

## THERAPEUTIC SUBSTITUTION

# Not what the doctor ordered

All medicines within a given class are not the same. However, some provincial governments are experimenting with therapeutic substitution policies, based on the false premise that competing treatments have a similar effect on patients. In reality, drugs within a class can be benchmarked as having different effects.

There are several forms of therapeutic substitution. Under the most familiar model, reference based pricing (RBP), the government drug plan imposes a price for all drugs in a class based on the “reference drug” – generally the least expensive product in that class. In BC (where the policy is used for five classes of drugs) if a patient is prescribed a medicine other than the reference drug, the patient is required to pay the difference between the two prices, or the physician must complete a lengthy approval process before the government will cover the cost. One can imagine the confusion and frustration that this causes for patients, especially elderly ones who cannot afford anything other than what their government drug plan offers.

Several BC MLAs promised to review this while they were in opposition. In government, they moved further than RBP and, for the proton pump inhibitor (PPI) class of drugs, introduced a more extreme form of therapeutic substitution – one that removed a patient's option to pay the difference. This means that if a doctor prescribes a medicine other than the government's preferred treatment, the patient must pay the full cost out-of-pocket to get the prescription filled as written. Patients that had already been using other PPIs were expected to switch medicines.

It would be unethical for a physician to take a patient off a medicine that is effectively managing his or her symptoms, but governments are not bound by such a code. Newspaper coverage from BC suggests that some patients experienced a painful worsening of symptoms after having been forced off the treatment they were using before the policy change. The health care system must absorb the cost of the additional visits to the doctor to get the disease under control again. This suggests that the least-expensive medicine is not always the best financial deal in the long run.

It is important to note that these practices are different from generic substitution, where the product the patient receives has the same active ingredients as the original drug prescribed by the physician.

Decisions around therapeutic substitution are made by government officials – not family doctors. It fails because of the assumptions that all medicines within a class are the same and that patients will have similar reactions to different medicines. The reality is that every patient is different. Therapeutic substitution does not recognize individual patients' needs

and the value of doctor-patient dialogue – placing too much power in the hands of government officials. Choosing a medicine based on price presents hazards, especially for those patients who have complex and co-existing conditions.

In New Zealand, after RBP was introduced for cholesterol medications, the number of reported acute events tripled, including heart attacks, unstable angina, stroke and blood clots. Patients were forced to either pay out-of-pocket for more expensive, newer medicines, or switch to the cheaper, older “reference product.” The government admitted that it did not save money, except for a brief period after its introduction. The pattern has been repeated in several European countries that have experimented with the scheme.

The primary objective of therapeutic substitution is to reduce government spending within selected drug categories. While there is no question that government can reduce line-item costs in a drug plan budget by restricting access to new medicines, there is a risk of increasing the costs for visits to doctors’ offices and hospitals. Most importantly, such restrictions prevent patients from receiving first-class care.

### **AstraZeneca’s Position**

**AstraZeneca believes that therapeutic substitution is a policy that puts patients at risk and should be abandoned immediately. Under therapeutic substitution, patients are less likely to receive the medicine that best meets their individual needs.**

**Ultimately we believe that treatment decisions should be the result of a discussion between the physician and the individual – not a government decree based on cost. It is naive to believe that the least expensive initial therapy will be the most cost-effective solution, once the cost of additional doctor visits and other expenses are considered.**

**AstraZeneca is working with governments to develop alternative solutions that control costs while maintaining the doctor-patient dialogue in decision-making. For example, we believe governments should examine disease management programs that reduce waste and inefficiency in overall health care budgets while offering better access to medicines – reducing costs and actually improving the quality of care.**