

# Fewer than half of new drugs add substantial therapeutic value over existing treatments, study finds

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New drugs are often used not only for one disease (first approved indication) but also for other diseases (supplemental indications).

But a study published by *The BMJ* finds that less than half of approved first indications for new drugs in the U.S. and Europe between 2011 and 2020 add substantial therapeutic value over existing treatments and only around a third of supplemental approvals add substantial therapeutic value compared with first approvals.

The researchers argue that when first or supplemental indications do not offer added benefit over existing treatments, this information should be clearly communicated to patients and reflected in the price of the drugs.

Previous research on the added value of new drugs is unclear. So researchers set out to examine all [new drugs](#) approved for more than one indication in the U.S. and Europe between 2011 and 2020 and assess the therapeutic value of supplemental indications compared with first indications.

They used publicly available data to identify 124 first and 335 supplemental indications approved by the U.S. Food and Drug Administration (FDA) and 88 first and 215 supplemental indications approved by the European Medicines Agency (EMA) between January 2011 and December 2020.

In the U.S., 48% of drugs had one supplemental indication, 20% had two, 14% had three, and 18% had four or more. In Europe, 48% of drugs had one supplemental indication, 23% had two, 13% had three, and 17% had four or more. Most (58%) of indications approved by the FDA and EMA were for treatment of cancer.

Therapeutic ratings from French and German health technology assessment (HTA) bodies were available for 107 (86%) first and 179 (53%) supplemental indications in the US and for 87 (99%) first and 184 (86%) supplemental indications in Europe.

Among FDA-approved indications with available ratings, 41% (44 of 107) had high therapeutic value ratings for first, compared with 34% (61 of 179) for supplemental indications. In Europe, 47% (41 of 87) of first and 36% (67 of 184) of supplemental indications had high therapeutic value ratings.

Among FDA approvals, when the sample was restricted to the first three approved indications, second indication approvals were 36% less likely to have a high value rating and third indication approvals were 45% less likely when compared to the first indication approval. Similar findings were observed for Europe.

These are observational findings and the researchers acknowledge that therapeutic value ratings were not available for all indications, particularly indications approved in the U.S. but not in Europe. Furthermore, the methods and value assessment system can be influenced by country specific factors and assumptions.

However, they point out that they focused on the highest [rating](#) provided by one of the two HTA bodies and did sensitivity analyses with the value scores of each authority separately, which confirmed the initial results.

As such, they conclude, "Fewer than half of approved first indications in the U.S. and Europe were rated as having high therapeutic value, and the proportion of approved supplemental indications rated as having high therapeutic value was substantially lower than for approved first indications."

"When indications do not offer added therapeutic benefit over other available treatments, that information should be clearly communicated to patients and reflected in the price of the drugs."

The fact that new does not necessarily mean better needs to be clearly

communicated to both patients and clinicians, agrees Beate Wieseler at the German Institute for Quality and Efficiency in Health Care, in a linked editorial.

"The system's current performance does not meet the expectations of patients and the public, clinicians, or policy makers," she writes. "Having experienced the potential of a coordinated [drug](#) development effort during the COVID-19 pandemic, we should seek to align current legislation on [drug development](#) more closely with defined public health goals."

**More information:** Therapeutic value of first versus supplemental indications of drugs in US and Europe (2011-20): retrospective cohort study, *The BMJ* (2023). [DOI: 10.1136/bmj-2022-074166](https://doi.org/10.1136/bmj-2022-074166)

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