NATIONAL CITIZENS INQUIRY

Vaccine Testing and Authorization

Excerpts from the NCI Interim Report

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Interim Report | **Vaccine Testing and Authorization**

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

Interim Authorization of Covid 19 Vaccine

Introduction

The Commission received detailed information about the procedure through which "approval" 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.

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:

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.

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.

Conclusions and Recommendations

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.