POLITICO Morning Health Care

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Patients groups and cancer charities are divided over suggestions in a prestigious medical journal that Europe's system for drug approvals is flawed.

The study in the British Medical Journal, published October 4, found that the European Medicines Agency's approvals of most new cancer drugs came despite little evidence that they improved quality or length of life — and those that did showed insignificant improvements over existing medicines.

An accompanying editorial said the findings were evidence of a "broken" system. The new treatments come at a high cost to health systems with little justification, it argued.

Patients groups are, gingerly, defending the EMA, while the European Cancer Leagues, an association of charities, said the drugs regulator isn't fulfilling its mission. The split reflects ongoing tension between offering new hope for patients and ensuring as many people as possible have access to the medicines that are available.

"New cancer medicines should always be better than those they aim to replace," said Eveline Scheres, head of the European Cancer Leagues' Access to Medicines Task Force, in a statement Thursday.

EMA approval is "usually (and should be) perceived as a guarantee of efficacy," the statement said. Innovative medicines put a heavy burden on national budgets, so the study raises a consequential question, according to the European Cancer Leagues: "Are new medicines expensive because they are effective or simply because they are new?"

The European Cancer Patient Coalition (ECPC) doesn't see it that way at all.

"Even if a treatment has equivalent quality, safety, and efficacy compared to the existing standard of care, the treatment should still be authorized by the EMA, as this can often result in decreased prices due to competition," the Brussels-based umbrella organization of national patient groups said in a statement to POLITICO on Monday.

The ECPC echoed the EMA's own rebuttal that it's up to national governments — not the drugs regulator — to make decisions about value. On pricing and reimbursement, the group said, "only cost-effective treatments must be approved." Furthermore, those value determinations should include factors like drops in absenteeism and reduced medical costs. "Unfortunately, this does not occur in most cases."

Both charities and patients groups want to boost the EMA's approach to monitoring drugs after they are already on the market.

"The EMA should initiate more post-authorization efficacy studies, in order to be sure that the new medicines deliver meaningful value to patients and do not cause any unnecessary harm," said the Cancer Leagues. The ECPC wants to see "existing safeguards to revoke authorization if the product is demonstrated to lack efficacy or safety … strengthened."