Health Canada's fast-tracked drug approvals can put public at risk

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Drugs streamed into Health Canada's accelerated review process are more likely to be withdrawn from the market or earn a serious safety warning than those that undergo the standard review, according to a recent paper out of York University.

The study, published online by the Archives of Internal Medicine on Oct. 8, is the first of its kind undertaken in Canada. It tracked a total of 434 new active substances (NASs) approved by Health Canada between 1995 and 2010, examining how many subsequently acquired either serious safety warnings or had to be withdrawn from the market for safety reasons. The NASs were then compared to see whether a difference in safety existed between those that had gone through Health Canada's standard 300 day review period vs. the 180 day priority process.

"I found that drugs that went through the standard process had a 1 in 5 chance of either having a serious safety warning issued or being withdrawn from the market for being unsafe," says study author Dr. Joel Lexchin, Professor in York's Faculty of Health. "However, if the drug goes through the priority process, it has a greater than 1 in 3 chance of having the same outcome."

Though some drugs are moved into the priority process because they provide major therapeutic advances for serious illnesses, such as cancer, HIV/AIDS, and multiple sclerosis, and thus may be put through with a lower benefit to harm safety ratio, Lexchin found that the types of drugs

in the priority category, and the types of diseases they treated, did not account for the difference in safety issues.

"Even drugs that provided no major therapeutic advances were still more likely to acquire serious safety issues if they were put through the priority review," says Lexchin. "This indicates that the difference is likely due to the faster review missing serious safety issues."

The study concludes that new products that offer major therapeutic advantages should be embraced, even with the significant gaps that exist about their safety, but because most NASs do not fall into this category, clinicians and patients should be using these drugs very cautiously.

Provided by York University