
CHARACTERISTICS OF A FAIR VACCINE INJURY COMPENSATION PROGRAM FOR CANADA

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As the most ambitious vaccination program in Canadian history ramps up, there will be occasions when individuals will experience an ‘adverse event following immunization’ (AEFI). The World Health Organization defines an AEFI as any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. Predictable non-serious AEFIs include redness, soreness or itching at the injection site, short-term poor appetite, light-headedness, or mild fever. It is the rare ($>1/10,000$ to $<1/1,000$) and very rare ($<1/10,000$) serious AEFIs that cause profound and disruptive outcomes – such as lingering joint pain, anaphylaxis, or neurologic conditions such as encephalitis – that demand policy attention.

How should we handle those occasions when a person is harmed by a recommended vaccine taken in furtherance of the public good? For those outside of Québec, the costs associated with a permanent or debilitating injury are currently borne by the injured individual (and their family), either personally as out-of-pocket expenses or through the purchase of private insurance, or by the actors who bear some responsibility for the injury (e.g., vaccine manufacturers, administering healthcare providers, etc.) through tort litigation. However, access to these options is dependent on the individual’s social and economic conditions and capabilities. And tort litigation imposes a range of additional personal costs, including delay of benefits, financial cost, evidentiary hurdles, and emotional toll.

Surely, the concerns and sense of solidarity that drove Québec to adopt its no-fault vaccine injury compensation program are shared across Canada. As such, it is time for the Government of Canada to enact a no-fault ‘vaccine injury support program’ (VISP) to compensate and assist these individuals. But what should such a VISP look like? Here are seven characteristics that are essential to the fair, transparent and efficient operation of a modern VISP:

1. **Foundation:** The VISP should be grounded in a statute which articulates its purpose, operational principles, and management, ensuring transparency and accountability.
2. **Coverage:** Benefits should be available to residents of all ages in relation to all vaccines recommended by public health authorities that are administered in Canada by authorized vaccinators, with clear instruction about the minimum or threshold injury or level of disability necessary to qualify.
3. **Accessibility:** The claims process should be simple and clear, and the VISP administrator should have an obligation to assist claimants and families throughout the process. The enabling statute should address limitation periods, the claims process and timeframes, evidence, costs, re-

assessments and appeals, and it should result in written decisions providing claimants insight into next steps.

4. **Preservation of Rights:** The VISP should not jeopardize a claimant’s right to pursue a civil action against potentially liable parties such as manufacturers, and it should ensure that the VISP fund is reimbursed for any benefits already provided when a court award is made in such litigation.
5. **Causality:** It is essential to determine when an AEFI is, in fact, caused by a vaccine, as this will impact on vaccine safety and efficacy profiles, on recommendations for routine use, and on general acceptance of the vaccine. While claimants must prove that their injury was caused by the vaccine, this issue needs to be handled with care and sensitivity.
6. **Compensation:** When a serious AEFI is caused by a vaccine, it is important for us—society—to compensate and support the injured individual. A national VISP should compensate: funeral expenses; income-replacement costs; medical expenses; physical, social, occupational rehabilitation expenses; personal assistance expenses; home alteration expenses; bodily injury indemnity, including compensation for pain and suffering; nominal damages for pain and suffering of the immediate family.
7. **Funding:** The VISP should be funded through the national treasury with contributions to the fund coming from a manufacturers’ levy.

For far too long, AEFIs caused by vaccines have remained unaddressed. The Government of Canada has signalled its intent to create a VISP through its call for expressions of interest to manage such a program. To the extent that the VISP embraces these seven characteristics, a national VISP will serve the interests of Canadians.

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