

### The 10 key measures proposed by Amalyste (excerpts)

The following are extensive excerpts from the 10 proposals made by the Amalyste patient group (1).

**“1 - Risk awareness.** The frequency and management of serious adverse drug reactions and their impact on society must be considered a national priority (...); the following measures must be implemented:

- an information and awareness campaign for healthcare professionals to improve the diagnosis of adverse reactions to healthcare products and to make prescribing safer;
- a national public information campaign on drug-related risks;
- a national “serious adverse drug reaction action plan” to fund research into these illnesses and to provide management for victims in specialised centres;
- a delegation to inform the French parliament, with participation by the different stakeholders and experts, is needed to challenge the concept of the “risk-benefit ratio”, from the scientific, ethical and legal points of view;
- the French Agency for Shared Healthcare Information Systems (*Agence des systèmes d’informations partagées de santé, ASIP*) should make concrete proposals to integrate data relevant to epidemiological monitoring of the harmful effects of drugs in health databases and individual medical records.

**2 - Risk governance.** Decisions on whether or not a risk is acceptable cannot be left solely to experts and drug companies, [but] (...) should include all stakeholders, including victims’ organisations. Stakeholders’ independence must be guaranteed through equitable funding (...).

**3 - Stakeholders’ roles – a fairer balance.** The French drug regulatory agency must refocus on its overriding priority: vigilance and monitoring of the risks relating to healthcare products. This will entail rein-

forcing and safeguarding the activities of pharmacovigilance networks (see below), and creating a dedicated team to monitor epidemiological studies. (...)

**4 - Risk assessment.** Evaluation of a drug’s risk-benefit balance must be based on a standardised methodology and an auditable, transparent process using measurable criteria. Criteria and indicators of risk acceptability must be based on “risk acceptance scenarios” that are also standardised. (...)

**5 - Framework for risk acceptability.** The decision to authorise a drug that may cause rare and serious accidents must be accompanied by the establishment of a pre-set threshold at which authorities are alerted (...); if this threshold is passed (occurrence of the risk), it will trigger an immediate reassessment of the drug’s risk-benefit balance. (...)

**6 - Pharmacovigilance.** Reporting of harmful effects to pharmacovigilance networks, and maintaining their visibility, must be reinforced, simplified and safeguarded:

- reporting of serious adverse events must become mandatory, under the threat of sanctions (...);
- anonymised raw data in pharmacovigilance databases should be made publicly available, online;
- reporting of harmful effects to pharmacovigilance networks must be systematically followed by epidemiological studies of all implicated medications.

**7 - Recognition of responsibility.** The probable drug-related nature of a serious accident must be validated by a committee of experts, independent of the public authorities and the pharmaceutical industry, who are known for their expertise in matters relating to serious adverse effects. (...) The victim should receive the benefit of the doubt. (...)

**8 - Responsibilities.** Marketing authorisation of a drug that might cause serious injury will be contingent on:

- notification of the level of risk by the manufacturer, clearly visible in the patient leaflet (...) (“black box”);
- contribution by the manufacturer to a “compensation fund for serious drug-related risks”, the level of which will be based mainly on the “risk acceptance scenario” (see note above) (...).

**9 - Risk management.** The compensation fund for serious drug-related risks will cover:

- fair compensation for victims (advance payments may be made when the injuries take several years to stabilise);
- registries for “the most frequent” serious adverse drug reactions;
- medical care for victims (hospitalisation, treatment, disability, etc.);
- funding of research on the mechanisms of serious adverse drug reactions, and on appropriate treatment of both the acute phase and sequelae;
- funding of epidemiological studies on risk monitoring for suspected drugs;
- assessment of the cost of the risk, based on the individual “risk acceptance scenario” (see note above).

**10 - French national health insurance system.** A specific branch of the French national health insurance system should be created. It should be funded by the “compensation fund for serious drug-related risks” and will cover 100% of the true costs of medical care, social support and home care necessitated by adverse drug reactions, as well as disability benefits, and any other spending necessary to maintain the victim’s autonomy” (1).

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1- Amalyste “La gestion du risque médicamenteux grave”. [www.amalyste.fr](http://www.amalyste.fr) accessed 8 February 2012: 7 pages.

► a risk. This is not the same as the risk-benefit balance at the individual level. A positive “collective” risk-benefit balance implies that the majority of the community may benefit at the expense of a minority, who must bear a sometimes disproportionate burden of harm at the individual level.

How, then, can the use of this concept be interpreted, other than as a vindication by the State of the choice to sacrifice a minority in order to preserve the well-being of the majority? As the entire com-

munity, with the legislator’s approval, may benefit by receiving a given medication, is it reasonable to leave a small number of victims to shoulder alone the burden of risk? How then to compensate for this implicit rupture of the social contract created by this disparity, at the individual level, between the benefits provided to some and the risks suffered by others?

The legal consequences of the ethical implications of this concept remain to be established.

### Towards fair compensation

While liability for “breach of equality of public burdens” was recognized during the 20<sup>th</sup> century, victims of drug-related accidents are still not covered, at the dawn of the 21<sup>st</sup> century, by a dedicated management procedure.

Theoretically, this responsibility is incurred whenever a private individual suffers an “abnormal” (serious) and “special” harm, resulting from a situation or measure by which some members of the