Prescrire a cosignatory of letters to various European institutions

● In late 2022, Prescrire was a cosignatory of letters to three institutions in Europe: the Council of the European Union, the European Patent Office, and the European Parliament's Special Committee tasked with evaluating the handling of the covid-19 pandemic.

Access to medicines. Prescrire and 18 international civil society organisations sent a joint letter to the Ministers of Health of member states of the European Union to express concerns over "transferable exclusivity vouchers" (1). The European Commission has proposed these vouchers as a means of encouraging pharmaceutical companies to develop novel antimicrobials, by prolonging companies' monopoly on their most profitable drugs, and thereby delaying the market introduction of generics.

The cosignatories urged the Ministers of Health to reject such a proposal and called on the Commission to explore alternative proposals with no negative impact on patients' access to medicines.

Patents. Prescrire and the European Alliance for Responsible R&D and Affordable Medicines sent a joint letter to the European Patent Office (EPO), asking it to apply stricter patentability standards when examining drug-related patents (2). The issue could be addressed by revising the EPO's guidelines.

Pandemic management. Prescrire was a cosignatory of a letter sent to the Chair of the European Parliament's Special Committee on Covid-19. The committee's purpose is to analyse the European Union's handling of the covid-19 pandemic and to draw lessons from it in order to better combat future epidemics (3).

The cosignatories pointed out that many questions need to be addressed, including:
– funding of the pharmaceutical industry's research and development (R&D), and relations with pharmaceutical companies;
– evaluation of the reliability and performance of the diagnostic medical devices brought to market in the wake of emergency authorisation measures, some of which did not even have CE marking;
– transparency and accountability in the use of public funds, as well as their oversight.

► Translated from *Rev Prescrire* July 2023 Volume 43 N° 477 • Page 547

References 1- "Civil society open letter to the Council of the European Union concerning transferable exclusivity vouchers for antimicrobials" 5 December 2022: 3 pages. **2-** "Letter to the Vice President on patent granting process - European Patent Office" 14 December 2022: 2 pages. **3-** "Letter to the EP Special Committee on COVID-19 pandemic" 16 December 2022: 2 pages.

Emergency Use Authorization of covid-19 tests by the FDA: failings

● A retrospective review of authorisations granted by the US Food and Drug Administration during the first months of the covid-19 pandemic revealed numerous problems.

In 2022, the US Health and Human Services Office of the Inspector General, whose roles include oversight of the Food and Drug Administration (FDA), embarked on a retrospective review of how the Emergency Use Authorization (EUA) process had been used during the first 5 months of the covid-19 pandemic to provide rapid access to tests to detect Sars-CoV-2 infection as well as to serological tests (1).

An EUA can be granted, during a public health emergency, for a drug or medical device for a serious disease if there is reasonable belief that its benefits outweigh its harms. In the case of covid-19, at a time when few people had acquired the infection, the FDA eased these rules: test developers could use a smaller set of blood samples from infected patients to validate the performance of their test, "contrived" samples (uninfected blood samples "spiked" with inactivated virus) could be used, tests were made available before their authorisation, and modifications were made to tests already on the market without validation (1).

The first EUA was granted to the US Centers for Disease Control and Prevention (CDC) for a diagnostic test that proved defective after a few days in use. However, the flexibility of this type of authorisation enabled the manufacturers to rapidly improve the test (1).

A retrospective analysis of the EUAs granted between 1 January and 31 May 2020 showed that 82 of the 125 requests received by the FDA for laboratory-developed tests to detect Sars-CoV-2 infection had design or validation problems. Two-thirds of serological tests also lacked adequate performance data, and 167 ("*of the dozens of tests on the market*") had been removed from the list of permitted serological tests by late 2020 (1).