

Price Strategy Bulletin

Mail Order To U.S.: Canada Isn't The Only Problem

Today's Reality

Globalisation has produced a new threat to profits for the pharmaceutical industry: Pharmacies worldwide dispensing into the US. Consider two recent actual cases:

- The New Zealand subsidiary of one of the leading multinationals was forced to take a large price cut with its top statin brand so as to retain its reimbursement subsidy with PHARMAC. Bad, but it could be worse, you might think. After all the New Zealand market is small, and its prices do not impact more major ones through parallel trade or geographic price referencing. Just a few months later, however, New Zealand became the main global source to fill on behalf of Canadian international pharmacies numerous prescriptions of this same statin and mailed to uninsured Americans.
- Faced with United Kingdom government demands for a 7% across-the-board price cut as part of the 2004 PPRS agreement, another major multinational decided to load much of the required savings on to a single anticancer brand in its portfolio, utilising the permitted modulation process. Sales of this product in the UK had experienced 60% penetration by parallel imports over the previous 12 months. What was perhaps not foreseen, however, was that after the 18% price cut the UK version became the first choice for international pharmacies supplying US patients.

How We Got Here

The first international pharmacies targeting the US started up in Canada in 2000. Four years later there were several hundred of them, predominately based in the provinces of Manitoba, British Columbia and Alberta. Some dispense more than 3,000 prescription items per day, others fewer than 50. Though they all have websites they are not strictly e-pharmacies as 90% of orders are received by phone, mail or fax. The postal system is used for dispatch. Customers are almost entirely retired people without health insurance on long-term medication, attracted by savings of 30-50% compared to US drugstore prices. Lipid lowering drugs, cardiovasculars, gastrointestinal agents,

anti-arthritics, and treatments for osteoporosis and diabetes among a total of just 100 brands make up 75% of affected lines.

An estimated 1.5 million US patients were supplied in this way in 2004, creating a trade valued at CAD 583 million (USD 480 million) at Canadian wholesale prices. Others crossed the US land borders on foot specifically to save money on prescription drug purchases (doctors' prescriptions are generally not needed in Mexico).

In strict legal terms, only drugs manufactured in FDA-inspected facilities that comply with FDA-approval standards may be imported into the US, and then only by their manufacturer. However, as a matter of enforcement discretion, FDA allows individuals to bring in up to three months' supply for personal use, and no patient has ever been prosecuted for personal importation.

As the business from Canada grew, fears were expressed within the country that local drug shortages or price rises might result. Over a 13-month period from January 2003, a total of five multinational manufacturers reacted by refusing to supply ('blacklisting') wholesalers that sold to pharmacies exporting to the US. Canada 'cannot be the drugstore of the United States', federal health minister Ujjal Dosanjh declared last December. He announced three possible measures (i.e. Canadian doctors could be stopped from co-signing prescriptions for patients they have not examined, prescribing for patients not physically present in the country might cease, or a list of drugs prohibited for export be drawn up), any one of which would have effectively stopped international pharmacy from Canada.

Pressure was allegedly being exerted on Canada from the Bush administration in the US to curtail the north-to-south trade. Yet at the same time Canadian politicians looked on with alarm as more US states (a total to date of 27 states plus DC) debated or enacted their own importation legislation, invariably naming Canada as the prime or only initial source. Rhode Island announced it was prepared to licence Canadian pharmacies and seniors groups' in a number of other states directed their members to cut-price Canadian deals they had negotiated with pharmacies there. Bills

designed to formalise personal importation and eventually legalise commercial importation were tabled in the US Congress, receiving strong bipartisan support.

Minister Dosanjh's June 2005 response came somewhat as an anti-climax. Though he promised 'the supply of affordable prescription medications would remain stable and sufficient to meet the needs of Canadians', actual details on how or when this would be achieved were absent. Canadian mail order pharmacies felt more secure than for two years... but they had already set in motion contingency measures just in case supply needed to be moved offshore.

An estimated three-quarters of members of the Canadian International Pharmacy Association (www.ciparx.ca), accounting for 80% of mail order sales, have arrangements for overseas dispensing now in place. Most retain full pharmacy functions plus the likes of customer relations, prescription screening, data entry and billing at their Canadian base. Only drugs approved by Health Canada are allowed in the country, even for immediate export, so additional supplies from foreign wholesalers are disbarred. Overseas operations have to be pharmacies.

The result for manufacturers is a double blow. Canadian mail order pharmacies continue to sell as much Canadian stock as they can find, and supplement this with drugs dispensed to the US on their behalf by partner pharmacies worldwide.

Initially the focus was on the UK, but as lower priced options emerged, Australia, Barbados, Bulgaria, Chile, Israel, the Netherlands, New Zealand, Turkey and others began to feature.

To add to the complexity, shipments sometimes neither originate from these countries nor go direct from them to the US. Expressions like 'transshipping' (routing through one or more country intermediates) and 'bag and burst' (assembling individual patient deliveries in one country to be collectively shipped to another where they separately enter the postal system) are now part of the mail order pharmacy lexicon. Their prime purpose is to prevent manufacturers closing off supplies and to deter inspection by the FDA at US entry ports.

Directly or indirectly, the Canadians are by no means the only players in the international pharmacy business today. Firms in countries like

Australia, Israel, Mexico, New Zealand and the Netherlands, where domestic mail order of medicines was already established or which have a history of low level supply to the US, have stepped up their marketing efforts there. At least one entrant from the UK, most probably a collective of independent pharmacies, is expected soon.

Without regulatory oversight, bioequivalence between a US and a foreign-sourced product, or intolerance to a particular excipient, may be a real problem too, as these are not issues routinely screened for by international pharmacies.

Implications for Strategy Development

A low price for a chronic use major brand in almost any country where English language labelling is employed in full or in part could be a target for an international pharmacy. On the face of it, the issue appears to be a serious threat to industry profit.

At least one leading company has already reacted strongly. Sales quotas to wholesalers in the UK and Ireland were applied for the first time within weeks of a report to Illinois governor Rod Blagojevich recommending '...prescriptions [for the state's I-SaveRx scheme] should be filled overseas by a network of approved and vetted pharmacies in Canada, the UK and Ireland'

But new sources are being added all the time. The trade is difficult to detect and even more difficult to stop. With fees for dispensing to the US averaging USD 10 a time, it is financially attractive to overseas pharmacies hit by government cutbacks. Pharmacies supplying individual patients at their request across national borders are furthermore not bound by anything like the same degree of legislation as wholesalers, or even pharmacies operating within a single country.

Given the patient population, any foreign language wording on the pack is a clear deterrent to use, and inter-country differences in brand name and product appearance require lengthy and repeated counselling and reassurance by the pharmacy, which is expensive to undertake. Over-stickered parallel imports are also not popular for this reason. However, specific ethnic or religious groups in the US, like Hispanics or the Jewish community, might positively welcome Spanish and Hebrew text.

When developing strategies to respond, manufacturers should remember that advocates of importation do not see this as the final objective. Their aim is to put pressure on manufacturers or the government to lower prices for US products and cap price rises.

Reaction must also be proportionate to the threat. At their peak, Canadian-origin drugs accounted for just 0.3% of the US market. Even when it was rolled out to four other states, poor publicity for Illinois' I-SaveRx scheme referred to earlier meant an average initial uptake of just 400 scripts a month.

There has even been research to suggest that if more than a certain level of Canadian imports (44.53%) represent new prescriptions, companies will come out ahead, as these prescriptions would be less likely to be filled at US prices.

If the matter is not handled correctly the political damage caused by mail order risks being far greater than direct revenue losses.

It seems better to focus on alternative solutions for those needy patients without health insurance who don't qualify for Medicaid. Solutions might be found among the patient assistance programs currently on offer from many pharmaceutical companies or from the Medicare Part D drug benefit due soon. However, such schemes should take a leaf out of the Canadian pharmacies' books and ensure entry to them is as simple and user-friendly as possible, preferably with toll-free telephone helplines.

The key is to rebuild trust in the pharmaceutical industry and in its pricing.

The prospects for high price countries other than the US becoming significant destination markets for international pharmacy are slight. Mail order is banned in several, including Japan. Though Germany has allowed distance selling of medicines since January 2004, with Doc Morris of the Netherlands becoming its leading pharmacy provider, all drugs sold there require a German or pan-European registration. Denmark only reimburses Danish-registered drugs.

PriceSpective is an international firm of pricing strategy experts, focused on providing strategic guidance in pricing and reimbursement to the pharmaceutical and biotechnology industries. PriceSpective has specific expertise on personal and commercial importation into the US.

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