Discrepancies in access to new cancer drugs revealed

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Access to potentially life-extending cancer drugs varies significantly in different regions of the world, two new studies show at the ESMO 2014 Congress in Madrid, Spain.

Researchers say the results demonstrate the need for better collaboration between doctors and health authorities on an international scale, to ensure patients have access to the best treatments.

Coordinated action is needed at an international level to ensure new cancer-fighting drugs are approved in a timely manner, oncologists said at the Congress. Their call came after a survey revealed that patients in some regions sometimes wait years longer than their counterparts elsewhere for new drugs to be approved.

The drug approval process is important to ensure that safe and effective therapies are made available for patients, explains study senior author Dr Sunil Verma from Sunnybrook Odette Cancer Center, Toronto, Canada.

To try and understand disparities in the drug approval time among various countries, Verma and coauthor Nardin Samuel compared approval times for 41 cancer drugs in Canada, the USA and the European Union.

They found that the average time to approval for these drugs by the US Food and Drug Administration (FDA) was 6 months shorter than for the European Union's European Medicines Agency (EMA) and 7.6 months

faster than Health Canada. Azactidine, for example, approved for haematological malignancies, had the greatest delay between FDA and Health Canada approval, stretching to 66.1 months. The EMA approved azactidine 10.3 months earlier than Health Canada but 55.8 months after the FDA.

The fastest approval time among the drugs studied was for cabazitaxel, which was approved for metastatic prostate cancer by the FDA just 17 days after the drug's manufacturer filed for approval. In Canada and Europe, the times to approval for cabazitaxel were 11.63 months and 11.03 months, respectively.

This is the first study to systematically compare cancer drug approvals between three major regulatory bodies, the authors say. While approval from regulatory agencies plays an important part in helping ensure the safety and efficacy of new drugs, delays in the approval process can have an impact on patient care, they note.

"Our main aim as clinicians is to ensure that patients are given an opportunity to receive proven, effective and safe treatment in a timely manner. We need to balance due diligence to review appropriate treatment by regulatory agencies and providing treatment to our patients that is effective," Verma says.

"There needs to be a dialogue amongst industry, regulatory agencies, patient bodies, research community and oncology professionals on how best we can reduce the time to approval while ensuring safety for approved drugs. We also need a coordinated international approach to reduce the disparity in time to access new drugs around the world."

Commenting on the study, Professor David Cameron, director of the Edinburgh Cancer Research Centre, UK, noted: "This interesting study compares the times to regulatory approval in USA, Canada and Europe.

There was little difference overall between the approval times for the EMA (Europe) and Health Canada, but both of these agencies approved new anti-cancer agents significantly later than the FDA in USA. Interestingly one drug, carbazitaxel, was approved in under 1 month in the USA."

"It is not clear why there were these differences, but they are of some concern in the sense that they suggest that in the absence of data to the contrary, there may be bureaucratic rather than medical/scientific reasons for differential geographical approval timelines —which of course will lead to differential geographical benefits from new agents," Cameron said.

Clearly more work is needed to understand the reasons for these differences, and any potential patient impact, but this work should stimulate such deeper investigations, Cameron said.

Access to breast cancer drug lacking in Eastern Europe

In a second study, Dr Felipe Ades Moraes from Institut Jules Bordet in Brussels, Belgium and colleagues found that patients in Eastern Europe had less access to the HER2 positive breast cancer targeted drug trastuzumab than their counterparts in Western Europe and the USA; differences they say can be linked to discrepancies in cancer survival.

Trastuzumab is used to treat breast cancer in patients with HER-2 positive tumours, which account for around 20% of breast cancers. The drug was first approved for use by the US Food and Drug Administration in 1998.

"The development of trastuzumab is considered to be one of the greatest

improvements in breast cancer treatment in recent years," Ades Moraes said. "But we found that there were significant differences in trastuzumab procurement between countries in Western Europe, the USA and Eastern Europe and that these differences could be partially related to discrepancies in cancer survival between these regions."

The researchers had previously shown that there were differences in health expenditure among the European Union countries and that these differences were related to discrepancies in cancer survival. "The more spent, the fewer patients died after a cancer diagnosis," Ades Moraes says.

Now the researchers say they have shown that differences in the uptake of innovative and life-saving drugs may be one of the explanations for why these discrepancies exist.

Using national registry data, the researchers estimated the number of new cases of HER2-positive breast cancer patients per year in 24 countries, including 14 in Western Europe and 9 in Eastern Europe. They then estimated the number of likely trastuzumab treatments per year using trastuzumab procurement data for each country.

Tracking how many possible patients could have been treated with the supply of trastuzumab within individual countries between 2001 and 2013, the researchers found that Eastern European countries acquired insufficient trastuzumab to treat all the patients who would benefit from it.

"Trastuzumab procurement levels only increased in Eastern Europe after 2005 when the drug received extended approval for use after surgery, to increase the cure rate of breast cancer, while Western Europe and the USA had a faster uptake, seen since the drug's first approval in the metastatic setting (2000 and 1998, respectively) and acquired sufficient

amounts of the drug to treat virtually all patients," Ades Moraes said.

"Advances in all areas of healthcare, ranging from screening to surgery and radiotherapy, endocrine treatment, and chemotherapy, have all contributed to the decreasing breast cancer mortality trend in the USA and Europe," the researchers say.

"Our demonstration of the higher trastuzumab uptake in countries with higher breast cancer survival strengthens the notion that the uptake of life-saving drugs is one of the many important factors in improving cancer survival."

"As cancer treatment and cancer drugs become more complex and more expensive, a close relationship between health authorities and doctors can dramatically improve patient care and cancer survival by determining priorities in health budget allocation," Ades Moraes says.

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