

negative or non-quantifiable added benefit ratings (2).

Median research and development costs were about \$700 million per antineoplastic (with a range of \$166 million to \$2060 million, depending on the drug), and the median time to offset these costs was estimated at 3 years for the drugs as a whole. For drugs with conditional marketing authorisation, which more frequently received negative or non-quantifiable added benefit ratings, the median time to offset costs was estimated at 4 years (2).

While this study has a number of limitations, as discussed by the authors, it shows that even when they provide little or no progress for patients, authorised anti-neoplastic drugs still typically represent a substantial source of revenue for pharmaceutical companies, and thus a major expenditure for health insurers. Those responsible for authorising drugs, and for negotiating drug prices, should take note.

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## Anti-competitive practices: a very "inventive" pharmaceutical industry

● A total of €780 million in fines was imposed in the European Union over the period 2018-2022. More than half of this sum related to a case in France that has been appealed by the companies concerned.

**P**harmaceutical companies employ various anti-competitive practices. Examples include misuse of the patent system and vexatious litigation designed to deter generic companies; "pay-for-delay" agreements between certain generic and originator companies to postpone the launch of generic drugs; disparagement of competitor products; abusive rebates (or "predatory pricing") to retain the business of a customer such as a hospital; steering patients toward a particular drug using a phone number on company materials; price fixing of an active substance between several companies; and the sharing out between companies of the supply of a drug to wholesalers (1-6).

The European Commission and European Union (EU) member states have the power to sanction

companies that infringe competition rules with prohibition or fines. Companies can avoid these penalties by coming to an agreement with these institutions regarding remedies for abusive conduct (1).

Over the period 2018-2022, 26 infringements of competition law in the pharmaceutical sector were sanctioned in the EU by either the Commission or member states, with fines reaching a total of €780 million. In 2024, 30 cases of suspected infringement were under investigation (1-4).

Companies can appeal against these sanctions for anti-competitive practices. Of the €780 million in fines imposed in the European Union, €444 million relate to a French case brought against three companies that has since been overturned by an appeal court (1).

Lack of competition between companies leads to massive increases in costs for national health insurance systems. But in the view of the Commission, enforcement of competition law only goes part of the way in ensuring patients' access to drugs at affordable prices. The EU still lacks an effective pharmaceutical legislative framework for achieving this goal (1,7).

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