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Changing channels

Adapting channel management to new environments



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Not long ago, almost all newly approved drugs were targeted to a wide patient population. Typically, product managers were not very involved in distribution of their drugs, which generally fell outside their scope of responsibility. With new developmental and production technologies, newer pharmaceuticals are increasingly targeted. A number of changes are evident:

- ⊕ Although not quite designer drugs, new drugs are frequently directed at limited patient populations.
- ⊕ Development and production of these drugs require more time and expense. Pressure from the development side and the smaller market necessitate higher drug pricing.
- ⊕ When a drug is used for a much smaller population, manufacturing production runs are proportionally fewer. On top of this challenge, the newer drugs are biotechnological molecules, usually with a shorter shelf life, less stability and difficult manufacturing processes. Smaller production runs also require tighter inventory management and control to ensure sufficient drug is available for those who need it. Although not just-in-time, the time between supply and demand is shorter. Market demand visibility information can be extremely important.
- ⊕ With improved drug potency comes the potential for more adverse events.

Better tracking and more intensive follow-up of these events will become increasingly important in the future.

Managing risks, increasing safety monitoring, limited supplies, and slower approval times all play a role in the evolution of pharmaceutical distribution models.

Distribution models

In the traditional wholesale model, pharmaceutical companies ship product to multiple wholesalers, who then sell drugs to retail pharmacies. Information available to the pharmaceutical company is

limited to the ship to/bill to points, and this only happens with some wholesalers. This model has been preferred for its convenience (one stop shop) and efficiencies.

With the changing environment, new distribution models are evolving to meet the needs of pharmaceutical companies. There are many possible permutations and combinations. Each touchpoint of the distribution continuum may have different levels of control imposed.

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Table 1: Emerging Distribution Models

Distribution Points	All Wholesalers	Limited Wholesalers	Single Wholesaler	Single Wholesaler	Single Wholesaler
Ship To Points	All pharmacies	All pharmacies	All pharmacies	Limited pharmacies	Single pharmacy (with appropriate geographic spread to provide national service)
Manufacturer Control	None	None	Medium	High	Very high
Demand Visibility for Manufacturers	Minimal	Minimal	Ship to and bill to points Inventory control	Ship to points may have aggregate information if patient registration is required	Detailed information on prescriber and patient population
Data Protection Against Competition	None	None	Some	High	Very high

Table 1 shows some examples of distribution models and their level of inventory control and monitoring.

Which model is best?

Choosing a distribution model is not always straightforward, and no single course of action can be prescribed. Constructing an inventory of requirements will assist in selecting a model. The following are some factors to consider carefully when determining a distribution model:

- Requirement for validated cold chain transport
- Requirement to limit to inventory storage locations
- Ideal data requirements and level of prescribing data needed
- Potential cross-border migration of drug
- Integration of reimbursement and financial processes with distribution
- Alternate setting(s) for drug administration (e.g., infusion clinics)



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Best practices in patient services programs

Developing initiatives that meet stakeholders' needs



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Patient services programs are dynamic initiatives sponsored by pharma that facilitate access to costly or inaccessible medications for patients. These programs are constantly evolving as they recognize and respond to the shifting needs of the target users and the environment in which they exist.

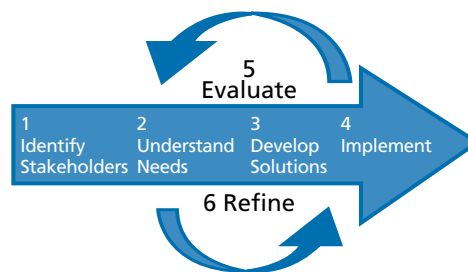


Figure 1: The Continuous Improvement Process in Patient Services Programs

1. Identify key stakeholders. The stakeholders will define their own needs. The challenge is to customize the objectives of the program to satisfy the unique requirements of each user group. Four primary stakeholders are usually involved:

- Client/sponsor
- Patients
- Healthcare professionals
- Other interested groups (e.g., regulatory authorities, advocacy and support groups, payers)

2. Understand needs by knowing your stakeholders. Develop collaborative relationships, and ask questions to understand the ultimate goals of the individuals and groups involved.

- What are the stakeholders' goals?
- What do they stand to gain by using the program?
- Does your program provide these benefits?
- What are the stakeholders' challenges and how can they best be overcome?
- What are the stakeholders' risks and what mitigation strategies should be employed?

3. Develop needs-focused solutions. By gaining a deeper understanding of the users' objectives, you can tailor solutions to meet their needs and address their challenges. By identifying and preparing for obstacles, you will promote successful outcomes and increase user acceptance. Where possible, involve the stakeholders in designing solutions.

4. Implement the solutions. After implementation, these programs will be subject to a cycle of review and revision.

5. Evaluate by assessing and monitoring for short-, medium- and long-term success.

➤ Short-term assessment enables immediate resolution to administrative and logistical challenges. This is supplier- and client-driven. Sales representatives are invaluable in this process.

➤ Medium-term assessment enables a greater degree of benchmarking against the program's objectives. Suppliers and clients should collaborate.

➤ Long-term assessment enables a review of the impact on larger business objectives. Clients must understand their longer-term objectives and whether or not it is feasible for the program to achieve all of them.

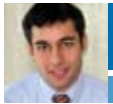
6. Refine the processes as needed. Refining and redesigning are not signs of failure. They are an opportunity to respond to feedback, surveys, logistic metrics and pre-determined quality measures, as examples. The key is to achieve a greater level of responsiveness in order to minimize the amount of corrective action needed.

A program that employs the above process has the best chance of success.

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Getting closer to your patients

Using consumer industry practices to target customers



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Over the past decade, the consumer product industry has followed a straightforward doctrine: "Listen to the customer." With the help of databases and analytical tools, consumer product companies have made the individual consumer the main unit of analysis. Armed with information, they tailor their products' messages to capture the attention of those individuals who will likely become loyal customers and eventually brand advocates. At the same time, these companies aim their marketing messages to reach consumers through many different channels, improving the effectiveness of their campaigns. Consumer product companies have collected an arsenal of consumer data, spanning from demographic to behavioural, turning data into knowledge and knowledge into formidable customer-targeting skills.

For pharmaceutical companies, segmentation is often a different exercise. Patients are segmented based on their disease state as well as the presence of co-morbidities. In some instances, this may provide an effective means of clustering patients, but to ensure that the right message is delivered using the right channel, pharmaceutical companies need to segment patients based on behavioural traits and therapeutic progression.

Rising above the clutter

Pharmaceutical companies, or for that matter, health professionals, have not been able to discover any reliable method to encourage compliance in patients. The message is often indiscriminate, emphasizing one common idea or the most clinically relevant benefit or attribute. Unfortunately, general information and mass distribution campaigns are no more likely to promote better compliance than untargeted messages are to induce buying behaviour in consumers. Recently we conducted interviews with pharmacists across Canada – one common theme resonated: "There exists many traditional patient education programs and not enough that address patients' individual needs." This type of disconnect illustrates the need for an in-depth and fact-based understanding of the individual patient.

Building intimate knowledge of your patients

Low compliance rates account for billions of dollars in lost revenue every year. Without an intimate knowledge of patients' attitudes towards therapy and their therapeutic progression, the educational component of the message is destined to fall on unreceptive ears most of the time. The key is to develop a rigorous, proprietary data-based approach to tailor the message and combine holistic education tools and information. The challenge for the pharmaceutical industry is to obtain this valuable profiling information in a cost-effective way. Consumer product managers never cease to canvas, study, survey and profile their customers. Pharmaceutical companies can become trapped in a cycle of focusing on and selling to the needs of physicians while failing to understand what leads to positive compliance among patients. Patient registries, online registries, card-based systems and direct contact with patients are among the tools that can be used to capture this important patient information.

Identifying the best touchpoints

Having a tailored, direct and comprehensive message that looks beyond the importance of compliance is a start in the right direction, but a critical issue remains: how to deliver the message effectively. In health care, key

messages are delivered at the usual touchpoints: physicians' offices and, it is hoped, pharmacies. These are largely ungoverned by pharmaceutical companies; there may be no message delivery in the latter at all. Developing new touchpoints and delivering tailored messages require additional effort involving quantitative, creative and operational expertise. Patient programs, online activities, telephone-based interactions, groups and other innovative ways to reach patients offer such touchpoints. Through such developments, patients will value and appreciate the delivered information – positioning the product as the leader in its therapeutic area.

Attracting and retaining patients in any given therapeutic area are much easier with the strong wind of data-driven creativity at your back.

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One drug, two indications

Pricing and reimbursement considerations



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Launching a product – particularly one with two indications – is no small endeavour. And in Canada, it is complicated further by pricing and reimbursement considerations that are unique to the Canadian market. These are largely influenced by two organizations: the Patented Medicine Prices Review Board (PMPRB) and the Common Drug Review (CDR).

While a drug's indications determine what can be said about it, these organizations determine what a drug's comparators will be, how much it can be priced at, and whether

or not it is likely to be reimbursed. Therefore, when a drug has two indications, a manufacturer must consider how this will affect the pricing reviews conducted by the PMPRB and the reimbursement reviews conducted by the CDR. Does the order in which the indications are submitted matter? Should they be submitted together or separately?

Thus far, the CDR has received submissions for three drugs that have two indications each (Vfend™, Humira™ and Sutent®). From a strategic perspective, there are a number of reasons why it is advantageous to submit separately for each indication:

See One drug on page 4

The high price of oncology drugs

New drugs offer hope, but costs are a barrier



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Recent biotechnology and genetic advancements have led to an increase in the availability of innovative cancer therapies, offering hope to many patients. However, patient access to the potential benefits of these drugs has been hindered by their high cost. Examples of such drugs include Alimta® (mesothelioma, \$20 - \$25,000 per standard course), Herceptin (adjuvant treatment of breast cancer, \$45 - \$50,000) and Avastin (metastatic colorectal cancer, \$30,000).¹

The majority of these therapies are delivered by intravenous (IV) infusion, and in Canada, this traditionally means they are administered in a hospital or specialized clinic setting and funded from hospital or cancer budgets. In response to increasing costs, most provinces have adapted this process to ensure universal coverage for cancer care through the public payer system. For example, in Ontario, Cancer Care Ontario (CCO), through the New Drug Funding Program, provides funding for IV cancer drugs. However, the different provincial approval and funding processes have resulted in uneven patient

access. For example, Alimta is approved and funded in five provinces, but not in Ontario and Quebec.² Erbitux™, for treatment of colorectal cancer, is not available in Canada at all because the manufacturer decided not to launch after it could not agree on a cost with the Patented Medicine Prices Review Board (PMPRB).³ As a result, eligible Ontario patients travel to the United States to receive Erbitux at a cost of \$24,000 (US) a month.³

This critical situation, one component of a continuing increase in healthcare costs, has repercussions among decision makers. The PMPRB is currently reviewing its Excessive Price Guidelines for all products, and this may impact the cost manufacturers can request for new cancer therapies. In addition, it is likely that most provincial cancer boards will pay increasing attention to the cost-effectiveness of new therapies. The CCO is forming a pharmacoeconomic evaluation unit and drafting guidelines for economic evaluations. Any manufacturer in Canada with a new oncology drug should therefore be aware of these changes and take appropriate measures.

⊕ Anticipate changes in PMPRB guidelines regarding drug classification and permitted pricing strategies.

⊕ Plan economic evaluations that incorporate appropriate target populations, relevant comparators, realistic time horizons and outcomes relevant to the drug administration setting. For therapies that increase patient life expectancy, cost-utility ratios are particularly relevant as they incorporate patient health-related quality of life, an important outcome in patients with advanced cancer.

⊕ The promise of new drugs is great, but payers and regulators need to have sound quantitative data on which to base their decisions.

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For more information about PMPRB regulations on pricing and on strategies for assessing the cost utility of cancer therapies, contact John McCormick at 1.800.811.9880, ext. 461, jmccormick@phase4health.com.

One drug continued from page 3

Separate submissions recommended for each indication

CDR would likely review each indication of the drug separately and issue a separate report and recommendation for each indication anyway.

⊕ A separate Pharmacoeconomic (PE) Analysis and Budget Impact Analysis (BIA) for each indication would likely be necessary in order to properly reflect the health economic impact of the drug.

⊕ Several key CDR documents, such as the Executive Summary, are subject to strict page limitations. Filing one submission for both indications would severely limit the amount of information that could be shared with CDR.

⊕ Filing one submission to CDR for both indications of the drug would result in an unnecessary delay if Health

Canada finishes reviewing one indication, but takes longer to review the second. Filing a submission for one indication would leave the door open to a resubmission to CDR (if necessary) once NOC is received for the second indication.

⊕ Filing a submission for one indication would allow a manufacturer to see how CDR responds to that submission before submitting for the second indication.

The situation is more complicated with the PMPRB and must be considered even more carefully in order for the drug manufacturer to be allowed the highest possible price for a drug with two indications. Drugs with multiple approved indications are categorized based on the approved indication for which the medicine offers the greatest therapeutic advantage in relation to

alternative therapies for the same indication in a significant patient population. It is important to note that once the introductory/benchmark price of a product has been established, it cannot be changed. The PMPRB's current guidelines lack a mechanism to re-evaluate/re-benchmark the price should the manufacturer seek a second indication for the drug later. However, if a new DIN for the product is approved (e.g., new strength, new formulation), then the new DIN will be evaluated by PMPRB and it is possible that it will be allowed a different introductory price.

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Pharmacy: Time to invest?

Pharmacists should be seen as important stakeholders



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In the past 10 years, pharmaceutical manufacturers have approached the pharmacy profession with a range of attitudes, from extreme interest to extreme trepidation. While pharmacists are potentially positioned to improve prescribing and outcomes, existing regulatory differences across Canada, current compensation models and the differing agendas of chains, independents and mass retailers have made a "win-win" relationship difficult to establish.

Quebec's recent Law 90 (Bill 33) expanded the scope of pharmacy, granting greater

professional involvement, authority to make dosage adjustments, and expanded therapy follow-up. Bill 102 in Ontario stipulates: "Pharmacists will be trained and compensated for providing patient counselling and medication management reviews and will increasingly have opportunities to work in primary care models." While the economics of these initiatives are far from clear, pharmacy groups will organize to respond to these challenges. Cognitive services will likely increase, fuelled by both public and private funding. Alberta is following a similar agenda. Canadian pharmacists are proposing legislation for the right to prescribe. Manufacturers that proactively engage this group today will be best poised for a fruitful relationship in the future.

No blanket pharmacy approach

Life cycle management At early commercialization phases, the role of pharmacy is to educate the patient and reinforce key

messages. New product knowledge is critical. On the other hand, in a more mature pre-genericization phase, patient loyalty mechanisms become a source of market share retention strategies.

Competition When patented alternatives are available, programs that guarantee availability and reimbursement or provide the pharmacy with valuable information for patients are critical. Pharmacy can be used as a supplementary source of awareness building for patient support programs.

Relationship with pharmacy Pharmacists' awareness of and confidence in a pharma company are key during new product launches. Is there awareness and dialogue? Is it positive? Answers to these questions may drive the pharmacist's investment level.

Compliance challenges? Whatever the stage in a product's life cycle, adherence is a challenge. Whether this is due to a complex method of drug administration, side effects or reimbursement challenges, providing pharmacy with information and solutions will reduce any discomfort that pharmacists may have about your product. While pharmacists are unlikely to debate prescription of a product with physicians, they can reinforce the physician's decision and provide additional or repeat information if adequately prepared.

It is impossible to prescribe a "pharmacy solution." Programs will vary depending on local regulations, competition and the manufacturer's existing relationship with pharmacy. Table 1 identifies potential partnership opportunities for manufacturers and pharmacy.

Table 1: Pharma-Manufacturer Situation

Pharma Manufacturer Situation	Solution
<ul style="list-style-type: none"> Manufacturer is launching a new complex medication into a competitive market; manufacturer has existing relationship with pharmacy 	<ul style="list-style-type: none"> Establish toll-free hotline and education service, and market to patients on behalf of pharmacist Company-sponsored disease management program with execution at pharmacy level
<ul style="list-style-type: none"> Manufacturer's medication has a strong competitive position in developed market; must respond to a new entry and has no existing relationship with pharmacy 	<ul style="list-style-type: none"> Assess pharmacy needs and develop "win-win" propositions Provide education to pharmacist on product handling Extensive communication to pharmacy on how drug is supported Involve pharmacy in "care network" through pharmacy-delivered study and/or disease management initiative
<ul style="list-style-type: none"> Mature medication approaching genericization; manufacturer has strong existing pharmacy relationship 	<ul style="list-style-type: none"> Medication-specific programs aimed at promoting compliance and store loyalty
Market Situation	Solution
<ul style="list-style-type: none"> In the Ontario marketplace, loss of generic manufacturer rebates will fuel interest among pharmacists in pursuing counselling and other patient-focused value-added services, which may supplement revenue from manufacturer and/or government Pharmacist counselling and screening can complement conditional listing agreements 	<ul style="list-style-type: none"> Manufacturers can differentiate their products in the marketplace by engaging pharmacists to support specialized drugs, such as biologics, through screening, follow-up counselling and adverse event management Pharmacist program can be presented to ODB in support of a conditional listing agreement whereby pharmacists encourage guideline adherence and appropriate utilization through physician education
<ul style="list-style-type: none"> Quebec pharmacists' ability to adjust dosages may be proactive risk management strategy when launching in the marketplace 	<ul style="list-style-type: none"> Pharmacist-driven telephone follow-up program that would screen patients at high risk of adverse events and identify opportunities for dosage adjustment

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The Special Access Program - evolving fast in changing times

Growing pressure on the Special Access Program



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In 2001, Catalyst published an article on Health Canada's Special Access Program (SAP). In the short span of time that has elapsed, the role of the SAP and the environment in which it operates have evolved considerably.

Originally known in the 1990s as the Emergency Drug Release Program (EDRP), the stated mandate of the SAP is to provide "access to non-marketed drugs for practitioners treating patients with serious or life-threatening conditions when conventional therapies have failed, are unsuitable, or unavailable." Such a mandate left a small opening for last-ditch treatments and presumably a small number of SAP requests. Yet today, Health Canada receives over 30,000 requests a year for about 500 different drugs, and approves approximately 75 percent of those requests – the majority for cancer therapies that have not yet been approved in Canada. For example, in the 20-month period between January 1, 2005, and August 31, 2006, the SAP approved approximately 16,000 requests for two cancer drugs alone – Eloxatin® and Thalomid®.

Health Canada is quick to point out that the SAP should not be considered a fast-track approval process for drugs. According to Health Canada, the "SAP is not intended to be a mechanism to promote or encourage the early use of drugs or to circumvent the clinical trials review and approval process or the new drug approval process, but rather to provide



compassionate access to drugs on a patient-by-patient basis." Yet, to a certain degree, the SAP has fallen into just that role because of a number of factors. Increasing pressure from patients and various advocacy groups who are in need of therapy – especially when it could save lives – are justifiably unwilling to wait for approval of those therapies through the full regulatory approval process. Patients today have immediate access to information from around the world that tells them these products are available in other countries – just not in Canada. As a result, various stakeholders – including patients, physicians and manufacturers – have turned to the SAP in numbers that were not envisioned by the original EDRP.

A recent court case highlights another stressor on the SAP's mandate. In July 2006, a Federal Court ruling overturned a partial ban on access to 714X – a controversial cancer therapy with no scientific evidence of efficacy. In its ruling, the court said that even if there is no scientific evidence a drug is effective or safe, Health Canada must consider releasing a medication under

the SAP purely for humanitarian reasons. A lawyer for the patient who took Health Canada to court admitted that this is "a new approach" and that, if the court ruled in favour of the patient, the decision could make things "very difficult for the future" for Health Canada. That is a reference to the likelihood that this ruling may boost the availability of a host of other unproven treatments through the SAP.

As a result of these factors, the SAP finds itself in a rapidly changing environment, with a mandate and structure that may not be flexible to all the changes. The number of drugs sought through the SAP will only increase.

For more information on how we can help you work with Health Canada's Special Access Program, please contact Nabil Tadros at 1.800.811.9880, ext. 109, ntadros@phase4health.com.

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