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France's health technology assessment body: pushed to lower the bar!

● The HAS's new principles for rating drugs, designed to facilitate access to new treatments, allow lower-quality evaluation. This may not be in patients' best interests.

In early 2023, the "Transparency Committee", which is part of the National Authority for Health (HAS), France's health technology assessement body, published its new principles for rating the "clinical benefit" provided by new drugs, and their "clinical added value" (i.e. whether they represent a therapeutic advance over existing alternatives). These two ratings affect drug pricing and the level of reimbursement provided through the national health insurance system (1).

While reaffirming that randomised comparative clinical trials are "*the prerequisite and the essential reference for the assessment of any medicinal product*", the HAS now also considers it acceptable to (our translation) "*incorporate less well consolidated data, provided they enable* [drugs to be] *compared to the treatments available*" (1,2). Behind this decision to accept lower-quality evidence lies a request from the French government, pushing the HAS to adapt its methodology to new types of clinical trials, in particular those employed by pharmaceutical companies to bypass randomised comparative trials.

Under the HAS's new principles, it becomes acceptable to assess new drugs through indirect comparison alone, against data obtained on historical controls or on groups of patients enrolled in other clinical trials or in cohort studies ("external" control groups) (1,2). The bar has been lowered.

Under the HAS's new principles, it is likely that fewer drugs will be rated as offering insufficient clinical benefit and no clinical added value, and that more drugs will be eligible for reimbursement in the community and approved for use in hospitals, despite weaknesses in their evaluation. This development fits with France's new "early access" scheme, in which the national health insurance system covers the cost of drugs in certain clinical situations before they have been assessed by the Transparency Committee (3). The new principles would help to avoid authorisations issued through this programme which are later assessed as offering insufficient clinical benefit, as occurred with the former temporary authorisation for use (ATU) programme, with the Transparency Committee subsequently recommending that reimbursement of at least one indication be revoked for one-quarter of the drugs granted an ATU between 2014 and 2021 (4).

The new principles were also undoubtedly developed in response to lobbying by the pharmaceutical industry, certain patient groups and medical specialists (5-7).

Many new drugs are poorly evaluated. Although certain parties want ultra-rapid access to new, poorly evaluated drugs, they should not, in the process, strip clinical benefit and clinical added value of their meaning. These ratings provide useful information about the value of drugs, information that benefits a great many current and future patients. And society as a whole, when deciding how best to allocate the resources at its disposal.

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