

## The Current Canadian Vaccine Environment

### Le contexte actuel de la vaccination au Canada

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Ce document forme une partie de la série, *Les vaccins au Canada, un héritage à faire fructifier : Valeur, possibilités et défis*. Pour lire la série entière, veuillez visiter [www.biotech.ca/vaccines](http://www.biotech.ca/vaccines). (Document disponible en anglais seulement.)

## 2.1 Executive Summary / Sommaire

### 2.1.1 Executive Summary

Vaccines are used extensively around the world as one of the most useful and cost-effective tools for reducing morbidity and mortality associated with infectious diseases. Currently, the vaccine sector represents an increasingly attractive market worldwide, characterized by strong growth prospects and increased research and development (R&D) activity. Several recent corporate deals, including Pfizer's acquisition of Wyeth, also testify to the renewed interest in vaccines by traditional "big pharma" players.

Valued at approximately \$US 16.3 billion in 2007, the global vaccine market is projected to increase at an annual rate of roughly 13-14 percent over the next several years – more than twice as rapidly as for traditional pharmaceuticals – and is expected to exceed \$US 30 billion by 2013. While precise estimates vary, the global vaccine market has traditionally accounted for only a small portion of the global pharmaceutical market, currently representing approximately 2 percent of the overall pharmaceutical business. In Canada, annual vaccine sales are estimated at roughly \$Cdn 450 million. Recent data from the Canadian Institute for Health Information (CIHI) regarding Canada's total health care spending helps put vaccine spending into appropriate perspective; vaccine spending represents a small percentage (4.0%) of Canadian public health expenses, and an extremely small fraction (<0.3%) of national health care expenditures in 2008.

Although vaccine spending represents only a tiny segment of Canadian health care expenses, vaccination programs are widely acknowledged as among the best investments in health, providing immense medical and economic benefits. However, vaccines continue to be (mistakenly) undervalued and underutilized in Canada, as in many other industrialized countries. Hence substantial work lies ahead to ensure that vaccines are adequately recognized and promoted in terms of providing excellent value for money spent.

In most developed countries, including Canada, successful incorporation of a new vaccine into a national immunization program requires addressing a broad set of issues, encompassing the following initiatives:

- establishing medical need, and demonstrating safety and efficacy (or immunogenicity) in clinical trials;
- obtaining marketing authorization (regulatory approval) for commercial launch;
- development of national recommendations for optimal use;
- securing funding to support vaccine program delivery; and
- providing necessary infrastructure for vaccine program implementation, via:
  - ensuring adequate vaccine supply and distribution capacity;
  - assuring education of (and acceptance by) the public and medical community;
  - establishing an appropriate infrastructure for vaccine distribution and delivery; and
  - monitoring vaccine use, safety and effectiveness through post-market studies.

Hence the process for introducing new vaccines is complex, and entails a series of actions involving multiple stakeholders and participants. As outlined below, key players in the Canadian vaccine enterprise include vaccine companies; the research community; the investment community and funding agencies; government agencies and regulatory authorities; national/provincial advisory bodies; public health officials; medical societies; health care professionals; public and private payers; and the general public.

As of early 2009, the Canadian vaccine landscape mirrors the highly concentrated structure of the global vaccine marketplace, with the "top tier" vaccine companies currently including GlaxoSmithKline Canada, Merck Frosst Canada Ltd., Novartis, sanofi pasteur, and Wyeth Pharmaceuticals Canada. Other industry

players in Canada include Solvay Pharma Inc., as well as the smaller vaccine developers Medicago, ImmunoVaccine Technologies Inc., and Variation Biotechnologies Inc., among others. The vaccine research community encompasses the discovery and clinical research departments of the lead industry players, as well as a broad array of players engaged in early-stage vaccine R&D at academic, hospital, and government laboratories and research institutions. Funded by a diverse group of major grant agencies, as well as private and public investors, Canada's vaccine industry players make a significant contribution to the national economy, in terms of both job creation and investment in R&D. Hence the vaccine sector should be actively promoted and fostered by stakeholders across all levels of the research community, the business/investment community, and government.

In Canada, the lead industry association is the Vaccine Industry Committee (VIC) of BIOTECanada, which is comprised of Canada's major vaccine developers and suppliers. The VIC aims to increase awareness regarding the value of vaccines, while advocating for a more efficient, favourable vaccine environment – supported by consistent and sustained funding of immunization programs in Canada. Thus VIC members actively engage with federal, provincial and territorial (F/P/T) governments to foster full access and availability of all existing and new vaccines for Canadians. The committee also promotes high-quality vaccine research and excellence in the development, manufacturing and distribution of vaccines.

Canadian industry players (as well as other stakeholders in the vaccine sector) operate within the infrastructure and policy environment created by several federal and provincial government bodies. At the broadest level, the two key federal agencies that regulate the vaccine industry include Health Canada as the federal regulatory authority (through its Biologics and Genetic Therapies Directorate, BGTD), and the Public Health Agency of Canada (PHAC), which acts as the lead body in overseeing immunization evaluation and recommendation processes. Within the existing PHAC structure, the key expert groups that guide immunization procedures are the National Advisory Committee on Immunization (NACI) and the Canadian Immunization Committee (CIC). Although official vaccine recommendations are made at the national level, decisions regarding the integration of new vaccines into publicly-funded immunization programs are primarily a provincial/territorial responsibility. Thus Provincial/Territorial Immunization Committees also play a fundamental role in introducing new vaccines in Canada. It should be noted that, to date, federal government roles have also included financing of vaccine programs, administration of bulk purchasing programs, and overseeing Canada's national vaccine surveillance systems.

In addition to the critical steps of vaccine licensure, establishing national recommendations, identifying adequate funding programs, and ensuring vaccine safety, the successful incorporation of a new vaccine into a national vaccination program also requires education of (and acceptance by) the public and medical community. Thus, a comprehensive and coordinated education program that targets physicians, pharmacists, nurses and the public is required to ensure smooth implementation of an immunization program. In this context, key players within Canada's immunization system also include medical/professional societies, consumer/patient advocacy groups, and other related associations.

A comprehensive plan for introducing new vaccines must also establish and maintain an appropriate infrastructure for vaccine distribution and delivery. In general, vaccines are delivered in Canada through multiple distribution channels, including public health clinics, physician-based practices, pharmacy-based clinics and travel clinics. Key vaccinators in Canada include physicians, pharmacists, and nurses, all of whom play a vital role in providing medical information, counseling and immunization to vaccine recipients. Target vaccine recipients (or vaccinees) encompass many segments of the general public, including infants, adolescents, adults/seniors, and other high-risk or special populations, such as international travelers, employees exposed to occupational hazards, and police/military personnel.

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In general, the vaccine marketplace has a number of unique characteristics that require carefully designed policy strategies, i.e. to ensure longer-term stability and viability of the overall system of product development, introduction and supply. Canada's current vaccine system needs significant improvement to protect the tremendous value and potential public health impact of both current and emerging vaccine technologies. Hence the following recommendations are put forward by BIOTECanada's VIC for consideration by F/P/T governments and other key stakeholders. While these general recommendations are intended to support broad policy objectives for improving the effectiveness of immunization programs in Canada, specific recommendations that address individual components of Canada's vaccine system are presented independently in subsequent papers, as indicated.

#### Federal/Provincial/Territorial Recommendations:

1. In formulating appropriate immunization policy, government officials and decision-makers at all F/P/T levels must recognize the unique (and potentially fragile) nature of Canada's vaccine industry, thus promoting and safeguarding the Canadian vaccine system from a business perspective.
2. In creating policies that impact the Canadian immunization system, government officials must acknowledge and defend the true value of vaccines as an important and cost-effective public health measure, while ensuring that all relevant strategies reflect the full medical, social and economic benefits of immunization (Paper 1).
3. Policy approaches to developing an efficient vaccine marketplace should encourage long-term investment in R&D in the vaccine sector (Papers 3 & 7). These initiatives should assist in: driving future innovation in the development of life-saving (preventive) and therapeutic vaccines; preventing manufacturers from exiting the vaccine market; and ensuring continued vaccine supply.
4. Policy strategies to enhance the operation of the vaccine market should include harmonization of regulatory practices and removal of procedural barriers to the rapid adoption of new immunization programs. These strategies should include the development of less duplicative and more consistent evaluation/recommendation procedures – as well as predictable, sustained funding mechanisms – to support timely patient access to existing and breakthrough vaccine technologies (Papers 4, 5 & 6).
5. Policy approaches designed to maintain and improve immunization coverage rates as the primary public health benefit should also ensure adequate resources are in place for effective vaccine program awareness/education and implementation, including appropriate infrastructure for vaccine distribution and delivery across the country. In addition, adequate resources should be deployed to effectively monitor vaccine use, including safety and efficacy, through enhanced surveillance programs (Papers 8 & 9).

#### Stakeholder Recommendations:

6. To help ensure vaccines remain one of the most important and cost-effective public health measures in Canada, stakeholders at all levels should work in collaborative partnership, not only to improve the effectiveness of immunization programs, but also to communicate the value of the effective immunization program to all Canadians.
7. In the context of protecting and improving the current Canadian vaccine enterprise, all relevant stakeholders should continue to engage in the discussion of common critical issues in immunization practice on the international stage. Canadian stakeholders should continue to seek best practices models that match those of the top immunization programs worldwide, i.e. with the goal of achieving optimal clinical outcomes and economic value through greater standardization and predictability within Canada's immunization system.

### 2.1.2 Sommaire

Très répandue dans le monde entier, la vaccination est l'un des moyens les plus utiles et les plus rentables de réduire la morbidité et la mortalité associées aux maladies infectieuses. Actuellement, les vaccins représentent un marché de plus en plus attrayant à l'échelle mondiale, caractérisé par de fortes possibilités de croissance et une activité accrue en recherche et développement (R et D). Plusieurs transactions conclues récemment entre sociétés, dont l'acquisition de Wyeth par Pfizer, témoignent également de l'intérêt renouvelé des « grosses compagnies pharmaceutiques » traditionnelles à l'égard des vaccins.

On prévoit que le marché mondial des vaccins, dont la valeur a été estimée en 2007 à près de 16,3 milliards de dollars américains, augmentera à un taux annuel de 13 à 14 pour cent au cours des prochaines années – une croissance plus de deux fois plus rapide que l'industrie traditionnelle des produits pharmaceutiques –, dépassant les 30 milliards de dollars américains d'ici 2013. Bien que les estimations précises varient, le marché mondial des vaccins n'a toujours constitué qu'une faible proportion du marché mondial des produits pharmaceutiques, soit environ deux pour cent actuellement du marché pharmaceutique global. Au Canada, on estime à près de 450 millions de dollars le chiffre annuel du marché des vaccins. Des données récentes de l'Institut canadien d'information sur la santé (ICIS) sur les dépenses totales de santé au Canada nous aident à replacer les dépenses en vaccins dans un contexte approprié; les dépenses en vaccins représentent une faible proportion (4,0 pour cent) des dépenses en santé publique au Canada et une proportion extrêmement faible (<0,3 pour cent) des dépenses nationales en soins de santé en 2008.

Bien que les dépenses en vaccins ne représentent qu'une infime partie des dépenses en soins de santé au Canada, les programmes de vaccination sont largement reconnus parmi les meilleurs investissements dans la santé, procurant d'immenses avantages sur le plan médical et économique. Cependant, les vaccins sont encore (à tort) sous-évalués et sous-utilisés au Canada, comme dans beaucoup d'autres pays industrialisés. Il reste donc beaucoup de travail à faire pour reconnaître et promouvoir comme il se doit l'excellent rapport qualité-prix des vaccins.

Dans la plupart des pays développés, y compris le Canada, l'intégration efficace d'un nouveau vaccin à un programme national d'immunisation nécessite qu'on réponde à un vaste ensemble de questions, dont les suivantes :

- Établir l'existence d'un besoin en matière de santé et démontrer l'innocuité et l'efficacité du produit (ou son immunogénicité) dans le cadre d'essais cliniques;
- Obtenir l'autorisation de commercialiser le produit (approbation réglementaire) aux fins de lancement commercial;
- Formuler des recommandations nationales en faveur de l'utilisation optimale du produit;
- Obtenir une aide financière contribuant à la prestation du programme de vaccination;
- Prévoir l'infrastructure nécessaire à la mise en œuvre du programme de vaccination, de la manière suivante :
  - Assurer une capacité suffisante d'approvisionnement en vaccins et de distribution;
  - Voir à informer le public et le milieu de la santé (et à obtenir leur acceptation);
  - Établir une infrastructure adéquate de distribution et d'administration des vaccins;
  - Surveiller l'utilisation, l'innocuité et l'efficacité des vaccins dans le cadre d'études de pharmacovigilance.

L'introduction de nouveaux vaccins est donc un processus complexe, qui nécessite une série de mesures auxquelles doivent participer de multiples intervenants. Comme il est mentionné ci-contre, parmi les principaux intervenants de l'industrie canadienne des vaccins, on compte les fabricants de vaccins, les chercheurs, les investisseurs et les organismes de financement, les organismes gouvernementaux et les organismes de réglementation, les organismes consultatifs nationaux et provinciaux, les responsables de la santé publique, les associations médicales, les professionnels de la santé, les payeurs publics et privés, et le grand public.

En ce début de 2009, l'industrie canadienne des vaccins est le reflet de la structure hautement concentrée du marché mondial des vaccins, comptant parmi ses principaux fabricants GlaxoSmithKline Canada, Merck Frosst Canada Ltée, Novartis, Sanofi Pasteur et Wyeth Pharmaceuticals Canada. Parmi les entreprises de plus petite envergure spécialisées dans le développement de vaccins et également intervenantes de l'industrie canadienne, nous retrouvons la société Solvay Pharma Inc., ImmunoVaccine Technologies Inc., Medicago et Variation Biotechnologies Inc., entre autres. . Le milieu de la recherche sur les vaccins englobe les divisions des principaux intervenants de l'industrie consacrées aux découvertes et aux recherches cliniques, ainsi qu'un vaste éventail d'intervenants participant aux travaux préliminaires de recherche et de développement de vaccins dans les laboratoires universitaires, hospitaliers et gouvernementaux, et les établissements de recherche. Financés par un groupe diversifié composé d'importants organismes subventionnaires et par des investisseurs privés et publics, les intervenants de l'industrie canadienne des vaccins apportent une contribution considérable à l'économie nationale, tant sur le plan de la création d'emplois que de l'investissement dans la R et D. L'industrie des vaccins doit donc faire l'objet d'une promotion active de la part des différents intervenants du milieu de la recherche, du secteur des affaires et des investissements, et du gouvernement.

Au Canada, le principal intervenant de l'industrie est le Comité de l'industrie des vaccins (CIV) de BIOTECanada, qui réunit les principaux développeurs et fournisseurs de vaccins du Canada. Le CIV contribue activement à sensibiliser les intervenants à l'importance des vaccins, tout en faisant la promotion d'un contexte plus favorable aux vaccins – soutenu par un financement uniforme et durable des programmes d'immunisation au Canada. Ainsi, les membres du CIV contribuent activement aux travaux des gouvernements fédéral, provinciaux et territoriaux visant à faciliter l'accès de tous les citoyens canadiens aux vaccins actuels et nouveaux, et en favoriser la disponibilité. Le CIV vise également à promouvoir la recherche de vaccins de qualité et l'excellence dans le développement, la fabrication et la distribution des vaccins.

Les intervenants de l'industrie canadienne (et les autres intervenants de l'industrie des vaccins) évoluent au sein de l'infrastructure et de l'environnement politique établis par divers organismes gouvernementaux fédéraux et provinciaux. À l'échelle plus générale, les deux principaux organismes fédéraux qui réglementent l'industrie des vaccins sont Santé Canada, qui agit par l'entremise de sa Direction des produits biologiques et des thérapies génétiques (DPBTG), et l'Agence de la santé publique du Canada (ASPC), principal organisme de surveillance des processus d'évaluation et de recommandation des vaccins. Selon la structure actuelle de l'ASPC, les principaux groupes d'experts chargés d'orienter l'élaboration des procédures d'immunisation sont le Comité consultatif national de l'immunisation (CCNI) et le Comité canadien d'immunisation (CCI). Bien que les recommandations officielles en matière de vaccins soient formulées à l'échelle nationale, les décisions concernant l'intégration de nouveaux vaccins à des programmes publics d'immunisation relèvent principalement des gouvernements provinciaux et territoriaux. Les comités provinciaux et territoriaux d'immunisation jouent donc aussi un rôle fondamental dans l'introduction de nouveaux vaccins au Canada. Il convient de

souligner qu'à ce jour, le gouvernement fédéral a également contribué au financement des programmes de vaccination, à l'administration des programmes d'achat en vrac et à la supervision des systèmes nationaux de surveillance des vaccins.

Outre les étapes importantes de l'homologation des vaccins – formuler des recommandations nationales, trouver des programmes de financement adéquats et assurer l'innocuité des vaccins – il faut également informer le public et le milieu de la santé (et obtenir leur acceptation) pour qu'un nouveau vaccin soit intégré avec succès à un programme national de vaccination. Un programme complet et coordonné d'information des médecins, des pharmaciens, du personnel infirmier et du public doit ainsi être mis en place pour faciliter la mise en œuvre d'un programme d'immunisation. Dans ce contexte, il convient d'inclure parmi les principaux intervenants du système d'immunisation au Canada les associations médicales et professionnelles, les groupes de défense des droits des consommateurs et des patients, et autres associations connexes.

Un plan complet de mise en marché de nouveaux vaccins doit également prévoir et maintenir une infrastructure adéquate de distribution et d'administration des vaccins. En général, les vaccins sont administrés au Canada par l'entremise de multiples réseaux de distribution, dont des cliniques de santé publique, des cabinets médicaux, des pharmacies et des cliniques santé-voyage. Au Canada, ils sont administrés principalement par les médecins, les pharmaciens et le personnel infirmier, ceux-ci jouant tous un rôle primordial dans la prestation de renseignements médicaux, de conseils et de services d'immunisation aux sujets vaccinés. Parmi les vaccinés ciblés, on compte de nombreux segments de la population, dont les enfants en bas âge, les adolescents, les adultes et les personnes âgées, ainsi que d'autres groupes particuliers ou à risque élevé, comme les voyageurs internationaux, les employés exposés à des risques professionnels, et le personnel policier et militaire.

En général, étant donné qu'il possède certaines caractéristiques qui lui sont propres, le marché des vaccins nécessite des stratégies politiques élaborées avec soin, visant notamment à assurer la stabilité et la viabilité à long terme du système global de développement, d'introduction et d'approvisionnement des vaccins. Des améliorations importantes doivent être apportées au système de vaccination en vigueur au Canada afin de protéger la valeur exceptionnelle des technologies vaccinales actuelles et nouvelles, et leurs répercussions possibles sur la santé publique. Le CIV a donc formulé les recommandations suivantes à l'intention des gouvernements fédéral, provinciaux et territoriaux, et d'autres intervenants clés. Alors que ces recommandations générales sont destinées à appuyer l'adoption d'objectifs généraux en matière de politiques afin d'améliorer l'efficacité des programmes d'immunisation au Canada, des recommandations particulières visant chacun des éléments du système canadien de vaccination sont présentées à part dans des documents subséquents cités ci-contre.

Recommandations à l'intention des gouvernements fédéral, provinciaux et territoriaux :

1. Afin d'élaborer des politiques d'immunisation adéquates, les responsables gouvernementaux et décideurs de tous les paliers FPT doivent reconnaître le caractère unique (et potentiellement fragile) de l'industrie des vaccins au Canada, et ainsi promouvoir et protéger le système canadien de vaccination d'un point de vue commercial.
2. Lorsqu'ils créent des politiques ayant une incidence sur le système d'immunisation au Canada, les responsables gouvernementaux doivent reconnaître et défendre la valeur des vaccins, intervention importante et rentable en matière de santé publique, tout en veillant à ce que toutes les stratégies

connexes reflètent l'ensemble des avantages médicaux, sociaux et économiques de l'immunisation (voir le document 1).

3. Les initiatives stratégiques visant à développer un marché des vaccins efficace doivent encourager les investissements à long terme dans les activités de R et D de l'industrie des vaccins (voir le document 3). Elles doivent contribuer à promouvoir l'innovation future dans le développement de vaccins préventifs et thérapeutiques d'importance vitale, à empêcher les fabricants de se retirer du marché des vaccins et à garantir un approvisionnement continu en vaccins.
4. Les stratégies politiques visant à améliorer le fonctionnement du marché des vaccins doivent prévoir l'harmonisation des méthodes de réglementation et la suppression des barrières administratives à l'adoption rapide de nouveaux programmes d'immunisation. Elles doivent également prévoir l'élaboration de méthodes d'évaluation et de recommandation qui évitent le chevauchement des tâches et qui sont plus cohérentes – ainsi que des mécanismes de financement prévisibles et durables – afin de favoriser l'accès rapide des patients aux technologies vaccinales actuelles et innovatrices (voir les documents 4, 5 et 6)
5. Les initiatives stratégiques destinées à maintenir et à améliorer le taux de couverture vaccinale, principal avantage en matière de santé publique, doivent prévoir l'affectation de ressources suffisantes pour tenir des activités efficaces de mise en œuvre des programmes de vaccination, ainsi que de sensibilisation et d'information, y compris une infrastructure adéquate de distribution et d'administration des vaccins dans tout le pays. Ces initiatives doivent également prévoir l'affectation de ressources suffisantes pour exercer une surveillance efficace de l'utilisation des vaccins, y compris leur innocuité et leur efficacité, dans le cadre de programmes de surveillance accrue (voir les documents 8 et 9).

Recommandations à l'intention d'autres intervenants :

6. Pour faire en sorte que les vaccins demeurent l'une des interventions les plus importantes et les plus rentables en matière de santé publique au Canada, tous les intervenants doivent travailler ensemble non seulement à améliorer l'efficacité des programmes d'immunisation, mais aussi à en promouvoir la valeur auprès de tous les citoyens canadiens.
7. Dans le cadre d'un mécanisme de protection et d'amélioration de l'industrie des vaccins au Canada, tous les intervenants concernés doivent continuer de participer au débat portant sur d'importantes questions d'intérêt commun liées aux méthodes d'immunisation sur la scène internationale. Les intervenants canadiens doivent continuer de chercher des modèles de pratiques exemplaires conformes à ceux des principaux programmes d'immunisation dans le monde, en vue notamment d'obtenir une valeur économique et des résultats cliniques optimaux dans le cadre d'un système canadien d'immunisation mieux uniformisé et plus prévisible.

## 2.2 Vaccine Market Dynamics

### 2.2.1 Global Market Overview

Historically, vaccines have been viewed as a mature product group, with less profit potential than traditional pharmaceutical products – based on the high cost of vaccine development and limited market opportunity, often involving only one or a few administrations per individual.<sup>1</sup> Recently however, newer vaccines, including Wyeth's Prevnar and Merck's Gardasil, have demonstrated the ability to generate "blockbuster" revenue streams (defined as exceeding \$US 1 billion per year globally) that resemble other pharmaceutical sectors with greater sales potential and more lucrative profit margins. In addition, barriers to entering the vaccine arena – such as manufacturing complexity and regulatory compliance expertise – hinder competition from generics, resulting in sustained volumes, pricing and margins for successful vaccines well beyond patent expiry. Thus the vaccine sector currently represents an increasingly attractive market worldwide, characterized by strong growth prospects, increased research and development (R&D) activity, and higher valuation from the capital markets and investment community.<sup>2</sup>

Major corporate deals, including the acquisition of Coley Pharmaceutical by Pfizer and MedImmune by AstraZeneca in 2007, as well as the purchase of Acambis by sanofi pasteur in 2008, also testify to the renewed interest in vaccines (both approved and in the pipeline) from the traditional "big pharma" players.<sup>3,4,5</sup> Indeed, part of the rationale for Pfizer's acquisition of Wyeth in the mega-merger announced in January 2009 was to permit Pfizer to diversify into the vaccine and biologics business through Wyeth's strong position in these areas – where Pfizer has had limited previous presence.<sup>6</sup>

At present, the United States and Europe represent the two largest vaccine markets on the global stage, with France, Germany and the United Kingdom accounting for over 75% of the latter market.<sup>7</sup> Valued at approximately \$US 16.3 billion in 2007, the global vaccine market is projected to increase at an annual rate of roughly 13-14% over the next several years, exceeding \$US 30 billion by 2013.<sup>8,9,10</sup> Although pediatric vaccines have historically dominated this field, 2007 was the first year that adult vaccine sales overtook pediatric sales, as adult sales (\$US 8.2 billion) rose to just slightly above 50% of global vaccine revenues. This surprising development has been attributed to robust sales of a group of vaccines against influenza and hepatitis, as well as the recent launch of Gardasil for the prevention of disease caused by the human papillomavirus (HPV).<sup>11,12</sup> While adult vaccine revenues have grown dramatically in the past few years, there has been no letdown in sales of pediatric vaccines. Recent pediatric vaccine sales (just over \$US 8.0 billion in 2007) have been driven primarily by increased childhood immunization with existing vaccines as well as new products, including Wyeth's pneumococcal vaccine, Prevnar. In general, adult vaccines are not expected to maintain a leadership position, as competition and volume are anticipated to reduce adult vaccine prices. However, the recent strength of the adult market lends weight to the argument that the pediatric and adult segments may roughly equal out in future years.<sup>13</sup>

While precise estimates vary, the global vaccine market has traditionally accounted for only a small portion of the global pharmaceutical market, representing approximately 2% of the overall pharma business – estimated at \$US 658 billion in 2007.<sup>14,15</sup> Yet the vaccines sector has recently outperformed most of the rest of the industry in terms of revenue growth, and with a projected growth rate of 13-14% through 2013, the vaccine sector is expected to increase more than twice as rapidly as for traditional pharmaceuticals (5-6%).<sup>16,17</sup> Indeed, according to analyst forecasts, the vaccines market is projected to be the fastest-growing therapeutic area over approximately the next five years, with its impressive growth rate superior even to that of oncology's 11% anticipated annual growth. Thus by 2013, the vaccine market

share is projected to increase to roughly 4.5% of worldwide pharmaceutical sales.<sup>18</sup> Significant contributions to this future growth will be made by recently approved products – including sanofi pasteur's quadrivalent meningitis vaccine, Menactra; the two new rotavirus vaccines (Merck's Rotateq and GlaxoSmithKline's Rotarix); and Merck's herpes zoster (shingles) vaccine, Zostavax – as well as Novartis' meningococcal type B vaccine, MenB, currently in late-stage development.<sup>19</sup> Other key drivers of near-term vaccine sales are anticipated to encompass emerging therapeutic and cancer vaccines, pediatric combination vaccines, and pneumococcal vaccines (including higher valent candidates to protect from a broader range of *S. pneumonia* serotypes); see Paper 3.

### 2.2.2 Canadian Market Status

In Canada, as for other countries, vaccines are used extensively as one of the most useful and cost-effective tools for reducing morbidity and mortality associated with infectious diseases. Thus, while adult vaccines are beginning to fuel the growth of vaccine markets in Canada, childhood immunization is still a top health priority and pediatric vaccines remain an important market segment. As described in Paper 6 (Section 6.5.1), the financing of vaccines has been quite different for childhood and adult immunization programs in Canada. Most childhood immunization programs are publicly funded, and delivered through a combination of public health programs (including school-based clinics) and physician offices. In contrast, public funding is much more limited for adult immunization,<sup>i</sup> and often depends on patients requesting vaccines (e.g. for influenza) from their health care provider, most often physicians.<sup>20</sup> Certain vaccines that are not publicly funded may be covered by employer or private insurance plans, particularly those that are recommended for specific risk situations such as occupation or travel.

Annual vaccine sales in Canada are currently estimated at approximately \$Cdn 450 million (for 2008), based on aggregate data provided by members of BIOTECanada's Vaccine Industry Committee (VIC). This estimate includes vaccine purchases in the public sector by provincial and federal governments, i.e. through Public Works and Government Services Canada (PWGSC) on behalf of the Vaccine Supply Working Group (VSWG), a federal, provincial and territorial (F/P/T) working group, as described in Section 2.5.2. The estimate also takes into consideration vaccine purchases in the private sector, i.e. through drugstores, hospitals, and other retail outlets. Independent analysis also helps substantiate the industry estimate of annual vaccine sales. Specifically, PWGSC purchases can be conservatively projected at approximately \$Cdn 250 million for 2008, extrapolating from 2006 purchases.<sup>21</sup> Vaccine purchases in the private sector can be estimated at roughly \$Cdn 200 million for 2008, extrapolating from IMS data, which reports drugstore and hospital vaccine sales of \$Cdn 183 million (from January to November 2008).<sup>22</sup>

To put this data into appropriate context, it is relevant to examine overall health care expenses in Canada. According to the Canadian Institute for Health Information (CIHI), Canada's total health care spending is expected to reach \$Cdn 171.9 billion in 2008 (representing 6.4% growth over 2007), corresponding to \$Cdn 5,170 per capita (Table 2.1).<sup>23,24</sup> The public- and private-sector shares of total health expenditure have remained relatively stable over the past decade, with governments accounting for 70% of total spending and the private sector (including privately insured and out-of-pocket expenses) accounting for 30%. In

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<sup>i</sup> Vaccines for adolescents may be evaluated as a distinct category, but are typically included in the adult vaccine segment. As one example, Merck's Gardasil is approved by Health Canada for the prevention of disease caused by the human papillomavirus (HPV) in females 9-13 years (prior to sexual debut for most Canadian females) as well as females 14-26 years, particularly those with no evidence of past or current HPV infection. While Gardasil is typically classified as an adult vaccine, Gardasil is publicly funded in all Canadian provinces (see Paper 6).

2008, public-sector health care spending is expected to reach \$Cdn 120.3 billion (70.0%), compared to \$Cdn 51.6 billion spent by the private sector (30.0%).

Expense Category	\$Cdn (Billion)	Percent of Total Health Care Expenditures
Hospitals	48.1	28.0%
Other Institutions	17.2	10.0%
Prescribed and Non-Prescribed Drugs	29.8	17.4%
Physicians	23.1	13.4%
Other Professionals (Dental, Vision Care, etc.)	18.8	10.9%
Public Health	11.3	6.6%
Research & Other Health Spending	10.7	6.2%
Capital	7.0	4.1%
Administration	5.9	3.4%
Total	171.9	100.0%

Source: National Health Expenditure Trends, 1975-2008, Canadian Institute for Health Information, 2008.

The top three categories that represent the largest components of overall health care spending in 2008 include hospitals (28%), prescribed and non-prescribed drugs (17.4%), and payments to physicians (13.4%), respectively. Each expense category has a unique breakdown of public- and private-sector spending components; while hospital and physician payments are financed mainly (over 90%) by the public sector, drugs and other professionals (e.g. who provide dental and vision care services) are financed primarily (over 60%) by the private sector. Spending on public health falls just below the top three categories, and is anticipated to reach 6.6% of the total Canadian health care expenditure in 2008. This category falls exclusively within the public sector, and includes spending on public immunization programs in Canada. More broadly, for the purpose of the CIHI report, the public health category captures spending by governments and government agencies, including expenditures for food and drug safety, health inspections, health promotion activities, community mental health programs, public health nursing, measures to prevent the spread of communicable disease, and occupational health to promote and enhance health and safety of the workplace in public sector agencies. Notably, the percentage of health care expenses devoted to public health has doubled since 1991, and growth in this category has generally been higher than in other categories throughout the same time period.

Overall, the 2008 CIHI data helps to place the magnitude of Canadian vaccine spending (\$Cdn 450 million) into appropriate perspective (Table 2.2). For example, vaccine spending represents a small percentage (4.0%) of Canadian public health spending, and an extremely small fraction (<0.3%) of total Canadian health care expenses. Given that prescribed and non-prescribed drugs account for 17.4% of total health care expenses in Canada (Table 2.1), this analysis indicates that vaccine spending is less than 2% of total drug expenditures in Canada – consistent with global sales ratios for vaccines versus traditional pharmaceuticals.

Table 2.2 – Canadian Vaccine Spending in the Broader Context			
Relevant Context (see Table 2.1)	Numerator (\$Cdn Million) [Vaccine Spending 2008]	Denominator (\$Cdn Million) [Specific Context 2008]	Percentage [Fraction of Vaccine Spending]
Canadian Public Health Spending	\$450	\$11,300	4.0%
Canadian Health Care Expenditure	\$450	\$171,900	<0.3%
Global Vaccine Market	\$450	\$18,419 <sup>ii</sup>	2.4%

Sources:

- i) National Health Expenditure Trends, 1975-2008, Canadian Institute for Health Information, 2008; and
- ii) Aggregate estimates provided by VIC member companies.

As a side issue – as presented in Paper 6 – the vast majority of vaccines approved in Canada to date are preventive, hence they fall well within the jurisdiction of provincial public health agencies and budgets. Yet it is currently unknown whether the emerging class of therapeutic vaccines will also be integrated into public health programs, or whether public provincial drug plans (formularies) will be responsible for assessing and funding these vaccines, as for other therapeutic treatments.<sup>25</sup> Since the total Canadian drug budget is more than 50 fold larger than that for vaccines, it may be tempting to speculate that it would be more favourable to fund therapeutic vaccines through provincial drug formularies. However, this analysis is not as straightforward as it might seem at first glance, since there are far more drugs than vaccines on the market (and in pipelines) to “compete” for domestic health care dollars, and data requirements may also differ for evaluating, recommending and funding vaccines via these alternative options. Paper 6 provides a more detailed discussion of key considerations and potential funding models for new therapeutic vaccines, with the over-arching goal of ensuring the Canadian population has timely, equitable access to these innovative vaccine technologies.

It should be emphasized that although vaccine spending represents <0.3% of national health care expenditures (Table 2.2), vaccination has been widely acknowledged as providing immense medical benefits (both at the individual and societal level)<sup>26</sup>, as outlined in Paper 1. Immunization programs have also been deemed to be among the best investments in health, based on extensive analyses of both cost-savings<sup>27</sup> and cost-effectiveness<sup>28</sup>, as summarized in Paper 6. By preventing the spread of infectious disease, vaccines have also been shown to reduce hospitalization and/or decrease the need for expensive treatment.<sup>29</sup> Thus when utilized as part of a primary prevention strategy, vaccines have potential to play a significant (yet currently underestimated) role in decreasing costs in those categories that represent the largest components of overall health care spending in Canada – payments for hospitals, drugs, and medical professionals. Simply put, immunization programs, which are central to prevention efforts, help to offset costs in other areas while effectively promoting public health. However, vaccines continue to be (mistakenly) undervalued and underutilized in Canada, as in many other developed countries.<sup>30</sup> Hence substantial work lies ahead to ensure that vaccines are adequately recognized and promoted in terms of providing excellent value for money spent, with emphasis placed on the broad medical, social and economic impact of immunization programs.

<sup>ii</sup> At a growth rate of 13%, the global vaccine market (\$US 16.3 billion in 2007) is projected to increase to \$US 18.419 billion by 2008. For the purpose of this analysis, we assume that Canadian and US currencies are at par for 2008.

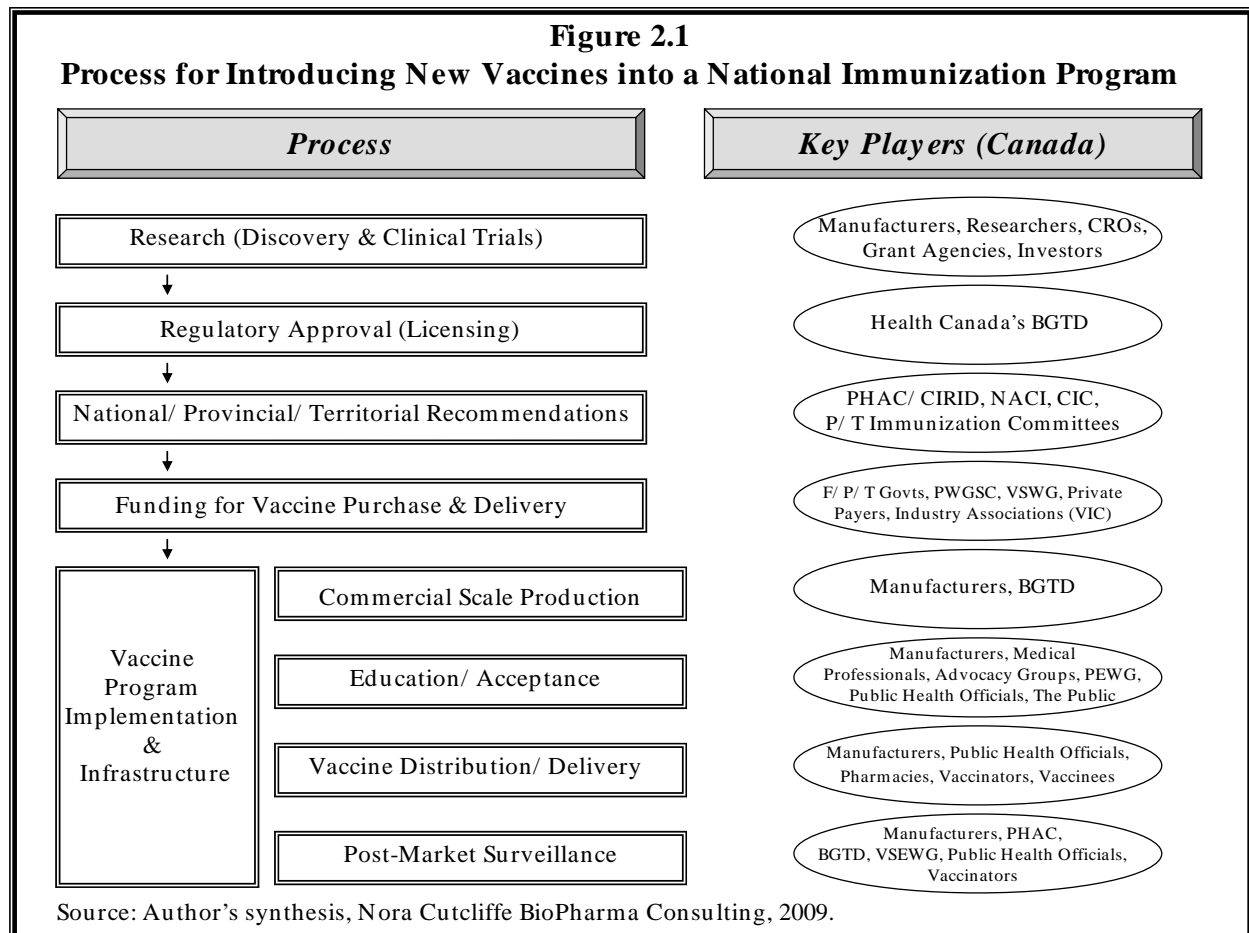
While vaccine spending accounts for a very small fraction of both public health expenses and total health care expenditure in Canada, national spending on vaccines also corresponds to a small proportion (2.4%) of vaccine spending worldwide (Table 2.2). Since the Canadian vaccine market represents only a tiny segment of the global vaccine market (which is itself small, within the context of global pharmaceutical sales), Canada's domestic vaccine market is considered unique and potentially fragile, and hence requires special consideration in terms of creating a supportive regulatory and public policy environment.

### 2.3 Process for Introducing New Vaccines

In most developed countries, including Canada, successful incorporation of a new vaccine into a national immunization program requires addressing a broad set of diverse issues, encompassing the following initiatives:<sup>31,32,33</sup>

- establishing medical need, and demonstrating safety and efficacy (or immunogenicity) in clinical trials;
- obtaining marketing authorization (regulatory approval) for commercial launch;
- development of national recommendations for optimal use;
- securing funding to support vaccine program delivery; and
- providing necessary infrastructure for vaccine program implementation, via:
  - ensuring adequate vaccine supply and distribution capacity;
  - assuring education of (and acceptance by) the public and medical community;
  - establishing an appropriate infrastructure for vaccine distribution and delivery; and
  - monitoring vaccine use, safety and effectiveness through post-market studies.

As illustrated in Figure 2.1, the process for introducing new vaccines is complex, and entails a series of actions involving multiple stakeholders and participants. Key players in the vaccine enterprise in most developed countries include vaccine companies; the research community; the investment community and funding agencies; government agencies and regulatory authorities; national/regional advisory bodies; public health officials; medical societies; health care professionals; public and private payers; and the general public.<sup>34,35</sup> Primary players in Canada's vaccine landscape are summarized in Section 2.5 below, with further detail presented in subsequent papers.



**Legend:**

- BGTD      Biologics and Genetic Therapies Directorate
- CIC        Canadian Immunization Committee
- CIRID     Centre for Immunization and Respiratory Infectious Diseases
- CROs      Clinical Research Organizations
- F/P/T Govts   Federal/Provincial/Territorial Governments
- NACI      National Advisory Committee on Immunization
- PEWG     Professional Education Working Group
- PHAC     Public Health Agency of Canada
- PWGSC    Public Works and Government Services Canada
- VIC        Vaccine Industry Committee
- VSEWG    Vaccines Safety Expert Working Group
- VSWG     Vaccine Supply Working Group

Note: The core mission of the VIC is to advocate for a more efficient, favourable vaccine environment, supported by consistent and sustained funding of immunization programs (as shown in Figure 2.1). However, VIC members also actively engage with F/P/T governments to promote the value of vaccines, and to develop appropriate policies pertaining to vaccine research, regulatory oversight, national recommendations, production/distribution and education to support immunization programs (not shown explicitly in Figure 2.1).

## 2.4 Protecting the Value of the Vaccine System

Figure 2.1 and Section 2.3 can also be considered as a guide to the general layout (presented in Table 2.3) of this series. As described in subsequent papers, the various required steps in the process of introducing new vaccines do not necessarily represent discrete, sequential functions, but rather involve considerable overlap and interdependencies in overcoming common hurdles. For example, Papers 3, 4, 5, and 6 summarize the unique challenges currently faced within the Canadian vaccine marketplace; these papers present policy recommendations to encourage investment in research, as well as to develop predictable, sustainable mechanisms for vaccine licensure, evaluation/recommendation and funding, i.e. to ensure timely access to innovative vaccines by all Canadians.

In addition, Paper 7 examines issues and policy recommendations surrounding vaccine manufacturing, and future protection of the potentially vulnerable vaccine supply. Paper 8 highlights the need to encourage vaccine acceptance by both the public and health care providers through comprehensive educational programs, as well as to establish efficient vaccine delivery channels. Paper 9 then presents several concerns and policy recommendations related to monitoring vaccine safety and efficacy in the post-licensure period, including surveillance studies to measure public health benefits. Lastly, Paper 10 summarizes key challenges and potential solutions for future development of the Canadian vaccine enterprise. Overall – as discussed in further detail below – there is an urgent need to promote and protect the Canadian vaccine industry from a business perspective, while reaffirming the extraordinary value of vaccination in terms of beneficial health and economic outcomes.

<b>Table 2.3 – Building on the Legacy of Vaccines in Canada: Value, Opportunities and Challenges</b>	
Paper	Process/Step in Introducing New Vaccines
1) Introduction to Vaccines: The Canadian Perspective	Establishing Medical Need & Public Health Benefits
2) The Current Canadian Vaccine Environment	Market Dynamics & Key Players
3) Research and Development: Fostering Vaccine Innovation in Canada	Research (Discovery and Clinical Trials)
4) Pathway to Access: Health Canada Oversight	Regulatory Approval (Licensing)
5) Pathway to Access: Improving the Evaluation and Recommendation Process	National/Regional Recommendations
6) Pathway to Access: Toward Sustainable Funding	Funding for Vaccine Purchase and Delivery
7) Manufacturing/Procurement/Supply	Commercial Scale Production
8) Awareness/Education/Implementation	Education/Acceptance & Vaccine Distribution/Delivery
9) Safety/Post-Market Surveillance	Post-Market Surveillance
10) The Future	Future Directions of Vaccine Enterprise

As a whole, the current Canadian vaccine system represents a complex collaboration across manufacturers, investors and grant agencies, governments, health care providers, payers, and the public (Figure 2.1). Overall, as emphasized in Paper 1, the decline in incidence and death from infectious diseases as a result of vaccination is considered one of the great triumphs of medical research and public health programming in Canada.<sup>36</sup> However, despite this triumph and well-recognized success, Canada's current vaccine system (as in other countries) is not yet working at optimal efficiency. When viewed from several perspectives, the current system is fragile and needs significant improvement to safeguard its tremendous

future value and potential public health impact. As described in Paper 3, the cost of research for new vaccines has markedly increased in recent years – and the development process typically takes longer than for other medicines<sup>37</sup> – thus manufacturers need incentives to invest in such high-risk, innovative technologies. Furthermore, as presented in Paper 4, there has been increased demand for vaccine safety data, which increases regulatory oversight and in turn contributes to the ongoing investment requirement faced by vaccine companies.<sup>38</sup>

In addition, Canada’s evaluation/recommendation and funding procedures that ultimately support the adoption of publicly-funded vaccine programs are currently characterized by unacceptable inefficiencies, duplication, inequities and delays. Unfortunately, these limitations can mean that Canadians suffer and/or die needlessly due to vaccine-preventable diseases. Thus, as summarized in Papers 5 and 6, significant work lies ahead in terms of achieving timely, equitable access to vaccines by all Canadians, and there remains an urgent need for predictable evaluation processes and sustained funding mechanisms for new vaccination programs. In general, the vaccine manufacturing base is limited since it depends upon a relatively small number of production facilities. Hence, as outlined in Paper 7, the manufacturing environment requires appropriate policy attention to protect long-term manufacturing capacity and to help avoid future shortages of vaccine supply. Clearly, vaccine companies need to operate in a favourable market environment (including adequate investment incentives) in order to remain within the business for the longer-term.

Another key aspect of the current vaccine system that must be carefully addressed is the need to overcome resistance to vaccine acceptance (as part of the “anti-vaccine movement”) and/or public apathy to immunization programs. Unfortunately, the absence of many vaccine-preventable diseases in Canada over the past several decades has inadvertently fostered a level of complacency among the public, since there is little knowledge of large-scale disease outbreaks or their concomitant fear and suffering.<sup>39</sup> Thus, as highlighted in Paper 8, there is a strong need for vaccine education and advocacy programs – targeting physicians, nurses and the public – to positively influence consumer acceptance and the “willingness to be vaccinated”.

Finally, for successful implementation of immunization programs, adequate resources and appropriate infrastructure must be in place to ensure timely vaccine distribution and delivery to the public. For example, in terms of program feasibility, key questions include whether the new vaccine can be administered as part of existing vaccine programs, and whether the target population will have easy access to the vaccine.<sup>40</sup> Moreover, as recommended in Paper 9, additional resources must be devoted to conducting post-licensure risk management studies, including surveillance of vaccine safety and public health impact.

In the process of introducing new vaccines into national immunization programs, it is noteworthy that the key roles supported or played by vaccine manufacturers have traditionally included the development, licensure and commercialization of novel vaccine technologies – particularly by providing technical data regarding vaccine safety and efficacy (or immunogenicity). However, in the evolving environment of vaccinology in the 21st century, the contribution of vaccine manufactures has expanded to include provision of additional information (e.g. epidemiology and health economics data) to support the establishment of optimal vaccination policies.<sup>41</sup> In essence, the current role of the vaccine industry consists of advocating the true value of vaccines as a public health intervention by providing convincing, reliable data for decision-makers at all levels.

Overall, the successful adoption of a new vaccine as part of a national disease prevention program is a lengthy, multifaceted process that goes far beyond regulatory approval of the vaccine. While assessment of the quality of the safety and efficacy data constitutes an obvious starting point, official (national) recommendations and appropriate funding are also required. Beyond scientific evaluation and the development of public health policies, political will also plays a crucial role in ensuring vaccine acceptance. Ultimately, the successful introduction of vaccination programs will rely on the quality of program implementation – not only through appropriate funding and health care infrastructures, but also on public trust and acceptability of vaccination policies that will translate into the willingness to vaccinate and to be vaccinated.

In summary, Canada's vaccine industry (as for other countries worldwide) needs adequate support at multiple levels to harness its true value and to realize its full potential in improving public health and economic outcomes. Indeed, vaccine manufacturers have recently presented several compelling arguments to articulate the need for a more favourable regulatory and policy environment, particularly through their collaborative initiatives in conjunction with BIOTECanada's VIC; see Section 2.5.4. Key priorities include the need for adequate research incentives and government funding (or intervention) to encourage future investment in preventive and therapeutic vaccine technologies,<sup>42</sup> and to develop predictable, sustainable evaluation/recommendation and funding procedures to ensure timely, equitable access to innovative vaccines by all Canadians.<sup>43</sup>

For Canada's vaccine industry players, a far-reaching goal is to ensure that manufacturers will thrive in future years, thereby increasing patient access to currently approved and emerging vaccines, thus in turn maximizing the medical, social and financial benefits offered by immunization programs within Canada's health care system. By enhancing its existing partnerships – with government agencies, national public health authorities, medical associations, and the research community – Canada's vaccine industry is poised to play a pivotal role in preventing vaccine shortages, while ensuring that national public health status is not compromised in the near (or longer) term future. Inevitably, critical success factors in improving the outcomes of such partnership relations will include greater recognition of the unique characteristics and remarkable value represented by those industry players conducting vaccine research and large-scale manufacturing.

Looking to the future, all Canadian stakeholders may have the opportunity to learn from best practice models put forward by other developed countries in building strong, sustainable immunization systems. As an example of such collaborative, educational opportunities, an International Forum on National Immunization Programs was recently convened in Toronto by the Public Health Agency of Canada (PHAC) in December 2008. Participants included PHAC staff, representatives from the provinces, Health Canada and Canadian vaccine industry players, as well as other invited guests from Canada, Australia, Austria, Belgium, Germany, Spain, Sweden, the United Kingdom, and the United States. International guests were asked to describe current schemes for vaccine evaluation/recommendation as well as funding mechanisms in their respective countries; the ultimate goal of this forum was to provide broader insight and policy perspective across all participants, and to generate discussion towards the development of improved best practice models – particularly in Canada – for optimizing immunization programs in the near-term future.

## 2.5 Key Players in Canada

### 2.5.1 Vaccine Manufacturers, Developers and Researchers

Despite the tremendous value of vaccines – and their proven impact on public health – fewer companies are currently investing in the vaccine market sector worldwide. As a whole, the global vaccine industry has recently undergone significant consolidation; over the past 30 years, the number of companies engaged in the development and manufacturing of vaccines has declined from roughly 25 to five.<sup>44</sup> Potential factors that have contributed to the decision for several companies to abandon their vaccine production lines (including, among other challenges, complexity of development, production and quality control) are discussed in further detail in Paper 7 regarding manufacturing and supply issues.

As of early 2009, the Canadian vaccine landscape mirrors the highly concentrated structure of the global vaccine marketplace, with the “top tier” vaccine companies currently including GlaxoSmithKline (GSK) Canada, Merck Frosst Canada Ltd., Novartis, sanofi pasteur, and Wyeth Pharmaceuticals Canada. All of these players represent Canadian divisions of the respective multinational companies headquartered in Europe (GSK, Novartis, sanofi aventis) or the United States (Merck, Wyeth). While sanofi pasteur has a large-scale vaccine manufacturing facility based in Toronto (known as the Connaught Campus)<sup>45</sup>, GSK has vaccine production facilities in Québec City and Laval, Québec.<sup>46</sup> These facilities supply vaccines for global clinical trials and/or commercial sales (e.g. for influenza and acellular pertussis vaccines, by GSK and sanofi pasteur, respectively). Merck, Novartis and Wyeth do not presently have vaccine manufacturing facilities in Canada. Key vaccines of these top tier companies that are currently available on the Canadian market are listed in Table 2.4. Further details are provided in Paper 5 (Tables 5.1 and 5.2) regarding these and other vaccines approved in Canada for infants, children, adults and travellers.

<b>Table 2.4 – Vaccines Approved in Canada (Top Four Vaccine Manufacturers)</b>			
<i>GlaxoSmithKline</i>	<i>Merck Frosst</i>	<i>sanofi pasteur</i>	<i>Wyeth Pharmaceuticals</i>
Boostrix	Gardasil	Act-HIB	Meningitec
Engerix-B	MMR II	<u>Adacel</u>	Prevnar
<u>Fluviral</u>	Pneumovax 23	Avaxim	
Havrix	Recombivax HB	Avaxim – Pediatric	
Infanrix-HEXA	Rotateq	<u>BCG Vaccine</u>	
NeisVac-C	Vaqta	Dukoral	
Priorix	Varivax III	Je-vax	
Priorix-Tetra	Zostavax	Imovax Polio	
Rotarix		<u>IPV (inactivated polio vaccine)</u>	
Synflorix		Menactra	
Twinrix		Menomune A/C/Y/W-135	
Typherix	<i>Novartis</i>	<u>PediaceL</u>	
Varilrix	Menjugate*	<u>Pentacel</u>	
	RabAvert*	Pneumo 23	
	*Distributed by	<u>Quadracel</u>	
	Merck Frosst	<u>Td Adsorbed</u>	
		<u>Td Polio Adsorbed</u>	
		Typhim Vi	
		Vaxigrip	
		Vivaxim	
		YF-Vax	
			Note: Vaccines developed and manufactured in Canada are underlined.

Sources: [www.gsk.ca](http://www.gsk.ca); [www.merckfrosst.ca](http://www.merckfrosst.ca); [www.sanofipasteur.ca](http://www.sanofipasteur.ca); and [www.wyeth.ca](http://www.wyeth.ca). Additional information regarding these vaccines, including full product monographs and target diseases, is available online.

In the context of major vaccine manufacturers, it is noteworthy that Merck Frosst Canada recently brought positive profile and distinction to the Canadian vaccine industry when its product, Gardasil, received the Prix Galien Canada 2008 Innovative Product Award.<sup>47</sup> This prestigious award, considered as the Nobel Prize for pharmaceutical research, is given to the product that has made the most significant overall contribution to patient care in Canada in terms of efficacy, safety, benefits and innovation. Approved by Health Canada in July 2006, Gardasil has benefited from ten years of R&D, including over five years in clinical trials involving roughly 25,000 individuals in 33 countries. Gardasil is currently indicated for females 9-26 years of age for the prevention of cervical cancer, vulvar cancer, vaginal cancer, precancerous lesions and genital warts caused by the four vaccine HPV types (6, 11, 16 and 18).

Solvay Pharma Inc. (the Canadian arm of Belgian-based Solvay Group SA) is another active player in the Canadian vaccine business, and has been a leader in developing and manufacturing influenza vaccines for over 50 years. Solvay Pharma Inc. introduced Influvac®, a sub-unit, thimerosal-free influenza vaccine to the Canadian market in 2005.<sup>48</sup> Other smaller vaccine developers include Medicago, ImmunoVaccine Technologies Inc. (IVT), Variation Biotechnologies Inc. (VBI), and PlantForm Corporation, among others.<sup>49,50</sup> These Canadian-based companies are currently conducting earlier stage (preclinical and Phase I clinical) research to advance the development of a wide range of preventive vaccines (against influenza, hepatitis B & C, HIV/AIDS, cryptosporidiosis and other infectious diseases) and/or therapeutic vaccines (targeting prostate, breast and other cancers). Medicago is publicly traded on the TSX Venture Exchange, whereas IVT, VBI, and PlantForm are all privately-held companies financed primarily by venture capital investors.

In Canada, the vaccine research community encompasses the discovery and clinical research departments of the lead (first and second tier) industry players mentioned above, as well as a broad array of players engaged in early-stage vaccine R&D at academic, hospital, and government laboratories and research institutions. These groups are described in further detail in Paper 3 in the context of vaccine research initiatives, along with major research funding agencies in Canada, including the Canadian Institutes of Health Research (CIHR), the National Research Council of Canada (NRC), the Natural Sciences and Engineering Research Council (NSERC), the Industrial Research Assistance Program of Canada (IRAP), the Canada Foundation for Innovation (CFI), the National Cancer Institute of Canada (NCIC), and the Canadian HIV Vaccine Initiative (CHVI).<sup>51,52</sup> It should be noted that larger, multicentre vaccine clinical trials (conducted by vaccine manufacturers as they advance through rigorous clinical development programs) are typically executed with the assistance of clinical research organizations (CROs) as major service providers.

Another unique and relatively new player within the Canadian vaccine landscape is the Pan-Provincial Vaccine Enterprise (PREVENT), established in February 2008. Based at the University of Saskatchewan, PREVENT is one of 11 new Centres of Excellence for Commercialization and Research (CECRs) established through the Networks of Centres of Excellence program.<sup>53</sup> PREVENT has been incorporated as a non-profit company that will help bridge the gap between basic science and licensed vaccines by partnering with Canadian stakeholders, and by shouldering the risk of early-stage vaccine development. As summarized in Paper 3, PREVENT will leverage existing vaccine expertise through partnerships with other key Canadian research organizations and facilities, including the Vaccine and Infectious Disease Organization (VIDO) and the International Vaccine Centre (InterVac), both at the University of Saskatchewan, as well as the Canadian Center for Vaccinology (CCfV) in Halifax, and the British Columbia Centre for Disease Control (BCCDC) in Vancouver.<sup>54</sup> Ultimately, the fundamental purpose of

PREVENT is to strengthen Canada's vaccine industry through enhanced public/private partnerships, thus promoting growth, investment and improved global competitiveness.<sup>55</sup>

Finally, the International Centre for Infectious Diseases Inc. (ICID) represents another unique player in the Canadian vaccine market segment; this independent, not-for-profit organization delivers innovative solutions to the global fight against infectious diseases. ICID was created in 2004 in the wake of the SARS crisis to build national public health capacity in Canada, i.e. by mobilizing public health expertise, building professional and technical capacity, and leading national/international initiatives. Based in Winnipeg, ICID works to increase collaboration among experts across the academic, business and government sectors to help Canadians achieve greater protection and value from public health investment and infectious diseases innovation.<sup>56</sup>

Although exact estimates regarding the number of jobs represented by Canada's vaccine industry are not publicly available, Canada's Research-Based Pharmaceutical Companies (Rx&D) reports that its member companies employ over 22,000 individuals across Canada, over 20,000 of which are located in Ontario and Québec.<sup>57</sup> In this context, it is noteworthy that Merck Frosst Canada Ltd., sanofi pasteur, GlaxoSmithKline (GSK) Canada, Wyeth Pharmaceuticals Canada, Solvay Pharma Inc., and Medicago are all members of Rx&D, and all are based in Ontario or Québec.<sup>58</sup> Overall, a significant subset of those individuals employed by Rx&D member companies (plus many employees of smaller Canadian vaccine developers, research labs and other affiliated organizations) are involved in vaccine R&D, manufacturing, and distribution/sales in Canada. Collectively, these vaccine companies and organizations also inject substantial funds into the Canadian economy, particularly via increased spending to support expanding R&D activities (including clinical research at multiple sites across the country) as well as via renewed investment in land, facilities and equipment. Given the significant contribution of the vaccine industry to Canada's economy – in terms of both job creation and investment in R&D – the vaccine sector should be adequately promoted and actively fostered by stakeholders across all levels of the research community, the business/investment community, and government.

### 2.5.2 Federal and Provincial Government Authorities

Canadian vaccine manufacturers, developers, and researchers – as well as other stakeholders in the vaccine sector – operate within the infrastructure and policy environment created by several federal and provincial government bodies. At the broadest level, the two key federal agencies that regulate and oversee the vaccine industry include Health Canada as the federal regulatory authority (see Paper 4), and the PHAC, which acts as the lead body in overseeing immunization evaluation and recommendation processes (see Paper 5). Although official vaccine recommendations are made at the national level, decisions regarding the integration of new vaccines into publicly-funded immunization programs are primarily a provincial/territorial responsibility. Thus Provincial/Territorial Immunization Committees also play a fundamental role in the introduction of new vaccines within the Canadian landscape.

Since its inception in 2004, the PHAC has provided national guidance, leadership and coordination in public health in Canada, with the goal of strengthening the country's abilities to respond to public health threats, outbreaks, and emergencies.<sup>59</sup> Within the existing PHAC structure, the relevant expert groups that guide immunization procedures fall under the jurisdiction of the Centre for Immunization and Respiratory Infectious diseases (CIRID). These groups – including the National Advisory Committee on Immunization (NACI) and the Canadian Immunization Committee (CIC) – are collectively known as the Public Health Network, which reports to the Federal/Provincial/Territorial Conference of Deputy

Ministers of Health (see further detail in Paper 5, Section 5.3). In September 2004, Dr. David Butler-Jones was also appointed as Canada's first-ever Chief Public Health Officer to head the PHAC, reporting to the federal Minister of Health.<sup>60</sup>

Like all medicines, vaccines must undergo rigorous review and testing before they are licensed for commercial use. Vaccines are regulated under a specific set of regulations for a subset of drugs known as biologics (i.e. derived or prepared from living organisms). Thus all vaccines authorized for sale in Canada are reviewed and approved by the Biologics and Genetic Therapies Directorate (BGTD) of Health Canada. Health Canada also supervises all aspects of vaccine production by manufacturers, to ensure safety, sterility, and quality of large-scale batches or “lots”.<sup>61</sup>

Within Canada's current national immunization system, once a vaccine has been approved by the BGTD, it is then subject to the scrutiny of NACI. Initially established in 1964, NACI is an independent committee of recognized experts (in the fields of pediatrics, infectious diseases, immunology, medical microbiology, internal medicine and public health) that provides expert advice on vaccines to the PHAC.<sup>62</sup> In essence, NACI is the national expert body that provides scientific recommendations for vaccine use in Canada – using evidence-based methods to assess whether the vaccine should be used, and to target groups that will most benefit from inoculation. All NACI recommendations on vaccine use in Canada are available on the PHAC website at [www.phac-aspc.gc.ca/naci-ccni/recs-eng.php](http://www.phac-aspc.gc.ca/naci-ccni/recs-eng.php). In addition, NAIC recommendations are published every four years in the *Canadian Immunization Guide*,<sup>63</sup> with additional updates published in the *Canada Communicable Disease Report*.<sup>64</sup>

Unlike NACI, the CIC is a much newer committee comprised of vaccine program representatives from the F/P/T ministries of health;<sup>65</sup> its first meetings were held in 2003.<sup>66</sup> While the fundamental objective in creating the CIC was to implement and meet the goals of the National Immunization Strategy (NIS, presented in Paper 5, Section 5.7), the CIC was also established to develop national goals and targets for immunization programs, and for making continued, collaborative progress in promoting the harmonization of immunization schedules across Canada. Currently, the CIC is also involved in creating programmatic (operational) plans for implementing feasible immunization programs (as recommended by NACI), including the identification of an acceptable range of target cohorts for vaccination. The CIC is supported by several working groups that assist in developing recommendations to submit to the CIC or NACI, and which also respond to questions from these national bodies. These working groups include, for example, the Vaccine Supply Working Group (VSWG), the Vaccines Safety Expert Working Group (VSEWG), and the Professional Education Working Group (PEWG).<sup>67</sup> The CIC also liaises with Health Canada and the U.S. Department of Health and Human Services, and convenes meetings with non-governmental organizations, professional organizations, and industry associations such as the VIC.

It should be emphasized that considerable concern has been expressed by many stakeholders regarding the potential overlap between BGTD and NACI review procedures in introducing new vaccines in Canada. In general, vaccine evaluation and recommendation procedures are highly complicated, particularly since the three key regulatory/advisory organizations effectively report into different bodies; the BGTD to Health Canada, NACI to the Chief Public Health Officer as head of the PHAC, and the CIC (as an F/P/T structure) to the Conference of Deputy Ministers of Health. Hence the current recommendation process for public vaccine programs in Canada involves several duplicative procedures, and thus may contribute to delays in patient access to innovative vaccine technologies (see Paper 5).

As summarized above, decisions to support vaccine approval (licensure) and recommendations for optimal use are made at the national level, yet publicly-funded immunization programs are primarily a provincial/territorial responsibility, including the purchase (procurement) of vaccines. While each ministry of health considers NACI recommendations in developing its own program schedules for children and adults,<sup>68</sup> each jurisdiction must plan, fund and deliver vaccine programs independently – taking into account its own unique set of circumstances – based on the decisions of provincial/territorial advisory committees. This final step is often viewed as yet another duplicative procedure, placing further strain on scarce human and financial resources within Canada’s immunization infrastructure.

As highlighted in Paper 6, federal funding has also played a key role in financing vaccine programs in Canada, particularly within the past five years. Specifically, the Canadian Immunization Trust Fund has provided \$Cdn 300 million under the NIS from 2004-2007 to support provincial/territorial immunization programs for four recently approved vaccines, and \$Cdn 300 million in 2007 for HPV vaccination programs across the country. However, as of February 2009, a larger or more permanent trust fund for other new vaccines has still not been established, thus it remains unclear how the system will be able to accommodate newly licensed and/or forthcoming vaccines over the near-term horizon. It should be noted that in the private system, the public may have immediate access to newly approved vaccines, assuming they are aware of the new vaccine and are able to cover the costs through out-of-pocket expenses, or through third party insurance. However, vaccination of individuals based on their economic means or insurance coverage status not only raises ethical issues; it also hinders the realization of mass immunization benefits across the population.

Although each jurisdiction must decide which vaccines to purchase, most of the vaccines used in publicly-funded immunization programs are purchased through a bulk purchasing program that is administered by Public Works and Government Services Canada (PWGSC)<sup>69</sup> and overseen by the VSWG sub-group of the CIC, as summarized in Paper 7. In some cases, provinces may purchase vaccines on their own behalf. In all cases, however, vaccine purchases must follow an open, fair, and transparent procedure – respecting Canada's obligations under applicable national and international trade agreements. Overall, the vaccine procurement process is intended to ensure that equal consideration is given to all eligible vaccines that meet the stringent requirements for regulatory approval in Canada.<sup>70</sup>

Another key role played by the federal government is to ensure the safety of immunization programs by overseeing Canada’s national vaccine surveillance systems. As outlined in Paper 9, the PHAC coordinates and supports the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS), a passive surveillance system which collects reports from health care providers on adverse events following immunization. Canada also has an active surveillance system, called the Immunization Monitoring Program ACTive (IMPACT) system, for documenting adverse events following immunization through 12 pediatric hospitals across the country.<sup>71</sup> The goal of this national vaccine safety surveillance is to monitor vaccines used in Canada and to detect, as quickly as possible, any evidence or concern regarding safety. If unexpected or increased side effects due to vaccines occur, the BGTD and PHAC/CIRID decide upon the best course of action for resolution.

### 2.5.3 Medical Societies, Advocacy Groups and Other Related Associations

In addition to the critical steps of vaccine licensure, establishing national recommendations, identifying adequate funding programs, and ensuring vaccine safety and adequate supply, the successful incorporation of a new vaccine into a national vaccination program also requires education of (and acceptance by) the public and medical community. Thus, a comprehensive and coordinated education program that targets physicians, pharmacists, nurses and the public is required to ensure smooth implementation of an immunization program.<sup>72</sup> In this context, key players within Canada's immunization system also include medical/professional societies, consumer/patient advocacy groups, and other related associations. Table 2.5 presents a summary list<sup>73,74</sup> of many of the major associations involved in education to support immunization practice in Canada; the roles of several of these organizations are described in further detail in Paper 8 on the topic of vaccine awareness and implementation programs.

Typically, manufacturers develop educational programs and materials for medical professionals and vaccine recipients or their caregivers, as an integral part of vaccine program planning activities. These educational resources are varied, and their contents are designed to meet the needs of the intended target group. Working in partnership with vaccine manufacturers, both the medical profession and the general public also play a key role in advocating the true value of vaccines to elected officials and civil servants, i.e. to promote strong support by relevant decision makers in creating a favourable vaccine funding and policy environment. In particular, as patients have become increasingly empowered and vocal in recent years, activities of consumer/patient groups have been integrated into advocacy programs to encourage the adoption of new vaccines.<sup>75</sup> In conjunction with broad endorsement by experts and professional societies, such advocacy initiatives have proven effective in achieving more equitable, timely patient access to innovative vaccines across Canada.

For certain vaccines, medical societies that focus on the relevant vaccine-preventable disease or therapeutic area(s) also play an important educational/advocacy role in endorsing the value of immunization. As one recent example, to support the implementation of HPV immunization programs in Canada, the Society of Obstetricians and Gynaecologists of Canada (SOGC) developed educational resources targeting both health care providers and teachers involved in school-based HPV vaccination programs.<sup>76</sup> Other advocacy activities to support HPV vaccination – based on compelling clinical recommendations from the most directly related medical societies in Canada<sup>77</sup> (including the SOGC; as well as the Society of Gynaecologic Oncologists of Canada, GOC; the Federation of Medical Women of Canada, FMWC; the Canadian Cancer Society, CCS; and the Canadian Paediatric Society, CPS) – underscored the potential value of HPV vaccination in reducing the burden of HPV-related disease. In addition to these highly favourable medical recommendations, several of these medical bodies actively advocated for federal government financing of the HPV vaccine, as presented in Paper 6, Section 6.3.2.

In general, recommendations put forward by professional and other related associations help to reinforce the benefits of vaccination, i.e. by contributing additional balance and sound medical judgement in the context of discussions and publications regarding disease prevention. Ultimately, such endorsement plays a vital role in shaping health policy, which in turn is critically important in realizing the value and appropriate positioning of new vaccine therapies, both in Canada and abroad.

Table 2.5 – Medical Societies* and Other Related Associations Supporting Immunization Education in Canada	
Association	Description & Website
CMA	Canadian Medical Association – A national, voluntary association of physicians that advocates on behalf of its members and the public for access to high quality health care, and provides leadership and guidance to physicians; <a href="http://www.cma.ca">www.cma.ca</a>
CFPC	College of Family Physicians of Canada – A national voluntary organization of family physicians that makes continuing medical education of its members mandatory; <a href="http://www.cfpc.ca">www.cfpc.ca</a>
CPS	Canadian Pediatric Society – The national association of pediatricians, active in advocacy, professional development and public education since 1922; <a href="http://www.cps.ca">www.cps.ca</a>
CPhA	Canadian Pharmacists Association – The national organization of pharmacists, committed to advancing the profession of pharmacy so as to contribute to the health of Canadians; <a href="http://www.pharmacists.ca">www.pharmacists.ca</a>
CAN	Canadian Nurses Association – The national professional voice of registered nurses, supporting them in their practice and advocating for healthy public policy and a quality, publicly funded, not-for-profit health system; <a href="http://www.cna-aiic.ca">www.cna-aiic.ca</a>
VON	Victorian Order of Nurses – Canada's largest, national, not-for-profit, charitable home and community care organization; <a href="http://www.von.ca">www.von.ca</a>
CASN	Canadian Association of Schools of Nursing – The national voice for nursing education, research, and scholarship, also representing baccalaureate and graduate nursing programs; <a href="http://www.casn.ca">www.casn.ca</a>
PHAC	Public Health Agency of Canada – The national body established in 2004 to help Canadians achieve better health and well-being through the prevention of chronic disease and injury, promotion of good health, and protection from infectious diseases and other major health threats; <a href="http://www.phac-aspc.gc.ca">www.phac-aspc.gc.ca</a>
CPHA	Canadian Public Health Association – A national, independent, not-for-profit, voluntary association representing public health in Canada with links to the international public health community; <a href="http://www.cpha.ca">www.cpha.ca</a>
CCIAP	Canadian Coalition for Immunization Awareness and Promotion – CPHA's national partnership across non-governmental, professional, health, consumer, government and private sector organizations with a specific interest in promoting the understanding and use of vaccines recommended by NACI; <a href="http://www.immunize.cpha.ca">www.immunize.cpha.ca</a>
CAIRE	Canadian Association for Immunization Research and Evaluation – A unique professional organization of Canadian vaccine researchers with a common interest in contributing to the scientific foundation for optimal immunization program, including novel education and advocacy initiatives as well as pro active emphasis on public health needs and priorities; <a href="http://www.caire.ca">www.caire.ca</a>
IEI	Immunization Education Initiative – A national group of nurses partnering with other immunization supporters, who educate regarding the importance of immunization to enhance the health of Canadians; <a href="http://www.immunizationeducation.ca">www.immunizationeducation.ca</a>
CNCI	Canadian Nursing Coalition on Immunization – A partnership of senior public health nurses, administrators, managers and epidemiologists from all provinces/territories as well as representatives from Health Canada/PHAC and non-government organizations; CNCI has worked with the PHAC since 2004 to develop web-enabled tools containing the latest provincial/territorial vaccine program information; see <a href="http://www.phac-aspc.gc.ca/im/ptimprog-progimpt/index.html">www.phac-aspc.gc.ca/im/ptimprog-progimpt/index.html</a>
PEWG	Professional Education Working Group – One of several sub-groups of the CIC; PEWG members represent front-line health professionals, immunization program planners, professional societies and academics from across Canada; this working group is responsible for developing strategies to improve immunization education among Canadian health care professionals; no website available.
<p>* For certain vaccination programs, additional medical societies (focused on relevant medical specialties) also play an active role in education/advocacy programs to promote awareness regarding the value of immunization.</p> <p>Sources: i) Immunization Competencies for Health Professionals, Public Health Agency of Canada Center for Immunization and Respiratory Infectious Diseases, November 2008; and ii) Exhibitor Guide, Canadian Immunization Conference, Public Health Agency of Canada, Nov. 30 - Dec. 3, 2008.</p>	

#### 2.5.4 Industry Associations

Within the Canadian vaccine landscape, the lead industry association is the Vaccine Industry Committee of BIOTECanada, which is comprised of Canada's major vaccine developers and suppliers. As part of its core mission, the VIC aims to increase awareness regarding the value of vaccines to the Canadian health care system, while advocating for a more efficient, favourable vaccine environment – supported by consistent and sustained funding of immunization programs (see Figure 2.1). Thus VIC members actively engage with federal, provincial and territorial governments to foster full access and availability of all existing and new vaccines for Canadians. The committee also promotes high-quality Canadian vaccine research and excellence in the development, manufacturing and distribution of vaccines. Moreover, the VIC plays a pivotal role in showcasing Canada's vaccine industry by demonstrating how manufacturers and other industry stakeholders work to improve the health of Canadians and those in other countries.

The VIC is dedicated to working jointly with NACI by engaging in open dialogue regarding relevant immunization issues, with the goal of promoting consistency and timeliness of NACI recommendations – and to achieve greater levels of transparency and accountability in the vaccine review process – for the collective benefit of all Canadian stakeholders. Other recent VIC achievements include participation on the Bar Coding Task Group and development of a resolution on bar code implementation in Canada, i.e. in the context of increasing requirements for regulatory compliance, and to enhance inventory management and protect patient safety. The VIC has also helped to advance priorities for cold chain management of vaccines with the VSWG sub-group of the CIC. In addition, the VIC has participated in consultations regarding funding programs supported by the Canadian HIV Vaccine Initiative (CHVI). Finally, in 2008 the VIC distributed brochures to Canadian stakeholders during National Immunization Awareness Week (April) and National Biotechnology Week (September), highlighting both the value of vaccines and the need for sustainable funding systems in Canada.<sup>78,79</sup> Overall, VIC initiatives have had considerable impact to date across the full spectrum of functional activities in vaccine program implementation, including vaccine research, regulatory oversight, national recommendations, funding, production/distribution and education related to immunization.

#### 2.5.5 Vaccinators and Vaccinees

In addition to clearing the technical, regulatory, recommendation, financing, and educational hurdles outlined above, a comprehensive plan for successfully introducing new vaccines must also establish and maintain an appropriate infrastructure for vaccine distribution and delivery. In general, vaccines are delivered in Canada through multiple distribution channels.<sup>80,81,82</sup> For most publicly-funded programs, vaccines are administered primarily through provincial/territorial public health clinics and offices, physician-based practices, school-based clinics, hospital-based influenza programs, and elderly drop-in centres. In contrast, non-publicly funded vaccines are delivered primarily by health care providers in physician-based practices, as well as in non-traditional settings, including pharmacy-based clinics and travel clinics.

As discussed in Paper 8, key vaccinators in Canada include physicians (frequently general practitioners and pediatricians),<sup>83</sup> pharmacists,<sup>84</sup> and nurses,<sup>85</sup> all of whom play a vital role in providing medical information, counseling and immunization to vaccine recipients. Vaccine administration by these health care professionals involves the development and execution of a checklist for pre-immunization patient assessment, including precautions, contraindications and indications for rescheduling of vaccination. Vaccine providers subsequently prepare and administer immunization agents carefully, with the goal of

ensuring the seven “rights” of immunization, including the right drug, right client, right dose, right time, right route, right reason, and right documentation.<sup>86</sup> Target vaccine recipients (or vaccinees) encompass many segments of the general public, including infants, adolescents, adults/seniors, and other high-risk or special populations, such as international travelers, employees exposed to occupational hazards, and police/military personnel.

## 2.6 Recommendations

Vaccines represent an essential component of public health policy worldwide. Despite historically challenging market conditions both in developed and developing countries, manufacturers continue to invest in vaccines, and several new products have recently been launched – with many other emerging vaccine technologies in the pipeline. However, the vaccine marketplace is highly unusual, with a number of unique characteristics that require carefully designed policy strategies to ensure continued stability and longer-term viability of the overall system of vaccine development, introduction and supply.<sup>87</sup> As detailed in previous sections, the Canadian vaccine market is relatively small and potentially fragile, with few manufacturers/developers that must compete for investment capital as they face an increasingly stringent and therefore costly regulatory environment. Other challenges include the fast pace of vaccine innovation and new product introduction (which currently exceeds that of many other drug categories),<sup>88</sup> as well as increasing globalization, including accelerated global travel and immigration – which in turn fuels the spread of infectious disease.

In the context of these rapidly evolving market dynamics, it is critical that decision-makers at all levels recognize the need for enhanced immunization programs, while striving to reinforce the full value of vaccines in formulating appropriate policies that will ensure the Canadian vaccine system remains strong. Overall, the adoption of new immunization programs represents a collective challenge for all Canadians, hence continued partnership and collaboration among industry players, government, and public health officials will be crucial in creating a supportive environment for ongoing investment and sustained success of the Canadian vaccine enterprise. In the spirit of such collaboration, the following recommendations are put forward by BIOTECanada’s VIC for consideration by federal, provincial, and territorial governments and other key stakeholders. While these general recommendations are intended to support broad policy objectives for improving the effectiveness of immunization programs in Canada, specific recommendations that address individual components of Canada’s vaccine system are presented independently in subsequent papers, as indicated.

Federal/Provincial/Territorial Recommendations:

1. In formulating appropriate immunization policy, government officials and decision-makers at all F/P/T levels must recognize the unique (and potentially fragile) nature of Canada’s vaccine industry, thus promoting and safeguarding the Canadian vaccine system from a business perspective.
2. In creating policies that impact the Canadian immunization system, government officials must acknowledge and defend the true value of vaccines as an important and cost-effective public health measure, while ensuring that all relevant strategies reflect the full medical, social and economic benefits of immunization (refer to Paper 1).

3. Policy approaches to developing an efficient vaccine marketplace should encourage long-term investment in R&D in the vaccine sector (refer to Papers 3 & 7). These initiatives should assist in:
  - driving future innovation in the development of life-saving (preventive) and therapeutic vaccines;
  - preventing manufacturers from exiting the vaccine market; and
  - ensuring continued vaccine supply.
4. Policy strategies to enhance the operation of the vaccine market should, at the broadest level, include harmonization of regulatory practices and removal of procedural barriers to the rapid adoption of new immunization programs. These strategies should include the development of less duplicative and more consistent evaluation/recommendation procedures – as well as predictable, sustained funding mechanisms – to support timely patient access to existing and breakthrough vaccine technologies (refer to Papers 4, 5, and 6).
5. Policy approaches designed to maintain and improve immunization coverage rates as the primary public health benefit should also ensure adequate resources are in place for effective vaccine program awareness/education and implementation, including appropriate infrastructure for vaccine distribution and delivery across the country. In addition, adequate resources should be deployed to effectively monitor vaccine use, including safety and efficacy, through enhanced surveillance programs (refer to Papers 8 & 9).

Stakeholder Recommendations:

6. To help ensure vaccines remain one of the most important and cost-effective public health measures in Canada, stakeholders at all levels (including F/P/T government representatives, public health officials, policy makers, medical professionals, vaccine manufacturers/developers and researchers, investors, payers, and the general public) should work in collaborative partnership, not only to improve the effectiveness of immunization programs, but also to communicate the value of the effective immunization program to all Canadians.
  - To this end, all relevant stakeholders must take greater responsibility in becoming more knowledgeable (and educating others) regarding the various types of vaccines, and their extraordinary benefits in terms of improving health and economic outcomes.
  - More open, frequent and formalized dialogue should be actively encouraged across governments, the academic research community, non-governmental organizations (NGOs), and other industry partners, i.e. to facilitate the flow of new scientific data in a more efficient, timely manner – particularly where new advances reinforce the value of vaccine technologies within Canada’s health care system.
7. In the context of protecting and improving the current Canadian vaccine enterprise, all relevant stakeholders should continue to engage in the discussion of common critical issues in immunization practice on the international stage. Canadian stakeholders should continue to seek best practices models that match those of the top immunization programs worldwide, i.e. with the goal of achieving optimal clinical outcomes and economic value through greater standardization and predictability within Canada’s immunization system.

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