Health technology assessment: an EU draft to be amended

In January 2018, the European Commission published a draft regulation that is a severe attack on the health technology assessments conducted on drugs and certain types of medical devices by agencies such as the French Pharmacoeconomic Committee that assesses the medical benefits of new drugs and provides recommendations on reimbursement (1). The EU Commission is proposing to impose a single assessment on all national health technology assessment agencies and to forbid any reanalysis at national level (1). The EU commissioner involved and some patient advocacy groups justify this proposal by claiming that the work of national agencies leads to unacceptable delays in patients' access to "innovation" and inequalities between patients depending on the country where they live (2,3).

The major and growing obstacle to access to new drugs is not how long health technology assessment agencies take to produce their reports but the exorbitant prices pharmaceutical companies charge for their drugs. With the European Medicines Agency (EMA) taking such a lax approach to its marketing authorisation procedure, certain national health technology assessment agencies are sometimes the only official bodies to publish critical information about drugs, making it possible to limit patients' exposure to drugs that are more dangerous than beneficial. The neutralisation of these agencies is part of the strategy adopted by those who dream of unimpeded access to "innovation" regardless of its health benefits.

The main reason why the work of national health technology assessment agencies takes so long is that new drugs are so poorly evaluated, making their added value difficult to determine. It would facilitate access to therapeutic advances if the EU regulation asked companies to supply health technology assessment agencies with the comparative data they need, and to do so as soon as the companies apply for marketing authorisation. Members of the EU Parliament have positively amended the Commission's proposal. It's up to Member States now to ensure that it is genuinely useful to patients by encouraging companies to focus their efforts on tangible therapeutic advances rather than on obtaining ever faster and easier market access.

Prescrire

▶ Translated from *Rev Prescrire* **August 2018**
Volume 38 N° 418 • Page 615

EDITORIAL

Sources

1- "Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU" 2018/0018 (COD) 31 January 2018: 51 pages.
2- "Q&A: Commission proposal on Health Technology Assessment - Fact Sheet" European Commission 31 January 2018: 3 pages.
3- "Transparency and Health Technology Assessment cooperation as proposed by the Regulation are the only real antidote to secrecy and political games" EURORDIS March 2018: 5 pages.