if there is no tangible damage)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
The Directive should harmonise the right of consumers to claim compensation for psychological harm (e.g. abusive robot in a care setting, home-schooling robot)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Some products, whether digital or not, could also cause environmental damage. The Directive should allow consumers to claim compensation for environmental damage (e.g. caused by chemical products)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Coverage of other types of harm	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

## Adapting the Directive to the circular economy

The Directive addresses defects present at the moment a product is placed on the market. However, changes to products after they are placed on the market are increasingly common, e.g. in the context of circular economy business models.

The Evaluation of the Directive found that it was not always clear who should be strictly liable when repaired, refurbished or remanufactured products were defective and caused damage. It is worth noting here that the Directive concerns the

defectiveness of products and not the defectiveness of services. So, a third-party repair that was poorly carried out would not lead to the repairer being held liable under the Directive, although remedies may be available under national law.

**Do you agree or disagree with the following statements?**

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion
Companies that remanufacture a product (e.g. restoring vehicle components to original as-new condition) and place it back on the market should be strictly liable for defects causing damage	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Companies that refurbish a product (e.g. restoring functionality of a used smartphone) and place it back on the market should be strictly liable for defects causing damage	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The manufacturer of a defective spare part added to a product (e.g. to a washing machine) during a repair should be strictly liable for damage caused by that spare part	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

Policy approach and impacts of adapting the Directive to the digital and circular economy

**Please rank the following options for adapting the Directive to the digital and circular economy from 1 (like best) to 3 (like least)**

	1	2	3
* Option 1. No legislative change	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
* Option 2. Make explicit that strict liability rules apply to products incorporating digital content (e.g. software, data). Address defects resulting from changes to products after they are put on the market (due to circular economy activities such as refurbishments, software upgrades, interactions with other products and services, or due to safety-related cybersecurity risks)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
* Option 3. Address defects resulting from changes to products as in Option 2 and extend strict liability to digital content itself (and producers of such digital content) when placed on the market separately from the tangible product	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

**In addition to the policy options presented in the previous question, should the EU take the following additional measures to adapt the Directive to the digital and circular economy?**

	Yes	No	I don't know /no opinion
* Harmonise right to claim for non-material damages under the Directive (e.g. privacy infringement, psychological harm, environmental damage)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
* Define liability rules where there is no EU importer	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
* Other measures	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

Please specify all the relevant impacts that you think the option you ‘like least’ and additional measures that you were against will have on the following aspects, compared to Option 1 (no legislative change). Only select an answer for those impacts that you expect the option you ‘like least’ to have. Impacts left blank will be processed as a ‘No opinion’ reply.

	Large increase	Small increase	No/negligible impact	Small decrease	Large decrease	No opinion
Legal certainty	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Costs for your company	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Consumer protection	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Consumer uptake of products in the digital and circular economy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Purchase price of products	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Incentives for companies to place innovative products on the market	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Competitiveness of micro, small- and medium-sized enterprises (SMEs)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Ability of producers to obtain product liability insurance	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

## Other impacts (please specify):

*200 character(s) maximum*

It is difficult to assess impact on any of these aspects, in absence of an actual proposal. We are however concerned about the exponential liability exposure that may result in new rules.

## Reducing obstacles to getting compensation

The Evaluation of the Directive found that in some cases consumers face significant difficulties in getting compensation for damage caused by defective products.

In particular it found that difficulties in proving the defectiveness of a product and proving that the product caused the damage accounted for 53% of rejected compensation claims. In particular, the technical complexity of certain products (e.g. pharmaceuticals and emerging digital technologies) could make it especially difficult and costly for consumers to actually prove they were defective and that they caused the damage.

**To what extent do you think that the following types of product present difficulties in terms of proving defectiveness and causality in the event of damage?** (See additional burden of proof question concerning AI in Section II)

	To a very large extent	To a large extent	To a moderate extent	To a small extent	Not at all	Don't know /no answer
All products	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Technically complex products	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pharmaceuticals	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
AI-enabled products	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
IoT (Internet of Things) products	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

## Other types of product (please specify):

*50 character(s) maximum*

In an effort to promote innovation, the Directive exempts producers from liability when a product’s lack of safety was not discoverable based on the best scientific knowledge at the time it was placed on the market (‘development risk defence’, Art. 7(e)).

However, the Evaluation found that this defence might be inappropriate when dealing with emerging technologies due to the increasing rate of development and the ability of certain products to adapt while in operation. Furthermore, certain stakeholders considered the defence too advantageous to producers.

**When should producers be able to use the ‘development risk defence’?**

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion
The defence should remain available without any change	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The defence should be removed	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
The defence should not be available for products designed to be influenced by other interconnected products or services (e.g. complex IoT systems)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
The defence should not be available for AI products that continue to learn and adapt while in operation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
The defence should not be available for any AI products	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

**Please specify any other conditions you think should apply to the use of the development risk defence:**

*1000 character(s) maximum*

We would not change the defences as they stand now. The defences that form part of the Directive were drafted deliberately narrowly and form part of the balance between consumer protection and innovation that the drafters of the legislation sought to achieve.

The Evaluation of the Directive found that in some cases consumers faced or could face significant difficulties in making compensation claims for damage caused by defective products. The current rules allow consumers to claim compensation for personal injury or property damage. Time limits apply to all compensation claims and several other limitations apply to compensation for property damage.

**To what extent do the following features of the Directive create obstacles to consumers making compensation claims?**

	To a very large extent	To a large extent	To a moderate extent	To a small extent	Not at all	Don't know /no answer
Producers are released from liability for death/personal injury 10 years after placing the product on the market	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Producers are released from liability for property damage 10 years after placing the product on the market	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Consumers have to start legal proceedings within 3 years of becoming aware of the damage	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Consumers can claim compensation only for damage to property worth more than EUR 500	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Consumers can claim compensation only for damage to property intended and used for private purposes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

**Policy approach and impacts of reducing obstacles to getting compensation and making claims**

**Please rank the following options for adapting the Directive to the digital and circular economy from 1 (like best) to 4 (like least)**

	1	2	3	4
* Option 1. No legislative change	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
* Option 2. Alleviate the burden of proof for technically complex products by: a) obliging the producer to disclose technical information (e.g. data from clinical trials or log data of a robot vacuum cleaner) to the injured party to better enable the latter to prove their claim; and b) allowing courts to infer that a	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

product is defective or caused the damage under certain circumstances (e.g. when other products in the same production series have already been proven to be defective or the product clearly malfunctioned).				
* Option 3. Reverse the burden of proof for technically complex products. In the event of damage, the producer would have to prove the product was not defective.	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
* Option 4. In addition to option 2 or 3: a) adapt the notion of 'defect' and the alleviation/reversal of burden of proof to the specific case of AI; and b) remove the 'development risk defence' to ensure producers of products that continuously learn and adapt while in operation remain strictly liable for damage.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

**In addition to the policy options presented in the previous question, should the EU take the following additional measures to adapt the Directive to reduce obstacles to making claims?**

	Yes	No	I don't know /no opinion
* Harmonise right to claim for non-material damages under the Directive (e.g. privacy infringement, psychological harm, environmental damage)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
* Define liability rules where there is no EU importer	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
* Other measures	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

**Please specify all the relevant impacts that you think the option you ‘like least’ and additional measures that you were against will have on the following aspects, compared to Option 1 (no legislative change). Only select an answer for those impacts that you expect the option you ‘like least’ to have. Impacts left blank will be processed as a ‘No opinion’ reply.**

*at least 4 answered row(s)*

	Large increase	Small increase	No/negligible impact	Small decrease	Large decrease	No opinion
Legal certainty	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Costs for your company	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Consumer protection	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Consumer uptake of products in the digital and circular economy	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Purchase price of products	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Incentives for companies to place innovative products on the market	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Competitiveness of micro, small- and medium-sized enterprises (SMEs)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ability of producers to obtain product liability insurance	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

## Other impacts (please specify):

*200 character(s) maximum*

We believe that a change of the liability rules, coupled with the new Representative Actions Directive will lead to a further lack of trust in healthcare systems.

---

## End of Section I on Product Liability Directive

---

- \* In Section II of this consultation the problems linked to certain types of Artificial Intelligence – which make it difficult to identify the potentially liable person, to prove that person’s fault or to prove the defect of a product and the causal link with the damage – are explored further.

## Would you like to continue with Section II on Artificial Intelligence?

- Continue with Section II on Artificial Intelligence
- Close the questionnaire

## Section II - Liability for AI

---

### Introduction

As a crucial enabling technology, AI can drive both products and services. AI systems can either be provided with a physical product (e.g. an autonomous delivery vehicle) or placed separately on the market.

To facilitate trust in and the roll-out of AI technologies, the Commission is taking a staged approach. First, on 21 April 2021, it [proposed harmonised rules for development, placing on the market and use of certain AI systems \(AI Act\)](#). The AI Act contains obligations on providers and users of AI systems, e.g. on human oversight, transparency and information. In addition, the recent [proposal for a Regulation on Machinery Products](#) (published together with the AI act) also covers new risks originating from emerging technologies, including the integration of AI systems into machinery.

However, safety legislation minimises but cannot fully exclude accidents. The liability frameworks come into play where accidents happen and damage is caused. Therefore, as a next step to complement the recent initiatives aimed at improving the safety of products when they are placed on the EU market, the Commission is considering a revision of the liability framework.

In the [White Paper on AI](#) and the accompanying [2020 Report on Safety and Liability](#), the Commission identified potential problems with liability rules, stemming from the specific properties of certain AI systems. These properties could make it difficult for injured parties to get compensation based on the Product Liability Directive or national fault-based rules. This is because in certain situations, the lack of transparency (opacity) and explainability (complexity) as well as the high degree of autonomy of some AI systems could make it difficult for injured parties to prove a product is defective or to prove fault, and to prove the causal link with the damage.

It may also be uncertain whether and to what extent national strict liability regimes (e.g. for dangerous activities) will apply to the use of AI-enabled products or services. National laws may change, and courts may adapt their interpretation of the law, to address these potential challenges. Regarding national liability rules and their application to AI, these potential problems have been further explored in this recent [study](#).

With this staged approach to AI, the Commission aims to provide the legal certainty necessary for investment and, specifically with this initiative, to ensure that victims of damage caused by AI-enabled products and services have a similar level of protection to victims of technologies that operate without AI. Therefore, this part of the consultation is looking at all three pillars of the existing liability framework.

1. The **Product Liability Directive**, for consumer claims against producers of defective products. The injured party has to prove the product was defective and the causal link between that defect and the damage. As regards the Directive, the proposed questions build on the first section of the consultation.
2. **National fault-based liability rules**: The injured party has to prove the defendant's fault (negligence or intent to harm) and a causal link between that fault and the damage.
3. **National strict liability regimes** set by each Member State for technologies or activities considered to pose an increased risk to society (e.g. cars or construction activities). Strict liability means that the relevant risk is assigned to someone irrespective of fault. This is usually justified by the fact that the strictly liable individual benefits from exposing the public to a risk.

In addition to this framework, the General Data Protection Regulation (GDPR) gives anyone who has suffered material or non-material damage due to an infringement of the Regulation the right to receive compensation from the controller or processor.

## Problems – general

### Do you agree or disagree with the following statements?

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion
There is uncertainty as to how the Product Liability Directive (i.e. liability for defective products) applies to damage caused by AI	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
There is uncertainty as to whether and how liability rules under national law apply to damage caused by AI	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
When AI operates with a high degree of autonomy, it could be difficult to link the damage it caused to the actions or omissions of a human actor	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

In the case of AI that lacks transparency (opacity) and explainability (complexity), it could be difficult for injured parties to prove that the conditions of liability (such as fault, a defect, or causation) are fulfilled	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Because of AI's specific characteristics, victims of damage caused by AI may in certain cases be less protected than victims of damage that didn't involve AI	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
It is uncertain how national courts will address possible difficulties of proof and liability gaps in relation to AI	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

**Please elaborate on your answers or specify other grounds of legal uncertainty regarding liability for damage caused by AI:**

*2000 character(s) maximum*

MedTech recognizes that there is a certain amount of uncertainty, in particularly as to how courts will apply applicable contractual, tort and product liability laws to fit the new paradigms created by AI, but we believe that this is the role of courts and that they are the right body to apply existing rules to different products and different situations in order to properly balance public interest and expectations of safety. Courts have addressed changes in technology over the last 30 years, and there is no reason to believe that AI will be an exception to this.

**Do you agree or disagree with the following statements?**

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion
The lack of adaptation of the current liability framework to AI may negatively affect trust in AI	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The lack of adaptation of the current liability framework to AI may negatively affect the uptake of AI-enabled products and services	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**Please elaborate on your answers.** You may reflect in particular on the recently proposed AI Act and on the complementary roles played by liability rules and the other safety-related strands of the Commission’s AI policy in ensuring trust in AI and promoting the uptake of AI-enabled products and services:

*2000 character(s) maximum*

Liability considerations might arise in at least two scenarios: (1) Under the AI Regulation itself, where a provider fails to comply with the Regulation’s requirements; or (2) for harms caused to a person or entity by an AI system, irrespective of whether it complies with the Regulation. The AI Regulation does not address the potential liability of providers or users of AI systems to natural persons for the physical, psychological, monetary, or other harms caused by their systems. This consultation is about addressing point (2). MTE recognizes that creating a liability regime that is suitable for the digital solutions is important, but we strongly advise that the legislator must strike the right balance between ensuring adequate protection from harm for consumers on the one hand, and incentivizing companies to develop new technologies on the other. We are concerned that upcoming EU liability policy, in particular where traditional products are also in scope will hinder the potential of any innovation and not only AI, and in particular in the medical technology industry, ultimately harm the development and delivery of innovative medical technologies for European citizens.

**If the current liability framework is not adapted, to what extent do you expect the following problems to occur in relation to the production, distribution or use of AI-enabled products or services, now or in the foreseeable future?** This question is primarily aimed at businesses and business associations.

	To a very large extent	To a large extent	To a moderate extent	To a small extent	Not at all	Don't know /no answer
Companies will face additional costs (e.g. legal information costs, increased insurance costs)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Companies may defer or abandon certain investments in AI technologies	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Companies may refrain from using AI when automating certain processes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Companies may limit their cross-border activities related to the production, distribution or use of AI-enabled products or services	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Higher prices of AI-enabled products and services	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

Insurers will increase risk-premiums due to a lack of predictability of liability exposures	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
It will not be possible to insure some products/services	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Negative impact on the roll-out of AI technologies in the internal market	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

**Please elaborate on your answers**, in particular on whether your assessment is different for AI-enabled products than for AI-enabled services

*2000 character(s) maximum*

No, our assessment does not differ depending on a difficult distinction between products and services. Already today, a number of medical technologies combine hardware, software and services and depending on perspectives, such medical technologies may fall into one or the other bucket. However, if they cause physical harm – the type of damage currently targeted by the Directive – this will be as a result of the actions of a physical product, and consumers’ rights to compensation for harm caused by physical products are already guaranteed by the Directive.

This is also one reason why our industry supports non legislative initiatives (e.g. guidance), since AI technologies are still in their infancy and we believe that it is too early to develop an European legislative framework, since there is a significant risk of error, which ultimately will affect innovation and ultimately patient care.

With the growing number of AI-enabled products and services on the market, Member States may adapt their respective liability regimes to the specific challenges of AI, which could lead to increasing differences between national liability rules. The Product Liability Directive could also be interpreted in different ways by national courts for damage caused by AI.

**If Member States adapt liability rules for AI in a divergent way, or national courts follow diverging interpretations of existing liability rules, to what extent do you expect this to cause the following problems in the EU?** This question is primarily aimed at businesses and business associations.

	To a very large extent	To a large extent	To a moderate extent	To a small extent	Not at all	Don't know /no answer
Additional costs for companies (e.g. legal information costs, increased insurance costs) when producing,	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

distributing or using AI-equipped products or services						
Need for technological adaptations when providing AI-based cross-border services	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Need to adapt AI technologies, distribution models (e.g. sale versus service provision) and cost management models in light of diverging national liability rules	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Companies may limit their cross-border activities related to the production, distribution or use of AI-enabled products or services	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Higher prices of AI-enabled products and services	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Insurers will increase premiums due to more divergent liability exposures	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Negative impact on the roll-out of AI technologies	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

**Please elaborate on your answers**, in particular on whether your assessment is different for AI-enabled products than for AI-enabled services, as well as on other impacts of possible legal fragmentation

*2000 character(s) maximum*

As mentioned in the previous commentary, our assessment does not change whether a medical technology qualifies as a product or as a service. As for the EC's concern relating to fragmentation, we support consistency throughout the EU and potentially even importantly also internationally, but EU legislation has not achieved this in other areas (e.g. GDPR), and therefore further questioning industry's support for EU legislative action on liability. In addition, we also do not believe that considerably broadening the scope of liability would increase legal certainty. Instead, it would likely increase the risk of frivolous litigation, which comes at its own costs.

## Policy options

Due to their specific characteristics, in particular their lack of transparency and explainability ('black box effect') and their high degree of autonomy, certain types of AI systems could challenge existing liability rules.

The Commission is considering the policy measures, described in the following questions, to ensure that victims of damage caused by these specific types of AI

systems are not left with less protection than victims of damage caused by technologies that operate without AI. Such measures would be based on existing approaches in national liability regimes (e.g. alleviating the burden of proof for the injured party or strict liability for the producer). They would also complement the Commission’s other policy initiatives to ensure the safety of AI, such as the recently proposed AI Act, and provide a safety net in the event that an AI system causes damage.

Please note that the approaches to adapting the liability framework presented below relate only to civil liability, not to state or criminal liability. The proposed approaches focus on measures to ease the victim’s burden of proof (see next question) as well as a possible targeted harmonisation of strict liability and insurance solutions (subsequent questions). They aim to help the victim recover damage more easily.

**Do you agree or disagree with the following approaches regarding the burden of proof?** The answer options are not mutually exclusive. Regarding the Product Liability Directive, the following approaches build on the general options in the first part of this questionnaire.

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion
The defendant (e.g. producer, user, service provider, operator) should be obliged to disclose necessary technical information (e.g. log data) to the injured party to enable the latter to prove the conditions of the claim	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
If the defendant refuses to disclose the information referred to in the previous answer option, courts should infer that the conditions to be proven by that information are fulfilled	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Specifically for claims under the Product Liability Directive: if an AI-enabled product clearly malfunctioned (e.g. driverless vehicle swerving off the road despite no obstacles), courts should infer that it was defective and caused the damage	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

<p>If the provider of an AI system failed to comply with their safety or other legal obligations to prevent harm (e.g. those proposed under the proposed AI Act), courts should infer that the damage was caused due to that person's fault or that, for claims under the Product Liability Directive, the AI system was defective</p>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<p>If the user of an AI system failed to comply with their safety or other legal obligations to prevent harm (e.g. those proposed under the proposed AI Act), courts should infer that the damage was caused by that person's fault</p>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<p>If, in a given case, it is necessary to establish how a complex and /or opaque AI system (i.e. an AI system with limited transparency and explainability) operates in order to substantiate a claim, the burden of proof should be shifted from the victim to the defendant in that respect</p>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
<p>Specifically for claims under the Product Liability Directive: if a product integrating an AI system that continuously learns and adapts while in operation causes damage, the producer should be liable irrespective of defectiveness; the victim should have to prove only that the product caused the damage</p>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
<p>Certain types of opaque or highly autonomous AI systems should be defined for which the burden of proof regarding fault and causation should always be on the person responsible for that AI system (reversal of burden of proof)</p>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
<p>EU action to ease the victim's burden of proof is not necessary or justified</p>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**Please elaborate on your answers and describe any other measures you may find appropriate:**

*2000 character(s) maximum*

We believe that the PLD should be the starting point of any reflection relating to new rules for AI liability, in particular in view of the burden of proof, as information imbalances are not unique to AI applications. This is not to say that we would not support an alleviation of the burden of proof, to the extent reflected already in reflecting the existing case law of the ECJ, by allowing courts to infer that a product is defective or caused the damage under certain circumstances, e.g. when other products in the same production series have already been proven to be defective or when a product clearly malfunctions, is a concept that was already applied by courts to different products and different situations to properly balance public interest and expectations of safety as demonstrated by the Boston Scientific case (joint case C-503/13 and C-504/13 ). However, such presumptions should be used only in specific, well-defined cases.

In addition, for medical technologies, in view of the existing requirements in our “safety legislation”, i.e. MDR /IVDR, requiring severe processes, evidence collections, risk/benefit assessment, provision of evidence in specific cases are already extensive, it does not justify any changes to the burden of proof as per the Directive.

For more information on the Boston Scientific case, please see: <https://curia.europa.eu/juris/liste.jsf?num=C-503/13>

---

Separately from the strict liability of producers under the Product Liability Directive, national laws provide for a wide range of different strict liability schemes for the owner/user/operator. Strict liability means that a certain risk of damage is assigned to a person irrespective of fault.

A possible policy option at EU level could be to harmonise strict liability (full or minimum), separately from the Product Liability Directive, for damage caused by the operation of certain AI-enabled products or the provision of certain AI-enabled services. This could notably be considered in cases where the use of AI (e.g. in autonomous vehicles and autonomous drones) exposes the public to the risk of damage to important values like life, health and property. Where strict liability rules already exist in a Member State, e.g. for cars, the EU harmonisation would not lead to an additional strict liability regime.

**Do you agree or disagree with the following approaches regarding liability for operating AI-enabled products and providing AI-enabled services creating a serious injury risk (e.g. life, health, property) for the public?**

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion

Full harmonisation of strict liability for operating AI-enabled products and providing AI-enabled services, limited to cases where these activities pose serious injury risks to the public	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Harmonisation of strict liability for the cases mentioned in the previous option, but allowing Member States to maintain broader and/or more far-reaching national strict liability schemes applicable to other AI-enabled products and services	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Strict liability for operating AI-enabled products and providing of AI-enabled services should not be harmonised at EU level	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**Please elaborate on your answer, describe any other approaches regarding strict liability you may find appropriate and/or indicate to which specific AI-enabled products and services strict liability should apply:**

*2000 character(s) maximum*

As mentioned above, MedTech Europe does not think that a distinction between products and services makes sense, since already today, a number of medical technologies combine hardware, software and services and depending on perspectives, such medical technologies may fall into one or the other bucket. Consumers can already recover compensation under the Directive for damage caused by a defect in a physical product.

At this stage, industry supports non legislative initiatives (e.g. guidance), since AI technologies are still in their infancy and we believe that it is too early to develop an European legislative framework, since there is a significant risk of error, which ultimately will affect innovation and ultimately patient care. In addition, we do believe that the existing reality rules allow sufficient room for maneuver for courts to apply appropriately.

The availability, uptake and economic effects of insurance policies covering liability for damage are important factors in assessing the impacts of the measures described in the previous questions. Therefore, this question explores the role of (voluntary or mandatory) insurance solutions in general terms.

The subsequent questions concern possible EU policy measures regarding insurance. **To what extent do you agree with the following statements?**

--	--	--	--	--	--	--

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion
Parties subject to possible harmonised strict liability rules as described in the previous question would likely be covered by (voluntary or mandatory) insurance	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
In cases where possible facilitations of the burden of proof would apply (as described in the question on approaches to burden of proof), the potentially liable party would likely be covered by (voluntary or mandatory) liability insurance	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Insurance solutions (be they voluntary or mandatory) could limit the costs of potential damage for the liable person to the insurance premium	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Insurance solutions (be they voluntary or mandatory) could ensure that the injured person receives compensation	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

### Please elaborate on your answers:

*2000 character(s) maximum*

MTE strongly recommends against mandatory insurance for either AI manufacturers or operators. Such system would make sense where there is a good understanding of the damages and related costs and/or where in view of the high claims, there is a need to spread the risks as well as the costs (e.g. car insurance – such insurance also exists to ensure that damages can be recovered, i.e. someone paying for the damage, even in case of insolvability). For the moment, in view of the nascency of AI technology, where there is no clarity of the type of damage, the liable organisation (i.e. patient, hospital, healthcare professional and/or manufacturer) nor the amount, mandatory insurance cannot practically be set up, and even where there was sufficient infrastructure, with no data, premiums would not be affordable. In other words, as the assessment is impossible due to the lack of data, there is either no offer of such coverage or it impossibly expensive, which will eventually have a repercussion on healthcare systems and patients. This is why, should a European legislative initiative be developed relating to insurance, MTE would support alignment with the approach applicable to medical devices, i.e. for medical technology (medtech) companies, article 10(16) of the MDR and article 10(15) of the IVDR require that medtech manufacturers ensure financial coverage to be proportionate to a medical technology manufacturer's size, the risk class of the products and the product types. Consequences of wrong coverage could be both that the national (regulatory) authority enforces and imposes fine and/or that the Notified Body finds non-conformity with these articles and suspend QMS certificate or device certificate.

Under many national strict liability schemes, the person liable is required by law to take out insurance. A similar solution could be chosen at EU level for damage caused by certain types of AI systems that pose serious injury risks (e.g. life, health, property) to the public.

Possible EU rules would ensure that existing insurance requirements are not duplicated: if the operation of a certain product, such as motor vehicles or drones, is already subject to mandatory insurance coverage, using AI in such a product or service would not entail additional insurance requirements.

**Do you agree or disagree with the following approach on insurance for the use of AI systems that poses a serious risk of injury to the public?**

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion
A harmonised insurance obligation should be laid down at EU level, where it does not exist yet, for using AI products and providing AI-based services that pose a serious injury risk (e.g. life, health, property) to the public	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

In reply to the previous question you expressed the view that there should not be a harmonised insurance obligation for AI-enabled products and services. This implies that you consider voluntary insurance and existing mandatory insurance regimes to be sufficient. **Please elaborate on the reasons for your opinion:**

*2000 character(s) maximum*

Please refer to our previous commentary. Since there is a system for healthcare products, both medtech and pharma, it seems that the reference to health here above is not appropriate. In addition, we are concerned about the duplication and confusion, even where exclusion would be the preferred avenue of the legislator.

**Taking into account the description of various options presented in the previous questions, please rank the following options from 1 (like best) to 8 (like least)**

	1	2	3	4	5	6	7	8
Option 1: (Aside from measures to ease the burden of proof considered in Section I) Amending the Product Liability Directive to ease the burden on victims when proving an AI-enabled product was defective and caused the damage	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>				

Option 2: Targeted harmonisation of national rules on proof, e.g. by reversing the burden of proof under certain conditions, to ensure that it is not excessively difficult for victims to prove, as appropriate, fault and/or causation for damage caused by certain AI-enabled products and services	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Option 3: Harmonisation of liability irrespective of fault ('strict liability') for operators of AI technologies that pose a serious injury risk (e.g. life, health, property) to the public	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Option 4: option 3 + mandatory liability insurance for operators subject to strict liability	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Option 5: option 1 + option 2	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Option 6: option 1 + option 2 + option 3	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Option 7: option 1 + option 2 + option 4	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Option 8: No EU action. Outside the existing scope of the Product Liability Directive, each Member State would be free to adapt liability rules for AI if and as they see fit	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**Please elaborate on your answers**, also taking into account the interplay with the other strands of the Commission's AI policy (in particular the proposed AI Act). Please also describe any other measures you may find appropriate:

*2000 character(s) maximum*

This ranking exercise is quite preemptory. For example, there is no option for the EU to maintain the current scheme of the Directive, or to make targeted changes to it via a recast, while also publishing guidance. We recognize that technology is evolving and that AI may pose specific challenges, on which experts have not yet found an agreement yet, but regulating this today risks to have a major negative impact European businesses as well as European citizens and patients. We believe that further consultation is needed, in particular before adjusting the burden of proof as well as imposing strict liability broadly and/or force mandatory insurance, and therefore our ask to develop guidance.

## Types of compensable harm and admissibility of contractual liability waivers

Aside from bodily injury or damage to physical objects, the use of technology can cause other types of damage, such as immaterial harm (e.g. pain and suffering). This is true not only for AI but also for other potential sources of harm. Coverage for such damage differs widely in Member States.

**Do you agree or disagree with harmonising compensation for the following types of harm (aside from bodily injury and property damage), specifically for cases where using AI leads to harm?** Please note that this question does not concern the Product Liability Directive – a question on the types of harm for which consumers can claim compensation under this Directive can be found in Section I. The answer options are not mutually exclusive.

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion
Pure economic loss (e.g. loss of profit)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Loss of or damage to data (not covered by the GDPR) resulting in a verifiable economic loss	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Immaterial harm like pain and suffering, reputational damage or psychological harm	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Loss of or damage to data (not covered by the GDPR) <b>not</b> resulting in a verifiable economic loss	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
All the types of harm mentioned above	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

**Please specify any other types of harm:**

*500 character(s) maximum*

The PLD definition of damage is sufficient and in line with the notion of safety. Other types of damages are covered by other EU legislations, e.g. GDPR covers personal data damages. Expanding the scope would create application problems and create legal uncertainty. Also, expanding the scope of damages to include e.g. data loss, emotional damages, etc. might infringe national rules and raise challenges around establishing an amount for these damages as well as create risks of abuse.

Sometimes the person who has suffered damage has a contract with the person responsible. That contract may exclude or limit the right to compensation. Some Member States consider it necessary to prohibit or restrict all or certain such clauses. The Product Liability Directive also does not let producers limit or exclude their liability towards the injured person by contract.

**If the liability of operators/users for damage caused by AI is harmonised at EU level, do you agree or disagree with the following approaches regarding**

## contractual clauses excluding or limiting in advance the victim’s right to compensation?

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion
The admissibility of contractual liability waivers should not be addressed at all	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Such contractual clauses should be prohibited vis-à-vis consumers	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Such contractual clauses should be prohibited vis-à-vis consumers and between businesses	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
The contractual exclusion or limitation of liability should be prohibited only for certain types of harm (e.g. to life, body or health) and/or for harm arising from gross negligence or intent	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please elaborate on your answer and specify if you would prefer a different approach, e.g. an approach differentiating by area of AI application:

*2000 character(s) maximum*

We agree in terms of business-to-consumer clauses, the PLD already prohibits such clauses which attempt to exclude or limit liability for personal injuries or death. With regards to B2B clauses, we do not believe that the EU should legislate on such contractual exclusions and support the general principle of freedom of contract, where parties agree on a common way of apportioning risk in a contract, even where such parties agree to exclude or restrict their liability to one another in specific events. This is particularly true where the contract is between a manufacturer and an operator, it’s a matter for parties to a contract to agree and/or to get insurance for.

## Additional information

Are there any other issues that should be considered?

*3000 character(s) maximum*

Relating to the Section Adapting the Directive to the circular economy, we strongly advise to further define specific concepts such as ‘remanufacturing’ and ‘refurbish’. MDR may provide a good reference. It is only where a product is “fully refurbishing” that the new manufacturer becomes liable. For spare parts, in case of medical devices, the manufacturer is already responsible for these.

Relating to the questions relating to the burden of proof, reversing the burden of proof, including via presumptions as to causation, will essentially require a defendant to prove a negative, which is difficult to do [how can a defendant who has complied with all safety requirements prove that it has not put a defect

product on the market?]. MedTEch Europe does not support such a change in the burden of proof but should this be decided nevertheless, for example in complex cases, it would be essential that (1) it is also clarified that presumptions are rebuttable by the producer/defendant (2) very clearly define what is “complex”.

You can upload relevant quantitative data, reports/studies and position papers to support your views here:

Only files of the type pdf,txt,doc,docx,odt,rtf are allowed

**046a0cf7-7f35-4c2a-95be-8544736e6de7/20220110\_pld\_cms\_final.pdf**

Do you agree to the Commission contacting you for a possible follow-up?

Yes

No

## Contact

Mark.BEAMISH@ec.europa.eu