Senate Standing Committee on Social Affairs, Science and Technology

Prescription Drugs: Post-Approval Monitoring

Dr. Anna Reid
President
Canadian Medical Association
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Check against delivery
Thank you Mr. Chair. The Canadian Medical Association is pleased to appear before this committee as part of the second phase of your study on prescription medication. As the CMA’s newly elected president, I want to extend our appreciation for the invitation. Previously, we outlined our position on clinical trials and the drug approval process. Today I will discuss the system for post-approval surveillance.

Prescription drugs are crucial to high quality, cost-effective health care, which is why the CMA continues to urge the federal and provincial/territorial governments to deliver on their longstanding commitment to a national pharmaceutical strategy. This would ensure that every Canadian has timely access to an adequate supply of safe and effective prescription drugs and this is our overarching recommendation today.

I will use my time today to discuss two elements of this recommendation: ensuring “safe and effective” drugs and ensuring an “adequate supply of drugs”

First, ensuring the safety and effectiveness of drugs:

The CMA supports a robust regulatory framework and system for researching and approving new pharmaceutical products. But even the best pre-approval system cannot identify every potential problem with a new drug; many problems are often identified only after widespread, long-term use. Canada must therefore have a robust regulatory framework and system to monitor the performance of prescription drugs after they come on the market. We believe such a system should contain three elements:

First, comprehensive processes for gathering drug safety and effectiveness data. Since a major source of data is adverse drug reaction reports from physicians and other health care professionals, Health Canada should encourage reporting by making the system as convenient to use as possible. One way to do this would be to incorporate the reporting form directly into Electronic Medical Record systems as these are developed.

The second element is capacity for rigorous data analysis. Information-gathering in itself does not constitute post-market surveillance. Of greater importance is the monitoring and analysis that occurs once an adverse drug reaction report has been received. We believe Health Canada should cultivate the capacity for analysis that
is rigorous and timely, enabling it to isolate quickly reports that indicate a serious health risk.

Post-market monitoring should also provide information about a drug’s efficacy and effectiveness. Does it achieve the health outcome for which it is being marketed? Does it perform better than other drugs or therapies for the same condition?

The third necessary element is effective communication. When a safety risk or other new facts about a prescription drug are found, physicians and other health professionals must be informed as quickly as possible, and advised on what they need to do: Should they monitor patients more closely or pull them off a certain drug?

Nearly one-quarter of the new drugs approved in Canada will eventually receive a serious safety warning. Given the potential risks to patients, we further believe Health Canada should be given the authority to, for example, require post-market studies of newly approved drugs if clinical trials identify possible safety risks; and to take action, including pulling a product off the market, when post-market research uncovers new safety concerns.

I would now like to turn to the key matter of ensuring an adequate supply of drugs. The CMA, among others, is deeply concerned about the persistent drug shortages in this country and believes monitoring drug supply and drug shortages to be essential to effective post-approval surveillance.

In a physician survey conducted by the CMA in September 2012:

- two-thirds of respondents said drug shortages were significantly affecting patient care and outcomes;

- of these physicians, 70 per cent indicated that a patient had received a less effective medication, and 20 per cent had patients who suffered clinical deterioration because an alternate drug was substituted.
and about one-quarter reported that a patient had suffered financially due to the cost of the substituted medication, since many of the drugs in short supply are older, low-cost generics.

Physicians are also frustrated with the time it takes to find an appropriate substitute drug – time which would be better spent caring for patients.

Although pharmaceutical companies now support a drug shortage reporting website, there is no certainty that it captures all of the drugs in short supply and lacks search functions for finding product listings easily. Also, a mechanism by which practitioners could obtain information on possible therapeutic substitutions would be of value.

Lastly, the CMA believes an investigation into the root causes of ongoing prescription drug shortages is warranted. We recommend that Health Canada work with provincial and territorial governments, industry groups and health professionals to find solutions.

In closing, the CMA wishes to commend this committee for bringing these vital issues to the forefront. We, as Canada’s physicians, stand prepared to work with governments, health professionals and the public in strengthening Canada’s post-approval surveillance system and to ensure that prescription drugs are safe, effective and available to those who need them.

I would be pleased to answer any of your questions. Thank you.