During the first months of the covid-19 pandemic, European regulations also enabled rapid access to unevaluated tests (2,3). Despite searching, we found no analyses of this experiment, equivalent to the one carried out in the US.

Expedited access to health products exposes patients to the risks of inadequate evaluation. As this review shows, poor-quality health products that deny patients access to effective ones are far from trivial.

► Translated from *Rev Prescrire* June 2023
Volume 43 N° 476 • Page 470

References 1- US Department of Health and Human Services-Office of Inspector General "FDA repeatedly adapted emergency use authorization policies to address the need for COVID-19 testing" September 2022: 51 pages. **2-** European Commission "Guidelines on COVID-19 in vitro diagnostic tests and their performance" 15 April 2020: 9 pages. **3-** APM "Covid-19: l'ANSM pas en mesure de surveiller en temps réel le marché des tests RT-PCR" 20 April 2020: 2 pages.

Publication of clinical trial protocols

● In a joint letter to the European Medicines Agency's Management Board, Prescrire contested an Agency plan that would delay publication of the protocols of drug trials.

In April 2022, the European Medicines Agency (EMA) released a draft guidance document for public consultation on the protection of personal data and commercially confidential information in documents published in the EMA-run clinical trials registry, the European Clinical Trials Information System (CTIS) (1).

In Prescrire's opinion, the section of the guidance document that addresses the protection of commercially confidential information violates the spirit of Europe's 2014 Clinical Trials Regulation, which stresses the importance of making this information transparent and accessible to all (2).

In the EMA's proposals, secrecy and deferred publication of trial documents would be the norm. Under the proposals the publication of protocols could be deferred for up to 5 years after trial completion, or even 7 years in the case of phase I trials.

While Europe's citizens legitimately expect the EMA to be committed to increasing transparency and public access to scientific data, its guidance document does not address the consequences that deferred publication of trial documents or redaction of the information they contain would have on the quality of health care and research.

On the initiative of Prescrire, and with the support of TranspariMED, a joint open letter was sent in October 2022 to the Chair of the European Medicines Agency (EMA) Management Board to contest the plan to defer publication of phase II and III drug trial protocols for up to 5 years after trial completion (3). The cosignatories (11 organisations and 4 academic experts) requested that this issue be added to the agenda of the EMA Management Board's next meeting (3).

They urged the Management Board to direct the EMA to protect and promote the interests of patients by fully implementing the transparency provisions set out in European law. A clinical trial's protocol should be made public at the time that the trial's results are published, i.e. 12 months at most after trial completion (3).

In the reply received to the joint letter in late November 2022, the Chair of the EMA Management Board agreed to our request, stating that the topic would be discussed at an upcoming meeting (4). At its December meeting the Board "*agreed to review the current rules on disclosure of certain clinical trial documents and a review of CTIS transparency measures for 2023*" (5).

► Translated from *Rev Prescrire* May and June 2023
Volume 43 N° 475 and 476 • Pages 390 and 469

References 1- EMA "Draft Guidance document on how to approach the protection of personal data and commercially confidential information in documents uploaded and published in the Clinical Trial Information System" 7 April 2022: 56 pages. **2-** Prescrire Rédaction "Submission of comments on draft Guidance document on how to approach the protection of personal data and commercially confidential information in documents uploaded and published in the Clinical Trial Information System (CTIS) (EMA/212507/2021)" 7 September 2022: 24 pages. **3-** "Collective open letter to the Chair of EMA Management Board" 17 October 2022: 4 pages. **4-** Chair of EMA Management Board "Reply to the Collective open letter" 14 November 2022: 2 pages. **5-** Minutes of the 118th meeting of the Management Board held on 14-15 December 2022 (cf. page 8) https://www.ema.europa.eu/en/documents/minutes/minutes-118th-meeting-management-board-14-15-december-2022_en.pdf.