

Catalyst

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Subsequent Entry Biologics (SEBs) – Generics or Not?



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A number of biologics will come off patent over the next five years and the mere fact that the growth of biologics has outpaced that of traditional pharmaceuticals has many manufacturers assessing the opportunity around 'generic biologics' and whether they should continue to invest in innovation or replication. In addition, the increasing impact of biologics on drug budgets has payors seeking less costly alternatives and patients demanding affordable access to life-saving treatments.

What is a SEB?

Biologics are derived through the metabolic activity of living organisms and tend to be more variable and structurally complex than chemically synthesized drugs. The manufacturing process is

very precise and the biologics themselves are very susceptible to changes in manufacturing process and external conditions. In fact, changes to source materials, manufacturing processes, equipment, facilities, lighting and temperature can result in significant unexpected changes to the final product.

According to Health Canada, the term "Subsequent Entry Biologic" (SEB) is used by the Biologics and Genetic Therapies Directorate (BGTD), the agency within Health Canada regulating biologic drugs, to describe a biologic product that would be similar to and would enter the market subsequent to an approved innovator biologic. SEBs are also commonly referred to as follow-on biologics, biosimilars and biogeneric.

Differences Between SEBs and Generic Drugs

The term "SEB" is an evolution of the commonly used "biogeneric" to better differentiate the regulatory framework supporting SEBs versus what is currently in place around generic drugs. While generics are bioequivalent to their innovator comparator, SEBs are merely similar therapies expected, for the most part, to act in a similar way. A Canadian Roundtable concluded that SEBs should not be considered pharmaceutically or therapeutically equivalent to preceding products and mandatory substitution should not be recommended unless a decision/understanding is reached between a physician and patient on the potential risks.

Regulatory Framework and Implications for SEBs in Canada

There is a common misconception that SEBs, like generics, face an easier path to regulatory approval. Although it continues to evolve, SEBs are currently regulated in a manner similar to biologics (i.e., manufacturers are required to file a New Drug Submission (NDS)). The key difference is the extent of the clinical data required which is largely driven by: 1) choice of innovator used to demonstrate comparability, 2) design of comparability studies and; 3) the details of the clinical data generated. In general, the complexity of the product, number of indications and therapeutic index (risk versus benefit) will drive the rigor around which comparability and study methodology will be assessed. US sources suggest the development costs of SEBs to be \$100-200M.

Unlike the case with generics, a SEB manufacturer has to develop their product and demonstrate comparability without access to the unformulated drug substance. Reproducibility of results around safety, efficacy and quality is also not possible due to variability in all the factors described earlier.

The FDA (USA) and EMEA (Europe) have taken a similar approach in the approval of SEBs. All agencies agree that SEBs are different from existing biologic therapies in terms of raw materials and manufacturing process that can lead to differences in safety and efficacy. Thus, approval is based on thorough review of studies that suggest minimal risk associated with these differences. →

Commercialization Needs

There is no guarantee that SEBs will be adopted by the markets they target. Regulators are in agreement that these therapies are not bioequivalent and thus automatic interchangeability will not be as openly allowed and/or endorsed as with traditional generics. In turn, SEB manufacturers will need to support the launch of these molecules to support efficacy/safety claims and ensure patient access.

A) Logistics and Distribution: Specialized logistics and distribution partnerships will be required to minimize environmental factors and maintain cold-chain integrity.

B) Reimbursement and Patient Access: Even at a lower cost SEBs are still significantly more expensive than most traditional pharmaceuticals and manufacturers will need to justify 'value for money' and support patients as they navigate reimbursement hurdles.

C) Post-Marketing Surveillance: Although Progressive Licensing has not yet been approved in Canada, the experience in the US around risk evaluation and mitigation strategies (REMS) and post-marketing legislation suggests an almost certainty that SEBs will need a post-marketing surveillance program to validate the similarities in safety/efficacy seen in comparability studies. The Canadian Roundtable also agrees that systems for proactive risk management, post-market surveillance, and pharmacovigilance be developed to support SEBs in Canada.

D) Specialty Pharmacy: Patients prescribed SEBs will need to be followed more closely to ensure access to the drug does not occur without proper screening, risk mitigation and follow-up. Technology systems linking physician offices and pharmacies are required to ensure uninterrupted communication and continuity of care. Special product handling and administration challenges also support a subspecialization.

E) Pricing: In consideration of the above it is easy to see how there may be differing expectations around the pricing of SEBs. Payors may expect similar pricing to that of generics whereas manufacturers may launch with a higher price justified by the additional research and marketing costs. It cannot be safely assumed that SEBs will or should be launched at a price below the innovator. However, with the absence of any

substantial innovation it will be difficult to justify a premium price. The sizeable investment needed to support SEBs suggests that the price will be higher than the current precedent set by generics.

Canadian and US Precedents

On April 20, 2009, Health Canada approved Sandoz's Omnitrope™, the first version of a previously approved recombinant biologic drug to be approved in Canada and under the SEB framework. Omnitrope™ is a recombinant human growth hormone used to treat both children and adults suffering from growth hormone deficiency (GHD). Omnitrope™ is not priced at typical generic levels but offers an attractive cost-saving alternative to current treatments.

According to Datamonitor, 16 biologics will lose their patent protection in the US by 2015. This number is expected to accelerate in jurisdictions where a regulatory pathway is already in place and where reimbursement authorities put pressure on legislators to generate cost-savings. Manufacturers are making significant investments in this market through development of their own biologic capability and next generation biologics (i.e., Amgen, AstraZeneca, Biogen Idec, Boehringer Ingelheim, Eli Lilly) and through the acquisition of generic manufacturing assets (Merck, Novartis, Pfizer).

There are many significant unresolved issues around SEBs, notably data protection, patent life, intellectual property protection, post-marketing surveillance and reimbursement. Some suggest that innovators are better off developing enhancements to their current biologics (next-generation biologics) than pursuing the more costly road associated with SEBs. As a result, it has been determined that SEBs are not generics. ■

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Product Listing Agreements – Friend or Foe?



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We all know the now infamous axiom regarding Common Drug Review (CDR) recommendations: "no means no and yes means maybe". However, the emergence of Product Listing Agreements (PLAs), especially in Ontario, is paving the way for a new, slightly more hopeful path to reimbursement: "yes means maybe and no means...let's negotiate".

In 2007 and 2008, 4 of 10 drugs (40%) that received a "no" from both the CDR and Ontario's Committee to Evaluate Drugs (CED) were listed by Ontario's Executive Officer (EO). An additional 3 drugs were listed by the EO despite receiving a "no" from the CED. These "reversals" came as a result of negotiated PLAs.

Currently, Ontario, Manitoba, and British Columbia (BC) use PLAs in some form. The most important difference is that Ontario's EO has much broader powers to negotiate a listing – even if the CDR issues a negative recommendation. Other provinces – at least for now – still want to see a positive CDR recommendation in order to negotiate a PLA.

PLAs may be associated with several types of commitments (in order of increasing risk to the manufacturer):

- ▶ Research/educational grants
- ▶ Rebates/price reductions
- ▶ Utilization management
- ▶ Outcomes-based reimbursement

PLAs can benefit both payor and manufacturer. For example, a PLA may give a provincial payor a price reduction on each unit of drug sold and allow the manufacturer to: 1) achieve listing where previously the CDR and/or a provincial drug review committee may have said "no"; and 2) maintain a higher, visible price on formulary, while being reimbursed at a lower, confidential price. The latter, is possible through reassurances from the Patented Medicine Prices Review Board (PMPRB) and the federal courts, that the lower price given in such agreements will remain confidential. In return, the provincial payor receives a price reduction (usually in the form of a rebate). The ultimate result is improved access – particularly to more expensive, innovative drug products – and that is a benefit to everyone.

Connectivity – Connecting Health Provider to Patient Data



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The traditional role of healthcare management as an episodic, institutional based health incident management is changing. Today, single providers make most of the treatment decisions. However, there is an emerging trend of community-based management of the whole person with a focus on “self management” as well as multi-disciplinary, evidence-based decisions with the patient as part of the team. More patients are on new and increasingly complex and targeted, specialized treatments, increasing the need for sensitive monitoring and the ability to track and treat.

While healthcare providers in Canada are doing their best to keep up with the emerging trend of managing complex treatment decisions, they are doing so in an environment where there is a lack of healthcare resources both in specialty and general practice fields.

The need exists for a flexible yet systematic approach to treating patients while on specialized therapies in a variety of clinic settings. This would provide the healthcare professional with the ability to access near real-time patient records and important patient and treatment information that effectively connect and link the entire circle of care for the patient.

A Near Term Solution

McKesson Specialty has been successful in developing customizable portal technology platforms that allow healthcare providers, patients, labs and other healthcare professionals to communicate effectively through a single electronic system that provides near real-time information to simplify the tracking and monitoring of patients. Such a system has many benefits as described below.

Healthcare Professionals

- ▶ Real-time access to their patient data in a variety of clinical settings reducing administrative time and unnecessary patient visits and calls.
- ▶ Ability to track initiation and adherence to complex therapy as well as monitor and communicate clinical outcomes to the entire circle of care.

What does the future hold for PLAs? Provincial payors are certainly not going to give up their newfound ability to get better prices. Indications are that PLAs will be emulated by other provinces:

- ▶ **Alberta:** Phase two of Alberta’s Pharmaceutical Strategy includes a PLA negotiation framework. Alberta has increased staff for this purpose.
- ▶ **Quebec:** Quebec has not yet said if its soon-to-be-created Institut national d’excellence en santé et services sociaux (INESSS) will use PLAs. Quebec has mandated that it receives the lowest price and therefore, negotiations have not been necessary. Also, Quebec, so far, has resisted the idea of a “confidential price”. Confidential PLAs in other provinces may jeopardize Quebec’s lowest price guarantee. The prospects of losing this guarantee may be an incentive for Quebec to try to implement PLAs.
- ▶ **Saskatchewan and the Atlantic provinces:** These provinces will likely be left with little choice but to adopt PLAs in an effort to compensate for their limited buying power to avoid paying higher, un-negotiated prices. At least one Atlantic province, Nova Scotia, is in the process of developing policies and guidelines regarding PLAs.

Ultimately, who will be the winners and losers in this new PLA paradigm? Winners will undoubtedly be the larger payors/provinces who, because of their buying power, will be able to extract better prices. Patients who are covered by these larger payors also win through greater access. This access may take longer (because negotiations will add time and complexity to the process), but at least it is more likely to occur in the end. In contrast, smaller payors – including some private payors – who do not have the same buying clout will be in a less favorable situation. Similarly, patients who are covered by these smaller payors will likely have more limited access and cash-paying patients will experience perhaps the highest prices.

Manufacturers also may stand to benefit as the era of “no means no” comes to an end. ■

Patients

- ▶ Communicating any “self monitoring results” to assist their healthcare providers in making treatment decisions.
- ▶ Avoid unnecessary visits to the doctor’s office.

A Real Life Application

McKesson Canada developed an online system connecting all parties, for a chronic and complex disease and its associated therapy.

The portal was designed to connect specialist prescribers, nurses, reimbursement experts, community resources and labs using an easy to use and secure electronic interface that provided shared and restricted views of patient information and outcomes.

This system has effectively allowed the healthcare provider to easily enrol the patient for support services and track patient progress from reimbursement efforts to initiation and administration of therapy and subsequently monitor progress via predetermined clinical markers throughout therapy.

All stakeholders have been able to realize the time-saving benefits of communicating and making treatment decisions via a single source where all relevant patient information is contained.

Critical Success Factors

Critical to the success of any portal design and development is in-depth understanding of the disease, treatment monitoring requirements and healthcare provider workflow. This ensures that the tool is efficient, easy to use and in compliance with clinical, privacy and security regulations.

Significant time and energy should be directed to the training and field testing of any portal to ensure user acceptance, technical compatibility, security and robustness in a variety of settings.

While there are many changes in electronic management of patient information in planning and in process, initiatives such as that described above fill an important short term gap using currently available technology. ■

Government Relations Corner



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▶ On June 7th, the Ontario government released the final regulatory amendments of its Drug System Renewal Process, which come into effect July 1, 2010. The final reform package includes a number of dramatic changes that have created much vocal debate, including generic drugs priced at 25% of the brand, elimination of professional allowances, and a ban on private label generics. However, pharmacists did receive increased dispensing fees and the promise of new professional service fees. As a result of the significant decline in the profitability of generic prescriptions, pharmacists will encounter increased financial pressures and seek strategies to mitigate them. Also, the new pharmacist service fees may provide more widespread community-based opportunities for specialized services around complex drugs.

▶ With the passage of Bill 179 in late 2009, regulations governing remote dispensing in Ontario are being developed by the Ontario College of Pharmacists for possible enactment in the fall of 2010. The current draft principles published by the College would see two forms of remote dispensing being allowed in the province, locations staffed by a registered pharmacy technician under the supervision of an off-site pharmacist, and automated dispensing machines in which patients would communicate with a pharmacist over an audio-visual link. Given the possibly finite 'shelf space' within automated dispensing machines, manufacturers will need to ensure their key products are accessible in this new, yet SKU-constrained, dispensing channel.



▶ The Western provinces are also moving forward with their own pharmacare reform plans. Alberta is the first to announce, among other updates, the use of various forms of product listing agreements for branded products. Saskatchewan is expected to unveil its own plans in Spring 2010, with British Columbia moving forward in Summer 2010. Manufacturers will need to be ready to demonstrate the pharmacoeconomic benefits of their products against others in the same therapeutic class, and be willing to 'put their money where their mouth is' in terms of pricing incentives, risk-sharing, and other forms of listing agreements.

▶ Private payors, who are increasingly bearing the brunt of drug costs by offloading public payors, are proactively exploring new measures to drive savings for their plan members. In the past year, Green Shield drew pharmacy ire for its brand agreements for selected auto worker plans, Telus Health Solutions reduced markups on indirectly sourced brand drugs in Ontario, and Medavie Blue Cross faced a pharmacy boycott over its unilateral cuts in the reimbursement of generic drugs in the Maritimes. Manufacturers should be monitoring the increasing activism of private payors who, if they become more organized, could become an opportunity to compete in the post-patent world, or a challenge if pricing concessions are sought. ■

Mixed Messages on Patient Programs from the PMPRB



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In June of 2009, the Patented Medicine Prices Review Board (PMPRB) released its revised Compendium of Policies, Guidelines and Procedures, incorporating the new Excessive Price Guidelines. The revised Guidelines came into effect on January 1, 2010 and will be the basis for price tests for patented drug products. The revised Guidelines also have implications for patient programs and their impact on a drug's price.

What We Do Know

The PMPRB is now accepting the 'cost of making and marketing' considerations. This allows the resetting of the Non-Excessive Average Price of a patented drug after receiving a Notice of Compliance if the drug was first sold on a compassionate use basis as an Investigational New Drug or through the Special Access Program. This is of particular interest to manufacturers utilizing patient programs.

Thus, manufacturers should not be penalized for SAPs and compassionate use programs, which would otherwise artificially lower the average transaction price, thereby lowering the maximum price that could be charged once the drug was approved for sale.

Issues That Are Uncertain

The reporting responsibilities of patent holders have yet to be announced. This, due to the Federal Court overriding a previous PMPRB Communiqué requiring patent holders to report all discounts/benefits provided, including those offered to provincial drug plans (such as through product listing agreements).

The Federal Court's ruling on discounts to third parties is but one example of the topsy-turvy environment patent holders are navigating as a result of recent PMPRB policy changes and the subsequent challenges from the industry.



For patent holders looking to utilize patient programs as part of their pre-launch and post-launch marketing strategy, the outlook is similarly uncertain as the mechanics for implementing 'resetting' of prices due to 'cost of making and marketing' considerations still remains unknown.

Recent Developments That May Help Guide Us

In December 2009, PMPRB claimed victory in an earlier judicial review of the PMPRB's decision to require Celgene to report pricing data for sales of Thalidomide made out of the US but through the Canadian SAP program.

Though the Federal Court did side with Celgene, ruling that the PMPRB did not have the jurisdiction in this matter, the ruling was subsequently overturned on appeal. So it seems that basing patient program sales out of the US is not beyond the jurisdiction of the PMPRB.

Conclusions

For now, it seems that any transaction conducted by a patent holder in Canada is subject to the rules of the PMPRB. On a positive note, there will be opportunities to incorporate patient programs as part of a cost of marketing argument. Patent holders should, as always, ensure that they track all transactions that they have with all Canadian purchasers, the costs associated with such programs (particularly for compassionate use drugs provided at no-cost), and have ready comparative pricing data from other jurisdictions to justify the 'reset price'. ■

Personalized Medicine



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Pharmacogenomics is the study of the underlying causes of disease based on an individual's genotype or DNA. One of many branches of pharmacogenomics is **personalized medicine**, where an optimal therapy is customized for the patient, based on their genetic makeup. Ideally, using pharmacogenomics, physicians will be able to predict which drug will be most effective for a particular patient based on their genetic profile.

Personalized medicine could have a major impact on healthcare. New diagnostic and prognostic tools will increase our ability to predict the likely outcomes of drug therapy, while the expanded use of bio-markers, biological molecules that indicate a particular disease state, could result in more focused and targeted drug development. The end game is to become more effective and efficient in risk stratification, prevention and to tailor drug therapies. Personalized medicine also offers the possibility of improved health outcomes and has the potential to make healthcare more cost effective.

Diagnostics and prognostics can:

- ▶ Determine whether the patient is at risk of developing a specific disease or condition
- ▶ Predict safety and efficacy of treatment
- ▶ Evaluate optimal dosing based on metabolic rates
- ▶ Monitor the course of treatment

The pipeline for drug development has over 350 biologics in Phase III with thousands in early development. This is reflected in a 35% increase in payor reimbursement and pharmacy prescriptions in 2008. Many of these biologics cost more than \$10,000 per month in treatment. It is imperative that the correct patients are receiving the treatment to maximize benefit and to minimize waste of healthcare expenditures.

Examples of drugs that require genomic tests to select treatment and dosing are: HER2/neu for Herceptin; KRAS/EGFR for Vectibix; EGFR for Iressa; HLA-B*5701, CCR5 for HIV therapies; CYP2C19 testing for Plavix.

Bio-marker testing is expensive and not available at all laboratories. Even labs that are able to execute the testing may need to achieve specific volumes before performing the test. There are over 30 distinct bio-markers that can be tested. Costs can be up to \$3,000 per test. As a result, stakeholders must address some important considerations:

- ▶ Prescribers – knowledge of necessity of bio-marker testing prior to prescribing; where to order specific testing and who pays for the testing. Additional follow-ups to analyze testing reports and planning with patients on clinical pathways for treatment options.
- ▶ Patients – drug therapy is no longer a straight forward directive from the physician. Patients will need to be educated sufficiently to be able to weigh their options before embarking on the process of deciding on a drug treatment. New factors for consideration:
 - Testing requirement may mean a delay in treatment; will this affect the final outcome?
 - Testing may not be covered by payors and yet testing yielding negative results still needs to be paid, but by whom?
 - Testing resulting in negative results means patient will have to evaluate alternate therapies, a possible further delay in treatment?
 - If drug is of marginal benefit, would it warrant the testing versus using standard of care?
- ▶ Pharmacists – could become gate keepers for access to biological drugs that require positive test results. They will need to ensure testing is complete and results are positive before filling a prescription. Added administrative activities such as reporting back to prescriber and verifying results before billing payor will need to be part of the process. Increased counseling time will also be required with patients. Will these activities become part of a billable service?
- ▶ Pharmaceutical Companies/Manufacturers – as more knowledge about the effectiveness of drugs for specific disease based on genotype increases, drugs may have better efficacy to safety and cost effectiveness ratios. Recruitment for clinical trials will focus on genetic pre-selection versus selection based on more non specific entry criteria. Since the patients selected will have a higher likelihood and magnitude of response, trial size and duration may be lower. The result may increase speed to market.

Marketing and Sales

Strong sales and marketing strategies will continue to be critical for a successful medication. However, the background and competencies of the sales force will need to change – understanding of the underlying mechanisms of the disease and the treatment in a more targeted world will be needed. Marketing will also become more dependent on the availability and reliability of diagnostic or genetic tools and new partnerships may be required.

Portfolio Management

Personalized medicine will bring new challenges. For example, should a company develop two drugs for the same disease state for patients with different genetic markers? Moving away from blockbuster drugs will mean that companies are less reliant on one drug as their main source of revenue, as their portfolio will be more diverse.

▶ Policy Makers

Existing regulations for drug approval are based on evaluation of drug safety and side effects. With personalized medicine, drugs that are effective for one patient may be extremely harmful or ineffective for another. Ideally, the drug would never be administered to the latter patient. The new regulatory model must be able to capture these differences as well as be able to assess the judgment accuracy of the prescriber.

▶ Payors

Payors' approach to personalized medicine will impact the business models for pharmaceutical and diagnostics companies as well as pharmacists (who depend on third-party payment). Insurance premiums will have to be restructured as statistics will no longer be based on large, heterogeneous predictable populations, but rather discrete groups with more predictable response.

In summary, pharmaceutical companies will need to address personalized medicine on several fronts:

- ▶ Research and development – targeting.
- ▶ Clinical trials – designing for pre-select and smaller patient population.
- ▶ Marketing – research on diagnostic tools, availability and reliability and market access strategies.
- ▶ Sales – more focus on disease states and mechanisms of action of personalized drug.
- ▶ Market access – out of the box budget impact analysis that weighs benefits versus standard of care. ■

Patient Recruitment in Post-marketing Studies: What Have we Learned ?



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The success of post-marketing research depends on the ability to formulate and implement effective patient recruitment strategies. Relatively little has been documented about recruitment in Phase IV studies compared to recruitment issues in Phase III trials.

Recruitment factors in Phase III trials differ from Phase IV studies. Phase III recruitment is affected by two key factors:

- 1) the availability of patients who meet the inclusion criteria, and
- 2) patient willingness to participate in a trial. Conversely, in Phase IV studies, physician interest and involvement in the trial as well as patient availability in their practice is important. Phase IV studies vary in design (i.e. they are not usually the typical randomized, blinded crossover trial), and therefore a patient recruitment strategy must be developed on a trial by trial basis.

McKesson Specialty analyzed patient recruitment data from 5 different post-marketing studies. The results are shown in Figure 1 below:

Findings

In all cases, patient recruitment accelerated after one or two months after study initiation. This was likely due to development of physician familiarity with study processes and adoption of a routine within their practice. This fact should be taken into account when launching studies for products that have peak patient recruitment periods and that are affected by seasonal factors, as is the case with Asthma or ADHD products. Ideally, the study should begin well before peak market potential.

As would be expected, recruitment in specialty areas such as Alzheimer's Disease (Study 2) occurs at a much slower rate than in primary care products which typically are more heavily promoted products such as Asthma (Studies 3 and 5) or Hypertension (Study 1). Interestingly, a non-promoted product with low levels of physician communication, as was the case for a second hypertension product (Study 4), resulted in a decelerated recruitment rate that mimicked specialty product patterns.

The Asthma study with one of the highest rates of recruitment (Study 5) coincided with a product launch and was designed with intensive physician communication and a strong patient value proposition. Excitement was created in the medical community because physicians believed in the scientific merits of the therapy, the value-added features of the study, and the clinical benefits that their patients would receive. Studies that are launched alongside newly launched products

typically result in accelerated recruitment patterns, although reimbursement issues must be considered if access is limited at the time of launch. Physicians may be reluctant to enrol patients in a study if they perceive that they will incur administrative burden or that patients will experience reimbursement hurdles on top of adopting a new therapy.

The study with the highest absolute number of patients recruited (Study 1) was associated with an aggressive recruitment strategy as well as visual and concise communications that clearly outlined patient benefits. Other considerations that influenced recruitment:

- ▶ Intensive physician training
- ▶ Adequate physician reimbursement for the administrative load of the study
- ▶ Intensive site support and management
- ▶ Succinct study documents and tools
- ▶ Information regarding drug coverage
- ▶ A study design that could be integrated into real-life clinical workflow
- ▶ Recruitment strategies timed with peak prescribing patterns (e.g. expected time to reach peak from time of study initiation, etc.)

Persistence does indeed pay off in recruitment. Study 1, for example, had a recruitment period of 11 months, and a full cohort of 13,524 patients was recruited.

Additional factors that influence recruitment include:

- ▶ Competing interests for physicians' time
- ▶ Availability of in-office resources
- ▶ Level of physician interest in the study itself
- ▶ Season of recruitment
- ▶ Study duration
- ▶ Planned tactics or compelling arguments for maintaining the study "top-of-mind"

A wide variety of factors impact patient recruitment in Phase IV trials. A careful case-by-case analysis is required to determine the best approach. With a keen understanding of recruitment patterns and proper planning for the product and the environment, your study can attract the requisite number of patients. ■

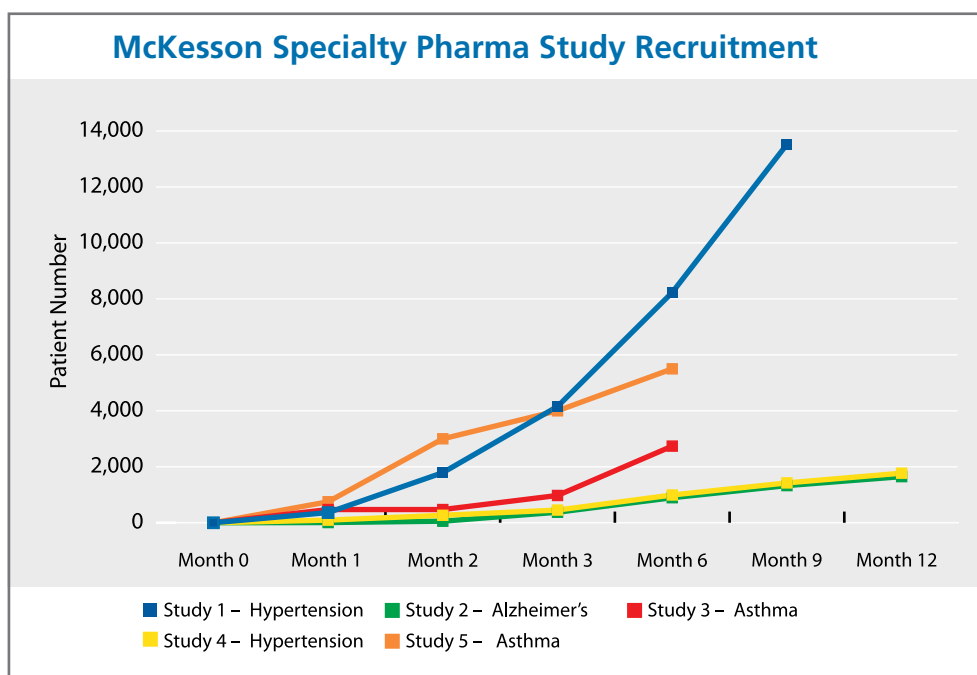


Figure 1. Patterns of Patient Recruitment

Patient Input into CDR Reviews – Influence or Illusion?



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A few years ago, I sat in a room with a former provincial Minister of Health and three other people. The Minister of Health recounted the impact of a campaign to get a drug reimbursed – a drug in which McKesson Specialty developed the reimbursement strategy. He said that all the letters which he received from physicians had no impact on the eventual government decision to reimburse the drug. However, the countless letters that he received from patients had a dramatic influence.

This was a politician, and in the world of politics – public opinion and votes – matter. We ask ourselves, in the “evidence-based” world of the Common Drug Review (CDR), is public opinion – or patient input – likely to result in different outcomes? With the recent consultations on patient input conducted by the Canadian Agency for Drugs and Technologies in Health (CADTH), that question is about to be put to the test.

The proposed template for providing patient input asks for specific and pertinent information. There is also a section for providing “additional information” that may not have been captured elsewhere in the template. However, there are several important limitations that should be noted about the proposed process:

1. The submission will be limited to a maximum of 6 pages.
2. Patient input will be required within 15 business days of a drug submission.
3. Individual patients or caregivers will not be permitted to make submissions.
4. Patient groups will not have an opportunity to make oral presentations.

Moreover, there are other, more significant limitations that may not be readily apparent:

1. Patient input has typically only been effective at the political level (as above), as opposed to the drug review committee level.
2. The CDR’s mandate is to make “evidence-based” recommendations, and patient input (or opinion) is not part of the evidence-based world. Indeed, potential criteria that are more patient-centered (e.g., quality of life, compliance, and patient convenience) have traditionally been given little weight among public payors.
3. The very first paragraph of the guidance document, for submitting patient group input to the CDR, conveys a familiar message: “Although prescription drugs contribute to improved health outcomes for many Canadians, they are the fastest growing component of the Canadian health care budget. This increases the financial pressures on the publicly funded drug plans and necessitates that they make drug coverage decisions that maximize health to the greatest extent within their available budgets.” Intended or not, the implication is that cash-strapped provinces are unlikely to let lay people over rule what the experts say about the evidence and the value of a drug.
4. By setting up a defined process for patient input, public payors may be attempting to limit patient input to the boundaries of this process.

In summary, patients will have their say, but it is unlikely to result in meaningful influence or alter the final outcome of a CDR recommendation. ■

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.

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