New drugs should be compared with existing treatments before approval, say experts

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Manufacturers should have to show how their drugs compare to existing treatments before approval to help ensure that the most beneficial and safest therapies reach patients and that limited healthcare resources are invested wisely, argue experts in *BMJ* today.

Currently, manufacturers have to compare the risks and benefits of a new drug against a placebo. Direct (head to head) comparisons with existing therapies are only required when use of a placebo is deemed unethical.

This, argue researchers at the London School of Economics and European Observatory on Health Systems and Policies, does not allow patients, clinicians, and other healthcare decision makers to determine whether a new drug is superior, equivalent, or inferior to its existing alternatives.

This can result in "the widespread use of potentially less efficacious and unsafe drugs," they warn. A number of studies have also questioned the true added value offered by new (and often more expensive) drugs compared with existing treatments.

The European Medicines Agency (EMA) has long encouraged that, when possible, pre-market studies should be undertaken to establish comparative efficacy and risk, but has yet to set comparative assessments as the default evidentiary standard for market approval, write the authors. Rather, requirements for comparative studies are made

on a case by case basis.

While estimates suggest that comparative efficacy data are available for 50-70% of new molecular entities at the time of approval, the authors argue that this varies across therapeutic areas and that only a fraction of evidence is often accessible at the time of market authorisation.

A further challenge is that no particular type of study is ideal for assessing comparative efficacy, they add.

Despite these limitations, they believe that "comparative efficacy evidence should have a formal role in drug licensing decisions."

They call for open dialogue between regulators, manufacturers and government agencies "to achieve better congruence between licensing and reimbursement requirements" and better public access to comparative data on the effectiveness and safety of new drugs.

"Numerous promising medicines have been developed and many more are on the way to initial clinical trials," say the authors. "With this success comes an equally important additional need – to develop a systematic approach to evaluate the risks and benefits of these new therapies in the context of existing alternatives. An important initial step is to support a formal role for comparative efficacy evidence in drug licensing," they conclude.

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