EDITORIAL

Victims of drug-induced harms: the need for recognition

No health intervention, and in particular no drug, can be assumed to be risk-free. The risk of serious adverse effects from taking a drug is acceptable if: the patient's clinical situation would expose them to serious harm if left untreated; the drug has demonstrated clinical efficacy; there are no better options; and the patient has, as far as possible, understood and accepted the risks involved (1).

Each adverse effect of a drug has a different probability of actually occurring and harming the individual patient. Efficacy, too, is only a matter of probability: even a drug with demonstrated efficacy does not produce clinical improvement in all patients. The harm-benefit balance weighs the probabilities of the negative outcomes against the positive outcomes. It is a statistical concept that holds at the population level, with highly divergent results at the individual level (1).

Some people are victims of rare, serious adverse effects of a drug whose harm-benefit balance is considered acceptable for a population as a whole. The low probability of being a victim of drug-induced harms is an implicit trade-off that is widely accepted: when it does happen, it is seen as "bad luck" (1).

But, in fact, it is not a question of being lucky or unlucky. The market introduction of a drug with a favourable harm-benefit balance for the majority is based on the acceptance that many people will experience mild adverse effects, and a number of others will experience serious adverse effects, even if measures are taken to avoid exposure to the drug in those identified as being at high risk of these effects. Society therefore needs to recognise these victims for who they are: people who have paid a high price for the market introduction of drugs that are useful to others, the majority, who were not harmed (1,2).

At present, however, it remains very difficult for victims of drug-induced harms to secure legal recognition of this status, and to be fully compensated for the damage they have suffered and the costs they have incurred. This lack of solidarity is unjust. The new European Product Liability Directive promises some improvement in this situation (see "Compensation for victims of drug-induced harms: new European directive is welcome but unlikely to have a major impact", pp. 218-222 of this issue). But this directive is not sufficient: although touted as favourable to victims and their caregivers, its intention is not only to define but also limit manufacturer liability.

As of mid-2026, the European Union still has no dedicated legal framework for recognising and compensating victims of health products (3).

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References **1-** "Determining the harm-benefit balance of an intervention: for each patient" *Prescrire International* 2014; 23 (154): 274-277. **2-** "Management of serious adverse drug reactions: proposals from a victims' organisation" *Prescrire Int* 2012; 21 (130): 220-223. **3-** "Responsabilité des firmes pour 'produits défectueux'" *Rev Prescrire* 2022; 42 (465): 547.

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