

onset of a disorder and the start of exposure to a drug, and by listening to patients. Where appropriate, the drug should be withdrawn or replaced with another drug, and the case reported to a pharmacovigilance centre. These measures help improve the quality of patient care and benefit society by improving the information available on drugs.

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## Defending the right to compensation for the victims of drug-induced harms

● Prescrire and France Assos Santé have proposed a series of amendments to members of the European Parliament working on the revision of the 1985 European Product Liability Directive.

In spring 2023, Prescrire worked closely with France Assos Santé, an umbrella organisation for patients' rights groups in France, on a proposal to revise the 1985 European directive on "liability for defective products". Under this directive, when a product (in any economic sector) is defective and causes damage to a consumer, the producer may be held liable even without negligence or fault on their part. A product is considered to be defective if it does not provide the safety that the public is entitled to expect (1).

On 27 April 2023, a joint letter signed by Prescrire, France Assos Santé and over forty organisations representing patients, consumers and health professionals was sent to the European Parliament. It was addressed to the members of the European Parliament (MEPs)

working on this project within the Committee on Legal Affairs (JURI) and the Committee on Internal Market and Consumer Protection (IMCO) (2).

The purpose of the letter was to urge the MEPs to submit amendments that would ensure the right to compensation for the victims of serious adverse effects linked to pharmaceutical products.

It proposed revisions in several areas:

- changing the definition of a defective product specifically for drugs, since the current definition means that the victims of adverse effects are not eligible for compensation if the risk is mentioned in the patient leaflet;
- removing the "development risk defence", which enables pharmaceutical companies to evade responsibility by hiding

- behind their ignorance of the risk at the time the damage occurred;
- simplifying the legal procedures and extending the period in which plaintiffs can apply for compensation;
- ensuring that the interests of patients and consumers take precedence over trade secrets, which are used to conceal clinical data;
- enabling member states to adopt measures that give patients and consumers greater protection than the minimum European standard (3).

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