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Relationship Building with Your Service Provider – Unlock Your Supplier’s True Potential



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Too often, the pharmaceutical industry and service providers find themselves on opposite sides of the negotiation table. The pharmaceutical sector, compared to other industries and given its financial size, consists of relatively few companies and people, both at the service provider and the pharmaceutical company levels. In industries with similar environments (e.g. aerospace, robotics), sustained business relationships are usually the norm – to the point where suppliers are virtually integrated. McKesson Specialty – a service provider to the pharmaceutical industry for over 20 years – has had numerous opportunities to enhance business and partnering activities with its clients, but there are a number of challenges that we as partners must face together:

- ☞ Both parties are looking for the “best deal” yet this does not necessarily translate into the best service
- ☞ Procurement departments may make buying decisions based purely on financial analysis, yet with a minimal understanding of the services being delivered
- ☞ Decisions made by these parties are only short term, yet over the longer term a different pricing model might be needed to ensure the sustainable delivery of quality services
- ☞ Some clients perceive that a service provider showing strength or sustained viability might reduce their leverage or negotiating powers

Despite the challenges mentioned above, we have developed excellent partnerships, resulting in a great deal of success for both ourselves and our clients. Based on these experiences we have observed that certain characteristics are mutually beneficial to partnerships. Table 1 summarizes some of these characteristics.

TACTICS OF RELATIONSHIP BUILDING

In addition to the characteristics shown in Table 1, some specific tactics that foster

good client/service provider relationships are listed in Table 2.

Effective relationship building is self-perpetuating and thus can potentially lead to exponential increases in value. Many pharmaceutical companies and their service providers agree that a healthy, trusting relationship between the two parties will unlock their creative powers, lead to more success in a much shorter timeframe, and the end result will be much more satisfactory to all concerned.

Table 1 Client and Service Provider Characteristics for Beneficial Partnerships

CLIENT	SERVICE PROVIDER (SP)
<ul style="list-style-type: none"> ☞ Understands SP’s strengths and weaknesses ☞ Sets expectations and defines needs in as much detail as possible ☞ Identifies key requirements, especially those not explicitly expressed in the project ☞ Exchanges information and shares strategic orientation ☞ Helps SP understand client-related internal organizational challenges ☞ Creates contracts able to evolve in a manner that better reflects changing needs, with minimal administrative burdens ☞ Strives to simplify purchase order (PO) generation ☞ Involves service provider in market strategy planning ☞ Identifies and communicates needs very early on ☞ Appreciates and recognizes mutual success 	<ul style="list-style-type: none"> ☞ Clearly communicates its own strengths and weaknesses ☞ Allocates time and budget needed to permit creative and innovative thinking for benefit of client ☞ All information supplied is relevant and ensures client will only obtain useful data (time savings for client) ☞ Recognizes client’s preferred “style” ☞ Shows initiative, ownership and enthusiasm regarding shared successes ☞ Harmonizes corporate policies across client programs ☞ Identifies any potential for economies of scale and one-time or fixed recurring cost reductions ☞ Provides structured communication plan and formal review of SP ☞ Has a simple and fair plan for change control ☞ Produces clear invoices

Table 2 Specific Project Tactics Foster Client and Service Provider Relationships

CLIENT	SERVICE PROVIDER (SP)
<ul style="list-style-type: none"> ☞ Acknowledges areas of uncertainty, and communicates and funds certain SP activities involving a risk of being changed or abandoned ☞ Allows adequate time for detailed needs discussions and solution preparations ☞ Carefully reviews SP activities and offers detailed feedback ☞ Identifies clear metrics needed to evaluate success ☞ Participates in setting mutual objectives ☞ Early and complete information and strategy sharing 	<ul style="list-style-type: none"> ☞ Participates in setting mutual objectives ☞ Provides client with continuity relative to management activities ☞ Centralizes communications where possible

Current State of Pharmaceutical Marketplace for Public and Private Payers



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McKesson Specialty's Consulting Services continues to contribute key strategic research and insight to the pharmaceutical industry. We recently conducted a Q&A session with Dr. Nabil Tadros, who has been with the company since 1996, hoping to learn more about his perspective on the current pharmaceutical marketplace.

In which areas of consulting or market access do your clients currently show more interest?

Today there is an increasing interest in the private payer market. This is somewhat different from the past when almost all efforts were devoted to obtaining reimbursements from the public payer side, due to significant challenges in this area, and also because private payer reimbursement was seen as almost automatic.

Why do you feel that some manufacturers are now paying greater attention to the private payer market?

A number of factors have likely contributed to this. Public payer reimbursement is becoming more and more difficult, and this effectively leads to certain products being shut out of the public payer market, or at least facing delays before being listed on public payer formularies. As a result, the private payer market has become more dominant and for some drugs the only method of reimbursement.

Some factors making the private market increasingly complex include:

- Various drug cost-containment measures have been implemented (e.g. tiered plans, co-pays, annual/lifetime maximums, formulary restrictions, contracts, special authorization, etc.).
- Private payers have seen the success enjoyed by public payers in securing better prices, given their clout and buying-power. Private payers will likely follow suit.
- Drug coverage by a private payer does not necessarily translate into increased claims and utilization, due to specific aspects of plan designs and special authorization criteria.

How do you help your clients better understand private payer market navigation?

McKesson Canada has produced an industry-recognized *Canadian Private Drug Plan Compendium*, the most comprehensive manual of its kind. It contains invaluable information and data on the Canadian private payer market, part of it also includes information and data from McKesson Canada's proprietary *Employer Survey of Canada's* top 200 employers.

Moreover, our clients have become very interested in private payer steering committees and advisory panels. These meetings are very productive and serve to engage private payers, build important relationships and develop a spirit of partnership relative to future projects that are focused on private payer interests.

What's new on the public payer front?

The public payer side has evolved as well however we have identified very simple steps that can be easily followed by manufacturers to improve the quality of their reimbursement submissions – particularly Common Drug Review (CDR) submissions.

The first step is to simplify pharmacoeconomic analyses. The CDR has relatively straightforward guidelines regarding the type of economic analysis required in a submission. In many situations, only cost-consequence analyses or cost tables are required yet too often manufacturers create very elaborate (and costly) models that are unnecessary and can even hurt rather than help their cause. Not only are such models more costly and very resource reliant to produce, they can also provide CDR a bigger target to critique. The bottom line: "Keep it Simple!"

The second step is to create clear, harmonized messages and positioning throughout the submission process. All submission documents – from the Executive Summary to the Budget Impact Analysis to the Pharmacoeconomic Analysis – must convey a clear, consistent message. This is too often neglected, primarily due to the presence of "too many cooks in the kitchen." In other words there are too many people involved in preparing the submission's various sections. My best advice would be to choose one team or one supplier, capable of competently completing the entire submission from start to finish. This helps ensure that the message conveyed throughout the entire submission is clear, consistent and unified.

Chronic Disease Management – Coming of Age in Canada



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Life expectancy in Canada is one of the highest in the world: 77 years for men and 82 for women. Indeed 60% of our general population generally rates their health as

excellent or very good, even though one in every four has one or more chronic diseases. Defined as long-lasting disabilities, these diseases (including diabetes, depression, congestive heart failure, hepatitis and asthma) affect people's ability to carry on with their daily routines and relationships. The resultant financial burden thus amounts to an estimated \$80 billion annually.

Chronic illness accounts for 67% of all direct health costs and 50% of emergency department visits.

Canadians can substantially reduce these costs, however, and improve the quality of their lives by focusing their health priorities on the prevention and management of chronic diseases once they have been

Risk Management Arrives in Canada



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The US Food and Drug Administration (FDA) passed the FDAAA in late 2007, giving the agency considerable new powers to regulate manufacturers in the area of drug safety. Most conspicuous is the ability to require a manufacturer to provide a Risk Evaluation and Mitigation Strategies (REMS) to ensure the safe use of their drugs. The advent of this REMS era has fundamentally changed the way many new drugs are launched, and in the US safety risks are monitored post-launch. REMS programs require pharmaceutical and biotechnology manufacturers to approach commercialization in a new way – formerly focused on efficacy, the FDA has mandated them to focus equally on safety. While not yet codified in legislations, Risk Management programs required by Health Canada are poised to arrive.

The US approach has been somewhat different from the approach pursued in Canada. Health Canada appears to invite proposals in a number of formats as stated in their Feb 12, 2009 guidance: “as an interim measure, Health Canada wishes to

further advise that the European Medicines Agency (EMA) *Guideline on Risk Management Systems for Medicinal Products for Human Use and the EMA Template for European Union Risk Management Plans (EURMP)*, as amended in the attached Appendix, represents an acceptable approach to fulfilling requests by Health Canada for Risk Management Plans.” The Appendix compares the two formats and notes changes.

The criteria for requiring a Risk Management Program are not however that different from those required by the FDA:

- 1 Any product containing a new active substance
- 2 Potentially those products with a significant change in indication
- 3 Those products which are new to a class for which a serious or potentially serious safety risk has been previously identified, or
- 4 Upon request by the regulator under circumstances where a safety risk has been identified such that the risk associated with the product is perceived to potentially outweigh its benefit

As in the US guidance, the criteria are left very broad, and presumably providing the regulator with the latitude to choose which

products might need a risk management solution.

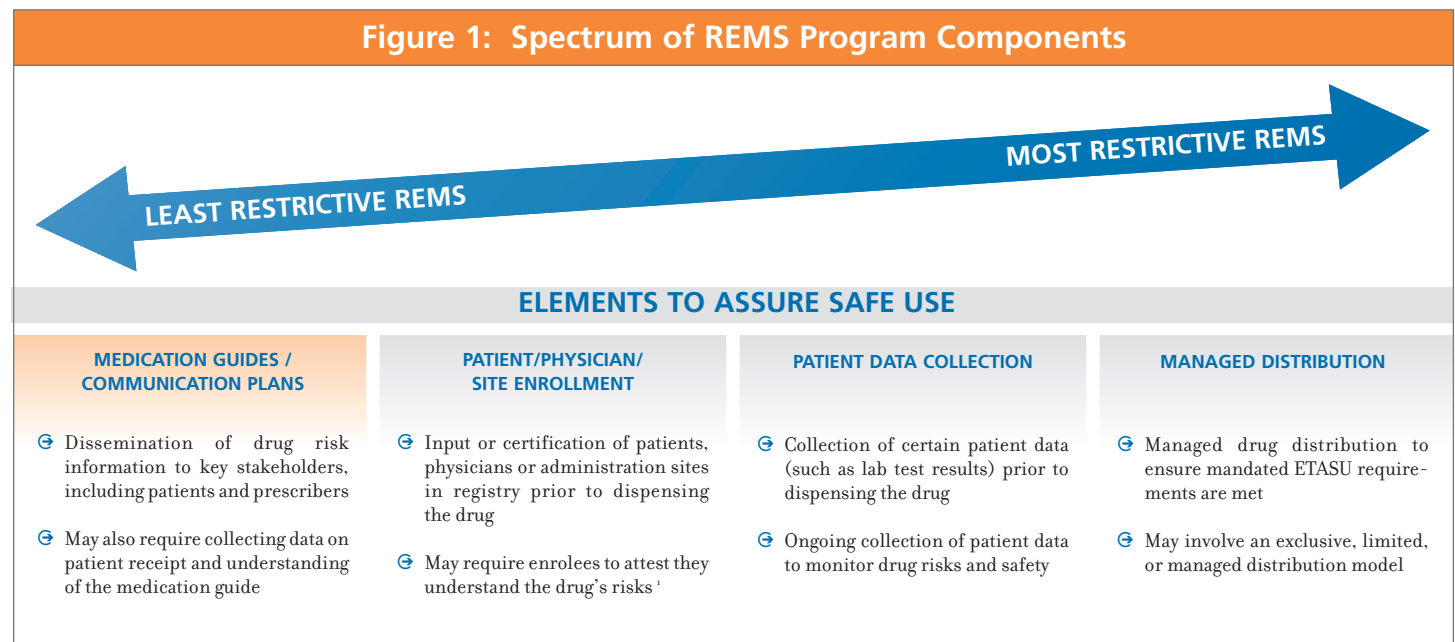
Health Canada has defined the key components for Risk Management Programs:

- 1 A Safety Specification, which is a summary of the known important safety information about the health product and serves as a means of identifying gaps in knowledge
- 2 A Pharmacovigilance Plan, based on the Safety Specification and which identifies and characterizes known or potential safety concerns
- 3 A Risk Minimization Plan (RMinP), which provides proposals on how to minimize any identified or potential safety risk

Health Canada will accept Risk Management Plans in other recognized formats (i.e. Risk Evaluation Management System), as long as they cover the elements described in the EU guidance.

The latter statement suggests that companies with US REMS programs may use a format or plan very similar to that used in the US.

US REMS programs have defined Elements for Safe Use or EASU. Fig 1 illustrates the spectrum of these components.



¹ Notice Regarding Implementation of Risk Management Planning, including adoption of ICH Guidance Pharmacovigilance Planning – ICH Topic E2E, Feb. 12, 2009

Quality Assurance and US REMS Programs – More Documentation to Maintain

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Other Riskmap requirements include:

- Additional labelling requirements
- Ensuring a medication guide is provided to the enrolled patient with each prescription
- Limitations on supply amounts and refills
- Product distribution by specialty pharmacy only
- Pharmacists interact with and counsel patient prior to dispensing
- Education packs: videos, brochures, etc
- Collection of adverse event data
- Multilingual translation services
- Stringent data reviews and audits
- Recording of client relations calls for quality assurance purposes
- Dedicated REMS teams
- Validated computer software and Web pages for capturing patient information

A significant amount of documentation and signature acknowledgements are required for quality assurance purposes. They must indicate completeness, full traceability and that all items are available, and where applicable the actions carried out. These may be requested during FDA inspections of such program sponsor manufacturing companies.

The Virtual Pharmaceutical Representative



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In the pharmaceutical world for decades the prevailing paradigm has been that sales representatives make calls on targeted MDs in a given territory. This pharmaceutical representative would use a variety of relationship building tactics and communicate key product messages, hoping the physician would understand and accept the benefits of the product. The process involved was high cost and very dependent on representative's individual's skills and degree of engagement.

Faced with today's new dynamics, pharmaceutical companies are now looking for new ways to communicate with an increasingly time constrained physician group using meaningful and cost-effective methods. To add to the complexities, developing share-of-voice or top-of-mind positioning with the targeted physicians is a highly competitive process, with the company most willing to spend on sales forces winning the top position. This new dynamic obviously requires different approaches.

TELEDETAILING/E-DETAILING

Teledetailing was not born out of creativity but out of necessity. While there is no disputing power of a live sales call, the cost is high and the number of possible contacts is low. Furthermore, with large, widely dispersed sales forces, human resource challenges are numerous and quality

management more difficult. Teledetailing on the other hand, instead of supplementing or replacing traditional sales force activities, offers an entirely different approach. Table 1 compares and contrasts teledetailing sales forces to traditional ones.

There are also certain inherent limitations. Not all physicians accept this type of interaction—even though experience has taught us that many physicians who were assumed not to respond to this route can be surprisingly easy to contact. With quality calls, even some no-see doctors can become accessible.

In summary, teledetailing offers a different and in some ways a superior method of reaching prescribers.

It offers:

- 1 An efficient and cost-effective way to engage in peer-to-peer discussions about therapies
- 2 A means for increasing awareness amongst targeted MDs in the event of increased pharmaceutical access, safety changes, new indications and new formulations
- 3 Access to busy practices – call back appointments can be set using an "on demand" format
- 4 Better management and forecasting of clinical evaluation packages

Table 1 Traditional Sales Force vs Teledetailing

RESOURCE	TRADITIONAL REPRESENTATIVE	VIRTUAL REPRESENTATIVE
Resource	Various backgrounds	Allied health professional (RNs, BSc. Phm, foreign trained MDs, BSc. with clinical background)
Management	Pharmaceutical company hires, trains and manages personnel	Usually outsourced – vendor manages workforce
Interaction	Advertorial presentation	Peer-to-peer discussions
Training (by manufacturer)	In-depth physiology and pharmacology	In-depth physiology and pharmacology
Cost	~\$200 per call	~ \$75 per call or less
Relationship with pharma/sales representative	Potentially strong – but based on individual relationship-building skills	Potentially weaker – but calling staff can be changed to obtain compatibility, ethnic/language flexibility
Missed calls	Representative must return at another time, resulting in wasted time	Easily rescheduled, little wasted time
Limits	6-8 calls/day	16-18 calls/day
Clinical Evaluation Packages (Samples)	Hand delivered, office inventory may be poorly managed	Requested by physician and sent directly. Inventory at each office tracked.
Call reports	Sporadic, dependent on diligence of sales representative	Real-time, hard wired into process



diagnosed. Good health care and self-care are crucial to minimizing health deterioration, yet a recent report by the Organization for Economic Co-operation and Development (OECD) reveals that in Canada, only 8% of total healthcare expenditures will go to public health and prevention. Moreover, compare the \$300 million to be spent over the next 5 years on a national healthy living strategy to the \$79 billion planned for all other health reforms over the next 10 years.

Various disease-specific programs began to be offered in the early 1990's, and the term "Disease Management" was coined. Today, Chronic Disease Management (CDM) is defined by the DMAA (Disease Management Association of America) as "a system of coordinated healthcare interventions in which patients' self-care efforts are significant". Effective CDM programs can improve the quality of patient care and services offered, while also reducing healthcare costs. Indeed, a good CDM program should include some of the following characteristics:

- Personnel and care processes needed to support proactive care
- Accurate identification of patients with chronic diseases
- Support for providers, including guidelines and protocols for disease management
- Access to patient data through high-calibre information systems, ensuring timely and relevant information
- Patient support in the form of empowerment and self-management (the Wagner model)
- Community resources to inform and support patients
- Integrated system support for chronic disease care among providers in all disciplines and all aspects of care

Most CDM programs have evolved to various models of complexity, such as:

- 1 Programs developed by pharmaceutical companies and pharmacies or Pharmacy Benefit Managers (PBMs) (in the U.S.).
- 2 Primary care model – specialized teams in healthcare organizations assisting primary care physicians in treating chronic diseases.
- 3 Comprehensive programs developed by health plans or public payers and delivered either in-house or outsourced to specialized CDM companies.

In the United States, where patient health spend is consolidated, it is apparent that comprehensive programs provide an ROI for providers.

Realizing that the current healthcare model targeting disease treatment is not sustainable, the Canadian government has begun exploring and developing CDM programs able to combat the exponential growth in chronic diseases. To address this increase in CDM, the Western Health Information Collaborative (WHIC) was formed under joint leadership from the Alberta and British Columbia governments, and the Manitoba and Saskatchewan health departments. It specifically focuses on developing the data and message exchange standards needed to support CDM for diabetes, hypertension and chronic kidney disease. Given the initial high investment needed by the government to kick-start this program, its implementation has generally been slow. Moreover, funding is required to establish viable information structures across care continuums in all provinces. CDM development has been prioritized across most provinces, and the Wagner approach is generally adopted. However, fragmented health cost data capture, and a generally siloed approach to healthcare makes ROI measurement difficult, and limited funding has stalled progress.

Disease Management programs have been applied by drug companies to ensure their products become an integral part of patient care provision while also providing value. The pharmaceutical industry is able to offer its expertise in chronic diseases, acquired through R&D or through claims data. Experts can design clinical protocols, conduct trials and collect patient outcomes, while also offering certain educational tools needed by their partners for patients, pharmacists and physicians. Opportunities for the government to partner with the healthcare industry do exist, but careful navigation is required. In developing these programs, drug companies and government can leverage existing experience in helping to build and manage chronic diseases, for example diabetes, heart disease and asthma, such as through the McKesson CareEnhances solutions. These programs coordinate a care management team comprising of doctors, registered nurses, social workers, pharmacists, health educators and other healthcare professionals, to improve the health of high-cost, high-

risk participants through patient-centric interventions designed to address certain barriers to care.

Results of this focus include:

- Improved health outcomes
- Reduced in-patient admissions and emergency department visits (7% decrease)
- Proven return on investment

Whether driven by pharma or part of a government sponsored program, a whole person approach to care management recognizes that to effectively manage chronic conditions, patients need tailored education, guidance in behaviour changes, a medical home, and help in accessing appropriate healthcare services. In addition, strategies should include:

- Proactive, near real-time identification and risk stratification
- Improved care coordination
- Removal of barriers to care
- Actively engaging physicians

Successful CDM programs not only improve the patient's quality of life, but they also enhance the healthcare system's resource efficiencies and deliver significant cost savings.

Use of nationally recognized and evidence-based clinical guidelines is key, and the collection and analysis of outcomes data is critical to demonstrating the benefits of CDM to all stakeholders.

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Evolution of Specialty Pharmacy: When is a Managed Pharmacy Model Right for You?



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Over the last few years Canada has seen the emergence of specialty pharmacies targeting patients with special drug needs. In their truest form, specialty pharmacies are complementary to traditional hospitals and retail channels, supplying specialty drugs and providing patients with simple means of 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.

The key characteristics of specialty pharmacies include:

- 1 Dispensing associated with specialized reimbursement services catered specifically to accessing "envelope" funding and public special access programs (e.g. Patient Exception, Section 16, special authorization, pre-determination)
- 2 On-site commercial fridges and central monitoring systems that maintain a product's cold-chain requirements
- 3 Premises that meet provincial College of Pharmacy and federal GMP requirements

- 4 Pharmacists trained in and experts in managing and reporting adverse events
- 5 Pharmacies with customized financial and patient management systems used to 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 programs and services that comply with cold-chain and handling requirements

While in many cases specialty pharmacies form part of a 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.

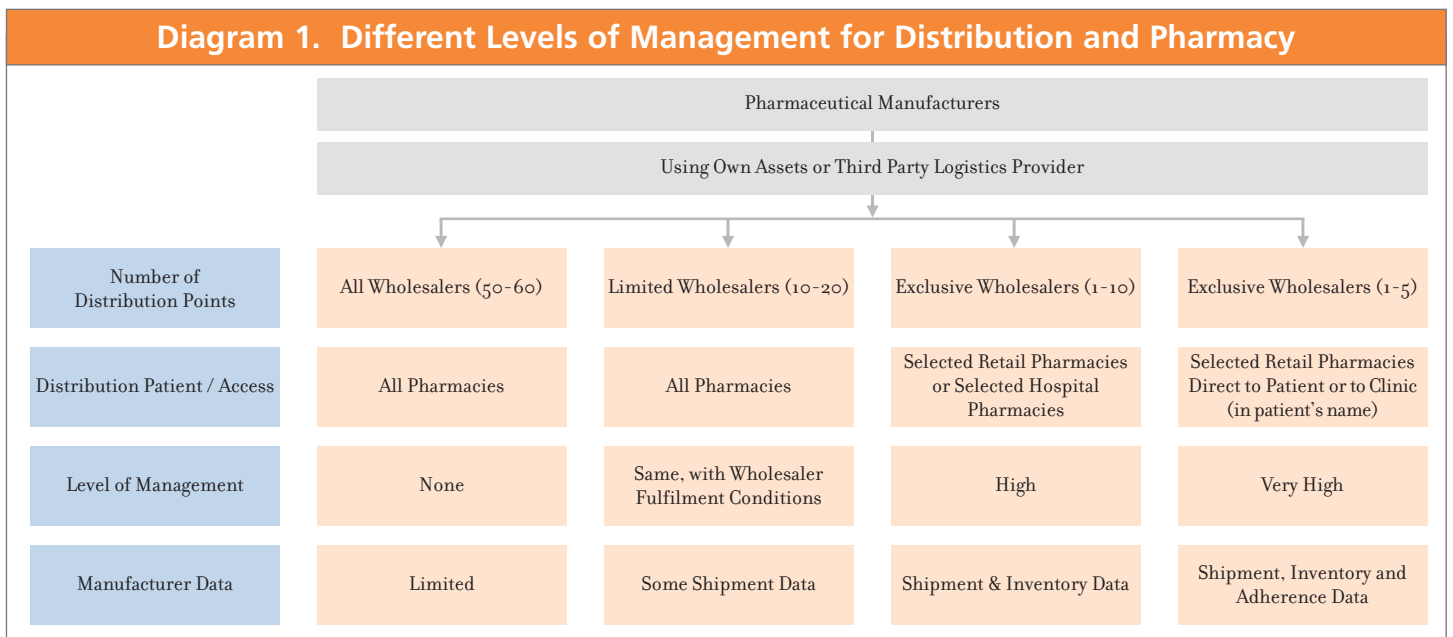
Pharmaceutical manufacturers must consider a variety of distribution and dispensing models in the planning and launching of a specialty product. Typically these products are costly, involve complex service and logistic requirements, and target small niche-patient populations. To introduce a complex product to the market, manufacturers

must exercise heightened levels of control for some or all of the following reasons, ensuring:

- ☞ Compliance with regulatory and post-marketing requirements
- ☞ Special niche prescribing populations are clearly understood and closely supported
- ☞ Limited access and appropriate utilization
- ☞ Harmonized messaging related to the product
- ☞ Standardization and expertise in relation to stakeholder education
- ☞ Training availability in terms of unique product administration requirements
- ☞ Support for product by reimbursement experts who understand the specific challenges involved
- ☞ Product integrity in the event of specialized storage and temperature monitoring conditions
- ☞ Product integrity throughout the entire supply chain, e.g. to point of reaching patient or prescriber
- ☞ Compliance with safety and screening requirements.

The type of model retained should be primarily a function of the degree of management required. Several available models are listed below.

Diagram 1. Different Levels of Management for Distribution and Pharmacy



Different models and levels of management vary depending on the stage of product development.

Actual examples include:

- 1** An oncology product is launched within a fully managed distribution and dispensing model because a substantial amount of compassionate-use distribution of the product is anticipated following its launch. Then, as reimbursement becomes available, it gradually evolves into a community pharmacy retail model.
- 2** A cold-chain product is launched to treat a very rare disease in a highly complex, very well-defined and small market (30-50 patients in Canada). Unless the product becomes indicated for additional, higher volume markets, it likely remains in a fully managed model.
- 3** An ambient product is launched in a therapeutic area where dispensing has historically been conducted via "somewhat managed" retail channels. A small and pre-defined number of out-patient hospital pharmacies carry 80-90% of products in this class. These community pharmacists are most familiar with the products and have established relationships with treatment teams and patients. Dispensing is carried out through these pre-existing traditional channels. The choice of distribution model will be made based on careful consideration of regular ordering methods used by the hospital pharmacists involved.

TESTIMONIAL OF A SPECIALTY PHARMACIST

Patient Counseling

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 pharmacists' 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 the drug is received, I help them to understand and manage side effects and stress the importance of adhering to treatment, despite 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. For this reason we actively push for insurance coverage and work with nurses, prescribers and our program team to anticipate and prepare the right documentation, and deliver on time.

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



Quality Assurance and US REMS Programs – More Documentation to Maintain



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Under the Food and Drug Administration Amendments Act of 2007 (FDAAA), the FDA can require manufacturers to submit safety plans called REMS (Risk Evaluation and Mitigation Strategies) when a drug is first brought to market or if the FDA becomes aware of new safety data about a drug. This new law became effective on March 25th 2008 and represents a significant additional mandate for the FDA's authority. REMS are the method by which the FDA will balance expedited approval of beneficial

new drugs against potential serious adverse events that might occur once a product is distributed across a wide market. REMS can range from prescriber education and patient medication guides to strict prescribing and distribution limitations.

McKesson Specialty is at the forefront of managing some of the industry's most innovative, dynamic, complex and rigorous REMS programs. Our team of experienced clinical, safety, product launch, data management and pharmacy experts are actively providing assistance to manufacturers through ensuring comprehensive end-to-end REMS compliance solutions. Currently we are running risk management

programs across a spectrum of therapeutic areas, including oncology, rheumatology, neurology, pain management and cardiovascular, among others.

REMS links various parts of the McKesson business to ensure that Riskmap drugs are only available under approved restricted distribution programs. Critical aspects of these programs may include mandatory assurance that physicians, pharmacists and patients have registered for the program and have been effectively educated. In some cases, the patient's current lifestyle is also taken into consideration.

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Risk Management Arrives in Canada

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In the US, the vast majority of REMS programs approved in 2008 required only that the medication guide be distributed and that the patient's receipt and understanding of the guide be assessed. Many REMS currently in development however are more stringent than their predecessors and several include Elements to Assured Safe Use. As a result the expectation is that programs will tend to become more restrictive, especially those related to specialty products.

And what should pharmaceutical companies do to prepare for the risk management era? Health Canada suggests pre-submission meetings to discuss known risks and possible strategies. Furthermore, applicants must clearly indicate whether a risk management plan is to be submitted at the point of screening.

Moreover, a number of additional strategies are useful:

④ Develop an internal team that includes regulatory, clinical, safety and commercial representation. If the Canadian market evolves in a manner similar to the US market, then required Risk Management Programs will intersect with traditional safety-type programs and begin to look a lot more like post-marketing patient programs or registries.



④ Do scenario planning. The most sensible course may be to plan for the restrictive program, and even build parts of it at risk. No company wants to delay a launch because of risk management requirements. Furthermore, if the US precedent may be seen as a guide, FDA has asked US companies to provide very detailed program materials as part of their risk program submissions.

④ Consider methods that will make your risk management program work for you. It may share synergies with other aspects of commercialization, such as reimbursement, or the ongoing collection of economic data.

Regardless of how pharmaceutical risk management takes place in Canada, its arrival is inevitable and the pharmaceutical industry must start preparing.

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