French drug agency's recommendations on dosing devices: a step forward

Multi-dose oral liquid formulations allow different doses of a medicine to be dispensed, a situation frequently encountered with children for whom the dose needs to be adapted to body weight. They involve the use of a dosing device. The analyses of drug packaging carried out by *Prescrire* highlight the dangers posed by many dosing devices (1). In 2016, the French drug regulatory agency (ANSM) published recommendations for companies regarding dosing devices (2). *Prescrire* had taken part in the 2013 public consultation on these recommendations (3).

The ANSM recommendations are consistent with the dangers pointed out following our analysis of hundreds of dosing devices. These include: absence of a dosing device; lack of precision of droppers and cups; illegible or superfluous graduations; risk of error in converting milligrams of the prescribed dose into millilitres of volume to be measured; and provision of several dosing devices in the same box.

Errors or switching between dosing devices = danger. ANSM is calling for a dosing device to be provided with all multi-dose oral liquid medications. Use of household spoons, which vary widely in capacity, is a source of error and should be banned (2,3).

Another risk is the use of a dosing device from a different medicine. *Prescrire's* analysis of hundreds of oral liquid preparations shows that companies frequently opt for mass-produced devices. These all-purpose devices are graduated in millilitres and lack specific labelling linked to the medicine to be measured. All of these cups, spoons and syringes for oral administration resemble each other, encouraging interchangeable use between different medicines. ANSM recommends reducing this risk by labelling the device (name of medicine, dose, pharmaceutical formulation), and by providing a means for attaching the device to its bottle as well as pictures of the device on the box and in the patient information leaflet.

Companies are failing to evaluate devices in real-life healthcare situations. Several of the ANSM recommendations are directed at customising dosing devices: making graduations as precise as possible, avoiding useless markings, and enabling measurement of both the smallest and the largest doses. These quality criteria are not met by imprecise cups and graduated spoons with markings that are hard to read, incomprehensible, or even superfluous (4-6).

In its recommendations to companies, ANSM is not asking that every dosing device and its directions for use be evaluated in a real-life situation, where doses are prepared by patients (or their family) or by carers. This, however, would be desirable. This evaluation should also apply to the many older medicines whose patient information leaflets provide little information on how doses should be prepared.

Another recommendation advises against using droppers, and prohibits their use when the dosage is always more than 10 drops per administration.

Graduated markings: in milligrams or millilitres? ANSM recommends that "*the device provided [should be] graduated in the same units as the dose recommended in the SPC and the patient information leaflet*". This makes it possible to choose the unit so as to provide consistency between the SPC and the dosing device.

Measurements of weight (for example milligrams (mg), international units) are most suitable for preparing the exact dose of a medicine. Clinical study reports, clinical pharmacology texts, agencies' evaluation reports, and the "dosage (posology and method of administration)" and "overdose" sections of SPCs, are all normally expressed in units of weight. It would be clearer if the SPC were expressed in mg and the dosing device graduated in mg.

A European-wide evaluation of the two main options for graduation (mg or ml) seems to be desirable. In the meantime, it is up to carers and patients to avoid errors, but if errors do occur, the adverse effects should be reported.

Recommendations which should be extended. The ANSM recommendations on dosing devices adopted in 2016 are to be welcomed. As we had suggested to ANSM, a few additional points could have been useful for completion: developing drug packaging well ahead of market authorisation, so that it can be evaluated; and, as far as possible, encouraging the use of unit-dose packaging (e.g. tablets, capsules, sachets) as first-choice options in order to guarantee the precision of dosing and reduce the risk of errors arising during preparation (3).

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