Over the last few years, Canada has seen the emergence of specialty pharmacies targeted primarily at serving patients with special drug needs. Specialty pharmacy, in its truest form, is complementary to the traditional hospital and retail channel by targeting the needs of specialty drugs only and acting as a conduit for patients in accessing manufacturer-sponsored programs and services. Specialty pharmacies, most commonly retained by manufacturers, have also evolved in Canada to service the unique needs of physicians in areas such as oncology, rheumatoid arthritis, hematology, cystic fibrosis and multiple sclerosis.

Key characteristics of specialty pharmacies

1. Dispensing is associated with specialized reimbursement services catered specifically to access “envelope” funding and public special access programs (e.g., Patient d’exception, Section 16, special authorization, pre-determination)
2. On-site commercial fridges and central monitoring systems that accommodate product cold-chain requirements
3. Premises meet provincial College of Pharmacy requirements as well as federal GMP requirements
4. Pharmacists are trained and expert at managing and reporting adverse events
5. Pharmacies have customized financial and patient management systems that manage special financial and safety needs (e.g., administer manufacturer financial assistance and means tests, compassionate use needs, risk management, safety monitoring, nursing coordination, etc.)
6. Sterile hoods for specialty compounding and validated packaging
7. Direct-to-clinic support and distribution mechanisms that comply with cold-chain requirements and handling

While in many cases specialty pharmacies are part of a controlled or managed channel, they may also work side-by-side with other hospital and retail pharmacists in servicing a patient’s specific drug needs thereby allowing community pharmacists to focus on managing the patient’s holistic drug-related needs.

Pharmaceutical manufacturers must consider a variety of distribution and dispensing models when planning the launch of a specialty product. These products typically are costly, have complex service and logistic requirements and target small, niche patient populations. In order to optimally
Introduce the market to a complex product, the manufacturer must exercise a heightened level of control for some or all of the following reasons:

- Ensure compliance with regulatory and post-marketing requirements
- Ensure that a special niche prescribing population is clearly understood and closely supported
- Limit access and ensure appropriate utilization
- Ensure harmonization of messaging relating to the product
- Ensure standardization and expertise in relation to stakeholder education
- Ensure that training is available if unique product administration requirements exist
- Ensure that the product is supported by reimbursement experts that understand its specific challenges
- Ensure product integrity where specialized storage and temperature monitoring conditions exist
- Ensure product integrity throughout the entire supply chain (e.g., to the point of reaching the patient or prescriber)
- Ensure that safety and screening requirements are met

The type of model retained is primarily a function of the degree of control that is necessary. Below are a number of available models:

**Specialty pharmacies, most commonly retained by manufacturers, have also evolved in Canada to service the unique needs of physicians.**

Different models and levels of control vary depending on the stage of product development. Actual examples include:

1. An oncology product launches in a fully controlled distribution and dispensing model because a substantial amount of compassionate use product is anticipated to be distributed following launch. It gradually evolves to a community pharmacy retail model as reimbursement becomes available.
2. A cold-chain product launches for a very rare disease in a highly complex, very well-defined and small market (30 to 50 patients in Canada). Unless the product becomes indicated for additional, higher volume markets, it will likely remain in a fully controlled model.

3. An ambient product is launching in a therapeutic area where dispensing has historically been conducted via “somewhat controlled” retail channels. A small and pre-defined number of out-patient hospital pharmacies carry 80% to 90% of products in this class. These community pharmacists are most familiar with the products and have established relationships with treating teams and patients. Dispensing will be carried out through these pre-existing traditional channels. The choice of distribution model will be made based on careful consideration of these hospital pharmacists’ regular ordering methods.

Careful consideration of distribution and dispensing models is critical for a product throughout its lifecycle. The degree of control required is the basis for selecting the model. The choice may be pure or hybrid or even sequential as the product and its environment changes. With the emergence of individualized medicine, the evolution of pharmacy to meet the needs of smaller groups of patients will ensure society benefits from the optimal outcome potential through these innovative treatments.

For more information about Specialty Pharmacy Solutions, please contact Kelly Sommerfeld at 1.800.811.9880 ext. 55465 or kelly.sommerfeld@mckesson.com

McKesson Specialty is a division of McKesson Canada that offers outsourced specialty distribution and pharmacy services, clinical and consulting services and direct-to-patient services to the pharmaceutical industry.

A testimonial relating to the role of McKesson Specialty Pharmacists

Patient counselling

My patient of two and a half years had been managing on escalating doses of Product X. I followed-up with him and he came to see me very regularly even though I could dispense his medication directly to his home. We developed a very close rapport so in January when his tumour progressed, he asked me what I thought about a revolutionary product that was available through an expanded access program to treat his disease. Together, with him and with his treating team, we decided that he should begin the program.

Relationships, continuity, support and education

Recently, I was invited by a physician and his team to attend a conference in order to provide a pharmacist perspective to patients with this specific disease. I saw my patient there and was so happy to hear that his tumour had shrunk by about 20% since starting a course of the new product. In working with treating teams and with prescribers over numerous years, I have found that patients with complex diseases need to hear about the experiences of other patients. They also need a lot of support along the way. Once they get their drug, I help them to understand and manage side-effects and to not abandon treatment due to certain reactions that are known to ultimately subside (e.g., cutaneous reactions).

Facilitating reimbursement and avoiding out-of-pocket costs to patients

Patients and their teams want facilitated reimbursement. They want quick access and elimination of out-of-pocket expenses. This is why we push for insurance coverage very actively and work with nurses, prescribers and our program team to anticipate and prepare the right documentation on time.