EDITORIAL

Victims of health products: a European opportunity to be seized

The 1985 Product Liability Directive established the rules to be followed by member states of the European Union regarding the liability of health product companies when a safety issue arises with their products. The new 2024 version of this directive is more favourable to the victims of such products.

In spring 2022, Prescrire and France Assos Santé worked together on the revision of the Product Liability Directive (1). According to this directive, when a product (including but not limited to health products) is defective and causes damage to a consumer, the producer can be held liable even if there was no fault or negligence on their part: "*A product… shall be considered defective where it does not provide the safety that a person is entitled to expect*" (2).

On 27 April 2023, a letter signed by Prescrire, France Assos Santé and about 40 European organisations representing patients, consumers and health professionals, was sent to the European Parliament. This letter invited Members of the European Parliament to submit amendments to further the rights of victims of serious adverse drug reactions (3).

The signatories sought, in particular, to:

– Remedy the fact that it was impossible for victims of adverse drug reactions to obtain compensation from a pharmaceutical company if the risk was mentioned in the product's package leaflet;

– Confirm that countries have the right, if they so wish, not to recognise the "development risk defence", which enables companies to avoid liability on the grounds that the risk was not known at the time the damage took place, a defence that is difficult for victims to challenge;

– Simplify the rules on legal action and extend the time limits for filing a claim (3).

The new version of the directive published in late October 2024 includes advances on all of these points. It stipulates, for example, that "*liability under this Directive cannot be avoided simply by listing all conceivable side effects of a product*" (2). Member states can also omit the development risk defence for medicinal products, which France (unlike Germany, for example) unfortunately chose not to do when it transposed the 1985 directive into national law (4).

Furthermore, the maximum time available to a victim to initiate legal action, starting from the date the product was placed on the market, was extended from 10 to 25 years, making it possible to take into account adverse effects with a long latency period, including transgenerational effects (see also "Depakine°: mother who sounded the alarm finally receives compensation", p. 249 of this issue). The 2024 directive also opens up possibilities to help victims demonstrate both the defectiveness of a product, and the link between a product and the damage (2).

In practice, this new directive has the potential to benefit victims of health products if patients' interests are prioritised when it is transposed into national law, and if courts take full advantage of the scope for its interpretation.

Prescrire

References **1-** "Proposal for a Directive on liability for defective products (…) Amendments proposals by France Assos Santé and Prescrire" 10 March 2022: 6 pages. **2-** Eur-Lex "Directive (EU) 2024/2853 of the European Parliament and of the Council of 23 October 2024 on liability for defective products (…)": 28 pages. **3-** "Letter to the members of the JURI and the IMCO Committees" 27 April 2023: 2 pages. **4-** Schwenzer I "L'adaptation de la directive communautaire du 25 juillet 1985 sur la responsabilité du fait des produits défectueux en Allemagne fédérale" *Revue internationale de droit comparé* 1991; 43 (1): 57-74.