Update to the Declaration of Helsinki

In January 2024, Prescrire responded to a public consultation organised by the World Medical Association on a proposed update to the Declaration of Helsinki, the gold standard for clinical trial ethics. Prescrire's comments related to the following sections of the text:
– Regarding the requirement for research ethics committees to be transparent, we suggested clarifying that this includes transparency over the comments, guidance and approval provided on the research protocols submitted to them;
– Regarding informed consent to participate in a trial, we suggested adding that patients' level of health literacy must be taken into account;
– We suggested clarifying the exceptional circumstances that would render a comparative trial impossible, and those in which the use of placebo is not practicable (1).

The updated version of the Declaration of Helsinki, published in October 2024, takes into account Prescrire's second comment, specifying that the information provided to potential trial participants must be presented in "*plain language*" (2).

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References 1- Prescrire Rédaction "Prescrire comments - World Medical Association Declaration of Helsinki 2024 Revision: Phase 1 Public Comment Document" 31 January 2024: 14 pages. **2-** World Medical Association "WMA Declaraton of Helsinki – Ethical principles for medical research involving human participants" October 2024: 6 pages.

A "prescription" from French civil society for a new pharmaceutical policy

In May 2024, in response to the failure of pharmaceutical policy to adequately address public health needs (resulting, for example, in drug shortages), a group of 14 organisations, including Prescrire, jointly published a "prescription from civil society" (1).

The objective of this collective is to champion a healthcare system based on the needs of patients and the principle of permanent access to health products. This collective consists of the following French health sector organisations: Action Santé Mondiale, AFM-Téléthon, Aides, Association française des hémophiles, DNDi, France Assos Santé, La Ligue contre le cancer, Médecins du Monde, Open Insulin France, Prescrire, Renaloo, UAEM, UFC-Que Choisir, and Vaincre la Mucoviscidose.

The "prescription" contains 15 articles covering all aspects of pharmaceutical policy: from basic research, to the loss of democratic control over the use of public resources, via the revision of Europe's pharmaceutical legislation, and access to therapeutic innovations.

The article contributed by Prescrire focuses on the revision of Europe's pharmaceutical legislation. The "prescription" (in French) is available from our French website at Prescrire.org > Nos actions > Politiques de santé.

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References 1- "L'ordonnance de la société civile pour une nouvelle politique du médicament. Garantir l'accès, maîtriser les prix" May 2024: 54 pages.

French Senate resolution on the European "pharmaceutical package"

In November 2023, Prescrire contributed to a hearing held by the French Senate's Committee for European Affairs as it prepared a resolution on the European Commission's revision of pharmaceutical legislation (also known as the "pharmaceutical package").

Various issues were discussed, in particular: drug shortages, marketing authorisations, drug dispensing, and incentives based on regulatory data exclusivity.

In January 2024, Prescrire followed up the hearing with a written submission on matters linked to supply issues and drug shortages: measures to support reshoring and thus strengthen health sovereignty, the requirement for pharmaceutical companies to hold contingency stocks, and compulsory licensing.

In October 2024, the Committee for European Affairs adopted the draft resolution, and it was approved by the Senate in December (1). The resolution incorporates a number of Prescrire's key demands, in particular:
– Rejection of the proposed shortening of the European Medicines Agency (EMA) evaluation period for marketing authorisation applications from 210 days to 180 days;
– Rejection of the proposed removal from the definition of an orphan drug that, without this status, developing the drug would be unprofitable;
– Transparency about the costs of pharmaceutical research and development, to include clear reporting of any research tax credits received;
– Rejection of the proposal to scrap risk management plans for generic and biosimilar drugs;
– Rejection of the proposed introduction of "transferable exclusivity vouchers", which are intended to encourage the development of high-priority antimicrobial drugs, but have the potential to substantially increase spending on other medicines by extending the duration of the market monopoly for highly profitable drugs.

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References 1- Sénat "Résolution européenne (...) révision de la législation européenne (...)" 29 November 2024: 18 pages.