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Drug Safety Is Influenced More by Business Interests Rather Than Public Health

What is this research about?

Prescription drugs go through a process of monitoring and approval in order to measure their benefits and risks. The Food and Drugs Act names Health Canada as responsible for this. However, drug companies are almost invariably a part of the negotiations for removing unsafe drugs from the shelves. As a result, Health Canada's power is limited. They can issue a public warning about a drug, but they do not have the power to recall the drug without the company's agreement. There is also a growing concern that decisions to approve drug products as "safe" are based on market friendly choices rather than concern for public health. The faster the drug approval process becomes, the less time there is to assess potential risks of these new products.

What did the researcher do?

The researcher began by examining some of the limits of Health Canada's legal power. He also examined the growing trend towards a business-friendly process in assessing drug safety, both in policy and with funding. The researcher looked at both the positive and negative attributes of how Health Canada manages information regarding drug safety in Canada. Finally, he evaluated one possible alternative for improving the ability to assess drug safety.

What you need to know:

The safety of pharmaceutical drugs in Canada is a concern. While Health Canada is given the power to measure safety and approve drugs, the process has its limits. There is a growing trend towards practicing "risk management" rather than the "precautionary principle" when drugs are approved. There is also a greater priority put on meeting the interest of drug companies compared to the potential harm to public health. "Progressive licensing" would allow for drugs to be assessed for safety even after it's approved.

What did the researcher find?

The researcher found that the authority and actions of Health Canada were geared towards making it easier for drugs to become approved. This was at the expense of a more a thorough process to assess their safety. Health Canada does not have the authority to recall a product if it is considered harmful. They may issue a public warning, but it is up to the manufacturer to withdraw it from store shelves. Companies cannot be forced to conduct new studies regarding the safety of a product once it has been approved for the market. The Marketed

Health Products Directorate (MPHD), a division of Health Canada, monitors the safety of drugs after they are approved, but they have limited resources. As a result, they have had to stop routinely assessing how likely it is that a drug caused an ADR (adverse drug reaction) when an adverse reaction report is received. Meanwhile, the Therapeutic Products Directorate (TPD), another division of Health Canada, is responsible for approving drugs, and receives one third of its funding from drug companies. The TPD is moving towards faster drug approvals and practicing "risk management" over the "precautionary principle".

The researcher also found some problems with different aspects of how Health Canada oversees drug safety. Health Canada has no standards for how long it should take between when an ADR report is filed and when it becomes posted on their website. There was also poor information on how Health Canada decides whether a safety issue should be communicated to health care professionals and the public. Compared to other countries, Canada allows its ADR reports to be accessed by the public on the internet. However, ADR databases are known to only cover 1 to 10 percent of all reactions to a drug because of under-reporting of ADRs by health care professionals. Information from clinical trials done before a drug is approved that assess how well the drug works and how safe it is, is also confidential, unless the company agrees to have it released. The researcher argued that "progressive licensing" was a useful alternative for Health Canada. Progressive licensing moves away from the "all or nothing" dynamic in drug approvals and allows safety to be assessed throughout the entire time a drug is on the market.

How can you use this research?

This research would be useful for service providers in the health industry. They might use it to improve public education on the risks and benefits of drugs on the market. This research would also be useful for policy makers dealing with public health and business interests. It offers insight on how to regulate the relationship between the two parties.

About the Researcher

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