BMJ

BMJ 2014;348:g2657 doi: 10.1136/bmj.g2657 (Published 8 April 2014)

NEWS

Only 3 in 20 new drugs approved in Germany in 2011 were an improvement, report says

Ned Stafford

Hamburg

Nearly 85% of new drugs in Germany that were approved in 2011 for outpatients covered by public health insurance showed little or no added benefit compared with drugs already on the market, says a new study commissioned by Techniker Krankenkasse, Germany's largest public health insurer.

However, the authors of the annual study, *Innovation Report 2014*,[1] noted that "drug innovation" figures for 2011 were an improvement on 2010 and that they expected the improvement to continue in the coming years, mainly because of a new German drug law.

Of the 20 new drugs approved in 2011 that the authors monitored through 2013 only three—ticagrelor, tafamidis, and abiraterone—were found to provide "innovative therapeutic advances" over drugs already in use. Ten of the drugs provided limited therapeutic improvements and seven drugs showed no new benefits. Of the 23 new drugs approved in 2010 two were rated as innovative, six as slightly innovative, and 15 as not innovative—showing no additional benefits over existing drugs.

The authors defined "innovative" by using three criteria: whether or not treatments already existed for a new drug's indications; whether a new drug showed one or more additional benefits over older drugs; and whether a new drug cost less than older comparable drugs. Of the 14 new drugs in 2011 whose prices could be compared with older drugs 11 were more expensive, two were similar in price, and one was cheaper. The authors then totalled the three criteria on each new drug to reach their final conclusions.

Gerd Glaeske, lead author of the study and head of health economics and health policy at the University of Bremen,[2] told *The BMJ* that the improvement in non-innovative drugs from 65% of the total in 2010 to 35% in 2011 could be attributed mainly to a major drug law that took effect at the start of 2011.

The law, known in Germany by its acronym AMNOG (*ArzneiMittelmarktNeuOrdnungsGesetz*), requires that a new drug first be evaluated by a federal committee supervised by the ministry of health, to determine whether it shows additional benefit compared with corresponding established drugs. If a drug shows added benefit and is approved, health insurers negotiate prices with the drug industry. The law has already been judged to have helped to lower drug costs for Germany's public health insurance[3] and has been criticised by Europe's drug industry.[4]

"I think we are seeing improvement because of the rising quality of licensing studies for new drugs," said Glaeske. "The better the studies are, the better the chances will be for the pharmaceutical companies to successfully pass the AMNOG process and enter into cost benefit negotiations with the representatives of the statutory health insurance system."

But Glaeske added that it would still take several more years until the AMNOG law took full effect. "We are in a kind of a transitional period at the moment, and the situation will continue to improve," he said.

1 University of Bremen. The "Innovation Report 2014" of the Centre for Social Policy Research is published. 3 April 2014. www.zes.uni-bremen.de/the-centre/news/en/?news=174.
2 University of Bremen. Gerd Glaeske. www.zes.uni-bremen.de/the-centre/organisation/members/gerd-glaeske/.
3 Stafford N. Measures to cut Germany's drugs bill start to take effect. *BMJ* 2011;343:d5999.
4 Stafford N. Manufacturers urge German government to revise proposals for pricing new drugs. *BMJ* 2012;344:e4069.

Cite this as: *BMJ* 2014;348:g2657