**Proposal for a Directive on liability for defective products :** [COM\_COM(2022)0495\_EN.pdf (europa.eu)](https://www.europarl.europa.eu/RegData/docs_autres_institutions/commission_europeenne/com/2022/0495/COM_COM(2022)0495_EN.pdf)

**Amendments proposals by** [**France Assos Santé**](https://www.france-assos-sante.org/) **and** [**Prescrire**](https://www.prescrire.org/fr/Summary.aspx)

*10 March 2022*

**The proposed revised directive does not guarantee the access of victims of adverse drug reactions to compensation**

For many years, France Assos Santé, its member associations (nearly a hundred) and Prescrire have drawn attention to the fact that medicines are not products like any other. We have also advocated for a new EU legal framework specifically dedicated to medicines and medical devices, which would guarantee an effective and adequate compensation of victims. Currently, the application of the Product Liability Directive strongly hinders the possibilities of compensation for victims of health products.

Although the Commission's proposal contains some timid progresses, it takes virtually no account of the contributions of the EC expert group on the specific problems of adverse drug reactions’ victims and will, as it stands, have no impact on the access of these victims to compensation.

**Amendment proposals**

France Assos Santé and Prescrire advocate for the introduction of the following amendments:

**Allow Member States to adopt more protective measures for patients and consumers**

The Commission has chosen to keep pharmaceutical products within the scope of the directive, while presenting a proposal which continues to largely promote the interests of producers. It is necessary, in this context, to delete or modify Article 3, which prohibits Member States from adopting national measures that are more protective of patients and consumers. This possibility is provided for in the Directive only for Member States which already have a specific liability regime for pharmaceutical products.

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| **Article 3**  Level of harmonisation  Member States ***shall*** ***not*** maintain or introduce, in their national law, ***provisions diverging from those laid down in this Directive, including*** more***, or less,*** stringent provisions to achieve a different level of consumer protection, ***unless otherwise provided for in this Directive*** | **Article 3**  Level of harmonisation  Member States ***may*** maintain or introduce, in their national law, more stringent provisions ***compared to those laid down in this Directive*** to achieve a ***higher*** level of consumer protection. |
|  | **OR (ALTERNATIVE PROPOSALS)**  ***Article 3 bis new***  ***For medicinal products, medical devices and health technologies in general, Member States may maintain or introduce, in their national law, more stringent provisions compared to those laid down in this Directive to achieve a higher level of patient protection.*** |
|  | **New recital**  ***Patients harmed by medicinal products, medical devices and health technologies in general deserve a particular protection because of the specificity of these products: their consumption does not rely on the patient’s own choice.*** |

**Default defectiveness when the risk of damage is known but unavoidable**

As it stands and is interpreted in the caselaw of national courts, the definition of the “defectiveness” of the products prohibits any compensation for the victims of adverse drug reactions when the risk is mentioned in the patient leaflet. However, such a warning should not exempt the producer from his/her liability because this information does not allow the patient, who does not know if he will be part of the minority who will develop this adverse reaction, to prevent or minimise the risk.

We therefore propose that the product be considered defective when the risk is indicated in the patient leaflet, but it cannot be avoided by the patient or the consumer.

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| **Article 6**  Defectiveness   1. A product shall be considered defective when it does not provide the safety which the public at large is entitled to expect, taking all circumstances into account, including the following:   a) the presentation of the product, including the instructions for installation, use and maintenance; | **Article 6**  Defectiveness   1. A product shall be considered defective when it does not provide the safety which the public at large is entitled to expect, taking all circumstances into account, including the following:   a) the presentation of the product, including the instructions for installation, use and maintenance, ***when they do not contribute to the eviction of the damage;*** |
|  | **ALTERNATIVE PROPOSAL: New article**   1. **r*isks of serious adverse effects of medicinal products listed in the patient leaflet without the possibility for the patient to know in advance whether he/she will be affected by these adverse effects.*** |

**The interests of patients and consumers should prevail over trade secrets**

Article 8, which allows national courts to order the defendant to disclose relevant evidence available to him, may help to rebalance the asymmetry of information between the producer and the victim provided the defendant cannot hide behind trade secrets. It would be desirable for the directive to be more protective of the interests of patients and consumers on this point.

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| **Article 8**  Disclosure of evidence  1. Member States shall ensure that national courts are empowered, upon request of an injured person claiming compensation for damage caused by a defective product (‘the claimant’) who has presented facts and evidence sufficient to support the plausibility of the claim for compensation, to order the defendant to disclose relevant evidence that is at its disposal. |  |
| 2. Member States shall ensure that national courts limit the disclosure of evidence to what is necessary and proportionate to support a claim referred to in paragraph 1. |  |
| 3. When determining whether the disclosure is proportionate, national courts shall consider the legitimate interests of all parties, including third parties concerned, in particular in relation to the protection of confidential information and trade secrets within the meaning of Article 2, point 1, of Directive (EU) 2016/943. | 3. When determining whether the disclosure is proportionate, national courts shall consider the legitimate interests of all parties, including third parties concerned, in particular in relation***:*** ***- to the right to an effective legal remedy within the meaning of Article 47 of the Charter of fundamental rights of the European Union;***  ***- to the objective of guaranteeing high levels of human health and consumer protection within the meaning respectively of Articles 168 and 169 of the Treaty on the functioning of the European Union;***  - to the protection of confidential information and trade secrets within the meaning of Article 2, point 1, of Directive (EU) 2016/943 ***unless there is an overriding public interest in disclosure.*** |
| 4. Member States shall ensure that, where a defendant is ordered to disclose information that is a trade secret or an alleged trade secret, national courts are empowered, upon a duly reasoned request of a party or on their own initiative, to take the specific measures necessary to preserve the confidentiality of that information when it is used or referred to in the course of the legal proceedings. |  |

**Withdrawal of the development-risk exemption**

Many pharmaceutical products entail a risk of rare but serious adverse reactions by their very nature. Most of these risks can only be evidenced through pharmacovigilance signals, after the product has been marketed and used by patients. The first years, patients are thus especially exposed to the risk of unknown adverse events.

It would therefore be unfair to exempt producers from their responsibility related to the development of high priced new pharmaceutical products, while they can insure themselves against this risk. Moreover, it would be a step backwards in the protection of consumers and patients’ rights as article 15 of directive 85/374/EEC allows Member State to renounce to this development-risk exemption. We therefore recommend deleting this exemption.

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| **Article 10**  Exemption from liability  1. An economic operator referred to in Article 7 shall not be liable for damage caused by a defective product if that economic operator proves any of the following:  (a) in the case of a manufacturer or importer, that it did not place the product on the market or put it into service;  (b) in the case of a distributor, that it did not make the product available on the market;  (c) that it is probable that the defectiveness that caused the damage did not exist when the product was placed on the market, put into service or, in respect of a distributor, made available on the market, or that this defectiveness came into being after that moment;  (d) that the defectiveness is due to compliance of the product with mandatory regulations issued by public authorities;  (***e) in the case of a manufacturer, that the objective state of scientific and technical knowledge at the time when the product was placed on the market, put into service or in the period in which the product was within*** ***the manufacturer’s control was not such that the defectiveness could be discovered;***  (f) in the case of a manufacturer of a defective component referred to in Article 7(1), second subparagraph, that the defectiveness of the product is attributable to the design of the product in which the component has been integrated or to the instructions given by the manufacturer of that product to the manufacturer of the component; or  (g) in the case of a person that modifies a product as referred to in Article 7(4), that the defectiveness that caused the damage is related to a part of the product not affected by the modification. | **Article 10**  Exemption from liability  1. An economic operator referred to in Article 7 shall not be liable for damage caused by a defective product if that economic operator proves any of the following:  (a) in the case of a manufacturer or importer, that it did not place the product on the market or put it into service;  (b) in the case of a distributor, that it did not make the product available on the market;  (c) that it is probable that the defectiveness that caused the damage did not exist when the product was placed on the market, put into service or, in respect of a distributor, made available on the market, or that this defectiveness came into being after that moment;  (d) that the defectiveness is due to compliance of the product with mandatory regulations issued by public authorities;  ***~~(e) in the case of a manufacturer, that the objective state of scientific and technical knowledge at the time when the product was placed on the market, put into service or in the period in which the product was within the manufacturer’s control was not such that the defectiveness could be discovered;~~***  (f) in the case of a manufacturer of a defective component referred to in Article 7(1), second subparagraph, that the defectiveness of the product is attributable to the design of the product in which the component has been integrated or to the instructions given by the manufacturer of that product to the manufacturer of the component; or  (g) in the case of a person that modifies a product as referred to in Article 7(4), that the defectiveness that caused the damage is related to a part of the product not affected by the modification. |
|  | **ALTERNATIVE PROPOSAL: New article**  ***In accordance with the objective to guarantee a high level of patient protection, the development-risk exemption laid down in article 10 (e) does not apply to medicinal products, medical devices and health technologies in general.*** |

**Simplification and extension of the deadlines for legal action**

The limitation periods for legal action are crucial for the effective access of victims to compensation and the double period of 3 years (limitation period) and 10 years (extinction of rights) is a major barrier. The 3-year limitation period is an obstacle for patients who are often not physically and/or psychologically able to take legal action for several years, and for whom the appearance and consolidation of the damage’s consequences on their state of health can also take several years. For instance, the loss of vision for the victims of a Lyell or Stevens-Johnson syndrome – a very serious skin reaction – can happen several years, even decades later.

The derogatory extension of the time period to 15 years for the extinction of rights is insufficient, in particular for the victims of transgenerational damages, which are sometimes evidenced at a very late stage (e.g. infertility in girls whose mothers took diethylboestrol during pregnancy, or autistic disorders in children whose mothers took sodium valproate during pregnancy).

We propose to introduce a single limitation period of 10 years, which should begin to run from the moment the victim became aware of the causal link between the damage and the product.

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| **Article 14**  Limitation periods  1. Member States shall ensure that a limitation period of ***3 years*** applies to the initiating of proceedings for claiming compensation for damage falling within the scope of this Directive. The limitation period shall begin to run from the day on which the injured person became aware***, or should reasonably have become aware,*** of all of the following:  (a) the damage;  (b) the defectiveness;  (c) the identity of the relevant economic operator that can be held liable for the damage in accordance with Article 7.  The laws of Member States regulating suspension or interruption of the limitation period referred to in the first subparagraph shall not be affected by this Directive. | **Article 14**  Limitation periods  1. Member States shall ensure that a limitation period of ***10 years*** applies to the initiating of proceedings for claiming compensation for damage falling within the scope of this Directive. The limitation period shall begin to run from the day on which the injured person became aware***, ~~or should reasonably have become aware~~,*** of all of the following:  (a) the damage;  (b) the defectiveness;  (c) the identity of the relevant economic operator that can be held liable for the damage in accordance with Article 7.  The laws of Member States regulating suspension or interruption of the limitation period referred to in the first subparagraph shall not be affected by this Directive. |
| 2. Member States shall ensure that the rights conferred upon the injured person pursuant to this Directive are extinguished upon the expiry of a limitation period of 10 years from the date on which the actual defective product which caused the damage was placed on the market, put into service or substantially modified as referred to in Article 7(4), unless a claimant has, in the meantime, initiated proceedings before a national court against an economic operator that can be held liable pursuant to Article 7. | ***Deleted*** |
| 3. By way of exception from paragraph 2, where an injured person has not been able to initiate proceedings within 10 years due to the latency of a personal injury, the rights conferred upon the injured person pursuant to this Directive shall be extinguished upon the expiry of a limitation period of 15 years. | ***Deleted***  . |
|  | **ALTERNATIVE PROPOSAL: New article**  ***Article 14 bis***  ***1. By way of exception from article 14.1, Member States shall ensure that a limitation period of 10 years applies to the initiating of proceedings for claiming compensation for damage from medicinal products, medical devices and health technologies falling within the scope of this Directive. The limitation period shall begin to run from the day on which the injured person became aware of all of the following:***  ***(a) the damage;***  ***~~(b) the defectiveness~~;***  ***(c) the identity of the relevant economic operator that can be held liable for the damage in accordance with Article 7.***  ***The laws of Member States regulating suspension or interruption of the limitation period referred to in the first subparagraph shall not be affected by this Directive.*** |