

Managing medication errors

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What are medication errors?

Mixing up two medicines, administering by the wrong route, taking an excessively high dose... These medication errors may cause severe adverse reactions in some cases.

Since 2005, ANSM, in collaboration with the RPC network, has been organising the collection and processing of reports of errors or risks of errors directly related to a medicine, whether these reports concern how the medicine is presented (labelling, packaging), its name, or any other relevant information (package leaflet, SmPC, accompanying documentation). Errors related to its use or to the practices of health professionals do not fall within this remit.

Different scenarios

This activity covers medication errors that have led to adverse effects (in coordination with pharmacovigilance), in addition to errors without adverse reactions. It may concern a potential error (i.e. an error that almost occurred), a proven error (which did occur) or a suspected risk of a medication error.

- **Proven** medication error: the patient received the wrong medicine, an incorrect dose, via the wrong route, or according to the wrong treatment schedule.
- **Intercepted** medication error: an error intercepted before the drug is administered to the patient
- **Risk of error**: a case report has helped identify a potential hazard for the patient (similar medicine packaging or name)

Causes of the error

The retrospective analysis of the error helps characterise it and describe its nature and type, the severity of its clinical impacts for the patient, and the stage where it arises in the healthcare chain. The source of the error may be found in:

- poor design of the medicine and its associated information (name confusion, unsuitable packaging, labelling or package leaflet problem, etc.);
- the systemic organisation of the patient's treatment process (organisation of medication circuit, human factors, environmental factors, work practices, etc.).

Error processing

The RPCs receive and process all reports of errors submitted to them. As in the case of pharmacovigilance, they draw ANSM's attention to potential signals, in the form of noteworthy medication errors. The Agency then assesses and reviews these signals.

It may put in place measures to ensure that the error does not happen again:

- an immediate action regarding the product on a national or European level: request for amendment of the MA, amendment of the package leaflet, packaging (pack, blister pack, means of administration, etc.), announcement to healthcare professionals and/or the public, etc.
- an action in the context of a more overarching strategy (e.g. improved and harmonised labelling of injectable solutions in small volumes, recommendations and information campaigns regarding means of administration for oral solutions, etc.).

- Always check the name of the medicine and that it matches that prescribed by your doctor.
- Read the package leaflet.
- Always use the prescribed dose, dosage schedule, and administration routes.
- If in doubt, ask your doctor, pharmacist or any healthcare professional for advice.



Reporting an adverse reaction