Huge variations between countries in time for reimbursement decisions on new cancer drugs

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Some European countries take more than twice as long as others to reach health technology assessment (HTA) decisions to reimburse new cancer drugs following their approval by the European Medicines Agency (EMA). The average decision time is longer than one year in some countries, according to a study to be reported at ESMO 2018 Congress.

Once the EMA has approved a new treatment, many countries evaluate its benefit and cost-effectiveness through a systematic health technology assessment process as part of making a decision on whether to reimburse use of the treatment for routine patient care.

Researchers identified all new cancer drugs approved for solid tumours by the EMA between January 2007 and December 2016. They then tracked the time between EMA approval for each of the drugs and HTA decisions being taken by health authorities in four European countries: England, France, Germany and Scotland.

Results for 47 drugs approved for 77 solid tumour indications revealed that the median time from EMA approval to HTA decisions was two to three times longer in England (405 days) and Scotland (384 days) compared to Germany (209 days) and France (118 days).

"In contrast to the centralised approval of anticancer drugs by the EMA, the time to HTA decisions remains a national responsibility," explained

study co-author Dr. Kerstin Vokinger, senior research scientist at the University Hospital of Zurich, Switzerland, and affiliated researcher at Harvard Medical School, Boston, USA. She added: "Among other things, the different amount of resources invested in such assessments and different national regulations regarding HTA systems may lead to variation in the time from EMA approval to HTA decisions in different countries."

Commenting on the findings, Dr. Bettina Ryll, founder of Melanoma Patient Network Europe and Chair of the ESMO Patient Advocacy Working Group, said: "We in melanoma still mourn the lives we lost due to the tardy and inconsistent introduction of approved innovative therapies. It is a country's responsibility to ensure sufficient administrative capacity so that processes like HTA that were put in place for the benefit of society do not start harming citizens. And we need more pragmatic approaches to reducing uncertainty- simply letting patients die while waiting for data to mature is not a civilised option."

The study found that health authorities generally made decisions much more quickly for drugs ranked as being of "highest benefit" on the ESMO Magnitude of Clinical Benefit Scale (ESMO-MCBS) compared to those with less clinical benefit. However, the variation in time from EMA approval to HTA decisions remained between different countries for these "highest benefit" drugs.

The ESMO Magnitude of Clinical Benefit Scale uses a rational, structured and consistent approach to grade the magnitude of clinical benefit that can be expected from anti-cancer treatments. "Lowest benefit" refers, for example, to drugs increasing median progression-free survival by a few weeks, whereas the category of "highest benefit" is given to drugs improving long-term survival in the neo/adjuvant setting (5,6).

In France, the median time to an HTA decision on "highest benefit" drugs was 154 days compared to 198 days for drugs of less benefit. Faster HTA decisions for "highest benefit" cancer drugs were also made in Germany and England but the time to HTA decisions was much longer in England (median 302 days) than in France or Germany (203 days).

Further analysis showed that nearly all cancer drugs ranked as being of "highest benefit" on the ESMO-MCBS were approved for reimbursement by all four countries: Germany (100%), Scotland (95%), England (92%) and France (90%)... In addition, the researchers found high concordance between ESMO-MCBS and scores health regulators gave in HTA procedures for cancer drugs of "highest benefit".

"Our study shows that there is a high concordance between ESMO Magnitude of Clinical Benefit Scale and HTA scores for the categorisation of "highest benefit". Therefore, the ESMO Magnitude of Clinical Benefit Scale could serve different countries as a helpful tool to assess the clinical value of anticancer drugs," suggested Vokinger.

Commenting on the findings for ESMO, Prof. Elisabeth de Vries, Medical Oncologist at the University Medical Center Groningen, Groningen, The Netherlands, Chair of the ESMO-MCBS Working Group, said: "It is reassuring that in the countries studied, anticancer drugs with greatest clinical benefit on ESMO-MCBS (version 1.1) are associated with faster times to HTA decisions and nearly all are approved for reimbursement."

Noting the variation in times to final decisions, she suggested, "Hopefully, this information can be helpful to raise the interest of HTA agencies in their performance and timeframes."

de Vries added, "Data were analysed only for England, France, Germany

and Scotland. This means data for HTA procedures and reimbursement decisions were reported for only part of Europe, with no countries included from Southern or Eastern Europe. Insights into these procedures in other European countries might be of interest."

Vokinger said the research group now plans to expand research in this area. "Among other things, we plan to include more countries for assessing HTA decisions and to explore access to new cancer medicines by individual patients," she said.

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