NCI NATIONAL CITIZENS INQUIRY

CANADA'S RESPONSE TO COVID-19

In the Public Interest: An Interim Report on the Covid-19 Vaccine Authorization Process

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Contents

Note to the Reader

This document is an excerpt from the Commissioners' full report which is expected to be released later this year. The information contained in this ***Interim Report*** is considered to be a matter of public interest and crucial for Canadians who are considering participation in future COVID-19 vaccination programs.

Interim Authorization of Covid 19 Vaccine

Introduction

The Commission received detailed information about the procedure through which "approval"[1] for COVID-19 vaccines was granted in Canada. According to the testimony, the conventional evaluation and endorsement process for the COVID-19 vaccines was not adhered to by the Canadian Government. Instead, a new process was established whereby Health Canada "authorized" the Covid-19 vaccines under an Interim Order (which was later adopted as a permanent regulation). It is important to understand that the Covid-19 vaccines were never approved under the traditional approval process for drugs in Canada. Under the alternative authorization process, the necessity to establish the safety and efficacy of Covid-19 vaccines through an objective manner appears to have been set aside.

Objectively and independently proving the safety and efficacy of any new drug before its introduction into the market is an essential cornerstone of responsible healthcare and public safety. This rigorous requirement serves as a critical safeguard for individuals' well-being, ensuring that potential risks are thoroughly assessed and weighed against the benefits. This principle becomes even more pivotal when the drug is intended for widespread use across all segments of the population.

The blanket use of a drug, especially one like the Covid-19 vaccines, necessitates an unassailable foundation of evidence. Rigorous testing, transparent evaluation, and independent verification of safety and efficacy are fundamental to instilling trust among both healthcare professionals and the general public. This approach ensures that medical interventions are based on the most accurate and reliable information available.

In the context of a global health crisis, these principles are vital to ensuring that public health measures are not only effective but also respectful of individuals' rights and dignity. It is imperative that all drugs proposed to be released to the public be objectively and independently proven to be both safe and effective. It is for this reason that strict proof of safety and efficacy have been required by our drug approval regulations. The need to prove both safety and efficacy take on particular importance for drugs intended for the entire population, including children and pregnant women. This approach forms the bedrock of responsible medical practice and contributes to a society that values health, science, and the dignity of each person.

Testimony Concerning Interim Authorization of Covid 19 Vaccines

The following vaccines were authorized by Health Canada under the Interim Order:

1. Pfizer-BioNTech on December 9, 2020 for ages 16 and older, and May 5, 2021 for ages 12-15;
2. Moderna on December 23, 2020 for ages 18 and over and August 27, 2021 for ages 12-17;
3. AstraZeneca on February 26, 2021 for ages 18 and older, and

[1] Throughout this Report, the terms "approval" and "authorization" are used synonymously to describe the process by which Health Canada made the Covid-19 vaccines available for use in the Canadian population. Health Canada appears to also use the terms somewhat synonymously, however, the distinction between drug approval under the normal procedures, and Covid-19 drug authorization under the Interim Order and the new regulation is discussed in this section.

4. Janssen (Johnson & Johnson) on March 5, 2021 for ages 18 and older.

The Commission received testimony from two key witnesses, Shawn Buckley and Deanna McLeod, regarding the procedure through which the authorization of Covid-19 vaccines took place in Canada. The initial authorization of all Covid-19 vaccines was provided under a temporary, Interim Order, which exempted them from the traditional regulations that demand manufacturers to demonstrate objective evidence of safety and effectiveness. The result was that while chief medical officers across the country repeatedly assured Canadians that the Covid-19 vaccines were "safe and effective" - the general Canadian population had no understanding that their authorization process had not required objective proof of safety nor efficacy.

Shawn Buckley The Political Approval of the Covid Vaccine: A Constitutional Lawyer's Perspective

The normal regulatory process for approving a new drug in Canada is set out in Division 8 of Canada's Food and Drug Regulations (the "Regulations").[2]

To receive approval for a new drug in Canada, the Regulations require evidence of both the drug's safety and effectiveness be demonstrated to the Minister of Health.[3] Once evidence of safety and efficacy is provided, the Minister considers whether the benefits outweigh the risks. If evidence of safety and effectiveness has been provided that shows the benefits outweigh the risk, the Minister may grant market approval of a new drug.

These first steps of demonstrating safety and effectiveness, before approval, are essential to ensuring that Canadians are not exposed to unknown risks in the name of unknown effectiveness. The Federal Government's creation of the Interim Order required Health Canada to approve the Covid-19 vaccines without proof of either safety or of efficacy which resulted in millions of Canadians taking a new drug whose safety and effectiveness could not be known.

The unfortunate result of authorizing the Covid-19 vaccines through the Interim Order (instead of under the traditional approval process under the Regulations) was revealed through NCI testimony – many Canadians were injured or killed, while at the same time the Covid-19 vaccine was revealed not to be effective in preventing infection and transmission nor reducing the severity of illness. The benefit of hindsight demonstrates clearly why the traditional tests under the Regulations are needed for all new drug approvals, and why Canada should not authorize drugs under Interim Orders, even in cases of public health emergencies.

The Traditional Drug Approval Process

The requirements that must be met to approve a new drug in Canada are found in C.08.002(2) of the Regulations. Of particular importance are high requirements for proof of both safety and efficacy. These are found as follows:

[2] *Food and Drug Regulations*, C.R.C., c-870.
[3] *Regulation* C.08.002(2)(g) and (h).

C.08.002(2) A new drug submission shall contain sufficient information and material to enable the Minister to assess the safety and effectiveness of the new drug, including the following:

1. detailed reports of the tests made to establish the safety of the new drug for the purpose and under the conditions of use recommended;
2. substantial evidence of the clinical effectiveness of the new drug for the purpose and under the conditions of use recommended[.]

Under the traditional approval process in the Regulations the first step is to establish the safety profile of the new drug and demonstrate to the Minister of Health that the drug is safe for use in the human population. The second step is to establish the new drug's benefit profile, in other words, is it effective, does it work. The third step, although not specifically included in the regulation, is to evaluate the Risk / Benefit profile for the drug. In other words, the regulatory review has to establish that the benefits of using the drug outweigh the risk of using the drug.

One cannot satisfy the requirement for a risk/benefit analysis without a complete understanding of the drug's safety and benefit profile.

Interim Order: Importation, Sale and Advertising of Drugs in Relation to COVID-19

Instead of following the Regulations, on September 16, 2021, the Minister of Health made an Interim Order exempting all Covid-19 drugs (including Covid-19 vaccines) from the normal review and approval process. The Interim Order was made under section 30.1 of the Food and Drugs Act, R.S.C., 1985, c. F-27, which permits the Minister of Health to make an interim order that overrides normal regulations. The section reads:

> 30.1 (1) The Minister may make an interim order that contains any provision that may be contained in a regulation made under this Act if the Minister believes that immediate action is required to deal with a significant risk, direct or indirect, to health, safety or the environment.

The term "significant risk" is not defined in the Act, nor is there any proportionality built into this section. Thus, there do not appear to be any legislative safeguards or guidelines for when this power to override is used by the Minister of Health.

Under this broad power, the Minister made the Interim Order which, rather than requiring significant evidence of safety and efficacy of the Covid-19 vaccines as mandatory requirements for approval, only required the vaccine manufacturers to provide:

> 3(1) … sufficient information and material to enable the Minister to determine whether to issue the authorization, including …
> (o) the known information in relation to the quality, safety and effectiveness of the drug.

By letting the Minister make a decision based on "known information" about safety and effectiveness, this allowed the Covid-19 vaccines to be authorized in advance of actual knowledge about their safety or

effectiveness. The Interim Order attempted to make up for this by having manufacturers promise to do more follow-up research as follows:

> 3(2) If, at the time an application is initially submitted to the Minister, the applicant is unable to provide information or material referred to in any of paragraphs (1)(g) to (k) and (m) to (o) or that information or material is incomplete, the applicant must include in the initial part of the application a plan as to how and when they will provide the Minister with the missing information or material.

However, as will be discussed further below, the Interim Order also prevented the Minister from revoking authorization once given, meaning that the Minister was absolved of the responsibility to protect the public if subsequent safety problems were discovered in the Covid-19 vaccines.

It is vital to recognize that when the Interim Order was issued, the Minister of Health at the time had attended Lakehead University, graduating with a Bachelor of Arts, and had received a Master of Public Administration from the University of Victoria. To our understanding, the minister possessed no medical training credentials that we would consider pertinent to making the required determinations under the regulations.

Approval of Covid-19 Vaccines was virtually guaranteed under the Interim Order

Remarkably, the Interim Order effectively required Health Canada to authorize a Covid-19 vaccine for use in the Canadian population even in the absence of detailed evidence of safety and substantial evidence of efficacy.

Section 5 of the Interim Order provides:

1. The Minister must issue an authorization in respect of a Covid-19 drug if the following requirements are met:
    (a) the applicant has submitted an application to the Minister that meets the requirements set out in subsection 3(1) or 4(2);
    (b) the applicant has provided the Minister with all information or material, including samples, requested under subsection 13(1) in the time, form and manner specified under subsection 13(2); and
    (c) the Minister has sufficient evidence to support the conclusion that the benefits associated with the drug outweigh the risks, having regard to the uncertainties relating to the benefits and risks and the necessity of addressing the urgent public health need related to Covid-19.

The test set out in (c) above is startling when compared to the traditional test for new drugs under the Regulations. Under the traditional test, evidence of safety and efficacy must be proven. Under the Interim Order, there only needs to be "evidence to support the conclusion" that the benefits outweigh the risks. This does not mean the Minister (i.e., Health Canada) has to be convinced and actually reach the conclusion. If the test was to convince Health Canada, the test would read:

the Minister has sufficient evidence to conclude

The difference in language is important. Under this test, it appears that a vaccine would have to be authorized as long as there was sufficient evidence to support an argument that the benefits outweighed the risks.

In addition, the risk versus benefit test need not be robust, as the Minister is to "have regard" for the "uncertainties" of the benefits and risks. It is not clear how the Minister is expected to perform a risk versus benefit analysis when there is insufficient safety and efficacy evidence to determine true risks versus benefits. It is even more unclear how to perform a risk versus benefit analysis while "having regard to the uncertainties" of the risks versus benefits.

Ultimately, the Interim Order reveals that the Minister's priority was the "necessity of addressing the urgent public health need related to Covid-19." The problem, of course, is that under this test, the government placed its perceived "urgent public health need" ahead of safety and efficacy of the Covid-19 vaccines. This appears to be what the Government of Canada actually did.

Regardless of whether the need for a drug is urgent, this cannot override a proper assessment of safety, particularly when Canadians are under the impression that a drug has been proven safe. The NCI was not made aware of any public health authority in Canada cautioning Canadians that the vaccines had been authorized without the traditional need to prove their safety.

Instead, the Government of Canada was under enormous pressure in the media to secure vaccines and make them available to Canadians. In response, it placed orders for millions of doses from the manufacturers. This placed the Government in a conflict of interest because it had purchased and imported unapproved vaccines while it waited for itself to approve the vaccines. The Interim Order appears to have been designed to ensure that the vaccines would have no problem in receiving authorization.

As indicated above, in the traditional drug approval process, chances are not taken. If there is uncertainty about either safety or efficacy, the drug is not approved. There must be strict objective evidence of both safety and efficacy. It must also be objectively clear that the benefits outweigh the risks before a new drug is approved. It can only be objectively clear that the benefits of a drug outweigh the risks when the benefits and risks are objectively known.

The test for Covid-19 vaccines abandoned this need for objective certainty.[4] Instead of requiring objective proof of:

- safety;
- efficacy, and

[4] An objective test is a type of assessment consisting of a set of items or questions that have specific correct answers (e.g., How much is 2 + 2?), such that no interpretation, judgment, or personal impressions are involved in scoring.

- benefit outweighing risk.

The Covid-19 vaccines were authorized under a subjective test[5] which mandated that authorization must be granted if an argument could be made to support the conclusion that the benefits outweighed the risk. The question arises: what if there was evidence that went both ways? In other words, what if there was evidence that pointed towards greater benefits, but there was also evidence that pointed towards risks? Under the Interim Order, it seems the Minister must then take into account the subjective factors of: uncertainty and the urgent public health need for a vaccine. This cannot be an appropriate standard for approving a drug that the Government intends to administer to the entire population.

It is difficult to conceive of a less-scientific test for drug authorization than that found in the Interim Order.

The Interim Order also ensured that the authorization of a Covid-19 vaccine could not be revoked:

- due to evidence the vaccine was unsafe or not-effective;
- due to assessments the benefits did not outweigh the risks.

This resulted from the fact that once a vaccine was authorized under the Interim Order, most of the Regulations did not apply, including C.08.006. This particular regulation is the safeguard that allows the Minister of Health to cancel a drug's market authorization if evidence is uncovered that the drug is not safe. Instead, the Interim Order contained its own vague safeguards allowing for cancellation only in a few limited circumstances.

The exclusion of the Minister's normal powers to revoke authorization, and the reliance on more restricted revocation powers under the Interim Order means that Canadians could not have confidence that the Covid-19 vaccines would be pulled from the market if there was evidence that they were not safe. This situation persisted for roughly a year.

Were the Covid-19 Vaccines Approved Without Safety or Efficacy Proof?

In addition to the Interim Order, Health Canada created a document called "Guidance for market authorization requirements for Covid-19 vaccines."[6] This document is intended to provide guidance to pharmaceutical companies applying for market authorization. As it must, it follows the new subjective test for the vaccines. For example, the current version includes:

> **About market authorizations for a Covid-19 vaccine**
> Health Canada will grant authorizations only if we determine that the benefits of the vaccine outweigh its potential risks. We will base our decision on the evidence provided on the vaccine's safety, quality and efficacy. For vaccines relying on the modified requirements in C.08.002 (2.1)

[5] A subjective test is an assessment tool that is scored according to personal judgment or to standards that are less systematic than those used in objective tests.
[6] Health Canada document - Guidance for market authorization requirements for COVID-19 vaccines. https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/ drugs-vaccines-treatments/guidance-market-authorization-vaccines.html.

> of the Food and Drug Regulations, the risk- benefit analysis weighs the uncertainties about a potential vaccine against the public health need for a vaccine at the time of the decision.
>
> Modified requirements for Covid-19 drugs make it possible for initial authorization, based on early data, while the manufacturer continues working on developing a vaccine. We will use terms and conditions to manage uncertainties or risk mitigation measures related to the vaccine in the context of public health.

The NCI heard testimony that the Health Canada employee who authorized all of the Covid-19 vaccines swore an Affidavit for a lawsuit for Federal Court File No. T-145-22 in which she described the basis of Health Canada's authorization of the Pfizer/ BioNTech and Moderna vaccines. Instead of setting out the evidence relied on in support of the authorization, she simply parrots the words of the test. In the case of Pfizer/ BioNTech, she stated that Health Canada reviewed "quality (chemistry and manufacturing), non-clinical (pharmacology and toxicology), and clinical (immunogenicity, safety, and efficacy) information" and then concluded that "the evidence supports the conclusion that the benefits associated with the Pfizer.BioNTech COVID.19 Vaccine outweigh the risks, having regard to a shorter term (median of 2 months) follow up of safety and efficacy at authorization, and the necessity of addressing the urgent public need related to COVID.19." In the case of Moderna, she stated similarly that: "the evidence supported the conclusion that the benefits associated with the Moderna COVID.19 Vaccine outweighed the risks, having regard to a shorter term (median of 2 months) follow up of safety and efficacy at authorization, and the necessity of addressing the urgent public health need related to COVID.19."

Notably, what she does not cite in support of the vaccine authorization is:

1. objective proof of safety;
2. objective proof of efficacy, and
3. objective proof that the benefits outweigh the risks.

Based on testimony to the NCI, and without further evidence from Health Canada, we cannot conclude that Health Canada properly evaluated the safety and efficacy of the Covid-19 vaccines before authorization. To the contrary, the authorization of the vaccines appears to have been all but pre-assured by the creation of the Interim Order.

The Interim Order Has Become Permanent

The Interim Order can only last for a maximum of one year. The Interim Order, therefore, was replaced on March 18, 2022, with permanent regulations that codify the subjective authorization test discussed above.[7]

The only notable change between the test in the Interim Order and the new permanent regulation is that the "public health need" that needs to be addressed is no longer described as urgent. Recall that the Interim Order required an examination of risks and benefits, while:

[7] SOR/2021-45.

> "having regard to "the necessity of addressing the urgent public health need related to Covid-19"

Now the test simply requires Health Canada to give consideration to "the public health need related to Covid-19."

Thus, under the permanent test, Health Canada no longer has to be swayed by urgency, but simply by the public health need related to Covid-19. In this way, it seems that so long as Covid-19 is a circulating virus, Health Canada must authorize any vaccine for which there is an argument to support the conclusion that its benefits outweigh its risks. In effect, we fear that there will never be a need for Covid-19 vaccine manufacturers to prove safety or efficacy of their products.

On a positive note, the NCI heard that the Minister's ability to revoke authorization of Covid-19 vaccines is now subject to the same regular rules as other drugs that are approved for the market. It does beg the question, however, of why was that particular rule modified for Covid-19 vaccines in the first place?

Conflict of Interests for the Approval of Experimental Vaccines

Canada normally prohibits drugs from being imported into Canada unless they have been approved by Health Canada for use in humans.

Despite this, the Interim Order allowed unapproved and unauthorized Covid-19 vaccines to be imported into Canada as long as the Canadian Government was the purchaser. This was called pre-positioning in the Interim Order, and later in the Regulations codifying the Interim Order.[8]

The rationale was to assist Canada in expediting its response to the perceived Covid-19 crisis, by pre-purchasing and distributing the vaccines so they would be ready as soon as they were authorized. However, this created a tremendous conflict of interest.

Once the vaccines were purchased, imported and ready for distribution, the Government of Canada would have suffered significant political blowback if it was unable to authorize them. Thus, it needed to authorize the Covid-19 vaccines, and it needed to do it quickly. The Government of Canada essentially put itself in charge of authorizing a drug that it had spent millions of public dollars on, had promised publicly on many occasions, and that it wanted to administer to every Canadian citizen.

The authorization of the Covid-19 vaccines was all but guaranteed. The Government of Canada ordered the vaccines, imported them, created new regulations to authorize them, and then took significant measures to convince and coerce every Canadian to take multiple doses. The political stakes were high, and the federal government had every motivation to get the vaccines authorized, regardless of their actual efficacy or safety.

[8] SOR/2021-45.

There was no opportunity for sober second thought. There was no impartial oversight. The entire authorization process appears to have been "gamed" for one result, and one result only: authorization of vaccines for every Canadian, including children. Once the federal Government made mass-vaccination its priority, it should no longer have been solely responsible for their authorization.

Timing of the Interim Order

The timing of the Interim Order is also curious and coincident. Notably, the September 16, 2020 Interim Order was created just two weeks before AstraZeneca's authorization application was filed with Health Canada, and just three weeks before Pfizer filed on October 8, 2020.

Since the authorization applications were made under the Interim Order, they would have been structured to meet the requirements of the Interim Order. Perhaps an authorization application is a standard document, however, the NCI suspects that it would be difficult for a company to prepare a detailed authorization application without knowing what the authorization requirements were going to be.

For this reason, there are further questions that need to be answered about how the applications could have been filed so quickly in a manner that satisfied the subjective test, and whether there was participation in creating, or knowledge of the contents of, the test in advance.

Phase Three Trial Data Alleged Manipulation of Data

Deana McLeod Insights into Covid Vaccine Approval and Trials

Deana McLeod's testimony has raised important concerns about the means and methods used in testing Covid-19 vaccines. Her testimony primarily centred on potential conflicts of interest and biases within the teams responsible for conducting and reporting Phase Three test data, which was submitted to Health Canada.

Additionally, McLeod shed light on Pfizer's historical legal issues and the broader issue of potential conflicts of interest within the regulatory and approval sector. Her testimony echoed Mr. Shawn Buckley's prior statement that objective tests demonstrating safety and efficacy were omitted from these products. Financial incentives at various stages of the testing and authorization process were also discussed, prompting the need for a thorough examination of motivations.

McLeod's testimony serves as a reminder of the importance of transparency, objectivity, and independence in the testing and approval of medical products, especially when it concerns a global health crisis. The potential for conflicts of interest and biases within such a critical process can erode public trust and compromise the credibility of the regulatory framework.

The reference to Pfizer's past legal issues underscores the necessity for scrutinizing the track record of pharmaceutical companies involved in the development of vaccines or drugs. The public has a right to be informed about any potential historical shortcomings or ethical concerns that might impact the reliability of the products in question.

The removal of objective safety and efficacy tests from the products raises alarming questions about the standards applied to these vaccines. Rigorous testing is the cornerstone of any vaccine's credibility and the foundation of public trust. Omitting such tests potentially undermines the credibility of the entire testing and approval process.

The mention of financial motivations at various levels of testing and approval emphasizes the need for greater transparency and accountability within the industry. The potential for financial incentives to influence decision-making is a cause for concern and demands further investigation to ensure that public health is prioritized over financial gain.

Lastly, the allusion to Statistics Canada data provided during the testimony highlights the need for comprehensive, reliable, and complete data when assessing the impact of any medical intervention. It is crucial to base decisions on thorough and unbiased information to ensure the well-being of the population.

In conclusion, Deana McLeod's testimony raises vital questions about the processes, motivations, and ethics involved in Covid-19 vaccine testing and authorization. This testimony underscores the necessity for transparent, objective, and unbiased approaches in these critical endeavours. The concerns raised must prompt a broader discussion about regulatory practices, industry accountability, and the integrity of medical interventions in the interest of public health and safety.

Conclusions

There appeared to be a disconnect between Health Canada messaging concerning vaccine approval and the actual test used for authorization. As indicated above, safety, efficacy and whether the benefits of the vaccines outweighed the risks did not need to be proven under the Interim Authorization process employed by Health Canada.

Despite the novel nature of the vaccines – in particular those using mRNA – the pharmaceutical companies did not have to objectively prove their safety and efficacy. It should be noted that the special authorization process created under the Interim Order was not mandatory, and pharmaceutical companies still had the option to apply for approval under the regular test which required objective proof of safety, efficacy and cost/ benefit.

The pharmaceutical companies did not choose to objectively prove safety, efficacy and cost/benefit. They chose to apply under the Interim Order test, and regulators did not require it of them. Of great concern is the disconnect between Health Canada's public messaging about the Covid-19 vaccines as safe and effective when the regulatory authorization process clearly does not require these be objectively demonstrated. Health Canada continues to message to the public that the regular drug approval requirements of safety and efficacy were met. For example, at the top of Health Canada's website page for the Pfizer vaccine, Health Canada states:

> All Covid-19 vaccines authorized in Canada are proven safe, effective and of high quality [emphasis in the original].

Recommendations

1. Newly implemented revisions to the Food and Drug Regulations related to the authorization of Covid-19 vaccines must be rescinded as they permanently exempt Covid-19 vaccines from the requirements to objectively prove the Safety or Efficacy as required under the Food and Drug Regulations.
2. The current use of Covid-19 vaccines in Canada that were authorized under the revised provisions of the Interim Order and the newly revised Food and Drug Regulations, should be stopped immediately.
3. A full judicial investigation of the process under which the Covid-19 vaccinations were authorized in Canada must be carried out. Criminal liability, if discovered, may be dealt with under existing Canadian law.
4. All documentation concerning the authorization process and information provided to the regulatory agencies by the manufacturers should be made publicly available.