

Pathway to Access: Toward Sustainable Funding

La voie de l'accès : Vers un financement durable

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6.1 Executive Summary / Sommaire

6.1.1 Executive Summary

On the global stage, immunization programs have been widely recognized as among the best investments in health, based on extensive analyses of both cost-savings and cost-effectiveness. Although the economic benefits of immunization are very well documented – and cost-effectiveness is greater than that of virtually any other preventive or therapeutic health care intervention – vaccines continue to be (mistakenly) undervalued and underutilized throughout the world. Greater strides must be made to recognize and promote the fact that vaccines provide excellent value for money spent, specifically in terms of their broad medical, social and economic impact.

In Canada, the current vaccine financing system is a mix of public and private sector effort, which funds the purchase and administration of recommended vaccines for children, adolescents and adults. Most childhood immunization programs are publicly funded, whereas public funding is much more limited for adolescents and adult immunization. In general, limited financing and the lack of timely funding decisions represent dominant barriers in achieving access to recommended vaccines across all age groups. In recent years, the growing number and cost of new vaccines have created a crisis within the vaccine reimbursement landscape, with increased stress on the both public and private provider systems. In particular, as for other countries, there is significant apprehension that the Canadian funding system may not be capable of keeping pace with newly approved/recommended vaccines in the near-term future.

Since health care in Canada is primarily a provincial or territorial responsibility, funding of immunization programs has been determined historically by provincial/territorial ministries of health. Hence each province and territory has a separate schedule; there is no national immunization schedule that is followed (and funded) across all jurisdictions. From 2003 forward, the federal government has played an increasing role in promoting the adoption and harmonization of vaccine programs across the country. Two major federal initiatives have included the launch of the National Immunization Strategy (NIS) in 2003, and the creation of Public Health Agency of Canada (PHAC) in 2004.

Unquestionably, tremendous progress has been made since 2003 in achieving equitable access to newly recommended vaccines across Canada. Specifically, under the NIS, \$300 million in federal funding has been injected to support immunization programs for four new vaccines (acellular pertussis, meningococcal C conjugate, pneumococcal conjugate and varicella), as recently recommended by the National Advisory Committee on Immunization (NACI). Subsequently, in 2007, the federal government committed an additional \$300 million to finance human papillomavirus (HPV) vaccine programs in Canada, thereby extending previous federal funding for national vaccination programs under the NIS.

Despite these recent advances, significant work lies ahead in terms of achieving timely, equitable access to vaccines by all Canadians, and there remains an urgent need for predictable, sustained funding mechanisms for new vaccination programs. Furthermore, the bureaucratic, duplicative nature of the Canadian Immunization Committee (CIC) structure (as introduced under the NIS) has been publicly exposed during the recent experience with introducing the HPV vaccine in Canada. Although the introduction of the high profile HPV vaccine was widely considered as a test case for the new NACI/CIC partnership in overseeing national immunization issues, many questions have been raised regarding whether this joint public health structure is accomplishing its goals in promoting a harmonized, nationally coordinated approach to adopting immunization programs in Canada. In general, these signals have indicated that the current Canadian system for funding and implementing vaccination programs is not yet

working at optimal efficiency; continued and improved leadership – particularly at the national level – is still urgently required.

Overall, Canada’s funding mechanisms for new vaccines can still be characterized as lacking in harmonization and transparency, resulting in unacceptable duplication, inequities, and delays in patient access. Another critical concern is that a larger trust fund for other new and/or forthcoming vaccines has still not been established, thus it remains unclear how the system will be able to accommodate newly licensed vaccines (e.g. quadrivalent meningococcal conjugate, rotavirus and shingles vaccines), as well as new combination vaccines against measles, mumps, rubella and varicella on the near-term horizon.

As the Canadian vaccine environment continues to undergo rapid change, several other issues remain unsettled and/or under consultation. For example, debate continues on the topic of whether vaccines should be exempt from Patented Medicine Prices Review Board (PMPRB) guidelines on excessive pricing. BIOTECanada and its Vaccine Industry Committee (VIC) maintain the position that vaccines, which undergo a competitive tendering process, should not be regulated like other traditional pharmaceuticals. As a second pivotal issue, it is currently unknown whether emerging therapeutic vaccines will 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.

In the latter case, therapeutic vaccines could potentially be reviewed by the Common Drug Review (CDR) or Joint Oncology Drug Review (JODR) procedures – quite apart from the current NACI deliberation system for preventive vaccines. This example underscores the imminent need for decision-makers at many levels to reassess potential recommendation, financing and reimbursement models. In this context, it will also be important for federal and provincial officials to consider best practices for vaccine program financing and implementation in other countries (including the Vaccines for Children Program, VFC, in the United States), to help achieve optimal clinical outcomes and economic value through standardized immunization programs.

In addressing the key challenges currently faced within the vaccine reimbursement environment in Canada, the highest level goal is to ensure equitable access to all recommended vaccines without financial barriers. To achieve this goal, Canada needs a predictable process and sustained financial support at the federal, provincial and territorial (F/P/T) levels for both existing and new public vaccine programs, including emerging vaccine technologies. The VIC has put forward the following recommendations – in the spirit of collaboration – for consideration by F/P/T governments and other key stakeholders. In continuing to build upon recent successes in improving vaccination programs, stakeholders at all levels must intensify efforts to enhance the existing immunization funding infrastructure for the benefit of all Canadians.

Federal Recommendations:

1. Federal funding for immunization programs should be renewed (potentially in the form of a permanent trust fund, and tied to the expansion of the NIS goals) to ensure new vaccine technologies can be incorporated into public vaccine programs.

2. With the imminent launch of therapeutic vaccine technologies in Canada, Health Canada should work in a transparent manner with manufacturers and other relevant stakeholders (including members of NACI, and those affiliated with CDR and JODR procedures) to determine the most appropriate route(s) of evaluation and reimbursement for therapeutic vaccines.

Provincial/Territorial Recommendations:

3. The provinces/territories should work towards an agreement with the Federal government regarding mechanisms and funding to ensure the adoption of new vaccines by public health programs within six months of Health Canada approval.
4. Notwithstanding Recommendation 3 (and as a contingency strategy), the provinces and territories should endeavour to reach consensus across all jurisdictions with regard to the creation of (and adherence to) a standardized, timely, consistent system for funding public immunization programs.

Stakeholder Recommendations:

5. A meeting of all relevant stakeholders should be convened (potentially by the VIC) to discuss:
 - i. The current vaccine funding and delivery system and its inherent flaws in equitably protecting the Canadian public;
 - ii. Best practices in other countries for vaccine financing and reimbursement; and
 - iii. Potential new models to encourage predictable, sustained funding mechanisms and efficient delivery for recommended vaccines in Canada.

6.1.2 Sommaire

Sur la scène mondiale, les programmes d'immunisation sont largement considérés parmi les meilleurs investissements en santé. C'est ce que révèlent des analyses effectuées à grande échelle sur les économies de coûts et la rentabilité. Bien que les avantages économiques de l'immunisation soient très bien documentés – et que sa rentabilité soit plus grande que celle de pratiquement n'importe quelle autre intervention préventive ou thérapeutique en soins de santé – les vaccins sont encore (à tort) sous-évalués et sous-utilisés dans le monde entier. On doit réaliser des progrès plus importants afin de reconnaître et de promouvoir le fait que les vaccins représentent un investissement rentable, notamment en ce qui a trait à leurs répercussions générales sur le plan médical, social et économique.

Au Canada, le système actuel de financement des programmes de vaccination est le fruit d'une collaboration entre les secteurs public et privé, qui permet de financer l'achat de vaccins recommandés chez les enfants, les adolescents et les adultes, et leur administration. La majorité des programmes d'immunisation destinés aux enfants sont financés par l'État, alors que les programmes destinés aux adolescents et aux adultes bénéficient d'une aide gouvernementale beaucoup plus restreinte. En général, le financement restreint et l'absence de décisions de financement prises en temps opportun sont des obstacles importants à l'accès de tous les groupes d'âge aux vaccins recommandés.

Au cours des dernières années, l'augmentation du nombre de nouveaux vaccins et de leur coût est venue bouleverser le système de remboursement des vaccins, imposant un stress accru sur les assureurs publics et privés. On craint notamment au Canada, comme dans d'autres pays, que le système de financement ne soit pas capable de suivre le rythme des nouveaux vaccins qui seront approuvés et recommandés dans un avenir prochain.

Étant donné que les soins de santé au Canada sont principalement du ressort des provinces et des territoires, c'est aux ministères provinciaux et territoriaux de la Santé que sont toujours revenus les décisions relatives au financement des programmes d'immunisation. C'est pourquoi chaque province et territoire a un calendrier d'immunisation qui lui est propre; il n'existe aucun calendrier national d'immunisation respecté (et financé) par l'ensemble des provinces et territoires. Depuis 2003, le gouvernement fédéral contribue de plus en plus à promouvoir l'adoption et l'harmonisation des programmes de vaccination dans tout le pays. Il a, à cette fin, mis en place deux initiatives importantes : la Stratégie nationale d'immunisation (SNI) en 2003 et l'Agence de la santé publique du Canada (ASPC) en 2004.

Il ne fait aucun doute que d'énormes progrès ont été réalisés depuis 2003 pour permettre à toute la population canadienne d'accéder équitablement aux nouveaux vaccins recommandés. Dans le cadre de la SNI, notamment, une aide fédérale de 300 millions de dollars a été allouée aux provinces et territoires pour faciliter l'introduction de quatre nouveaux vaccins (vaccin anticoquelucheux acellulaire, vaccin conjugué contre le méningocoque, vaccin conjugué contre le pneumocoque et vaccin contre la varicelle), recommandés dernièrement par le Comité consultatif national de l'immunisation (CCNI). Par la suite, en 2007, le gouvernement fédéral a engagé un montant additionnel de 300 millions de dollars pour financer les programmes de vaccination contre le virus du papillome humain (VPH) au Canada, prolongeant de ce fait l'aide qu'il avait allouée précédemment dans le cadre de la SNI à l'égard des programmes nationaux de vaccination.

Malgré ces récents progrès, d'importants efforts doivent encore être déployés pour que tous les citoyens canadiens aient accès aux vaccins d'une manière équitable, en temps opportun, et l'on observe toujours un besoin urgent de mettre en place des mécanismes prévisibles et soutenus de financement des nouveaux programmes de vaccination. En outre, le public a été mis au courant de la structure bureaucratique du Comité canadien d'immunisation (CCI) (constitué dans le cadre de la SNI) et du chevauchement des tâches qui la caractérise quand le vaccin contre le VPH a été introduit au Canada récemment. Bien que l'introduction de ce vaccin très médiatisé ait été largement considérée comme un indicateur du succès du nouveau partenariat établi entre le CCNI et le CCI en matière de surveillance des questions d'immunisation d'importance nationale, on a soulevé de nombreuses questions à savoir si cet effort concerté en santé publique permettait d'atteindre l'objectif qu'on s'était fixé, soit de promouvoir l'adoption de programmes d'immunisation au Canada selon une approche harmonisée et coordonnée à l'échelle nationale. Ces signes révèlent, en général, que le système canadien actuel de financement et de mise en œuvre des programmes de vaccination n'atteint pas encore son rendement optimal. Un leadership continu et amélioré – notamment à l'échelle nationale – est encore requis de toute urgence.

En général, on peut affirmer que les mécanismes canadiens de financement des nouveaux vaccins comportent encore des lacunes sur le plan de l'harmonisation et de la transparence, ce qui entraîne un chevauchement des tâches, des injustices et des délais inacceptables qui nuisent à l'accès des patients. Autre problème important, on n'a encore créé aucun fonds plus substantiel d'affectation spéciale en vue de financer d'autres vaccins nouveaux et/ou à venir. On ne sait donc pas encore avec certitude comment le système pourra financer les vaccins nouvellement homologués (p. ex., le vaccin conjugué quadrivalent contre le méningocoque, le vaccin antirotavirus et le vaccin contre le virus zona-varicelle), de même que les nouveaux vaccins combinés contre la rougeole, les oreillons, la rubéole et la varicelle, dans un avenir prochain.

Alors que le système canadien de vaccination continue d'évoluer rapidement, d'autres questions demeurent sans réponse et/ou sont encore à l'étude. On continue, par exemple, de se demander si l'on devrait exempter les vaccins des Lignes directrices du Conseil d'examen du prix des médicaments brevetés (CEPMB) sur les prix excessifs. BIOTECanada et son Comité de l'industrie des vaccins (CIV) maintiennent leur position selon laquelle les vaccins, qui font l'objet d'un processus d'appel d'offres concurrentiel, ne devraient pas être assujettis à la même réglementation que d'autres produits pharmaceutiques traditionnels. Autre fait important, on ne sait actuellement pas si les nouveaux vaccins thérapeutiques seront intégrés aux programmes de santé publique ou si les régimes (formulaires) provinciaux d'assurance-médicaments auront la responsabilité d'évaluer et de financer ces vaccins au même titre que d'autres traitements thérapeutiques.

Dans ce dernier cas, les vaccins thérapeutiques pourraient éventuellement être évalués par le Programme commun d'évaluation des médicaments (PCEM) ou le Processus conjoint d'examen des médicaments oncologiques (PCEMO) – mécanismes totalement indépendants de l'actuel processus décisionnel du CCNI relatif aux vaccins préventifs. Cet exemple souligne la nécessité imminente que les décideurs, à de nombreux échelons, réévaluent les modèles possibles de recommandation, de financement et de remboursement des vaccins. Dans ce contexte, il sera important aussi que les fonctionnaires fédéraux et provinciaux tiennent compte des pratiques exemplaires qui sont utilisées dans d'autres pays en matière de financement et de mise en œuvre de programmes de vaccination (y compris le Vaccines for Children Program [VFC] des États-Unis), afin d'obtenir une valeur économique et des résultats cliniques optimaux dans le cadre de programmes d'immunisation normalisés.

Afin de surmonter les principaux défis auxquels fait face le système canadien de remboursement des vaccins, il importe d'abord et avant tout d'assurer un accès équitable à tous les vaccins recommandés, et ce, sans contraintes financières. À cette fin, le Canada doit mettre en place, à l'échelle fédérale, provinciale et territoriale, un mécanisme prévisible et durable de soutien financier des programmes publics de vaccination actuels et nouveaux, y compris les nouvelles technologies vaccinales. Dans un esprit de collaboration, le CIV a formulé les recommandations suivantes à l'intention des gouvernements fédéral, provinciaux et territoriaux, et d'autres intervenants clés. Afin de continuer de miser sur les récents progrès visant à améliorer les programmes de vaccination, tous les intervenants doivent redoubler d'effort pour améliorer l'infrastructure actuelle de financement des programmes d'immunisation au profit de tous les citoyens canadiens.

Recommandations à l'intention du gouvernement fédéral :

1. Le gouvernement fédéral doit renouveler son aide financière aux programmes d'immunisation (peut-être sous la forme d'un fonds permanent d'affectation spéciale et en lien avec l'accroissement des objectifs de la SNI) pour que les nouvelles technologies vaccinales puissent être intégrées aux programmes publics de vaccination.
2. Devant le lancement imminent de vaccins thérapeutiques au Canada, Santé Canada doit travailler en collaboration avec les fabricants et autres intervenants concernés (dont les membres du CCNI et les personnes associées au PCEM et au PCEMO) d'une manière transparente afin de déterminer les modes d'évaluation et de remboursement des vaccins thérapeutiques qui conviennent le mieux.

Recommandations à l'intention des gouvernements provinciaux et territoriaux :

3. Les provinces et territoires doivent travailler en collaboration avec le gouvernement fédéral afin de mettre en place les mécanismes et le financement nécessaires à l'adoption de nouveaux vaccins par les programmes de santé publique dans les six mois suivant l'approbation de Santé Canada.
4. Par dérogation à la recommandation 3 (et par mesure de prévoyance), les provinces et territoires doivent s'efforcer de venir à un consensus général concernant la création (et le respect) d'un système normalisé, opportun et cohérent de financement des programmes publics d'immunisation.

Recommandations à l'intention d'autres intervenants :

5. Tous les intervenants concernés doivent être conviés (peut-être par le CIV) à une réunion visant à débattre des enjeux suivants :
 - i. Le système actuel de financement et d'administration des vaccins, et ses faiblesses quant à la protection équitable de la population canadienne;
 - ii. Les pratiques exemplaires qui sont utilisées dans d'autres pays en matière de financement et de remboursement des vaccins;
 - iii. Les nouvelles méthodes pouvant favoriser la mise en place de mécanismes prévisibles et durables de financement des vaccins recommandés au Canada, et d'un système efficace d'administration de ces vaccins.

6.2 The Need for Predictable and Sustained Funding Mechanisms

Economic factors, including financing of immunization programs, play a key role in the development and use of vaccines throughout the world. An over-arching goal is to ensure universal access to all recommended vaccines for children, adolescents and adults without financial barriers.¹ However, a number of concerns have been raised regarding the ability of the current public and private vaccine delivery systems to maintain access to recommended vaccines for all persons. For example, the growing number and cost of new vaccines in recent years – coupled with new vaccine recommendations – have created a crisis in the delivery system, with increased stress on both the public and private provider systems. These pressures have led to instability in immunization coverage, with significant disparities and delays in access to recommended vaccines across geographic and demographic populations. Currently, such disparities are most marked for newer vaccines.

In the face of these trends, consistency and continuity in financing vaccine programs remain essential in realizing their full benefits, particularly since efficient delivery of immunization programs depends upon broad, uninterrupted coverage across targeted cohorts.² While evidence from past studies supports the premise that the availability of financing positively affects immunization rates,³ consistent financing also enhances the stability of supply and encourages innovation in new vaccine technologies. Conversely, limited financing and a lack of timely funding decisions represent dominant barriers in achieving access to recommended vaccines. Furthermore, unpredictable expansions and contractions in financing may lead to resurgence or outbreaks of disease. Overall, if Canada's health care system is to truly benefit from advanced vaccine technologies, it will need a more favourable vaccine environment for consistent, sustained funding of immunization programs. Indeed this is a fundamental element of the core mission of BIOTECanada's Vaccine Industry Committee, VIC.⁴ This paper examines the current status of the vaccine reimbursement environment in Canada; it also provides key recommendations for future direction in working towards sustainable funding mechanisms for recommended vaccines for all Canadians.

6.3 Historical Perspective – Provincial and Federal Roles

6.3.1 The Late 1990's to Early 2003 – Primarily a Provincial Role

In Canada, health care is primarily a provincial or territorial responsibility, and as such, funding of immunization programs has been determined historically by provincial and territorial ministries of health. As described in Paper 5, NACI makes national recommendations on routine use of vaccines, yet the establishment of immunization program is at the discretion of the provincial and territorial public health agencies. Thus the integration of new vaccines into publicly-funded immunization programs is ultimately the responsibility of provinces and territories, and each jurisdiction decides which products will be purchased and offered free of charge to certain target groups. Traditionally, each jurisdiction weighs the economics of providing the preventive vaccine against treating the associated illness, and typically chooses the most cost efficient option. However, other factors also come into play, including the significant costs associated with training health care professionals, ensuring supply, and conducting public awareness campaigns for new vaccines.⁵

Up until 1998, when the chicken pox (varicella) vaccine was licensed for use in Canada, the provinces and territories were doing a relatively good job of introducing newly licensed vaccines to prevent childhood morbidity and mortality, and ensuring their populations were immunized. Examples of such vaccines include *Haemophilus influenzae* type b (Hib) for infants (1992) and whooping cough (acellular pertussis)

combination vaccines for infants and children (1997). At this stage, federal support had been limited to regulating vaccine licensure and lot-by-lot release, as well as supporting NACI and maintaining a small staff and budget to assist the provinces and territories in coordinating limited activities.

Subsequently, during the late 1990s – at a time of cutbacks in health care budgets and a gradual weakening of public health in Canada – provinces and territories began to delay the adoption of new immunization programs. Disparities continued to widen until early 2003, by which time several new vaccines had been licensed (also including meningococcal C conjugate, and pneumococcal conjugate), and a patchwork of inconsistent immunization programs had unmistakably emerged across the provinces and territories.⁶

6.3.2 2003-2007 – Increasing Federal Role

During the next few years, two major changes occurred at the national level to alter Canada's immunization landscape. First, in response to concerns regarding disparities across jurisdictions, the National Immunization Strategy (NIS, as introduced in Paper 5) was launched under Liberal government leadership in 2003 with the key goals of ensuring equitable access to recommended vaccines and reducing the incidence of vaccine-preventable diseases. To help meet the goals of the NIS, the Canadian Immunization Committee (CIC) was also established in 2003 with the key objective of making continued, collaborative progress in conjunction with NACI in promoting the harmonization of immunization programs in Canada.

Initially, in February 2003, the federal government allocated \$45 million over five years to assist with NIS development. Subsequently, the 2004 federal budget promised a further \$300 million over the three year period from 2004-2007 under the NIS (through the Canadian Immunization Trust Fund) to support the introduction of four newly recommended vaccines across all provinces and territories.⁷ These programs included varicella vaccines, adolescent and adult acellular pertussis vaccines, infant and child pneumococcal conjugate vaccines, and infant and adolescent conjugate meningococcal C vaccines. Virtually all jurisdictions have now successfully introduced these programs using the NIS funds; it has been estimated that twice as many Canadian children were protected against the associated vaccine-preventable diseases in 2006 compared with 2003,⁸ and there have been documented reductions in hospitalization due to these infections.⁹ The progress made under the NIS program over this period has been a well-known success story for immunization in Canada. While it is premature to assess the full economic impact of the \$300 million NIS investment – in terms of savings within the Canadian health care system – there is unanimous agreement that this program has prudently distributed the \$300 million fund to provide more equitable access for the four relevant vaccines.

Over the same time period, the Public Health Agency of Canada (PHAC), as introduced in Paper 5, was created in 2004 to provide national guidance, leadership and coordination in public health.¹⁰ In essence, the PHAC was formed in response to the global SARS epidemic, since it had become clear that the health of the Canadian public is very much connected to the health, well-being and success of communities outside their borders. The SARS outbreak reinforced Canada's understanding that infectious diseases are not constrained by provincial or national boundaries – and that taking an isolated approach to public health would ignore the interconnectedness of the modern world. Hence, while health care remains predominantly a provincial/territorial responsibility in Canada, the prevention and control of serious infectious disease (also including emerging threats such as West Nile virus infection and a possible influenza pandemic) represents an area of exception that has come more sharply into focus for the federal

government in the new millennium. Indeed, the federal government should acknowledge its need to play a stronger leadership role in preventing and controlling infectious disease, including consultation with the provinces/territories in assisting in the implementation of their operational plans. It is noteworthy that since the creation of the PHAC, both NACI and the CIC have reported to the federal/provincial/territorial Conference of Deputy Ministers of Health within the newly formed Public Health Network (see Figure 5.1, Paper 5).¹¹

Unfortunately, despite the creation of a national public health agency, and notwithstanding the fact that the NIS had injected new funding for vaccination programs over a 3 year period, a lack of uniformity across jurisdictions still existed by 2007 with respect to patient access to recommended vaccines. Thus, while these recent federal initiatives were credited with improving immunization programs in Canada¹², they have also been severely criticized¹³. In particular, the VIC of BIOTECanada has expressed its opinion that the NIS had a strong impact on the affordability of the four vaccine programs that were publicly funded, yet there was still an urgent need for predictable, sustained funding mechanisms and timely implementation of new vaccination programs. Furthermore, the VIC called attention to the cumbersome, duplicative nature of the CIC structure introduced under the NIS, while emphasizing the need for enhanced transparency and accountability in achieving a nationally coordinated approach to immunization programs in Canada.¹⁴ Overall, it became evident there was significant work ahead in terms of achieving equitable access to vaccines by all Canadians.

With the arrival of the human papillomavirus (HPV) vaccine, vaccine financing in Canada entered another new stage. In July 2006, Gardasil (Merck's breakthrough quadrivalent vaccine against HPV types 6, 11, 16 and 18) was approved by Health Canada as the first HPV vaccine, and is currently the only HPV vaccine available in Canada. Gardasil is intended to prevent the majority of HPV-related clinical disease, primarily cervical cancers¹⁵, but also includes vaginal and vulvar cancers, as well as genital warts. In February 2007, NACI subsequently announced its positive recommendation that all Canadian females 9-13 years of age (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, should receive Gardasil.

Given that previous funding for vaccine programs through the Canadian Immunization Trust Fund would come to a halt in March 2007, the vaccine industry had actively been advocating for continued federal funding for other newly approved or imminently anticipated vaccines, including Gardasil, Menactra (sanofi pasteur's quadrivalent meningococcal conjugate vaccine to protect against all four vaccine-preventable serogroups of meningococcal disease), Rotateq (Merck's oral pentavalent rotavirus vaccine to prevent rotavirus gastroenteritis in infants) and Rotarix (GlaxoSmithKline's live monovalent human rotavirus, also for infants). In particular, advocacy activities for Gardasil were based on compelling clinical recommendations for HPV vaccination in Canada from the most directly related medical societies – such as the Gynaecologic Oncologists of Canada (GOC), the Society of Obstetricians and Gynaecologists of Canada (SOGC), and the Federation of Medical Women of Canada (FMWC) – all of which 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.

Based on the positive recommendations for the HPV vaccine put forward by key regulatory, advisory and medical authorities in Canada, the federal government – now under Conservative leadership – announced \$300 million in financing for HPV immunization programs across the country in March 2007. This funding represented an extension to previous federal financing for national vaccination programs under the NIS.

The federal funding commitment was to be allocated over 3 years, on a per-population basis. In response to this federal funding, the provinces were quick to take action; Ontario, Prince Edward Island, Nova Scotia, and Newfoundland took the lead, all announcing school-based HPV immunization programs to begin in 2007. Other provinces followed suit, and as of mid-2008, all 10 provinces announced they had initiated, or would initiate, HPV vaccination programs.¹⁶

The unique feature of this new federal financing agreement was that it represented the first time that federal funding had been targeted to a specific disease immunization program; it also allocated an unprecedented amount of funding to a single vaccine. However, the announcement to fund HPV vaccination to prevent cervical cancer was consistent with the Conservative government's broader initiatives for the prevention and treatment of cancer, including its \$260 million commitment to the five-year Canadian Strategy for Cancer Control, announced in May 2006, and the subsequent establishment of the Canadian Partnership Against Cancer in November 2006.¹⁷ Hence the federal government financing of the HPV vaccine was aligned with one of the health care priorities recently established by the new Conservative government. This alignment may have played a role in the decision to exclusively fund HPV vaccination programs in targeting cervical cancer, rather than more broadly funding a series of new vaccines, as had been done under previous federal government leadership.

Overall, tremendous progress has been made over the five-year period from 2003-2007 in achieving equitable access to newly recommended vaccines across Canada. Specifically, five new vaccines (against chickenpox, pneumococcus, adolescent whooping cough, meningitis, and HPV-related diseases) have been introduced from coast to coast during this time, as supported by significant Liberal and Conservative federal funding programs. Thus the federal government has a history of bold leadership in promoting the adoption of vaccine technologies across the country. These recent advances underscore and reinforce the need for strong federal government leadership (and continued momentum) in achieving sustainable, predictable funding mechanisms for immunization programs in Canada.

6.3.3 2008 Forward – The Need for Continued National Leadership

In evaluating recent events in securing funding for HPV vaccination, it is noteworthy that joint NACI/CIC deliberations regarding HPV immunization programs continued throughout all of 2007, and recommendations of the newly formed NACI/CIC Task Force were not publicly issued until mid-2008.¹⁸ Hence the March 2007 announcement regarding federal government funding for HPV vaccination came a time when joint NACI/CIC deliberations were still in progress. Although the HPV vaccine was widely considered as a test case for the new NACI/CIC partnership in vaccine program planning,¹⁹ this case demonstrated that public funding of vaccine programs via the federal government, as well as implementation by the provinces and territories, can occur prior to (or irrespective of) any consensus achieved through the NACI/CIC collaborative process. Thus, while the joint public health structure – created to oversee national immunization issues – is still in a stage of relative infancy, the current influence of this intergovernmental bureaucracy has been called into question.²⁰ In general, these signals have indicated that the current Canadian system for funding and implementing vaccination programs is not yet working at optimal efficiency; continued and improved leadership at the national level is still urgently required.

In addition to weaknesses already identified in achieving consistent, timely access to newly recommended vaccines in Canada, another major concern is that a larger trust fund for other new and/or forthcoming vaccines in the future has still not been established. Thus, without a long-range plan in place for

sustaining broader immunization program funding, critical questions remain in terms of how the system will be able to accommodate newly licensed vaccines (e.g. quadrivalent meningococcal conjugate, rotavirus and shingles vaccines), as well as new combination vaccines against measles, mumps, rubella and varicella on the near-term horizon. Specifically – where is future funding for new vaccines likely to come from?

Leadership from the federal government in this respect is crucial, since it is under such leadership that the provinces and territories are more likely to align themselves with federal initiatives and tap into their own resources in establishing and implementing necessary vaccine programs.²¹ In general, key opinion leaders have voiced the need for a permanent federal trust fund to be established, not only to provide funding for the introduction of new vaccines, but also to support publicly-funded catch-up campaigns, i.e. to cover vaccines, populations and jurisdictions for which catch-up programs would be appropriate.²²

Currently, in the absence of a more unified, streamlined system, many uncertainties persist surrounding the funding and administrative infrastructure(s) that support vaccination programs in Canada. One key issue is that federal funds recently allocated to specific disease immunization programs (e.g. against acellular pertussis, meningococcal group C infection, pneumococcal disease, varicella, and HPV-related disease) will not finance such vaccination indefinitely into the future, thus the provinces/territories may be required to bear additional future costs.

In addition, although immunization programs are currently funded by a combination of both federal and provincial/territorial funding, there are competing priorities among governments at all levels. For example, an extremely inefficient flow has been observed in the transfer of federal funding for targeted vaccine programs to provincial treasury boards, and subsequently to provincial ministries of health. The basic point of contention in these negotiations is that while the provinces wish to receive the funding, they do not want to be explicitly advised on how to allocate such funds. A further source of tension has been more recently introduced, i.e. when increased transfer payments to the provinces/territories were made by the Conservative government in efforts to “fix” the “fiscal imbalance”.²³ While a significant portion of such funding would be presumed to be directed towards provincial health initiatives, none of this additional funding has yet been used to finance immunization programs in Canada.

In essence, the provinces and territories are often wedged in the middle between two dysfunctional systems. On one hand, delays and the lack of predictability in the NACI/CIC recommendation process prevent them from implementing timely provincial public health programs, while on the other hand, provincial/territorial ministries of health are frequently blocked from receiving previously committed (or new) federal funding for immunization programs through transfer/equalization payments, as described above. From a broader policy perspective, Canada’s current system for making national vaccine recommendations, but not supporting timely delivery (and/or efficient deployment of funds) for such immunization programs, makes little sense. Unambiguous national leadership and improved national funding mechanisms will be required to resolve these intricate reimbursement conflicts and obstacles.

Overall, vaccine schedules in Canada can still be described as a patchwork quilt; there is no national immunization schedule that is followed (and funded) across all jurisdictions. While there are some reasons to support certain variations across the country – from a geographical or disease prevalence standpoint – there is no evidence for the need for other variations that persist. One underlying, confounding issue in this context is that each province/territory tends to view its current vaccine schedule as superior and more appropriate for its specific needs (based on the number of cohorts and target ages

for administration), relative to vaccine schedules in other jurisdictions. This type of potentially false bias has been counterproductive in moving towards a national consensus for vaccine priorities across the country. Finally, funding mechanisms for new vaccines are still characterized as lacking in harmonization and transparency, and the process continues to involve confusing, duplicative procedures (including the potentially overlapping NACI/CIC criteria and provincial/territorial decision-making processes) without established timelines. This acute lack of standardization and reproducibility within the vaccine reimbursement landscape represents a formidable barrier that stands in the way of achieving equitable access to immunization programs across the country.

Interestingly, quite apart from its role in overseeing NACI/CIC recommendation processes, the PHAC has recently been criticized more broadly by the Auditor General for its lack of progress towards the protection of Canadians from the threat of infectious disease. Specifically, it has been noted that after three years in existence, the PHAC has not yet clearly defined roles and responsibilities or set objectives and priorities for the surveillance of infectious disease.²⁴ This evaluation does not bode well for the strength of the PHAC infrastructure; results of this preliminary assessment point to the need for more aggressive, proactive national planning in preventing the spread of infectious disease and saving lives, as well as in reducing the economic burden of potential future outbreaks in Canada.

6.4 Economic Value of Vaccines

The tremendous value offered by vaccine technologies has been a key driver for the federal government in taking a strong leadership position in funding specific immunization programs to date. In general, immunization programs are among the best investments in health,²⁵ and wide recognition of the value of vaccination is not unique to Canada. Indeed, on the global stage, most developed countries (most notably the U.S.) have implemented sophisticated vaccine funding and delivery mechanisms to ensure that the value and medical benefits of vaccination are fully realized (see Section 6.7). As many countries continue to develop best practices to improve efficiencies in their respective domestic vaccine markets (and to help shape the global vaccine enterprise), there may be valuable lessons for advancing the Canadian vaccine industry – particularly in terms of achieving optimal clinical outcomes and economic value through standardized immunization programs.

As described in Paper 1, vaccines have saved hundreds of millions of lives over the past century, and are therefore credited with providing immense medical and social benefits. To date, vaccination has done more to reduce human mortality than any other health care intervention.²⁶ Mass immunization programs have resulted in the global eradication of smallpox and the elimination of polio from the Western hemisphere, Europe, and much of Asia, while vaccines for diseases like measles, pertussis, and diphtheria have dramatically reduced childhood mortality worldwide.²⁷ Globally, the effectiveness and low cost of vaccines (relative to the cost of disease treatment and long-term care) have made immunization programs essential to maintaining public health.

Although the cost-effectiveness of immunization is very well documented – and is greater than that of virtually any other preventive or therapeutic health activity²⁸ – vaccines continue to be (mistakenly) undervalued and under-utilized throughout the world.²⁹ Greater strides must be made to recognize and promote the fact that vaccines provide excellent value for money spent, specifically in terms of the broad medical, societal and economic impact of immunization programs. While all stakeholder groups hold responsibility in raising such awareness, public health officials in particular need to do a better job of endorsing the value and importance of vaccines, and thus to avoid further erosion of public trust.

6.4.1 Cost-Savings

With regard to economic benefits, most vaccines in use today are cost-saving to society. For example, in a review of 20 economic evaluation studies which met the selection criteria for childhood vaccination strategies in industrialized countries, the majority (70%) of these studies demonstrated that universal vaccination programs are cost-saving from the perspective of society, compared to no vaccination.³⁰ It has been estimated that for every dollar invested in childhood vaccination against nine vaccine-preventable diseases (diphtheria, tetanus, pertussis, *Haemophilus influenzae* type b, polio, measles, mumps, rubella, and hepatitis B), \$US 5.80 are saved in direct medical care costs. Further, when indirect benefits are taken into account, such as time off from work to care for ill children, the amount saved rises to \$US 17.70. Thus, the benefit-cost ratios for these vaccines are in the range of 5:1 for direct costs and 17:1 for societal costs.³¹ More generally, a broader cost-benefit analysis found that every dollar invested in vaccines saved \$US 2.00 – 27.00 in health costs.³² In Canada, one impressive estimate is that the introduction of polio immunization in 1955 and the subsequent eradication of polio in this country has saved approximately \$Cdn 3.3 billion in health care costs to date.³³ Overall, several Canadian studies have demonstrated that new vaccines are cost-effective and compare favourably to other treatment or preventive measures.³⁴

6.4.2 Cost-Effectiveness

Early vaccines introduced prior to 2000 set a high standard because they were cost-saving, as described above – since for every dollar spent on vaccination, more than one dollar was saved in medical or societal costs. In contrast, vaccines introduced for routine use in children and adolescents in 2000 and thereafter have typically not been cost-saving.³⁵ One notable exception is Prevnar, Wyeth's 7-valent pneumococcal conjugate vaccine – licensed in Canada in 2001 – for which vaccination of healthy infants has been projected to be cost-saving to society, under specific model assumptions in both Canadian³⁶ and American studies.³⁷ In general however, health interventions do not have to save money to be cost-effective. In fact, among U.S. rankings of 25 widely recommended clinical preventive services in 2006, childhood vaccination received a perfect score, based on clinically preventive burden and cost-effectiveness.³⁸ In developing nations, childhood vaccination in particular is recognized as a high-priority intervention strategy; indeed, it represents the most cost-effective investment that can possibly be made within limited health budgets (see also Section 6.7.3).³⁹

To date, most vaccine economic analyses have measured costs-effectiveness in terms of dollars per life year saved or per disease case prevented. Using the former measure, vaccine programs generally compare favourably with other public health interventions, including (among others) smoking cessation counseling, bicycle helmet laws, annual screening for cervical cancer and use of smoke detectors (Table 6.1).⁴⁰ However, comparisons of dollars per life year saved may still underestimate the economic value of vaccines, since these analyses do not give credit for averting pain, suffering, or disability attributable to disease.

Table 6.1 – Cost per Life Year Saved for Selected Vaccine Programs and Other Public Health Interventions	
Vaccines	Cost per life year saved
Measles, mumps, rubella for children	< 0 (\$16 saved per \$ spent)
DPT (diphtheria, pertussis, tetanus) for children	< 0 (\$6 saved per \$ spent)
Influenza for adults aged ≥ 65 years of age	< 0 (\$45 saved per \$ spent)
Pneumococcal polysaccharide for adults aged ≥ 65 years	< 0 (\$8 saved per \$ spent)
Hepatitis B screening in pregnancy and vaccination of children of carriers	\$164
Varicella vaccine for children	\$16,000
Conjugate pneumococcal vaccine for children	\$125,000
Other Interventions	
Mandatory seat belt law	\$69
Chlorination of drinking water	\$3,100
Smoking cessation counseling	\$1,000-10,000
Bicycle helmet law	\$39,000
Annual screening for cervical cancer	\$40,000
Driver and passenger air bags/manual lap belts (vs. airbag for driver only and belts)	\$61,000
Smoke detectors in homes	\$210,000
Low cholesterol diet for men over age 20 and cholesterol over 4.65 mmol/L (180 mg/dL)	\$360,000
Crossing control arm for school buses	\$410,000
Radiation emission standard for nuclear power plants	\$100,000,000

Source: Public Health Agency of Canada, Part One, General Guidelines, The Benefits of Vaccines, Canadian Immunization Guide, Seventh Edition, 2006.

To facilitate comparisons of vaccines with one another or with other health services (including therapeutic drugs), economic analyses should give vaccines credit for preventing disease and disability (as opposed to solely mortality, as in the measurement of life years saved) by using quality-adjusted life years (QALYs) saved or disability-adjusted life years (DALYs) averted. QALYs are often used as the standard for economic analyses in North America, whereas DALYs are more commonly used for international or cross-cultural comparisons.⁴¹ Opinion varies widely regarding what constitutes a reasonable standard for cost-effectiveness in terms of QALYs saved, but potential benchmarks of \$50,000 or \$100,000 per QALY saved have been suggested,⁴² or 1-3 times the country's gross domestic product (GDP) per capita per DALY averted. By these dollar-value or GDP-based standards, all recommended vaccines in developed countries are cost-effective, as are many vaccines that await widespread adoption in developing countries.⁴³

As an example of QALYs measurement, a landmark Canadian study has recently demonstrated that immunization of adolescent girls with the human papillomavirus (HPV) vaccine is likely to be a cost-effective use of limited health care resources.⁴⁴ This study involved a cohort model of the natural history of HPV; key results indicated that vaccination with Gardasil of 12-year-old girls is estimated – under

conservative base case assumptions – to cost the health provider \$Cdn 21,000 per QALY-gained. Using \$Cdn 40,000 per QALY-gained as strong evidence for cost-effectiveness, vaccination with Gardasil is estimated to be cost-effective under a wide range of parameter assumptions and vaccination scenarios. Based on the results of this study, the main benefit of HPV vaccination is expected to be associated with the reduction of cervical cancer mortality. Taking a broader perspective, the early medical and economic benefits of HPV vaccination are primarily attributed to reducing the burden of disease caused by HPV types 6 and 11 (such as genital warts).⁴⁵

Using a similar mathematical model, the same Canadian research team has also estimated the “numbers needed to vaccinate” (NNV) to prevent HPV-related diseases and death.⁴⁶ In this context, NNV is defined as the number of women (within a specific age cohort) who would need to be vaccinated to prevent a single HPV-related event during their lifetime. Among 12-year-old girls, it was estimated that the NNV to prevent an episode of genital warts would be 8, to prevent cervical cancer would be 324, to prevent death from cervical cancer would be 729, and to prevent one life year lost would be 16. These estimates were based on the assumption that the Gardasil vaccine procures lifelong protection and that its efficacy is 95%. Putting these results into perspective, comparative data for 3 other vaccines (against varicella, meningococcal and influenza) indicate that the NNV values to prevent one death from each of these diseases have been estimated at 34,000, 21,000 and 5,000 respectively. While there are limitations in all health-economic modelling, this assessment provides an excellent indication that Gardasil offers significant clinical benefits from an NNV perspective, comparing favourably against other common immunizations.

6.4.3 Additional Economic Benefits

Vaccines are also believed to offer additional economic benefits, particularly because they result not only in protection of immunized individuals, but they also indirectly protect those who have not been immunized. This concept, known as “herd immunity”, suggests that vaccines uniquely offer additional value in terms of the public good, although the economic impact of these broader community effects can be difficult to measure. In addition, because multiple vaccine doses are typically recommended, vaccination programs serve to draw patients into health care facilities, where patients receive other recommended (and often cost-effective) preventive services.⁴⁷

Furthermore, with regard to the four vaccines funded under the NIS Canadian Immunization Trust Fund (acellular pertussis, meningococcal C conjugate, pneumococcal conjugate and varicella), there have been documented reductions in hospitalization due to these infections.⁴⁸ Recent projections have also estimated that immunization of infants against rotavirus infection has the potential to prevent approximately 85% of rotavirus-related hospitalization, corresponding to roughly 4,300 hospitalizations per year in Canada (assuming a 90% immunization coverage rate).⁴⁹ Since the average hospital stay in Canada has been reported to be almost \$Cdn 7,000,⁵⁰ this clearly indicates the potential for vaccines to ultimately reduce hospital expenditures. Taken together, these observations strongly suggest that economic measurement of the value of immunization is complex, and at present, the full economic value of vaccines is very likely to be underestimated.

Finally, cost-effectiveness analyses of immunization programs have indicated that vaccination can positively affect worker productivity by reducing absenteeism in the workplace. As one key example, influenza affects 5%-10% of the workforce annually, costing billions of dollars in lost productivity.⁵¹ However, a cost-effectiveness analysis based on 10 years (1993-2002) of surveillance data from the World

Health Organization has estimated that, on average, vaccination against influenza could be expected to prevent 49 cases of influenza per 1000 workers vaccinated, avoiding 93 lost workdays, or 0.09 days per employee, at a net cost of approximately \$US 3 per employee vaccinated.⁵² The study also demonstrated that annual vaccination against influenza was less expensive than no intervention in half the years evaluated. Overall, this analysis indicates that primary prevention strategies involving influenza vaccination may play a critical role in terms of maximizing productivity of the workforce in sustaining the global economy.

Looking to the future, vaccines may provide even further value in preventing morbidity and mortality associated with emerging disease. For example, infectious diseases such as severe acute respiratory syndrome (SARS), the West Nile virus, and the threat of pandemic influenza have been a wake-up call to Canadians, and we are better informed of the medical dangers as well as the enormous economic pressure that infectious disease can place on trade, travel and tourism.⁵³ While the development of next-generation vaccines should allow the health care system to become more proactive in dealing with both infectious and non-infectious diseases (such as cancer, and neurological disorders), the introduction of these new technologies is also expected to generate additional cost savings in the future.⁵⁴

6.5 Funding Mechanisms for Major Target Populations

6.5.1 Childhood, Adolescent and Adult Vaccination

Although vaccines have proven to be one of the most cost-effective health care interventions worldwide, this evidence has not necessarily led to their optimal use.⁵⁵ In Canada, the current vaccine financing system is a mixed public and private sector effort, which funds the purchase and administration of recommended vaccines for children, adolescents and adults. The system has often been described as a patchwork of funding mechanisms, and has been criticized as lacking in harmonization and transparency, resulting in unacceptable duplication, inequities and delays.⁵⁶

In general, pediatric immunization dominates the North American vaccine market, whereas demand for adult vaccines tends to be less concentrated and weaker, relative to pediatric vaccines.⁵⁷ The financing of vaccines has also 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 and physician offices. In contrast, public funding is much more limited for adult immunization, and often depends on patients requesting vaccines (e.g. for influenza) from their health care provider, most often physicians.⁵⁸

In cases where immunization program are not publicly funded, vaccines may be covered by employer or private insurance plans, particularly those that are recommended for specific risk situations such as occupation or travel. Depending on the type of plan, private insurance coverage may involve patient cost-sharing in the form of deductibles and/or co-payments. In cases where private insurance does not reimburse for a particular vaccine, the patient must typically bear the full cost of the vaccination (plus any administrative fees) as an out-of-pocket expense. It is noteworthy that – in theory – the public may have immediate access to newly approved vaccines through the private system, assuming they are aware of the new vaccine and are able to cover the costs, either first party or through third party insurance.

Although public funding and uptake for childhood vaccines is relatively high, the system is not without disparities in vaccine coverage that create inequities and financial barriers, which in turn can contribute to lower immunization rates in certain populations of young children.⁵⁹ In addition, vaccinating the adolescent population presents additional challenges; first, since adolescents may not have the same level of public and/or private funding for vaccines as younger children, and second, because teenagers do not tend to have regular health care check-ups, thereby reducing clinician access to this population. Hence adolescent vaccination and coverage rates vary substantially from one province to another. Finally, with regard to adult immunization, common barriers reported by physicians (particularly for pneumococcal and influenza vaccination) include inadequate reimbursement, lack of access to immunization history, and patient concerns regarding vaccine safety.⁶⁰ Overall, limitations in vaccine financing are dominant barriers to access across all age groups, with increased reimbursement typically corresponding to increased immunization coverage rates.⁶¹

6.5.2 Underserved Populations

In addition to financial barriers for children, adolescents and adults, there has been some concern regarding vaccine access among certain underserved populations in Canada, including Aboriginal peoples. Since the federal government has jurisdiction for health care services to First Nations people and Inuit, federal government formularies control reimbursement policies affecting access to medicines for these populations. Specifically, the federal government's Non-Insured Health Benefits (NIHB) program provides eligible (registered) First Nations people and Inuit with a specified range of medical benefits, including prescription drugs, when they are not covered through public provincial/territorial programs or private insurance plans.⁶² However, vaccine coverage is not included in the NIHB program.

While publicly-funded vaccine coverage has increased in the Yukon and Northwest Territories and Nunavut in recent years,⁶³ there remain significant gaps in public health immunization programs in these regions. Furthermore, for all Canadians living in remote regions, there may be difficulties in gaining access to public health programs, even in provinces or territories where such programs do exist. In one recently documented case, the First Nations people of northern Ontario have expressed concern regarding their ability to gain equitable access to government vaccine stockpiles during a possible influenza pandemic.⁶⁴ Other examples of underserved populations include patients who don't have a family physician⁶⁵ or pediatrician (even in urban areas) who are less likely to be reminded of the value of vaccines. A great deal of effort will be required in the near-term future to improve funding and logistics of vaccine delivery for such vulnerable populations in Canada, particularly where they fall outside the mainstream (or reach) of public provincial/territorial immunization programs.

6.5.3 A Shift Towards Private Sector Funding

Overall, as vaccine technology evolves and investment in research increases – thus increasing the cost of vaccines – the difficulty in securing adequate funding for recommended public vaccine programs has increased concomitantly. These pressures have raised concerns regarding the ability of the current public vaccine delivery system to maintain access to all recommended vaccines for routine use in children and adolescents without financial barriers. Thus many experts anticipate that a shift away from public funding towards private sector financing for vaccines will be more evident in the future. Interestingly, an international study has demonstrated that in higher income countries, the share of national funding for vaccine programs tends to be lower than in lower-middle income countries; this observation has been

attributed to the trend (already in progress) towards private funding of vaccines.⁶⁶ Unfortunately, such a shift may potentially exacerbate current gaps and inequities in patient access to immunization programs.

Within Canada's private system for vaccine funding and delivery, a current limitation is that the private sector is not adequately equipped to provide broad access to vaccines – let alone equitable access across the country. Apart from limited financing options, effective mechanisms for vaccine distribution and promotion are also presently lacking within Canada's private sector. However, certain benefits might be derived from bolstering private sector resources and capabilities; vaccine industry players should therefore consider future paradigms in which private sector immunization plays a greater role.

For example, in Canada's current public system, vaccines are currently sold by manufacturers to provincial/territorial governments and public health officials – who focus primarily on benefits to the population and the broader societal value of immunization – and who therefore have significant expertise regarding vaccination programs and cost-effectiveness issues. In contrast, in the private system (particularly in the U.S.), vaccines are sold directly to physicians, who are then reimbursed by private health plans. These physicians (including a large percentage of general practitioners) tend to be more concerned with the well-being of individual patients than the broader societal benefits of immunization, and they consequently place less emphasis on cost-effectiveness data. Hence the latter scenario may represent a less cumbersome sales model. Following this rationale, there may be fewer barriers to entry for vaccines within the private system. Manufacturers may therefore wish to investigate potential advantages of supporting an expanded role for private-sector vaccine funding/delivery in Canada in the future – particularly where patients may ultimately benefit from more timely access to vaccines within the private system.

At present, private health insurance plan managers in Canada have already begun to identify new vaccines as potential cost drivers within private plans, with relatively high utilization.⁶⁷ For example, as of early 2008, the HPV vaccine was estimated to account for 40% of the cost of all vaccines paid for by employer insurance plans. Thus, private insurance plans might be expected to introduce more restrictive limits on vaccine coverage (in addition to those for other new devices and diagnostics) to manage future plan spending.⁶⁸ In addition, private health care providers in Canada may have less incentive to pay for preventive vaccines, relative to U.S. private insurance providers. This is because private Canadian payers (unlike their U.S. counterparts) seldom pay for the curative portion of a patient's follow up treatment; such curative care would typically be funded separately, under provincial health care and hospital budgets. The net effect of these emerging trends in reimbursement policy is that patients will likely be required to personally bear a higher proportion of future vaccine costs, i.e. as first party payers.

6.6 The Role of PMPRB, CDR and JODR

As described in Papers 4 and 5, the route to market entry for vaccines in Canada requires (at a minimum) approval by Health Canada and a positive recommendation by NACI. Long before market approval, however, a manufacturer should be considering vaccine price and marketing strategy. Two key components of the pricing and reimbursement system for most drugs (although not necessarily vaccines) include the Patented Medicine Prices Review Board (PMPRB) and the Common Drug Review (CDR) process.

In the context of vaccine funding and gaining market access in Canada, it is relevant to provide an overview of the PMPRB and CDR processes for two reasons. First, since the government invests heavily in the development of novel vaccines (both current preventive and future therapeutic vaccines), mechanisms (including PMPRB review) must be in place to ensure the Canadian public and health care system receives good value for money spent. Achieving a fair pricing structure plays a critical role in demonstrating the excellent value of vaccines. Second, since future reimbursement pathways are currently unknown for the imminently anticipated wave of therapeutic vaccines, it is pertinent to provide additional background perspective on the CDR process as one potential avenue for providing reimbursement recommendations for this new class of vaccines. Overall, the Canadian vaccine environment is undergoing rapid change, and this is forcing decision-makers at many levels to reassess potential financing and reimbursement models.

Established in 1987, the Patented Medicine Prices Review Board (PMPRB) is a national regulatory body that reviews patented drugs to ensure the price is not excessive, thus playing a key role in regulating costs in the Canadian health care system. For most new drugs, prices are limited to those of the most expensive existing treatment in the class. A drug that represents a breakthrough or substantial improvement can set its own price (given there are no therapeutic comparators), provided it does not exceed the median of prices for the same drug in seven other industrialized countries: France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States.⁶⁹

Since 2003, the Common Drug Review (CDR) has been in place as a single nationalⁱ process to conduct evidence-based assessment of the clinical and cost-effectiveness of new drugs (e.g. new chemical entities and new combination products, except oncology drugs), for the purpose of providing common reimbursement recommendations to publicly-funded federal, provincial and territorial drug benefit plans in Canada.⁷⁰ The CDR is managed and overseen by the CDR Directorate, Canadian Agency for Drugs and Technologies in Health (CADTH). Recently, a cross-jurisdictional, interim process for a single review of cancer drugs – known as the Joint Oncology Drug Review (JODR)ⁱⁱ – was also introduced in March 2007.⁷¹ The JODR concept is not dissimilar to the role of the CDR in the reimbursement decision-making process; it was created to help address the issue that the review of oncology medicines requires a particular expertise.

6.6.1 Patented Medicine Prices Review Board (PMPRB)

In the context of challenges in pricing and reimbursement for biologics, several issues remain unsettled and/or under consultation. For example, BIOTECCanada has put forward its position that the proposed PMPRB guidelines on excessive pricing cannot be effectively applied to biologic products.⁷² Specifically, biologics are unique with respect to the type(s) of product produced, the size of the market, development costs, and the limited availability of comparable or substitute products. Moreover, the appropriateness of PMPRB guidelines has been questioned in markets where prices are determined through competitive tendering and negotiation (including vaccines), and also where prices are negotiated with a single buyer and based on international markets (including blood products).⁷³

ⁱ All provinces/territories participate in the CDR except Québec. The NIHB program also participates in the CDR.

ⁱⁱ As a collaboration of all provinces (except Quebec), the JODR will be in place for approximately 18 months, after which period it is anticipated that evaluations will be conducted, and recommendations for a permanent cross-jurisdictional process will be made to the Deputy Ministers of Health.

With regard to vaccine pricing in Canada, most vaccines are sold under contracts established between the manufacturer and the provinces/territories; these contracts are under the administration of Public Works and Government Services Canada (PWGSC). BIOTECanada's Vaccine Industry Committee (VIC) has argued that the provinces/territories and PWGSC are sophisticated, knowledgeable, and able to secure purchasing power to negotiate contracts that provide optimal arrangements in terms of vaccine price, quality, supply, and potential future investment. In addition, vaccines procurement policy is based on a competitive tendering process, whereby the lowest bidder is granted a contract to supply the customer with a specific vaccine.⁷⁴ This federal tendering system ensures that patented vaccines are fairly priced within the Canadian marketplace. The tender process also results in very little price discrepancy among provinces, since provincial rules do not allow an individual province to pay a higher price than elsewhere in Canada. Given that the competitive bid process through PWGSC establishes a fair market price for vaccines, BIOTECanada has expressed its view that further intervention by PMPRB as an additional federal regulatory measure is not necessary. Currently, debate continues on the topic of whether vaccines should be exempt from PMPRB guidelines on excessive pricing; BIOTECanada maintains its position that vaccines should not be regulated like other traditional pharmaceuticals.

6.6.2 Common Drug Review (CDR)

As described in Paper 4, vaccines are considered for approval at the federal level by Health Canada's Biologics and Genetic Therapies Directorate (BGTD), as for other biologics. However, unlike the process for most biologic drugs, once a Notice of Compliance (NOC) has been issued, the Common Drug Review (CDR) process does not currently encompass the vaccine product subclass.⁷⁵ Instead, vaccines are presently reviewed by the National Advisory Committee on Immunization (NACI), as outlined in Paper 5. This divergence in the review and recommendation process has predominantly stemmed from the fact that most vaccines approved to date are preventive – and they target infectious diseases – hence vaccines are considered to fall well within the jurisdiction of federal and provincial public health agencies.

Against this backdrop, the question has been raised regarding future review and reimbursement processes for vaccines in Canada, particularly as therapeutic vaccines begin to enter the marketplace. At the broadest level, it is unknown whether therapeutic vaccines will 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.⁷⁶ There has been some speculation that emerging therapeutic vaccines could be reviewed (subsequent to Health Canada approval) by the CDR or JODR process – quite apart from the current NACI deliberation system for preventive vaccines. In this case, provincial government drug plans might then be asked to take on the funding of vaccines recommended by the CDR/JODR. At present, public provincial drug plans in Canada are not typically involved in providing coverage of vaccines, although certain exceptions have been reported, including coverage of pneumococcal vaccine for individuals with HIV/AIDS.⁷⁷

While future pathways regarding reimbursement recommendations for therapeutic vaccines are presently undecided, this represents but one example of a broader array of issues that need to be resolved (or reassessed) regarding approval and funding mechanisms for biologics and vaccines in Canada. However, given the imminent anticipated arrival of therapeutic vaccines, collaborative discussions among all stakeholders (including vaccine manufacturers, public health officials and those affiliated with CRD/JODR procedures) should be held as early as possible to begin to define the most appropriate route(s) of evaluation and reimbursement for these new therapeutic products. A fundamental objective of these discussions will be to agree upon efficient future models that ensure the Canadian population has

timely, equitable access to new therapeutic vaccines. Once the relevant parameters and guidelines have been established, adequate clarity and warning will be required in time for vaccine manufacturers to target the appropriate audience(s) for market access.

Some of the key issues that must be considered early-on in determining which process (i.e. via NACI or CDR/JODR) would be most appropriate for therapeutic vaccines include the following:

- precise definition of therapeutic vaccines (e.g. to include/exclude immunoglobulins and monoclonal antibodies?)
- potential impact of therapeutic vaccines in protecting public health and/or improving chronic care (e.g. emerging diabetes vaccines)
- appropriate review/recommendation processes for vaccines with both preventive and therapeutic effects (e.g. HIV, cancer and shingles vaccines)
- components of appropriate submission package(s) for target review bodies, and how best to avoid duplicative procedures, e.g.:
 - data from clinical trials conducted to support Health Canada approval, which is currently used for vaccines that undergo the NACI review process, and/or
 - potential requirements for cost-effectiveness or other relevant data that is currently submitted for drugs reviewed by the CDR/JODR process
- capability/experience of target review bodies in assessing key elements of submission dossiers
- anticipated timeliness of recommendation decisions

In general, the CDR process has been criticized, based on its performance in assessing new drugs to date. For example, BIOTECCanada has publicly stated its observation that the CDR process has been a deterrent to many new biotechnologies.⁷⁸ Although CDR was designed to streamline the drug approval process, it appears to be causing extra delays, since each additional regulatory layer can further impede patient access.⁷⁹ Furthermore, as of November 2008, the CDR has completed reviews for 118 drug products, yet positive recommendations (i.e. “list”, “list with criteria or conditions”, or “list in similar manner to drugs in same class”) have been issued for only 56 (47%) of these drugs.⁸⁰ The remaining 62 drugs have received negative recommendations (i.e. 51% “do not list” and 2% deferrals pending clarification of information). Hence current CDR approval rates – defined as positive formulary listing recommendations – are abysmally low.

Finally, the CDR process is not accountable to the Canadian public since the review committee does not conduct open meetings.ⁱⁱⁱ Interestingly, results of a recent international study indicate that – even in countries where the use of health technology assessment (HTA) is advanced, including Canada – stakeholders of the respective health systems often have no way of knowing the specific rationale used to drive HTA decisions.⁸¹ This is because many HTA bodies worldwide avoid defining clearly (and/or making public) the threshold(s) used to determine the cost-effectiveness of a given therapy. This appears to be the case in Canada, for which the CDR process lacks transparency and responsiveness to public needs, and is therefore fundamentally flawed.

ⁱⁱⁱ As an independent agency, the CADTH is not formally part of the federal or the provincial governments. Its management and staff, including those with CDR, are accountable only to a board of directors comprising solely of deputy ministers and other senior officials of the federal/provincial/territorial governments. The CADTH therefore is not directly accountable to the public and thus CDR is not subject to the rigorous checks and balances that underlie our system of elected, responsible government.

Based on the major drawbacks of the CDR process, BIOTECanada has recommended that the federal government withhold additional funding to the CDR until this body recognizes the value of innovation, develops a review mechanism that can evaluate breakthrough, first in class products, and ensures the process becomes fully accountable to the Canadian public.⁸² Moreover, industry stakeholders have suggested that the current CDR process undermines the regulatory reviews conducted by the BGTD, not only by duplicating safety and efficacy reviews, but also by referencing decisions made by the Food and Drug Administration (FDA) rather than Health Canada. Thus, overall, it appears that potential review of therapeutic vaccines by the CDR process will likely meet with significant resistance.

6.7 Funding Mechanisms in Other Countries

6.7.1 United States

Like the Canadian system, the current vaccine financing system in the United States represents a mix of public and private sector efforts, particularly for children and adolescents. The U.S. public sector purchases vaccines for approximately 55% of the birth cohort through three major sources of public sector funding: i) the Vaccines for Children (VFC) program; ii) the Section 317 federal discretionary grant program (317 program); and iii) state funds.⁸³ Private sector purchase accounts for about 45%-50% of the childhood and adolescent vaccines sold annually, a proportion that has remained relatively constant over the 14-year life of the VFC program.

The VFC is an entitlement program that provides recommended vaccines at no cost for children (up to age 19) who are served by Medicaid, those without health insurance, and American Indians and Alaska Natives. The VFC program is unique (and differs from the Canadian system for childhood vaccines), in that once the U.S. Advisory Committee on Immunization Practices (ACIP) has voted to include a recommended vaccine in the VFC program, federal financing for state immunization programs is then automatic,⁸⁴ following endorsement of the Committee's recommendation by the U.S. Department of Health and Human Services.

All states use the 317 program to cover non-VFC eligible and adolescents – usually those who go to public health department clinics for vaccination – who may be underinsured or fully insured. In contrast to VFC, the 317 program is not an entitlement, but is dependent on annual discretionary appropriations determined by Congress. In recent years, these annual appropriations have not increased commensurate with new vaccine recommendations.⁸⁵ In some states, state funds have also been used to purchase vaccines for children not eligible for VFC. A combination of 317 and state funding has been used by a number of states to purchase all recommended vaccines for all children (called “universal purchase” states). Recently however, the number of states that exercise this option has been decreasing because of the increasing costs of vaccines.⁸⁶

Financing for adult immunization in the U.S. is quite different from that for childhood immunization, since there is no counterpart to the VFC or Section 317 program for adult vaccines. Although no federally supported programs exist for adult vaccination, Medicare beneficiaries are reimbursed for pneumococcal and influenza immunization.⁸⁷ Private insurance plans may or may not cover adult vaccination, hence many adults pay out-of-pocket for immunizations received. Roughly half of all U.S. adults aged 18-64 lack insurance coverage for immunization.⁸⁸

In general, significant gaps and fragmentation currently exist in U.S. immunization programs for children, adolescents and adults, creating barriers for vulnerable populations, and also contributing to lower immunization rates.⁸⁹ For example, in 2000 it was estimated that 14% of children aged 0-17 years were underinsured in the U.S., requiring families to pay out-of-pocket for the cost of vaccines not covered, or to forgo recommended vaccines.⁹⁰ In addition, no mechanism currently exists to ensure that newly recommended adult vaccines will be covered by existing public funding sources in a timely fashion, i.e. to ensure use of these vaccines on the large scale required to support national disease prevention goals.⁹¹ From a broader North American perspective, the U.S. system for financing immunization programs is experiencing many of the same pressures and concerns as recently observed in Canada. Thus, it remains a challenge to deliver vaccines recently recommended by ACIP, and there has been significant apprehension that the funding system may not be capable of keeping pace with newly approved/recommended vaccines in the near-term future.⁹²

While the U.S. faces many of the same challenges as Canada, several aspects of the U.S. vaccine financing system are generally perceived to be superior to those in Canada. The VFC program described above represents the most straightforward example, since state funding is guaranteed for recommended vaccines that receive a positive federal ACIP vote. Hence funding for childhood vaccination under the VFC program is more clearly defined and highly predictable. In addition, the U.S. system appears to have fewer delays in market access, since ACIP recommendations can be made within weeks of FDA approval, in comparison with NACI recommendations being announced within months of Health Canada approval, followed by lengthy NACI/CIC deliberations.

Overall, the U.S. system is believed to have less duplication and bureaucracy than observed in Canada, and there appears to be earlier and more equitable access to vaccines by the U.S. public, particularly for children and vulnerable populations. Furthermore, the ACIP is subject to the federal Open Meetings Act and thus holds transparent meetings in public,⁹³ in sharp contrast to the closed NACI decision-making process. Finally, although some aspects of the U.S. system appear to be working better than in Canada, the U.S. has also recognized that the system is far from optimal. Through the National Vaccine Advisory Committee (NVAC) and the Institute of Medicine (IOM), several major stakeholder meetings have recently been convened to define specific problems and find appropriate solutions in strengthening the U.S. system for financing immunizations.⁹⁴ These deliberations and interim conclusions have been well documented,⁹⁵ and a provisional vote was held on September 2008 regarding draft recommendations.⁹⁶ All acceptable recommendations will be analyzed regarding their potential fiscal impact and will be presented for a final vote at the February 2009 NVAC meeting. Final recommendations will then be formally made to the Assistant Secretary for Health, who will determine implementation options and next steps.⁹⁷

Stakeholders within the Canadian vaccine financing system should be inspired by these proactive initiatives to identify and solve inherent problems in a timely fashion. As the U.S. continues to develop best practices for its domestic vaccine industry, there may be potential lessons for Canadians in taking steps towards developing customized solutions (and proposing strategies to relieve tensions) within the vaccine funding environment in Canada.

6.7.2 United Kingdom

Several major differences exist in the immunization programs of the United Kingdom, relative to the U.S..⁹⁸ The U.K. has had a recent history of providing social support through government programs for society as a whole, whereas in contrast, the U.S. is typically seen in the paradigm of individualism, in which personal accomplishment (independent from the state) is held in higher regard. In both countries, vaccination programs have unique components that are appropriate within their own unique context. For example, the U.S. vaccine financing system is a mix of public and private funding, which requires a separate distribution and storage system for private-sector providers. In the U.K. however, the purchase and distribution of vaccines are managed centrally, under a single governmental budget and administrative authority. This system also allows for national coordination of vaccine supply in times of absolute or relative shortages, a desirable feature that is clearly lacking in the U.S..

The U.K. system also simplifies vaccine availability for the entire childhood population, since government recommended vaccines are administered at any National Health Service (NHS) provider at no charge. This lies in stark contrast to the U.S. system, in which complex eligibility requirements exist for children to participate in government-funded vaccine programs. However, no laws exist in the U.K. to enforce vaccination prior to school entrance, whereas all U.S. states have passed such regulation. In this seemingly paradoxical instance, the U.S. enforces immunization for the public good through legislation, while the U.K. relies on each individual's sense of responsibility to society to promote the same outcome. Finally, budgetary constraints seem to play a stronger role in the U.K. in the decision to include a new vaccine in the recommended schedule, since additional funds must be secured in advance for a new vaccine to be included in the national schedule. Although the U.S. ACIP considers the cost of individual vaccines, recommendation decisions are not made with cost as a primary factor.

6.7.3 International Funding

A detailed discussion of vaccine funding in other international regions falls outside the scope of this paper, but it is relevant to provide a brief overview of vaccine funding in underdeveloped countries. In such countries, the gap between ideal and actual immunization coverage is far greater than that in industrialized countries, and such disparities have grown over the past three decades. The lack of sustainable funding to purchase new vaccines is the most important barrier to their adoption in developing countries.⁹⁹ This problem occurs despite an international two-tier pricing structure, in which vaccine prices for developing countries are far lower than those in higher income countries.¹⁰⁰

New partnerships between private philanthropy and public resources have recently assumed an important role for immunization programs in developing countries. As an example, in 1999 the Global Alliance for Vaccines and Immunization (GAVI) established the vaccine fund with an initial \$US 754 million donation from the Bill and Melinda Gates foundation, as well as other substantial grants from additional donors.¹⁰¹ Through this continuously expanding fund, GAVI has offered support for vaccine programs in the world's 75 poorest countries.

Other vehicles for promoting vaccination programs in underdeveloped countries include advance-purchase contracts, commonly termed Advanced Market Commitments (AMC), which help to reduce the risk associated with unpredictable future demand and ability to pay. An AMC for immunization programs is a financial commitment by donor countries (such as Canada) to provide funding for the future purchase of vaccines; such commitments are designed specifically to meet the needs of developing

countries. For example, Canada recently announced a pilot pneumococcal AMC to benefit the world's poorest nations. This program is estimated to cost a total of \$US 1.5 billion, with the first vaccine purchases anticipated to begin in 2010, and lasting for roughly 10 years into the future.¹⁰² While this type of AMC is anticipated to encourage private sector vaccine investment and development, it will also give targeted countries time to budget for the vaccines at a predetermined, affordable price after AMC funding concludes.

The International Finance Facility for Immunisation Company (IFFIm) – based in the U.K. – has also been established as an innovative funding program to ensure reliable and predictable funding flows for immunization programs in 70 of the world's poorest countries, up to and including 2015.¹⁰³ It is noteworthy that for both the Canadian pilot pneumococcal AMC program and all IFFIm initiatives, administration costs will be minimized by relying on the expertise of existing institutions wherever possible, including the World Bank and the GAVI Alliance.

6.8 Recommendations

Returning to the fundamental objective for vaccine reimbursement in Canada, the highest level goal is to ensure equitable access to all recommended vaccines without financial barriers. To achieve this goal, Canada needs a predictable process and sustained financial support at the Federal, Provincial and Territorial levels for both existing and new public vaccine programs, including emerging vaccine technologies. At present however, Canada's vaccine financing and delivery system is fraught with multiple problems and concerns regarding disparities, delays, duplicative role and responsibilities, and most importantly, the sustainability of future immunization programs. Hence there is an urgent need to improve the reimbursement environment for vaccines in Canada, while addressing future funding infrastructure. The VIC of BIOTECanada is dedicated to working with relevant industry stakeholders to be part of the necessary dialogue and to generate potential solutions in improving the funding of Canada's vaccination programs. In the spirit of collaboration, the VIC has thus put forward the following recommendations for consideration by federal, provincial and territorial governments and other key stakeholders.

Federal Recommendations:

1. Federal funding for immunization programs should be renewed (potentially in the form of a permanent trust fund) to ensure new vaccine technologies can be incorporated into public vaccine programs.
 - The federal government must continue to assume the lead role in supporting the principles established under the National Immunization Strategy (NIS), thus sustained funding of immunization programs should be tied to the expansion of the NIS goals – which are still important in terms of improving access to recommended vaccines.
 - This approach would continue to build upon the momentum achieved to date in strengthening the federal government investment in Canada's vaccine programs.

2. With the imminent launch of therapeutic vaccine technologies in Canada, Health Canada should work in a transparent manner with manufacturers and other relevant stakeholders (including members of NACI, CADTH and those affiliated with CDR and JODR procedures) to determine the most appropriate route(s) of evaluation and reimbursement for therapeutic vaccines.
 - While this approach will facilitate the timely preparation of submission dossiers by manufacturers, who must target the appropriate audience(s) for reimbursement decisions, it will also help avoid potential delays in patient access to these new therapeutic products.

Provincial/Territorial Recommendations:

3. The provinces/territories should work towards an agreement with the Federal government regarding mechanisms and funding to ensure the adoption of new vaccines by public health programs within six months of Health Canada approval.
 - This joint approach should facilitate the timely implementation of recommended vaccine programs for all Canadians.
4. Notwithstanding Recommendation 3 (and as a contingency strategy), the provinces and territories should endeavour to reach consensus across all jurisdictions with regard to the creation of (and adherence to) a timely, consistent system for funding public immunization programs.
 - This system should involve standard, reproducible guidelines and procedures for implementing publicly-funded vaccine programs, independent of potential discrepancies or delays at the national level (in terms of announcing NACI/CIC recommendations and/or federal funding initiatives) in supporting individual vaccine technologies.

Stakeholder Recommendations:

5. A meeting of all relevant stakeholders should be convened (potentially by the VIC) to discuss:
 - i. The current vaccine funding and delivery system and its inherent flaws in equitably protecting the Canadian public;
 - ii. Best practices in other countries for vaccine financing and reimbursement; and
 - iii. Potential new models to encourage predictable, sustained funding mechanisms and efficient delivery for recommended vaccines in Canada.
 - Stakeholder participation should include all players in the vaccine financing and delivery system, including: vaccine manufacturers, federal and provincial/territorial government representatives, Health Canada and CADTH officials, public health and public policy officials (e.g. representing PHAC, NACI, CIC), politicians and bureaucrats, medical professionals, payers, the scientific and research community, and patients or parents.
 - Potential solutions should be proposed to address how immunization agencies, organizations, departments and governments could work collaboratively and in conformity with achieving the common goal of eliminating financial barriers to recommended vaccination programs in Canada.
 - Alternative models for vaccine funding and reimbursement should be viewed as opportunities to attain the optimal medical and economic value of immunization, while also promoting stable investment to support future innovation in vaccine technologies.

Although the recommendations proposed herein do not address all challenges within the Canadian immunization landscape, they should assist with improving the system in incremental stages, while helping to end the pattern of ad-hoc prioritization in implementing vaccine reimbursement policy. It must be acknowledged that the current vaccine funding system is severely flawed, yet given greater consensus and appropriate collaborative efforts in moving toward a common goal, this same system has the potential to ensure equitable access to current and emerging vaccines for all Canadians. In building and improving upon the foundation of the current system, it is incumbent upon each stakeholder group to do its part (in consultation and coordination with other participants) in advancing the Canadian vaccine enterprise to the next level of success.

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