National Pharmaceutical Procurement Strategies and Tactics 2014

STRENGTH IN UNITY

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Executive Summary

Canadians pay more than twice as much per capita for pharmaceuticals as do the English or New Zealanders. Reducing expenditure on pharmaceuticals in Canada was made a priority by the Premiers in their *First Report of the Health Care Innovation Working Group* in July 2012.

This paper provides recommendations on strategies and tactics to achieve that vision expediently. These recommendations build on the work commenced through the pan-Canadian Pricing Alliance.

The paper identifies the fundamental tension between buyers and sellers in the public sector of the Canadian pharmaceutical market, describes core components of an optimum pharmaceutical procurement process and recommends how they be applied to achieve public sector savings of at least $2 billion per year.

Cost Drivers in Canadian Pharmaceuticals

Changing patient demographics across Canada, the end of a period of major patent expiry and the comparatively high cost of innovative new treatments are placing increasing pressure on public budgets. Meanwhile, the fragmented nature of the public procurement process dramatically limits Canada's ability to implement the effective and efficient national pharmaceutical cost control strategies established in most of the world's major markets. Given the pharmaceutical industry's comparatively low level of investment in Canadian research and development, Canada can be seen as an industry profit centre or a major opportunity for deployment of effective pharmaceutical procurement.

Cost effective pharmaceutical procurement requires a balance of two opposing interests. Manufacturers seek to create product differentiation (whether through the launch of technically unique products or through effective marketing techniques) that commands a price premium. Buyers look to engage competition between multiple sources of the same product, or alternatives that achieve the same therapeutic result safely.

Its global scale allows the pharmaceutical industry to maximize production volumes and research efficiency whilst deploying, across Canada, already proven marketing strategies. For pharmaceutical manufacturers, Canada, with a mix of relatively small purchasing units, is a cash cow with high prices and comparatively low research and manufacturing investment.

Within the comparatively small Canadian hospital sector, the pharmaceutical procurement process already rationalizes minor product differences and leverages maximum volumes to achieve lower prices across multiple jurisdictions. Clinical and procurement specialists work together to this end.

Comparable bulk buying of pharmaceuticals for the much larger public community sector represents a far greater opportunity for savings. Procurement is currently managed at the jurisdictional level, with many locations of procurement excellence ready to provide best practice to the whole. Most jurisdictions, are already co-operating in the pan-Canadian Pricing Alliance to conduct some joint negotiations and price setting.

Public healthcare expenditures account for almost 50% of all provincial and territorial spend. Pharmaceuticals, at $12 billion, are the second or third largest component of total healthcare expenditures. The Premiers are seeking to co-ordinate pharmaceutical purchasing processes to fully leverage multi-jurisdictional demand. In addition to financial benefits, a coordinated approach to pharmaceutical procurement will also help create consistent access to pharmaceutical treatments for all Canadians. Combining multi-jurisdictional volumes will dramatically increase the provinces' leverage. That leverage will increase further with the implementation of a single procurement process that allows pharmaceutical manufacturers to bid, or negotiate, for defined volumes. The scale and discipline of such price bids and negotiations, will allow Canada to achieve pharmaceutical prices that are at least in line with other similar sized countries, particularly in Europe.

Components of Optimized Pharmaceutical Procurement

Effective pharmaceutical procurement shares some features with, and is also quite different from, other healthcare procurement. A new unified pharmaceutical procurement process will be based on four key components:

1. **Ability to maximize volume and share risk in competitive bidding and negotiation processes**.
   Experience has demonstrated that high volume and corporately visible market share risk draws more attention within manufacturers, encouraging incrementally better bids. Smaller regional opportunities do not create such visible risk of failure at the corporate level, and therefore do not attract such assertive bidding, but provide opportunities for suppliers to experiment with and re-apply winning strategies.

   A recommended approach is to find a future common time horizon where maximum Canadian volume can be offered, in a single process, accepting or rejecting any option periods and creating contract extensions by mutual agreement, where competition law allows. Combining volumes in an extra jurisdictional and extra political process will be key in encouraging all jurisdictions, including Quebec, to add their volumes to a multi-jurisdictional process to truly maximize volume. This commercial model does not conflict with any political perspectives. Inclusion of all available volumes in this single process will produce better results for all parties compared to some jurisdictions combining volume and others using *Best Price* contract clauses to subsequently acquire such prices.

2. **Ability to standardize or commoditize pharmaceutical products to increase competition**
   Many healthcare consumables require a two stage procurement process, with a pre bidding trial or validation phase. Pharmaceutical products are clearly defined in terms of active ingredients and safety, allowing a price-driven commodity procurement methodology, particularly where multiple sources of supply exist, at the molecule and, depending on degree of similarity, the therapy class level.

   Global manufacturing, the convergence of Health Technology Assessment, and multi-national clinical trial work support the application a commodity procurement process at the molecule and often at the therapy class level.

   Availability of Drug Identification Numbers, with the addition of a stock availability record assessment, can all be set as prerequisites for bidding or negotiation, leaving price as the differentiator.

3. **Achieve prices based on the degree of product innovation**
   The product price: value relationship is a major issue from both pharmaceutical marketing and procurement perspectives. Products that raise treatment standards expect to command a premium.

   Innovative pharmaceutical manufacturers seek prices that not only to cover research and development costs, new manufacturing processes, but also recompense for other healthcare cost offsets and the value of improved patient lifestyle. Price can also be used, as a marketing strategy, to endorse product efficacy.

   For procurement, price is related to the degree of product scarcity and the number of current or potential manufacturers or other options. A simple as possible measure of comparative cost per effect would be ideal in assessing relative value. Germany uses such a value based pricing assessment scheme. This approach encourages the development of products that meet unsatisfied need. It also discourages the launch of higher priced or therapeutically undifferentiated products. The trend towards increased pricing transparency, led from Europe, assists in bringing objectivity to this pricing per effect consideration.

4. **Implement the most cost efficient procurement process**

   Disease etiology, treatment protocols and product approval are similar across Canada. This facilitates the replacement of the current highly fragmented procurement process with a single, unified process that will generate significant process saving. Pharmaceutical manufacturers are global or national in scale. The cost of a single unified procurement process, expressed as a proportion of net savings achieved, compared to the same metrics for the sum of all the current individual jurisdictional processes, will be a key performance indicator.

   All jurisdictions will retain budgetary control of their public healthcare expenditure, including pharmaceuticals, but can pool volumes to achieve lower prices and reduce cost. Procurement, that achieves this scale of activity and cost efficiency, and operates outside existing jurisdictional and political entities, is the recommended solution. Commercial objectivity and focus will mirror that of the pharmaceutical industry.

Case Study in Multi-Jurisdictional Pharmaceutical Procurement

These recommendations are based on prior experience in the private sector. A single Canadian multi-jurisdictional pharmaceutical procurement process replaced multiple individual contracting processes, resulting in an overall 13% saving on a wide range of single and multi-source products. Critical success factors included:

(i) *Creation of consensus from the buying participants across Canada to take a risk in issuing a single bidding process*
(ii) *Successful engagement of over eighty pharmaceutical manufacturers in the bidding process; and*
(iii) *Assertion of strong contract compliance, validated by prior performance*

Applying Procurement Components to Current Practice

Approval of a new sole source product can bring unique and important therapeutic benefits and challenge budget constraints. For new single-source products, confidential **product listing agreements** (including those with tiered rebate and volume caps) can mitigate this challenge. A unified volume approach to negotiation will introduce a major opportunity to expediently secure maximum business in one process. It also creates an internationally visible risk of failure that manufacturers may want to avoid. A single negotiation will also remove the experimentation and learning opportunity from the supplier side.

In setting pricing goals and benchmarking achievements in PLAs, the emergence of greater pricing transparency (particularly from Europe) will be utilized. Assuming access to net German pricing, a volume-based algorithm can be developed to help determine appropriate prices.

From single-source products with similar modes of action, one or a selected number of products can be selected through a competitive *bidding* process for purchase or remuneration. Clinical experts will determine where this process is applicable and a **therapeutic tendering** or class **reference pricing** process will be applied. Named patient exception systems in other markets support patients who need to maintain treatment on particular brands or other generics, due to reaction to particular excipients for instance. It is recommended that a systematic review of therapy classes is completed to identify opportunities for therapeutic tendering**.**

For multi-source products, **requests for proposals [RFPs]** and product level **reference pricing/price setting as a percentage of list price** are also used. RFPs have been used in the community sector, with Saskatchewan Health having been particularly successful. Price setting as a procurement technique is simple, adjustable, and immediate, but it does not find true market bottoms, resulting in missed savings. Price setting also does not formally engage the supplier community in finding the lowest sustainable prices or provide suppliers with the benefits of a contractual relationship from which they can achieve manufacturing and other sharable efficiencies. Even after the major progress initiated by Bill 102 in Ontario in 2006, prices compared to other markets still remain high.

This paper recommends using, wherever possible, a competitive bidding process that will achieve a volume and share risk driven price reduction for multi-source products in the community sector. Once multi-jurisdictional product usage patterns are fully integrated, faster **reverse auction** procurement processes can be added to the mix.

Benefits

In summary, the benefits of this unified procurement process for Canada include**:**

- An ability to trade maximum volume to generate significantly lower prices, equivalent to comparable markets abroad.
- A single acquisition process, including at the federal level, will incur considerably less operating costs than the existing fourteen provincial/territorial/federal processes
- Experience and consensus built pre-defined business and therapeutic rules that result in shortest decision times.
- Extra-jurisdictional and extra-political process, functioning on an exclusively commercial basis, will also encourage full jurisdictional participation.
- Unified acquisition process goes on to support consistent patient access to new and existing treatments across Canada and creates the option for savings achieved on older and multi-source lines to be used to purchase leading edge new medicines for Canadians.

Objectives for this paper

This paper provides some options and recommendations on how to significantly reduce the cost of pharmaceuticals purchased by public payers within Canada.

Its creation has been motivated by the *Emerging Themes* section of the Council of the Federation Working Group on Health Care Innovation, *First Report of the Health Care Innovation Working Group,* July 2012, (**1**) and later developments associated with individual pharmaceutical procuring jurisdictions and the pan-Canadian Pricing Alliance.

These ideas are offered to build on progress already made in the effective public procurement of pharmaceuticals, recognizing that at a time of great demand for public funds the potential for a significant and rapid reduction in expenditure on pharmaceuticals is considerable.

The following are circumstances that justify the consideration of new options for Canada that quickly improve the cost effectiveness of public expenditure on pharmaceuticals:

- An aging population, expecting maintained access to effective and safe pharmaceutical treatment.
- Patient demand for new treatments. Public payers with multiple and growing spending priorities.
- A global pharmaceutical industry that may see the highly fractionated Canadian pharmaceutical market as complex to manage but meanwhile a significant profit centre in a global market where public payers in other markets are becoming increasingly effective and efficient at procuring pharmaceuticals.

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Public procurement of pharmaceuticals now and in the future

Canada has a fractionated market for publicly paid prescribed pharmaceuticals consisting of thirteen uneven sized provincial and territorial jurisdictions (some containing disease-specific agencies) making purchasing decisions and a significant federal pharmaceutical purchasing entity.

The Canadian public pharmaceutical market has two sectors: community (retail) and hospital. In the public hospital sector, multi-province volume aggregation, in a range of negotiations and competitive bidding processes, is already deployed to generate savings.

The larger community market sector has yet to routinely nationally aggregate volumes in competitive bidding processes or negotiate sole source agreements across all jurisdictions for all products and therapy classes for publicly paid pharmaceuticals.

The community market sector represents the greatest opportunity and progress is beginning to occur through the activities of individual jurisdictions and the pan-Canadian Pricing Alliance. A complete and systematic procurement approach is a logical next step.

In political terms, there is no clear ascendant political model that currently holds sway across a majority or a significant number of political jurisdictions in Canada. This means that ideas for logical process improvements that potentially transcend multiple jurisdictions in order to be accepted and supported, cannot impinge on any critical or unique political axioms in any jurisdiction.

At the same time, the opportunities for savings from combined jurisdictional action are so large, that every jurisdiction will have great purposes for the deployment of such additional funds.

The situation in Canada is unlike any other significant pharmaceutical market and has created a number of challenges and opportunities to significantly improve the effectiveness, in terms of lower prices or value for expenditure, and the efficiency of pharmaceutical acquisition, in terms of combined total and relative costs of running procurement processes.

The potential savings to be achieved are in an area of public spending that is large and growing ahead of total public expenditure.

Canada is forecast to spend $211.2 billion on healthcare in 2013 (2), which represents 11.2 % of its economy. (3) Healthcare spend is forecast to grow at 2.6 % % in 2013, (2) with growth in Canada's health care spending per capita exceeding economic growth over the last decade (3).

At $33.0 billion, pharmaceuticals represented, after hospitals, the second largest component of all healthcare spending for the year 2011, at 16.5 %.(4) Of prescription pharmaceuticals, those purchased by public funds amounted to $12.0 billion in 2011 or 43 % of total prescription pharmaceuticals (5).

Population aging, population growth and price inflation continue to be the forecast cost drivers for Canadian health expenditure, with the increasing proportion of the population over the age of 80 years of age causing particular concern with respect to growth in healthcare provision. (6)

Public expenditure on healthcare accelerates in the population segment over 65 years old. (7) As the large "boomer" generation passes through this threshold, disproportionate pressure on the publicly funded Canadian pharmaceutical market sector will occur, compared to the younger and smaller demographics predominantly receiving private healthcare insurance coverage.

This demographic trend was prominently cited as a significant challenge in the provincial and territorial Health Ministers summary of their October 2013 meeting (8).

In addition to the impact of population aging, the decline in the value of commodities such as oil and gold may decrease the value of the Canadian dollar, resulting in potentially higher net costs for, at least, branded pharmaceuticals, a very large proportion of which are imported.

It is reasonable to assume, however, that Canadians who receive publicly funded treatment and their providers will:

- Continue to expect existing access to modern, safe pharmaceuticals
- Seek more access, even as demand increases
- Welcome all strategies that maintain and grow access to such at the lowest sustainable prices.

Sustainable prices can be characterized as prices which are competitive to those in similar markets, offered for at least the medium term, by two or more manufacturers, where supply has met demand.

Such pricing broadly indicates the presence of a healthy pharmaceutical market for a particular molecule or therapy class.

Healthcare, including pharmaceuticals, is a large and increasing proportion of provincial and territorial GDP, ranging between 8.3 and 20.9 % for the provinces and territories. This will potentially challenge the allocation of resources for other important priorities.(9) In Ontario, $49 billion or 38% of the annual provincial budget for 2013-14 is spent on healthcare (*10*).

There is a growing concern that jurisdictional healthcare expenditure will continue to approach 50 % of all budgetary expenditure, as economic and demographic trends indicate.

All Canadian jurisdictions have a strong motivation to provide the best treatment options that are affordable. Buying pharmaceuticals as effectively and efficiently as possible, will significantly help public payers make this happen.

Canadians do not have universal, consistent, access to pharmaceuticals. Price and access, at all or by indication or stage of therapy, varies across jurisdictions. This is atypical of other comparable markets, where product licensing, listing and remuneration are usually completed at a single national unit level. Usually there is also a single public payer or coordinated national insurance coverage.

In Canada, Health Technology Assessment and product licensing is completed by two bodies, one for Quebec and another for the other jurisdictions, while product listing and remuneration, for public payers, is completed at the provincial, territorial, agency, or federal level.

As a result, fractionated purchasing, by various jurisdictions, or sub-groups, cannot leverage full potential collective volumes, prospectively and consistently, in aligned contracting timelines.

Since volume is so important in achieving the best results, this paper encourages totally pragmatic inter-jurisdictional cooperation that achieves greatest volume based strength, including by aggregating volumes in single procurement processes in common contracting timelines, across maximum geography and end users.

One model could consist of some jurisdictions working together, in leveraging their collective volume, to achieve lower prices, with other individual jurisdictions requiring, of pharmaceutical manufacturers, *best price* contract price adjustment to those prices, without participating in the collective process.

Combining all volume, in a single process, generates higher leverage.

Non-participation in unified procurement processes maintains a fractionated market model and the loss of all the potential to get the very best prices.

All potential volumes, working together, have the best potential to find a sustainable market bottom price, comparable with another major markets. If full predictable volume, in aligned timelines, does not become the case, manufacturers may be less open to agree to lowest comparable international prices.

Why would manufacturers concede significant pricing concessions without larger integrated volume expectations or commitments in return?

Negotiated prices, prices set by payers or those obtained as a result of competitive bidding, are managed in numerous contracts with various start and termination dates across Canadian jurisdictions.

Not only do these multiple contracts have different start and finish dates, some will also have renewal and extension provisions, including option periods. These can be set up to be able to be actualized by either party, individually, or by mutual agreement. They are usually constructed to give the purchaser the option to renew, at least for one defined contract extension term.

The many different contracts that exist, across Canada, help maintain the fractionated nature of the Canadian public pharmaceutical market.

In terms of procurement effectiveness, there is a significant opportunity to align contract terms, including adding contract extension options that all aim at a ***common horizon****, such that future procurement activity can benefit from full volume potential.*

The fact that pharmaceutical market conditions in Canada are about to change should encourage public payers to better align and organize their procurement capability, in parallel with their suppliers.

The end of the patent cliff (*11*) is arriving soon, characterized as the end of a several year period where, in addition to payer driven generic reimbursement reductions, the growth in total drug expenditure was optically stabilized by several significant mature major single source brands going generic and falling in price, sometimes nearly an order of magnitude, while a range of new high price biological products acquired market dominance.

With not many major blockbuster drugs anticipated to go generic or significant planned generic price reductions in Canada, and the impact of new drug costs not being offset, the market is expected to return to former growth rates.

This change in market growth potential makes finding and deploying effective and efficient pharmaceutical procurement particularly important, given the demographic trends in Canada already outlined.

Future innovation

It can be expected that the pharmaceutical industry will continue to create new treatments that will prolong and improve lives and cut costs elsewhere in healthcare.

The industry is always evolving, to create better, more differentiated, solutions, like all well managed industries. Specialist-initiated, *genomically* tailored, pharmaceuticals, will be developed to treat patent subsets of a particular disease.

This will create new niche markets segments, with high barriers to entry, for competitors and procurement functions.

In addition, more biological products, sometimes with dedicated diagnostics, with many patents, including on their specific manufacturing processes, are expected to replace traditional pharmaceuticals.

Awaiting generic alternatives may take a long time, if ever, to be possible.

A logical approach to the emergence of these more effective and individualized treatments is to ensure that the most public funds are available for them by minimizing budget expenditure on those lines that react to competitive bidding processes.

This approach could include multisource, generic lines and in groups of usually older brands and generics where therapeutic differences are slight, where therapeutic tendering, or at least reference pricing, are options to minimize expenditure.

In Germany, Jumbo Groups and now the AMNOG *(Arzneimittelmarktneuordnungsgesetz)* pricing process achieves this. (12) A benefit over exiting therapy has to be proven in order to maintain a premium price, otherwise a new brand moves to the class reference price.

In this way the pharmaceutical market can be treated more like other markets, where technical innovation warrants most value, and where older and less technically differentiated solutions attract cost saving procurement activity.

Selling pharmaceuticals to public buyers now and in the future

Like every other business, pharmaceutical companies have an absolute loyalty to their shareholders and have two overarching priorities, the first is to survive and the second is to make a profit. From the perspective of these basic business school axioms, the supply side of the pharmaceutical market is always focused on achieving their commitments, including competitive differentiation.

Manufacturers of branded pharmaceuticals achieve success on the basis of their creativity in finding, and taking to market, innovative pharmaceutical solutions and by effectively positioning them with clearly differentiated benefits.

Companies have also succeeded by effectively marketing less pharmacologically differentiated products.

The pharmaceutical industry, like other industries, uses both technical innovation and marketing creativity to capture share. This is the nature of the free market system.

In addition to being innovative in all aspects, pharmaceutical manufacturers are also highly aligned across their global market subsidiaries, seeking to achieve maximum efficiencies as well as to re-deploy the most successful marketing strategies across all markets.

This means that the manufacturers in this customer-supplier relationship are already highly organized to leverage their strengths and best practice in negotiations and bidding positions with Canadian customers, including individual jurisdictions or health authorities and agencies specializing in cancer and other chronic diseases, within such jurisdictions.

Commercial aptitude and the application of global best practice are hallmarks of the pharmaceutical industry, in all their interactions with public pharmaceutical purchasers. Hence a major opportunity exists for right sizing, and standardizing around successful practice, in Canadian public pharmaceutical procurement.

Canada is not generally considered an investment market by the pharmaceutical industry. Branded companies reported Canadian R&D expenditures of $894.8 million, 5 % of their sales, in 2012. This was a decrease of 9.8 % compared to previous year. (13)

In reality, Canada can be judged to be a *Cash Cow*, for the global pharmaceutical industry, in marketing segmentation terms, with high prices and profitability, relative to comparable markets, and relatively little pharmaceutical industry market investment.

Most significant pharmaceutical research functions have already been consolidated in other pharmaceutical markets, judged as investment opportunities for price or volume growth or to defend local market pricing in branded pharmaceutical manufacturing nations.

Not disturbing the climate for more research and development investment is often cited as an important consideration when building an effective pharmaceutical procurement plan. The high price of branded pharmaceuticals, relative to their manufacturing cost, supports the research and development of new products.

In markets with major pharmaceutical industry investments in manufacturing and research, the host governments, consider the dangers of dis-incentivizing such economic and high quality job action by restricting growth of or attempting to lower domestic prices.

Canada is no longer a major centre for the creation and development of new pharmaceuticals, at least in branded manufacturer research facilities.

Research and development of treatments are focused in major pharmaceutical manufacturing hubs, often in Europe and the United States.

Global efficiencies will continue to direct investment to these centres of excellence, in home manufacturing markets.

When seeking to classify the position of foreign branded manufacturers, in terms of their market entry strategy position, with respect to Canada, they mostly directly export to commercial subsidiaries here in Canada.

In practical terms that generally means warehouses and local marketing and sales teams, but not local manufacturing and research or global strategy development. The fractionated nature of the market in Canada, and the complexity of market access, all mitigate against full market entry, including manufacturing and research.

Generic (multi-source) pharmaceuticals, by definition, are commodity items and are therefore already capable of being purchased in a range of competitive bidding processes.

The Canadian generic market has major manufacturing capacity, and market share, in Canada (14). This sector is also a significant exporter.

Canada is in an atypical, disadvantageous market position without local branded manufacturing and R&D, but with the high prices normally associated with protecting them.

These facts lend weight to the argument that Canada should purchase pharmaceuticals in the most cost effect manner possible. That means Canada can move to an open competitive bidding process as a predominant purchasing strategy and away from other tools, including confidential PLA s and price setting based on, un-calibrated to market, percentages of manufacture list prices.

Uncertainty exists as to how a new national procurement process will impact the pharmaceutical industry (15). How, and by whom, pharmaceuticals will be purchased in Canada effects pharmaceutical industry organizational design.

Knowing if a full size salesforce calling on physicians with a supporting product management team or a key accounts and negotiating function that competes in national bidding processes, or both, are needed is an important business strategy and investment question.

Pharmaceutical company re-organizations and re-engineering activities, are currently not infrequent, in Canada, usually in the marketing and sales functions, potentially related to individual jurisdictional or pan-Canadian Pricing Alliance changes in product listing and reimbursement policy.

In the field, some of the pharmaceutical sales representative time with physicians is likely deployed in discussion about jurisdictional patient access to coverage issues.

This includes helping physicians to prepare patients to be able to request exceptional coverage on drug plans.

The highly fragmented nature of the Canadian pharmaceutical market must create a considerable requirement to build such argumentation for so many different geography-payer permutations.

A move towards a national approach, on the public payer side, will yield major efficiencies for the pharmaceutical industry in this respect.

An ideal solution could be single national new product launches, not staggered by jurisdictions, with a set prices and consistent market access for all patients, for defined indications. There has to be major efficiencies for both buyers and sellers in this model, which will manifest in reduced prices.

Pricing transparency is now becoming available in some major markets. It is desired in others, including by Canadian buyers.

Global branded manufacturers may have to justify an all Canadian or individual jurisdictional price based on their internal price benchmarks, which may include an inverse relationship between volume and price. The growth in demand for pricing transparency will accelerate this trend.

The size and consistent stability and predictability of an integrated Canadian market will therefore generate lower prices than smaller purchasing entities.

A larger predictable volume and greater global market share impact can also attract more suppliers and engage more senior corporate level management in bidding lower prices to capture or protect share.

Canada will become an important single market, resulting in wider industry focus and ultimately competitiveness.

Benefits of the current public drug procurement processes to public payers and suppliers

Per capita spend on pharmaceuticals, in Canada, is second highest in the world, after the USA. The per capita spend was Canada was $752 in 2011, compared to $375 in the United Kingdom and $298 in New Zealand (16). Both the comparators have national public pharmaceutical schemes, the latter with national pharmaceutical procurement functions for both community and hospital sectors.

It is also interesting that the United Kingdom, with twice the population of Canada, spends an equivalent total amount on pharmaceuticals as Canada.

The current fractioned nature of Canadian pharmaceutical procurement generates benefits for suppliers. Even the potential buyer benefit of a smaller unit being closer to the customer is not an advantage to buyers as disease etiology, treatment protocols, licensed products available, are mostly the same, across Canada and the world. Smaller than optimum sized procurement units have a loss of opportunity to apply scale and consistency in procurement.

In terms of benefits now from a pharmaceutical industry perspective, the current mix of at least fourteen purchasing entities, are a profitable customer base, even with the sales costs of managing bidding and negotiating in a high number of sub-markets.

Few of the individual jurisdictional markets can leverage sufficient volume, in competitive bidding processes or negotiations, to risk dramatic share lose for individual companies.

The comparatively high prices, paid in Canada for pharmaceuticals, testifies to this situation.

Consolidation of volumes, contracts, and the application of procurement methodology, in Canada, could be seen as a threat to pharmaceutical industry business growth, branded and generic.

There are, however, opportunities that market organization and consolidation can bring to the industry in terms of customer base clarity and consistency.

Knowing how much is needed, when and for how long, creates manufacturing efficiencies for suppliers.

Efficiencies created by national procurement can also help the industry in terms of scaling promotional expenditure. The cost of sales can be considerably less in a business process that is considerably less fractionated, with much less duplication of effort and unaligned decisions. New marketing and pricing strategies, as well as new products launches, have the potential to be introduced simultaneously across Canada, allowing multiple cost efficiencies and the ability to measure change on a scale that supports simultaneous inter market comparisons.

After the introduction of a unified procurement process, the Canadian pharmaceutical market will be able to be function with maximum efficiencies captured by both buyers and sellers.

What could a new unified public pharmaceutical procurement process look like?

A new unified public procurement process will apply a simpler and more standardized approach to buying pharmaceuticals for public payers, with the goal of achieving lower and sustainable prices.

In that simplicity of approach are some important components. They are all active tests in recommendation development and decision making relating to when to apply procurement tools and which ones to use in particular situations.

What are the components of an optimum pharmaceutical procurement program for Canadian jurisdictions, working together in a single model?

1. **Ability to maximize volume and share in a procurement process.**
2. **Ability to standardize or commoditize what is being procured.**
3. **Achieve the best price, recognizing the positive relationship between innovation and price.**
4. **Implementing a procurement solution with the greatest cost efficiency.**

1. Maximize Volume:

The first component is volume. Experience has demonstrated the relationship between size and relative size (market share) of bidding opportunity and the competitiveness of bidding. More senior pharmaceutical management will be involved in larger bidding processes, increasing the appreciation of risk of losing the business while also holding the authority to take more calculated bids. Small or regional procurement events spreads risk to bidders and negotiators, encouraging less risk taking and offers of lowest prices.

Supporting volume and market share, good contract compliance drives further competitive bidding. Unifying volumes, across Canada, generates a responsibility on the part of the procurer to at least maintain, if not improve, the level of contract compliance attained in the individual jurisdictional processes.

A manufacturer considering bidding in a range of sub national procurement events will usually have a range of expectations, based on experience, on each bidder's expected contract compliance performance. Taking a median view of such compliance behaviour is likely to temper assertive bidding while a large single event, with a pre-defined high level of contract compliance, stimulates lower price bids. From a manufacturer perspective, not having to reconcile different procurer's degree of compliance, is a significant efficiency.

It may also be strategically advantageous to wait until all jurisdictions have completed existing contracts on key lines and are able to fully participate in a single procurement process for a molecule or therapy class. All this makes the degree to which jurisdictional alignment on contract compliance can be attained and maintained, rate limiting to success in achieving significant savings.

A range of predominantly independent procurement functions will generate procurement processes with at least some significant variances of approach and methodology.

Time is taken by manufacturers to clarify variances and become familiar with new approaches. Since few jurisdictions will have such large volumes as to risk significant market share lose, experimentation in this almost test market situation, allows for significant industry learning on how to mitigate new procurement processes or ideas. Large volume, however, brings internationally noticeable share lost possibility and therefore less risky bidding, resulting in lower prices.

Regional procurement already results in more total procurement cost, without benefits in terms of volume and process driven procurement effectiveness.

Adding a partial national procurement process for some items uses considerable incremental capability from existing jurisdictional resources. Running parallel processes with existing resources is an opportunity for team building and best practice transfer in the short term, but is a challenge to maintain consistency, in the medium and long term.

Additional work is required to separate particular product lines from all existing jurisdictional and agency contracts, on-going negotiations and bidding processes. In addition, the liaison time and decision making processes will be considerable incremental work, particularly given the expected need to achieve consensus, across all participating entities, on all decisions. This observation is based on experience in procurement processes and decision making across multiple jurisdictions.

Having first achieved agreement on process, decision making becomes faster, even more consistent, and objective. It is a valuable expenditure of time to build consensus on process before dealing with live bid decision making. Removal or mitigation of unexpected exceptional issues, in advance, pays dividends.

Separate provincial, territorial and federal purchasing functions and processes create cost duplication and volume and process fragmentation for what could be an integrated process that captures all needs. This is a pragmatic assertion, born of prior successful experience in seeing parties across multiple jurisdictions in Canada appreciate the practical advantages of working together and resolving to overcome issues that prevent the creation and maintenance of a consistent united procurement process.

An approach to being able to maximize volume and contract compliance leverage, in Canada, must be able to exist and operate without conflicting with existing, changing, and future jurisdictional constructions. Plainly, medical indications and pharmaceutical products available for listing and reimbursement are not different across Canada.

Effective and efficient pan-Canadian pharmaceutical procurement needs a budget or an amalgamation of budgets, combined volume requirements, and decision ratification and oversight from participating jurisdictions. Procuring pharmaceuticals is a consistent but evolving business process with no political complexion. It is just best practice, applied to acquire the most value, as volume or price, from available healthcare budgets. Such an extra-political stance will encourage the development of a focus on optimizing procurement practicalities such as offering and achieving the highest consistency of compliance and deploying creative competitive bidding processes leveraging maximum collective volumes.

Quebec currently does not appear to formally engage with other jurisdictions in hospital or retail pharmaceutical procurement activity. Quebec uses best price provisions, however, to require price adjustments, based on better pricing found in other jurisdictions.

Adding the quarter of total Canadian pharmaceutical volume, consumed in Quebec to the total of other jurisdictions, will form the maximum leverage and generate the lowest prices for all jurisdictions. Separating the aggregation of pharmaceutical volume, for the purpose of most effective procurement, from any political or overtly jurisdictional administrative constructs is a potentially viable way of achieving this.

A separate, extra political, extra jurisdictional procurement entity, with the purpose only of leveraging maximum combined volumes will be an effective solution.

In such a model, deeply held cultural and political views can be held and prosecuted, with vigour, while in the background pharmaceutical procurement works the best way it can, with most volume, collective compliance, and other synergies all at work to generate the best value for available spend by all participating parties.

2. Commoditize what is being procured

The second component of a new procurement process would build the commodity or defined product definition nature of pharmaceuticals. Government sectioned bodies credibly review product safety and effectiveness, including cost effectiveness.

Once licensed, the presence of a DIN number for each pharmaceutical product entity effectively means that they can be treated as commodities from a procurement perspective.

There can be no acceptable variance in the pharmaceutical properties of the active ingredients. In the procurement of pharmaceuticals the requirements for each product, down to product form and strength, are clearly definable, and with the application of appropriate product quality prerequisites to bidding or negotiation, the risk of unsuccessful product contract performance is minimal. This allows price to be predominant in contract award criteria for all pharmaceuticals.

Pharmaceutical brands come in standardized formats across markets, with manufacturing now often in one global center, clinical data supporting common protocols, and increasing net price transparency diminishing the ability to pragmatically price in each market.

Identifying safe therapeutic effect per dollar, compared to other treatment options in a therapy class or category, is an approach to find best value for expenditure on branded lines.

Licensed generic products are differentiated on price, in each market. On product attributes, they are differentiated only by the extent of sub sets of patients who are intolerant to particular pharmaceutical excipients and in terms of logistics by the value of some supply chain strategies.

If a generic line obtains a license to be sold in Canada, price can be the procurement decision maker.

This situation is not the case for many other healthcare markets, where some products in some markets are less well defined or standardized and a risk exists of unsatisfactory performance. In those situations, two step processes, involving pre selection on quality, safety and past performance, followed by a price driven phase, can be used. Alternatively, a mix of technical and price criteria, as well as past performance, in a single procurement process, are required to determine awards.

Pharmaceutical procurement is comparatively simple, compared to other healthcare consumables, which means that more objective methodologies, including competitive bidding, can be used to identify true market bottoms and sustainable pricing, with less ancillary caveats or dependencies adding subjectivity to the process.

This also allows for faster procurement processes compared to situations where product composition is not identical and product feature differences have to be scored in a subjective weighting process and sometimes field tested.

The logical approach to the emergence even more effective and more individualized treatment is to ensure that most public funds are made available for those options by minimizing budget expenditure on those items that can be treated more as commodities. In this way the pharmaceutical market can be treated more like others, where innovation warrants value.

Fractionation of product safety and effectiveness approval and licensing processes will tend to help suppliers' segment markets and achieve higher prices. Effective and efficient pharmaceutical procurement utilizes the product efficacy, biological, financial, and safety assessments completed by Health Technology Assessment agencies. The Canadian Agency for Drugs and Technologies in Health completes both individual molecule assessments and also therapy class or category Therapy Reviews.

The *Institut national d'excellence en santé et en services sociaux* (INNESS) completes assessments for Quebec and the Joint Oncology Drug Review for oncology lines. Given that the most diseases and their treatments are becoming ubiquitous, encouraged by global marketing, there should continue to be a broad convergence of processes and principles in HTA, creating consistency of assessments, which helps procurement.

Cognizant of absolute and relative measures of safety and effectiveness provided by HTAs, with further specialist advice from pharmacists, the practice of procurement seeks to acquire the best value for expenditure, in any market, as it stands. The greater the degree of HTA convergence the greater the opportunity to deploy competitive bidding and other procurement activity, with the largest volume and greatest market share risk or opportunity, at play, soonest after a market event such a new product launch, that re shapes a therapy class or category, or a successful patent challenge.

3. Achieve the best price

The third component in a new unified pharmaceutical procurement model relates to the price and value of the items acquired. The challenge of achieving a multifaceted value based market appreciation, for a brand, instead of a simple comparative cost per effect appreciation, is a major recurrent challenge for pharmaceutical marketing.

Novel innovation in areas of unmet medical need will command a premium that respects the degree of therapeutic differentiation achieved.

Price and value connect, limited only by budget availability. In this situation, as long as budget exists, or savings will be evident in other parts of the current treatment process, procurement techniques will not appreciably constrain price.

For new products that enter well serviced markets, procurement techniques can activate competition, at the therapy class or molecule level. The implementation of professional procurement, particularly in the community market sector, will encourage therapeutically innovative product development.

Procurement could also discourage the development and launch of technically undifferentiated products.

In practical terms, this means that the subsequent launch of new brands, in a particular therapy class, may not as easily be able to command a marketing technique only driven premium or equivalent net price to the original innovator.

In sole source negotiations, product List prices need to be complemented with net prices for pharmaceutical procurement practice to be effective.

Canadian jurisdictions, to varying degrees, have completed confidential product net

pricing agreements, making internal Canadian and external market benchmarking difficult. Transparent pricing offers, in negotiations, will allow benchmarking of prices within markets and with other therapeutic options.

In Germany, the government has effectively introduced, into the public domain, the transparency of negotiated prices in their supply chain. If Germany's AMNOG 2012 pricing process has resulted in consistent net transparent pricing, this is a development that will provide valuable benchmarks for other markets. (17)

A strong aspiration in the EU Pharmaceutical Transparency Directive (18) is the provision of access to net pricing to encourage completion.

Open pricing creates more competitive opportunities, allowing competitive bidding to function at molecule and therapy class level accurately.

A volume based algorithm for Canada, based on the net German and other available net prices, for a particular single-source product, could be a very factual starting point to in a negotiation. Jumbo Group type reference pricing and therapeutic tendering are some alternative strategies to counter the need to agree to confidential pricing agreements. There is an opportunity for Canada to continue to work with other countries to foster open public pharmaceutical procurement.

Lowering drug costs, reducing procurement process duplication, leveraging the combined buying power of pharmaceutical purchasing jurisdictions, harmonizing of pricing and increasing access to treatment across Canada, are the current stated goals of the pan-Canadian Pricing Alliance. They echo the Premiers vision described in the *Emerging Themes* section of the Council of the Federation Working Group on Health Care Innovation, *First Report of the Health Care Innovation Working Group,* July 2012.

By deploying effective and efficient procurement practice, this can be achieved. Canadian jurisdictions, with no reason do so, pay significantly higher prices for pharmaceuticals than equivalent sized markets.

Coordination of pharmaceutical procurement, using the best techniques, can generate a $2B saving in public spending, in a timeframe determined by the rate of movement to a new model.

This target is a top level projection based on prior experience in aggregating volume, across jurisdictions, and applying an effective competitive bidding process, including making awards at the molecule and therapy class level. This saving is also dependent on the delivery of a combined jurisdiction commitment on compliance.

Given the existence of effective procurement at the jurisdictional level and a common realization that volume, singularity of process, and commitment to decisions drive the extent of competitive bidding and negotiating flexibility by manufactures, implementation of a significant cost reducing model should take three years. An assumption is that new products and existing pharmaceutical lines will be unified, expediently, and no existing jurisdictional agreements optionally renewed, but individual jurisdictions may have some pre-existing contractual obligations that need to expire before all available volume can be aligned.

Experience, in Canada, has also shown that just the existence of a plan to move to a new single procurement model will instantly change manufacturer behaviour, starting with the testing of the integrity of jurisdictional alignment, followed by deployment of a number of other individual company driven strategies, testing various parts of a new paradigm. This experience occurred, in parallel, in New Zealand's national procurement agency, Pharmac, in its early years. (19)

Once through this phase, manufacturers will benefit from clarity on volume requirements, stability of price for defined contract terms, less complicated and staggered market access.

As well, a general predictability of demand will bring them a secondary benefit of being able to achieve positive manufacturing variances, helping to avoid the significant problem of drug shortages.

4. Cost-efficient procurement processes

Achieving the most cost effective manner of procurement is the **fourth component** of a new unified model. Procurement efficacy relates to the public payer costs of obtaining lowest sustainable prices. This section considers the efficiency of the current pharmaceutical procurement systems in Canada.

Efficiency should be measured as the cost of resources deployed against the procurement process as a proportion of all procured product dollar volume and, ideally, the cost of resources deployed against the procurement process as a proportion of the net expenditure reduction achieved.

This latter measure would be an indication of return on capital employed. Such indices could be compared to other pharmaceutical procurement functions, abroad and in the private sector in Canada, subject to data availability. This paper does not provide such analysis, but suggests these potential indices of absolute and relative performance for further reference. Such metrics are potential key performance indicators for a new pan-Canadian pharmaceutical procurement process or function.

Disease etiology and treatment protocols are very similar if not identical across Canada, and, at least, the First World. Canadian national recommendations on treatment and comparative cost effectiveness in oncology are already being provided and unitized in individual jurisdictional and agency procurement decision making. With no inter jurisdictional variances in needs or available solutions, a single national procurement approach must be financially most efficient. Clearly it must also capture best practice and all particular requirements through a process of consensus building.

Duplication of efforts, by having multiple procurement functions and events, no matter how individually efficiently performed, loses the low price attainment benefits resultant from offering all possible volume in one procurement process as well as generating more procurement costs than would reasonably occur by deploying a single national procurement process.

A potentially useful benchmark to consider in looking at cost of procurement efficiencies is New Zealand's dedicated national pharmaceutical agency, Pharmac.

Pharmac currently has two roles, one controlling supply costs, using effective procurement methodology and latterly a responsibility to impact demand including by patient and physician education.

Pharmac, in the operating year 1998/9 had grown to a staff of 15 and procurement cost of $2.9 million US, for a managed volume of $312 million US, a percentage procurement cost of less than 1% (19). In the Pharmac Annual Report of 2013 (20) the procurement part of Pharmac's role, with headcount of 80, has a cost of $14.3 million US, on a contracted volume of $647.6 million US, a 2.2% procurement cost.

Some points of similarity and differentiation need consideration when comparing the New Zealand national pharmaceutical procurement cost experience with what may be the case in Canada.

Such a budget should cover community level procurement, as hospital pharmaceutical procurement is separate in Canada. Pharmac has incorporated hospital pharmaceutical and medical devices procurement from July 2013.

When considering the national procurement processes that would likely be deployed in Canada, they do not appear to be dissimilar to the negotiation, reference pricing and competitive bidding tools used in New Zealand.

In terms of human resources, in the supply management function, Pharmac currently has a pharmaceutical procurement management team segmented by therapeutic category. The pharmaceutical procurement process is supported by analytics, IT, legal, communications and medical functions. Total pharmaceutical procurement related headcount is about eighty.

Management by therapeutic category has the advantage of creating a focus on finding effective and cost efficient solutions at the indication level, and invites consideration of many potential procurement strategies, including German Jumbo Group type therapy class reference pricing and therapeutic tendering.

The New Zealand, or really any other of the other current national pharmaceutical procurement models, are not completely comparable or applicable in Canada. Healthcare budgets and responsibility to deliver services clearly reside with the provinces and territories in Canada. That needs to be accommodated in a new model.

Australia had a similar situation to Canada but relocated healthcare from a state to a shared federal and state responsibility, after World War II, with the federal government now proving funding for pharmaceuticals, in a national scheme (21).

Such a change is not evidently foreseeable event in Canada. This means that Canadian jurisdictions will retain responsibility for budget provision for healthcare and for obtaining maximum value for their expenditures.

Any new procurement process and organization, in Canada, setting out to purchase pharmaceuticals more effectively and efficiently, has to build on current jurisdictional responsibilities.

Each Canadian jurisdiction can provide volume requirements, allocate funds and make a commitment to comply with decisions jointly made, to an extra jurisdictional procurement body or process.

Adherence to the agreed business rules of such a process will determine the integrity of the model. This is why time spend on achieving the maximum degree of inter jurisdictional alignment and commitment to a relatively simple and consistently applied extra jurisdictional process is critical to achieving credibility with the supplier population. Underachieving against such expectations and commitments will confuse the marketplace, resulting in high national bids and the parallel provision of lower side bids to individual jurisdictions, in turn causing failure to achieve forecast savings and frustration on the part of all buyers and sellers.

In other words, launching an ineffective extra jurisdictional process or body is likely to be a retrograde step with respect to achieving sustainably lower prices.

Volume, defined product definition, price and cost efficiency are the key vectors down which a new procurement model will achieve the most sustainable savings.

Examples of how this unified approach has already worked in Canada

The specific ideas and emphasis described here were born of particular experience directing the purchasing of pharmaceuticals for a national Group Buying Organization, on behalf of major hospital groups across Canada. Prior to the development of an integrated approach, contracts with individual companies, both branded and generic, where negotiated and renewed in isolation from each other, reducing the potential for most competition, and incidentally not maximizing contracting workload efficiency.

A single national competitive bidding process replaced multiple individual contracting processes. As a result, an overall 13 % savings, on a wide array of both single and multisource pharmaceuticals, was achieved over the previous assortment of individual contracts.

In addition, much duplication of work was removed, improving also contract management consistency and allowing time for focus on new contracting opportunities. During this strategy development period, pharmaceuticals, under contract, grew from $128,000,000 to $480,000,000, yielding considerable savings for many hospitals across Canada.

Some critical success factors in achieving this bear consideration. The idea of switching to a fully leveraged procurement model was intuitively attractive. But being able to demonstrate to all participating members the viability, with calculated but acceptable risk, of placing a very large amount of business, in one contracting event, was key.

Most important, however, was working closely together with pharmacy leaders of the different member unit across Canada, to achieve unity of purpose and internal consensus.

On that bedrock of unity, the competitive bidding process worked to generate considerable savings, with the full participation of over eighty pharmaceuticals manufacturers in the bidding process.

Consideration of the drivers behind such a high level of industry participation is also instructive. Compliance is, without doubt, the strongest tool that a GPO or similar group, buying collectively, can use to gain concessions and process participation. This already existed, and had been consistently applied in prior, including complex, contracting activities. The industry recognized that significant opportunities and risks were at play.

Once a reputation for contract compliance is asserted, or evident, larger volumes, with visible share opportunity and risk, as well the quality of the procurement process, will amplify industry participation and attractive bidding.

How the unified process would work in Canada for new and existing, branded and generic pharmaceuticals

Tactical tools are available for pharmaceutical procurement as new products are introduced and eventually become generic. They consist of Sole Source Agreements including Product Listing Agreements, Tendering and Reference Pricing at therapy class and molecule levels, and other tools such a Reverse Auctions.

Pharmaceutical products all tend have a common life cycle, coming on to the market and achieving approval in a particular therapy area, as unique entitles, protected by a patent. They often join or are joined later by different molecules that are similar in action or achieve the same therapeutic objectives. Eventually their patents are challenged successfully and multiple manufactures can then produce them. Against each step of this journey, effective procurement techniques need to be applied.

For new branded pharmaceuticals in Canada, **Product Listing Agreements** tiered rebates and volume caps are commonly used to find financially acceptable and volume controllable solutions to mitigate the considerable potential risks of budget excess associated with listing significant or breakthrough new products, particular where patient advocacy is high. In this situation, the procurement tool in operation is often simply the degree of availability of budget, hence the use of volume caps, which make the contracted manufacturer responsible for paying for volume usage in excess of an agreed expenditure target. Usage rebates provided by manufacturers, against list prices, are also common. For innovative unique products, that bring important therapeutic advance, with no competitors with similar modes of action or similar therapeutic effects, budget availability and savings elsewhere in the health system determine the degree of public remuneration. The frequent lack of transparency of such agreements is a growing concern to those engaged in completing them, on the procurement side.

Conferential agreements inhibit the process of net price benchmarking, with Canada, and with other markets.

Germany, however, has halted the use of non-transparent agreements on pricing (17). This action, along with changes in other markets, will result in greater branded pharmaceutical pricing transparency.

A potential end point in this change will be open negotiated prices, in each market, for unique products. Price will need to be negotiated with variance from other markets driven by two factors. The first factor will be the amount of budget that public payers chose to make available for any new unique product(s) and the second a volume related price adjustment, based on international bench marketing.

Pharmaceutical manufacturers have a major collective concern that payers, particularly public payers, do not appreciate the value of their innovative unique new products in absolute terms. In reality, they may have that appreciation, but budget constraints will drive pragmatic negotiations, sometimes without a listing and reimbursement solution. Volume, the second driver, also matters, and larger markets agreeing to take larger volume could attract lower prices. This will assist a national Canadian process in obtaining lower net prices than individual Canadian jurisdictions negotiating separately.

In this process, price is determined by mutual agreement between buyer and seller, with list price almost irrelevant.

In the product life cycle journey, the emergence of similarity, in terms of mode of action or therapeutic effect, between single-source branded products creates an opportunity to deploy the next procurement tool.

Therapeutic Tendering:

One or more brands which cover equivalent forms and strengths of all brands in the same class, are selected for reimbursement.

Between the individual brands in the therapy classes, inter molecular or therapeutic differences are judged by experts to be slight enough to support price driven procurement.

One molecule in a therapy class or broader therapy category of products is selected, by a competitive bidding process, to be funded to provide a particular therapeutic effect.

This allows for some other exceptional use of other brands, with particular important additional indications or routes of administration not available by the class winner.

Another approach used to control expenditure, at a therapy class or category level, is **Reference Pricing**. A single price is set by the payer for the reimbursement of equivalent doses of all approved brands and generics within a class.

The reference pricing of a major gastrointestinal class, all proton pump inhibitors, brands and generics, for patients covered by the public plan in Quebec, provides a case on which to consider the relative attributes of therapeutic tendering and referencing pricing, for most cost effective sourcing, at the class level.

INNESS first determined, after expert consultation, that no significant therapeutic differences existed between the various PPI products. Then, from October 2013, a maximum payable price of $0.55 was applied to all branded and generic PPI s in Quebec. Patients, not provided fee coverage, have to pay the difference between the government payment and the actual cost of the PPI they used. The patient can pay the difference, if higher, or be switched to a lower priced PPI.

The branded pharmaceutical industry reaction was one of frustration and the ending of some sales promotion of certain PPI brands in Quebec. INNESS spoke of a $35M annual saving (22).

Therapeutic tendering, applied in this situation, may have resulted in different outcomes for all the stakeholders. What stays constant is the need for acceptance, by experts, of the minimal variances between the treatment options being considered for rationalization to a single main option.

Engaging all potential suppliers in a bidding process should generate viable offers on price in return for a volume commitment of exclusively of use, baring exceptional individual patient need.

The bids submitted will contain prices that suppliers are willing to receive for a guaranteed commitment. A contract will establish mutual responsibilities, on price and supply and indicate a date when the market can revisit the opportunity. Saskatchewan Health has shown that using a procurement process that includes competitive bidding has generated lower prices than that that achieved in larger jurisdictions using other procurement strategies (23).

Exceptional need to provide the alternative treatments can be supported.

The New Zealand Pharmac program, for both their schedule of community and cancer treatments, as well their new hospital list, of medicines, has a Named Patient Pharmaceutical Assessment process, including a Rapid Assessment process, to provide specific patients with access to treatments that are not on the public schedules, but which their physicians deem necessary.

In a public healthcare system, with growing need and constant budget pressure, the application of procurement processes effectively, for all pharmaceuticals, including single source brands, is necessary.

This paper recommends, wherever possible, the use of a competitive bidding process to make a choice that decreases cost. This allows both the buyer and all the potential sellers to participate in finding the solution.

The market works. The selection of a particular supplier, or a number of suppliers, gives them some return on price concessions, in terms of at least a minimum demand for a set time period. A reference pricing process has many advantages, but does not trade price for volume, find a true market bottom, or capture the responsibility of suppliers to maintain supply. In a new national procurement process both Therapeutic Tendering and Reference Pricing at the Therapy Class level will be available for deployment, subject to internal consensus and technical advice on each opportunity.

Next on the product life cycle journey is the point when a successful patent challenge to a single source brand is achieved.

At that point **Price Setting as a Percentage of List Price** techniques are often applied to public plans. This can happen when a number of generic alternatives are filed to synchronize with the known end of a brand patent life or when a single alternative manufacturer successfully challenges the original patent, perhaps on a technical flaw.

Through whatever strategy, the successful challenging of the patent creates new procurement opportunities. Unlike the branded pharmaceutical market sector, there is not a need to make expert determinations about product interchangeability.

Once approved, the generics of a particular brand form and strength are considered therapeutically identical, allowing pure price driven procurement.

The Transparent Drug System Act for Patients Act, Bill C-102, in Ontario, from 2006, contained a component which significantly impacted the pricing of generic pharmaceuticals. Instead of the relatively minor decreases from list price that occurred before Bill 102, on successful generic arrival, a 50% mandatory price decrease from list took effect. This policy was widely adopted and set a trend for further reductions in Ontario and most other jurisdictions, culminating in some generic prices currently as low as eighteen percent of list.

Canadian jurisdictions have been paying higher prices for generics than comparable markets. This is demonstrated by the fact that market failure has not occurred following the introduction of Bill 102 and its decedents, including significant further reductions introduced by the pan-Canadian Pricing Alliance. Setting an arbitrary price point is problematic in that the suppliers have no way of participating in the process unless by ceasing manufacturing or no longer wanting public business on any unprofitable lines.

Since current Price Setting as a Percentage of List Price levels has not caused a market failure, it could be read as an indication that they are still too high.

Generic prices, at an average of only 8% of list price in New Zealand's Pharmac program, were highlighted at the 2006 Canadian Pharmacare conference, in Vancouver, setting a much discussed benchmark (24). New Zealand had used tendering as part of their procurement mix (19) .

Price Setting as a Percentage of List Price, as a procurement technique, has the great benefits of simplicity, immediacy of action and easy adjustability. Like reference pricing, it may not, however, find the true market bottom, resulting in Canadian jurisdictions still paying too much. Neither will manufacturers achieve the security of demand for lower prices.

Competitive bidding, in a Tender Process, will find the market bottom and provide both payer and supplier with the benefits of a contractual relationship, including security of supply for patients.

Tendering processes have been frequently used in in pharmaceutical procurement for hospitals, with success. In the community sector, Saskatchewan Health deploys a tender process for defined high volume lines, in the community, where multiple manufactures are present. Saskatchewan has an extended record of achieving lower prices for pharmaceuticals, than other jurisdictions, using a range of procurement methods, including tendering.

A Request for Standing Offer is issued to solicit bids where the actual final demand is not known. Delivery is made, against firm prices, when demand occurs, during the contract period. The successful bidder wins exclusive business and users order product through agreed distribution channels, including direct supply from the winning manufacturer or through third partly logistic providers. It is possible to arrange to award business to more than one supplier in a Standing Offer Contract process, which can be a valuable option in certain market conditions.

Before the advent of Bill 102 in Ontario in 2006, Saskatchewan Health was issuing invitations to tender for wide range of molecules. Bill 102 set off a series of other jurisdictional generic price reductions, based on percentage of list price.

The Saskatchewan Standing Offer Contract program had already achieved prices comparable to those mandated when Saskatchewan generic prices were reduced to 35% of list. This Standing Offer Contract program used comparatively small volumes and had resistance from some manufacturers not wishing to trigger best price causes, particularly in Quebec.

Pure price based tender processes include **Reverse Auctions.** High volume product lines, with a number of potential suppliers, with capacity, can repeatedly bid within an on line tool, within a time deadline, to secure defined volumes. This is a fast, effective and efficient technique used in other commodity markets. Propriety bidding tools are available for a test market reverse auctions in Canadian public pharmaceutical procurement.

Competitive bidding processes and negotiations, because they engage of all concerned parties, can achieve win-win outcomes.

Price setting techniques may run the risk of leaving money behind, or encouraging supplier divestment or shortages.

Both price setting and competitive bidding sets of procurement techniques have their respective strengths and weaknesses.

Appreciation of the lay of the land within the buyer and supplier environments will direct selection of the most appropriate procurement techniques, but the natural first choice in any situation where interchangeability as an option is available, is a competitive bidding process.

Distribution channels:

Pharmaceutical distribution between manufacturers and pharmacies, in both the community and hospital channels, is achieved by direct delivery from manufacturers and indirect delivery via distributors, including cold chain and other specialty distributors.

These channels are very well established throughout Canada.

The deployment of therapeutic or generic tendering or other procurement strategies described will not alter the current patient experience with respect to obtaining their medicines from a retail pharmacist.

The public payer rather the than the individual pharmacist may dictate which generic manufacturer's product is dispensed, but it is the same active ingredient and the patient never made a choice of which generic previously.

There are significant differences between Canada and other markets with respect to the mix of distribution channels used, particularly when seeking to identify cost saving through effective and efficient pharmaceutical procurement.

Mail Order distribution, absent from Canada, may be able to provide additional savings by dispensing long term treatments.

For repeat prescriptions there will be a reduced human cost, particularly at the physical retail pharmacy level. In addition, a mail order delivery strategy will assist in allowing the lowest price bulk sourcing of high volume lines from a single supplier. This is a common distribution channel in the US market and is associated with savings on volume lines.

There will be a cost synergy in Canada between sourcing particular product lines from defined manufacturers, through competitive bidding processes, and then providing them to recurrent public paid users via an efficient mail order channel. This is a rigorous option, recommended by this paper. Live pharmacy contact is also recommended to manage treatment initiation and change.

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This walk down the pharmaceutical product life cycle illustrates that viable options are available, at each stage, to secure the very best value for public expenditure.

Preferences on procurement and distribution technique choice, where available, are also made and justified.

The techniques have worked before and are scalable to all Canadian community pharmacy volumes, in a unified procurement model.

What would be the benefits of a unified approach?

The benefits of a unified and integrated process to purchase pharmaceuticals collectively for Canadian jurisdictions are:

1. Total Canada volume demand leverages significantly lower prices than individual jurisdictions currently obtain

2. Canada, working together, will obtain prices comparable to similar sized markets in Europe

3. A single acquisition process will cost significantly less to run than the 14 existing functions

4. A single process will move faster than multiple units to acquire savings and affordability list new products

5. Effective procurement of older and generic products will leave more budget for innovative new products

6. A unified acquisition process will support more consistent access to new and existing treatments across Canada

These benefits are in line with the direction and aspiration provided by the Premiers in *Emerging Themes* section of the Council of the Federation Working Group on Health Care Innovation, *First Report of the Health Care Innovation Working Group,* July 2012, (1) and the stated objectives of the pan-Canadian Pricing Alliance.

What are some potential objections to a unified approach?

Small procurement is closer to the customer.

Disease etiology, treatment protocols, licensed products available, are mostly the same, across Canada and the world. Smaller than optimum sized procurement units lose the power of scale. They may be physically closer to the customer but in so being generate more expensive options.

Lack of political will to make it work.

The Premiers of our country started this process. It is a stated major priority given the recognition of demographic change and increasing demand for resources across all their responsibilities. It has also been supported by the Federal Minister of Health.

Too difficult to co-ordinate. Canada has extreme regional autonomy.

By using a separate independent procurement function that sits outside all current jurisdictions, involvement in maximum volume purchasing, by all pharmaceutical purchasing jurisdictions, can be done solely on the basis of commercial expediency. This solution engineers out complex political models, assumptions, and negotiations. It also continues to function through political change, as its only purpose is to leverage the most volume to get the lowest prices.

What you are suggesting is monopsony, with too much concentration of purchasing. Innovation would stop.

New process or entity will, at maximum, buy 43% (5) of the Canadian prescribed pharmaceutical market. The rest is provided by a number of private insurance companies. On a global scale this would still be a lower medium size market, exerting no pressure on pharmaceutical industry R&D investment decision making. Also, single national public pharmaceutical procurement functions already operate in most European counties, generating much lower prices than currently occur anywhere in Canada.

Great procurement expertize exists already in the jurisdictional procurement functions. This would all be lost.

Best practice captured will be applied in the context of more volume. The best procurement process, coupled with a maximum volume demand, causes suppliers to engage, at a senior management level, and offer better bids, if significant and internationally visible market share is at stake. There is an exciting opportunity to create synergy between exiting jurisdictional procurement processes and most volume.

Strategic threats to this new unified approach

There are some strategic threats that need consideration with respect to optimum pharmaceutical procurement for Canadian jurisdictions. They include the possible impact of international trade agreements on procurement process and the growing problem on drug shortages.

From the perspective of sourcing pharmaceuticals most cost effectively, international trade agreements can introduce risk of constraint on the types of procurement strategies that are able to be deployed, such as reference pricing, in each participating market.

This is currently a concern in New Zealand, with respect to the Trans Pacific Partnership Agreement and how it may impact Pharmac's ability to use all current procurement strategies (25).

Clearly, the impact that international trade agreements have on the possibilities for effective pharmaceutical decisions are a political judgment, at the highest levels, with multiple trade-offs in consideration.

In Canada, *The Comprehensive Economic and Trade Agreement*, between Canada and the European Union, once ratified, will extend branded pharmaceutical patent life, in some situations. That will delay patent challenges and generic alternatives. Potential upside, from a procurements effectiveness perspective, is that many generic manufacturers will be ready to compete when a branded pharmaceutical is successfully patent challenged in several markets, within a narrow time frame.

The comparatively higher spending on pharmaceuticals, in Canada, compared to other equivalent markets, suggests that a potential saving of at least $2B in total spend on publicly purchased pharmaceuticals should be actualized and protected. Jurisdictions with spending responsibility for pharmaceuticals need to be very vigilant with respect to the potential impact of international trade agreements on pharmaceutical procurement capability. Two years extra patent life on some molecules is completely insignificant, in terms of cost impact, to losing the ability to deploy a full range of procurement tools in the Canadian pharmaceutical market. TPPA and CETA, from a pharmaceutical procurement perspective, are an opportunity and a risk that need continuing active management.

Drug shortages have become an increasingly common problem. In the United Stated, the FDA issued a Strategic Plan for Preventing and Mitigating Drug Shortages (26). Based on 2012 manufacturing problems, quality problems, discontinuations, component shortages, and increased demand were the major reasons behind shortages.

For patients affected by drug shortages, the risks are obvious.

Mitigating the consequences of drug shortages are, perhaps, from the allocation of time perspective, the antithesis of the Pharmaceutical Care Model.

From the procurement perspective, drug shortages cause considerable work in sourcing nominated alternatives and managing the considerable additional administrative workload, including calculating penalties applied to contracted suppliers and communicating details of expediently made changes. For public payers, drug shortages may also result in additional cost, elsewhere in the healthcare system, for a number of reasons.

A primary question to ask, when confronted with an actual or potential drug shortage, is the reason why. Is it a weakness in the procurement model that only works if all components in the process work effectively in series, with no shortage mitigation parallel tracks? Is it a market failure, where the contracted original manufacturer ceases

manufacturing of a particular line, and no alternative manufacturer is available or interested in that business? Is there a third party related reason, such as a global Active Pharmaceutical Ingredient shortage?

Whatever the reason, a vital component of a new procurement model is its ability to prevent and manage drug shortages, with accent on prevention

Relying on a single contracted supplier, without safeguards to mitigate out of stocks, for whatever reason, is sub optimal, and a risk to patients.

First set a defined order fill rate, as per the U.S. Veterans Affairs procurement process. They require contacted suppliers to deliver a 97 per cent delivery rate against orders, minus Manufacturer Back Orders, some of which will out of the control of the contracted manufacturer.

Then have a pre agreed Plan B for shortages, if possible, with a pre nominated viable secondary supplier. This will save time in individual pharmacies sourcing alternative supplies. The secondary suppliers may keep the business for the remaining contract term if predefined remedies are not achieved. A switch to a predefined alternative medicine, with adequate stock availability, is another strategy to alleviate a drug shortage.

The fine details of the mechanics of managing drug shortages are less important than having a plan in place. That plan can evolve to handle all the reasons identified.

In the case of a short term shortage emergency, sole sourcing an alternative supplier, without deploying a full competitive bidding process, is an appropriate approach. The key decision point is that a fair and equitable competitive bidding process will have failed, including any back up. Patient demand must drive expediency, given that life and death risks may be at hand. Once supply is stabilized, appropriate reversion to the normal procurement process can be followed.

Important extended or recurrent drug shortages, market contraction in numbers of viable suppliers or periodic or total absence of particular generic lines prompt the need to identify and implement longer term strategies to redress these problems.

With shortages of generic pharmaceutical lines increasing in the US, to 250 lines in 2012 and no manufacturer-driven solutions efferent, creative solutions may be needed. Given the global spillover effects of shortages, Canadian public payers may find it expedient to create an actual or contract pharma-ceutical manufacturing capability, if not, a direct sourcing capability to obtain consistent adequate supplies of, at least, critical older generic lines such as 5-fluorouracil and succinylcholine, or any generic line which has suffered from repeated shortages.

Direct or contract manufacturing, in the absence of a market supporting sole sourcing or a competitive bidding process, is not ideal, but a viable and necessary option, when an open market is not working. Such potential action, alone, may encourage existing and potential suppliers into re prioritizing decisions about finding alternative capacity during manufacturing improvements or discontinuing products in the absence of alternatives.

Either way, a means must exist, in a national pharmaceutical procurement plan, to supply critical pharmaceuticals lines for particular patient needs. The spectrum of sourcing action is competitive bidding processes where possible, sole sourcing as necessary, and contract manufacturing as an expediency.

About the Author

John Moynihan, founder and president of Collective Canada, is a passionate pharmaceutical industry professional with extensive experience negotiating with major healthcare manufacturers and government representatives, known for actively pursuing "win-win" conclusions among all stakeholders.

John's thirty-five years of industry experience, both in Europe and North America, has given him an international perspective on the procurement of pharmaceuticals for public payers, marketing management for new and established brands, and sales management techniques.

A creative problem solver known for his persistence, self-direction, and successful implementations, John believes that the best results can be achieved through process improvement and negotiation.

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References

1. From Innovation to Action: The First Report of the Health Care Innovation Working Group. s.l. : Council of the Federation , 2012. p. 20.

2. National Health Expenditure Trends, 1975 to 2013. CIHI. s.l. : Canadian Institute for Health Information, 2013. p. 3.

3. National Health Expenditure Trends, 1975 to 2013. CIHI. s.l. : Canadian Institute for Health Information, 2013. p. 10.

4. National Health Expenditure Trends, 1975 to 2013. CIHI. s.l. : Canadian Institute for Health Information, 2013. p. 22.

5. National Health Expenditure Trends, 1975 to 2013. CIHI. s.l. : Canadian Institute for Health Information, 2013. p. 29.

6. National Health Expenditure Trends, 1975 to 2013. CIHI. s.l. : Canadian Institute for Health Information, 2013. p. 5.

7. National Health Expenditure Trends, 1975 to 2013. CIHI. s.l. : Canadian Institute for Health Information, 2013. p. 55.

8. Provincial and Territorial Health and Wellness Ministers Focus on Quality and Prevention for Patients and Their Families. s.l. : Ontario Ministry of Health and Long-Term Care, Oct 3 2013.

9. National Health Expenditure Trends, 1975 to 2013. CIHI. s.l. : Canadian Institute for Health Information, 2013. p. 44.

10. Expenditure Estimates of the Province of Ontario for the fiscal year ending March 31, 2014. s.l. : Ministry of Finance, 2013-14.

11. C. Harrison. s.l. : Nature Reviews Drug Discovery, 2013, pp. 12, 14-15.

12. AMNOG - evaluation of new pharmaceutical, GKV Spitzenverband. 2013.

13. Annual Report 2012 Analysis of Research and Development Expenditures. s.l. : Patented Medicine Prices Review Board, 2012.

14. The Role of the Generic Pharmaceutical Industry . s.l. : Canadian Generic Pharmaceutical Association , 2013.

15. Canada: Developing A Framework For Pan-Canadian Drug Pricing Negotiations. Adrienne M. Blanchard, Bill Dempster,Johanne Chambers. s.l. : Norton Rose Fulbright, 2013.

16. National Health Expenditure Trends, 1975 to 2013. CIHI. s.l. : Canadian Institute for Health Information, 2013. p. 78.

17. Payer's Delight: European Drug Prices Could Spiral Downward Thanks To Germany. Senior, Melanie. s.l. : Real Endpoints Health Technology Assessments,Product Contracting , 2012.

18. European Commission. Transparency Directive 89/105/EEC. s.l. : EU, Enterprise and Industry, 2012.

19. Managing Pharmaceutical Expenditure while Increasing Access: The Pharmac Experience. Richard Braae, Wayne McNee, David Moore. s.l. : Pharmacoeconomics, 1999, Dec, Vol. 16 (6).

20. Pharmaceutical Management Agency Annual Report. s.l. : Pharmac, 2013.

21. Griffith, Gareth. Briefing Paper No 17/06 Commonwealth-State Responsibilities for Health – 'Big Bang' or Incremental Reform? s.l. : NSW PARLIAMENTARY LIBRARY RESEARCH SERVICE , 2006.

22. Québec, Régie de l'assurance maladie du. A maximum price payable by insured persons is set Proton-pump inhibitor (PPI) class drugs. [Online] 2013.

23. Annual Report of the Provincial Auditor of Ontario. 2001. p. 192.

24. Toward a National Pharmaceuticals Strategy. Vancouver : s.n., 2006.

25. The Neutering Of Pharmac – Trans Pacific Partnership. Campbell, Gordon. s.l. : Werewolf, Vols. December 16, 2013 | ISSUE 45.

26. Strategic Plan for Preventing and Mitigating Drug Shortages. s.l. : Food and Drug Administration October 2013 .