Health Canada to call for better data from drug trial sponsors to address gaps affecting women, racialized populations

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Dr. Supriya Sharma, Chief Medical Advisor for Health Canada, says regulation could be in place in the first half of 2023.

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Health Canada will propose regulations requiring drug trial sponsors to provide data broken down by sex, age and race in an effort to better protect groups, including women, racialized populations and the elderly, from ineffective treatments and adverse side effects.

“We absolutely need to do better,” said Supriya Sharma, chief medical advisor at Health Canada. “I can’t go back and correct or change the history. What I can say is that now there

really is a genuine concerted effort, not only in Canada, but internationally, to make sure they're adequately represented."

While age, sex and racial diversity in clinical trials has increased somewhat in recent decades, research has shown that data on diverse participants is regularly amalgamated rather than analyzed separately. As a result, information on how well drugs work for under-represented groups is often lost. The impact, according to experts, is that these groups may be receiving less effective or even more dangerous treatments.

"There are big gaps out there potentially when you don't have that kind of information," said Paula Rochon, a geriatrician and senior scientist at Women's College Research Institute. Historically, she said, there has been a "mentality that one size fits all and I think we're becoming increasingly aware that that's not the case."

Health Canada acknowledges that the gap means the risks and benefits of pharmaceuticals are unclear for some groups. In practice, Dr. Rochon said this means that patients could be developing needless side effects.

Dr. Sharma said the department wants "to make sure that we have therapies, medications and treatments that are available to people that are accurately studied."

In early October, the federal government launched a questionnaire for new drug submissions asking trial sponsors – industry, academic institutions and contract research organizations – to report on whether their data is disaggregated by sex, age and race or ethnicity. Starting in December, submissions that fail to answer the questionnaire can be rejected for review. Health Canada is seeking to establish a baseline, with the aim of "improving capacity to collect the disaggregated data that we need to assess, monitor and report on."

While this initiative does not require trial sponsors to collect this information, experts said it's a positive step. "Women have been calling for more stringent accountability by federal regulators for drug approvals for women for over 30 years. I am thrilled that Health Canada is taking leadership," said Dr. Cara Tannenbaum, a women's health researcher and professor at the University of Montreal.

Health Canada said the questionnaire is phase one of a plan to strengthen the oversight of drug submissions. The second phase is the regulatory amendment that would compel drug

manufacturers to submit disaggregated data.

The proposed regulation, expected before the end of the year, will require drug trial sponsors to submit data disaggregated by sex, age and race, but only if this information has already been submitted to the European Medicines Agency or the U.S. Food and Drug Administration.

This caveat will water down the impact of this regulation, said Joel Lexchin, a recently retired emergency room doctor and a former professor at York University who has been researching pharmaceutical policy in Canada for 40 years. “Basically, all they’re saying is if you’ve already done the work, you may as well give it to us, too.”

It is not mandatory that submissions to the EMA include such information. However, the FDA has required all new drug submission applications to include trial data broken down by sex, age and race since 1998.

The fact that Canada is not a large market means companies are less inclined to cater trial design to Canada-only requirements, Dr. Lexchin said. The attitude, he said, can be, “If you’ve got to do things specifically for the Canadian market, why bother?”

There is a fine balance to strike, said Lorraine Greaves, a medical sociologist and the chair of the Scientific Advisory Committee on Health Products for Women, which is advising Health Canada on the proposed regulatory change.

Canada receives submissions from international companies doing research in other jurisdictions. So for Canada to ask for data that isn’t required in other markets would raise the bar for trial sponsors, she said.

“Our committee endorses that higher bar and we believe that should be our aspiration, but there are likely market forces and other kinds of issues that are at play in those regulatory decisions and policy decisions in Canada.” The Canadian government, Dr. Greaves said, “does not want to diminish the accessibility or availability of certain drugs.”

Health Canada plans to publish its draft guidance on the regulatory amendment in the Canada Gazette by the end of December 2022 for public consultation. Dr. Sharma said that if the process moves quickly the regulation could be in place in the first half of 2023.