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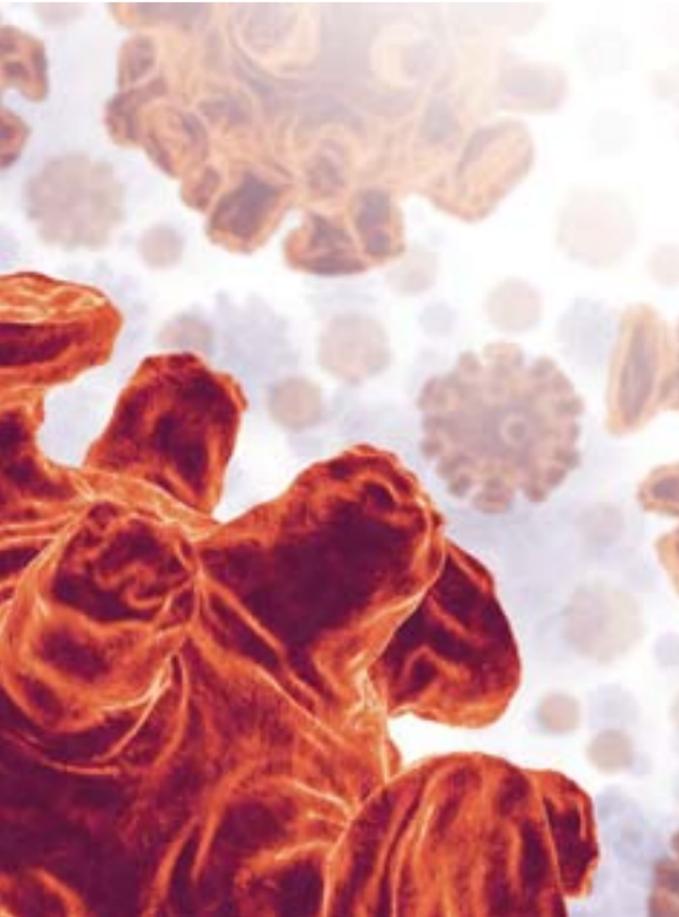
Santé  
Canada

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safety... our priority.*

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# ACCESS TO THE SEASONAL FLU VACCINE IN CANADA

How the flu shot makes its way from  
the laboratory to the doctor's office.



Canada 

*Health Canada is the federal department responsible for helping Canadians maintain and improve their health. We assess the safety of drugs and many consumer products, help improve the safety of food, and provide information to Canadians to help them make healthy decisions. We provide health services to First Nations people and to Inuit communities. We work with the provinces and territories to ensure our health care system serves the needs of Canadians.*

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– *Comment le vaccin contre la grippe se rend du laboratoire jusqu'au cabinet médical*

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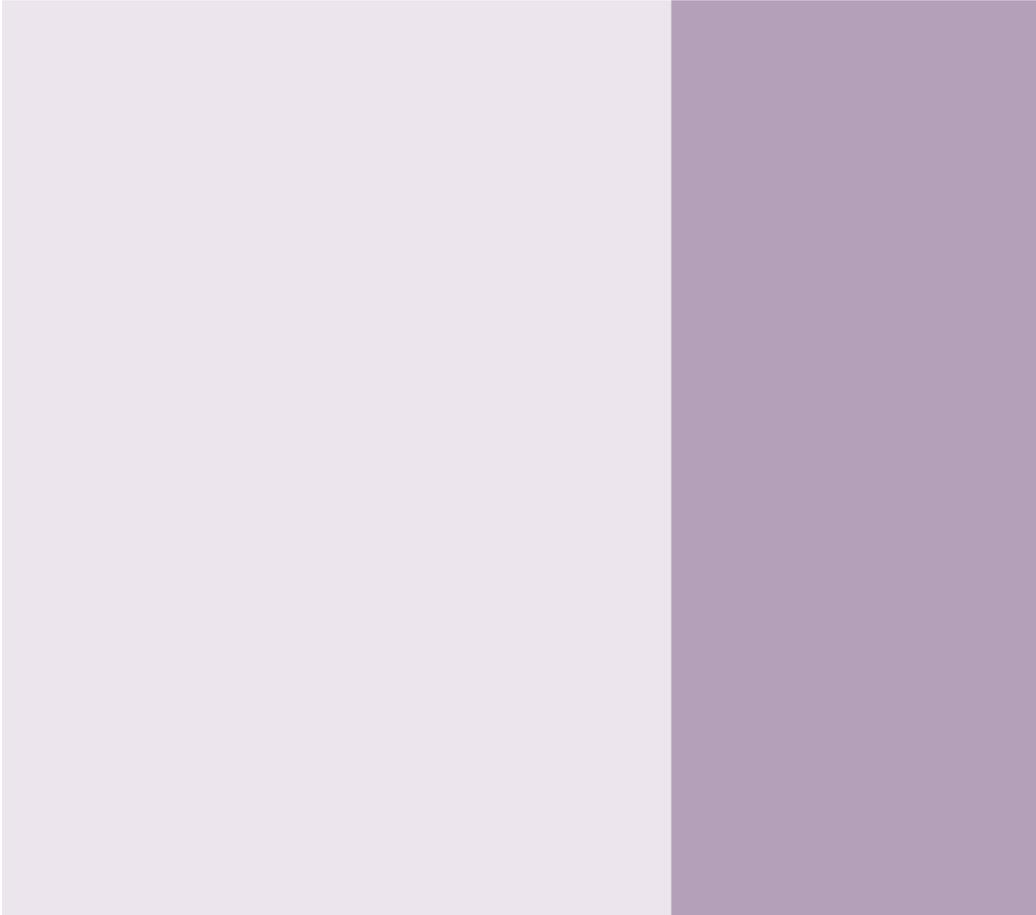
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# **ACCESS TO THE SEASONAL FLU VACCINE IN CANADA**

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## **How the flu shot makes its way from the laboratory to the doctor's office.**

Every year, millions of Canadians are affected by the flu (influenza), a respiratory illness caused by a virus. Those who get the flu have high fever, chills, sweating, headache, sore throat, dry cough, muscle aches, extreme tiredness and weakness. Those who are particularly vulnerable to the flu and its effects are the very young, the elderly, and those with a weakened immune system.

The flu can cause a range of problems from a few sick days, to hospitalization and even death. Therefore the seasonal flu vaccine is an important protective resource that Canadians have access to every year, in time for the flu season.

The following publication describes the pathway for the development, regulation and distribution of the flu vaccine in Canada.



# Step 1: Identifying the Virus

The flu virus strains circulating the globe change on a regular basis. Therefore the process for flu vaccine development starts off on a global scale annually. Each year in February, the **World Health Organization (WHO)** selects three influenza virus isolates which form the basis for flu vaccine production for the following fall and winter flu season.



## Step 2: Constructing the Strain and Reagents

In general, vaccines are produced by isolating or creating an organism (or part of one) that retains specific proteins called **antigens** which are responsible for inducing the body's immune response.

WHO collaborating centres oversee the construction of vaccine strains from the three selected influenza virus isolates. These organizations also produce special reagents to monitor the quality of vaccine production.

The **vaccine strains** and **reagents** are then distributed to flu vaccine manufacturers.



## Step 3: Production of Flu Vaccine

There are a handful of flu vaccine manufacturers responsible for running the production process and distributing the vaccine across North America and Europe.

### Vaccines are Biologics:

Vaccines differ from other drugs because of their biological (and hence, variable) nature, the raw materials used in their production and the biological methods used to test them. Special procedures are needed for their manufacture, control and regulation.

The current manufacturing process involves the replication of vaccine strains in eggs. A few manufacturers use animal cells instead.

Clinical trials (studies) are conducted on humans to ensure that the vaccine is safe and effective.

Once the manufacturer has acquired sufficient scientific evidence that the vaccine is safe, effective and of suitable quality, a submission may be filed with **Health Canada** for market approval.

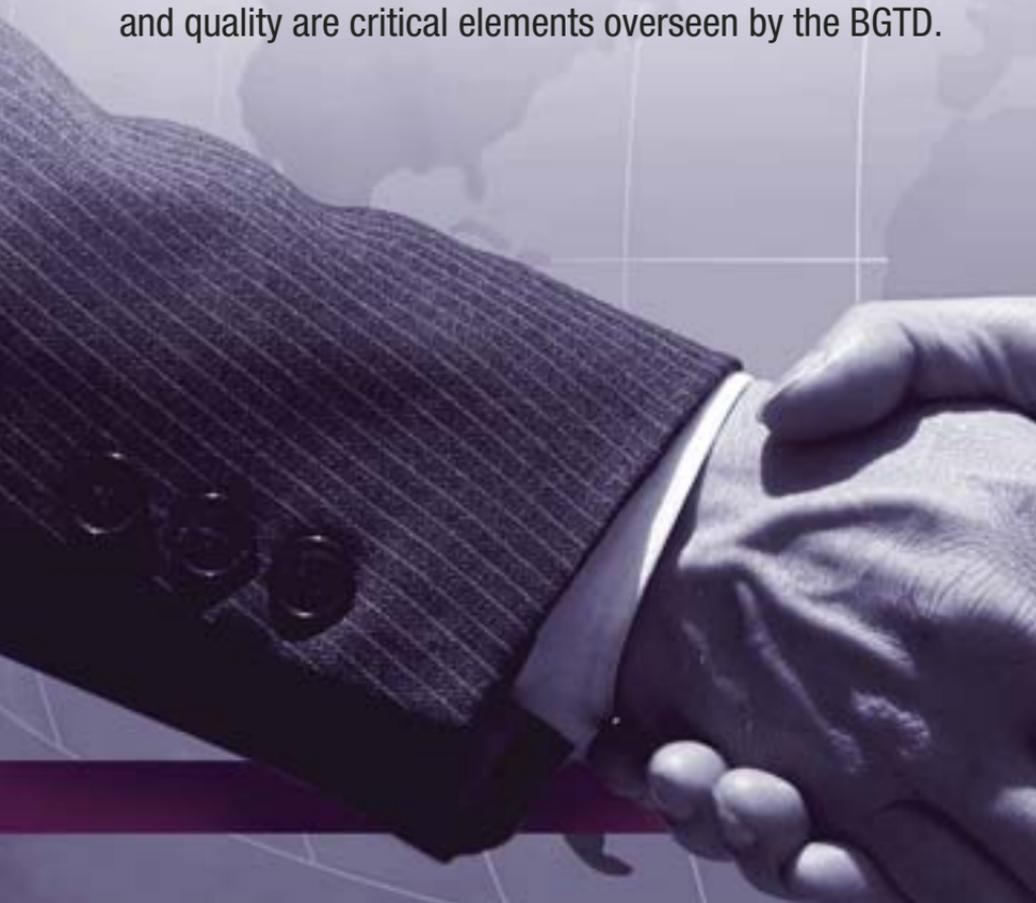
### The Future of Vaccine Manufacturing:

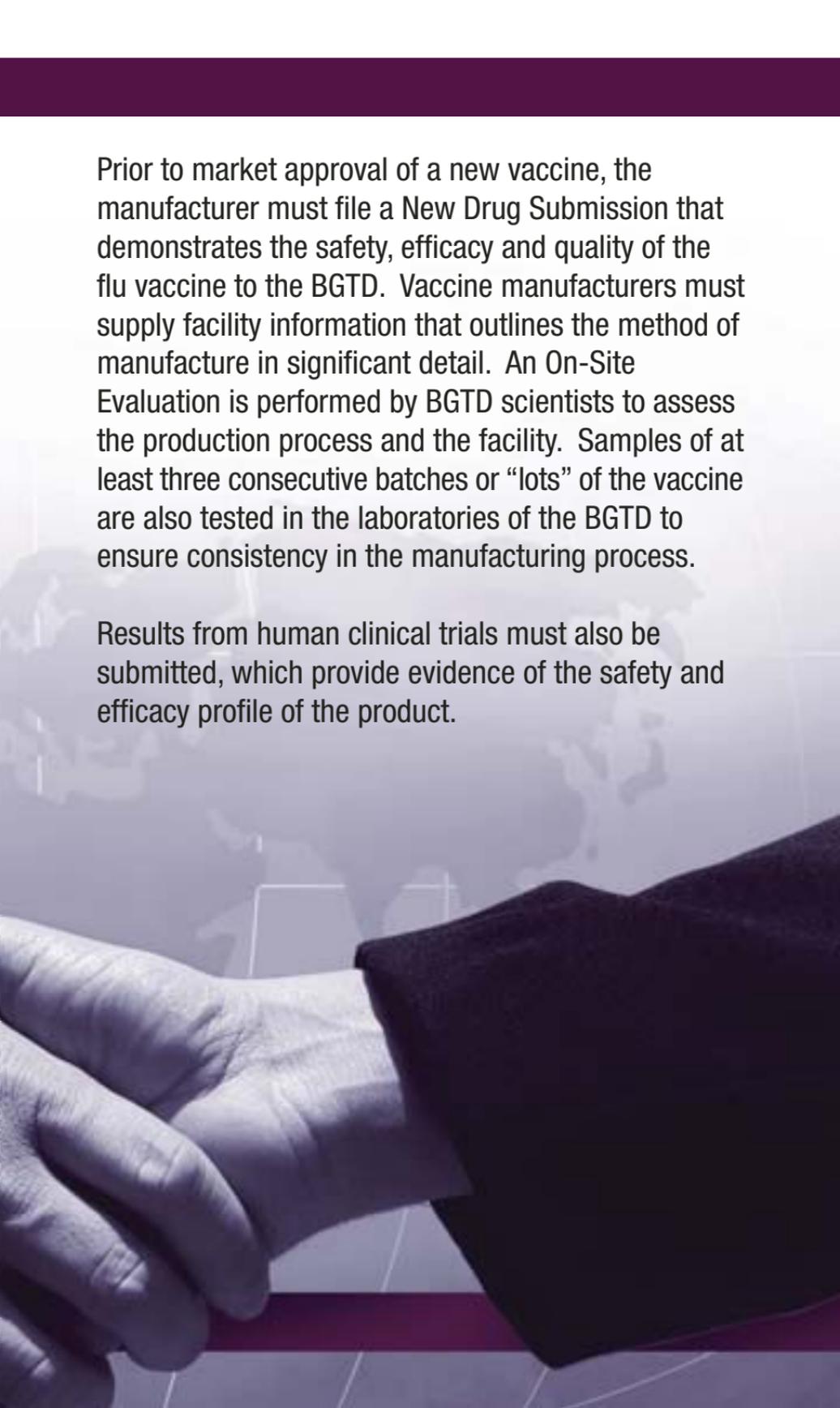
New methods using modern molecular techniques (e.g. recombinant protein and plant based technology) are under development to improve the ability to duplicate protective properties of the vaccine strain. Such techniques may have the potential to expand manufacturing capacity to produce larger flu vaccine supply in a shorter timeframe.

## Step 4: Market Authorization

The **Biologics and Genetic Therapies Directorate** (BGTD) is the federal program within Health Canada's Health Products and Food Branch that is responsible for the regulation of new biological drugs, including vaccines.

Although they have an excellent safety record, vaccines are strictly regulated because they are unique in the fact that they are commonly administered to very large numbers of healthy people, including infants and children, in national immunization programs. Safety and quality are critical elements overseen by the BGTD.





Prior to market approval of a new vaccine, the manufacturer must file a New Drug Submission that demonstrates the safety, efficacy and quality of the flu vaccine to the BGTD. Vaccine manufacturers must supply facility information that outlines the method of manufacture in significant detail. An On-Site Evaluation is performed by BGTD scientists to assess the production process and the facility. Samples of at least three consecutive batches or “lots” of the vaccine are also tested in the laboratories of the BGTD to ensure consistency in the manufacturing process.

Results from human clinical trials must also be submitted, which provide evidence of the safety and efficacy profile of the product.

If, after the completion of the review, it is concluded that the benefits of the vaccine outweigh its risks, then the vaccine is issued a Notice of Compliance (NOC) and a Drug Identification Number (DIN), indicating that it is authorized for sale in Canada.

Following the issuance of an NOC, the manufacturer is required to submit samples of each lot to the BGTD for lot release testing. After confirming the safety and potency of each vaccine lot in its own laboratories, the BGTD issues a lot release letter authorizing the manufacturer to sell it in Canada.

Since the flu vaccine changes every year, manufacturers must send updated information on their manufacturing process with the selected strains as well as data from small clinical trials to demonstrate that the vaccine produced is able to stimulate the immune system of vaccinated individuals. The BGTD conducts an expedited review of the data and authorizes these modifications. This period typically occurs between July and September each year.



## **Step 5: Supply and Distribution of Flu Vaccine in Canada**

The Government of Canada, through Public Works and Government Services Canada (PWGSC), purchases flu vaccines on behalf of the provinces and territories. Long-term contracts are established with manufacturers and estimated requirements are provided several months in advance of the flu season, to secure adequate supply. The vaccine is available at public health clinics and doctor's offices in accordance with provincial and territorial influenza immunization programs. Flu vaccines are also available through private market contracts – and can be found at local pharmacies for those individuals seeking to buy them.



The **Public Health Agency of Canada** (PHAC) assists in the coordination and oversight of public market supply and distribution, in collaboration with PWGSC, BGTD (Health Canada), the manufacturers and Federal/Provincial/Territorial (FPT) committees. FPT Committees include the Canadian Immunization Committee that advises on immunization program planning and the Vaccine Supply Working Group that advises on vaccine supply issues across Canada.

The National Advisory Committee on Immunization (NACI) is an expert committee reporting to Canada's Chief Public Health Officer. NACI makes annual recommendations for the use of influenza vaccines in Canada including the identification of groups at risk of influenza for whom vaccine programs should be targeted.



## Step 6: Post-Market Surveillance

PHAC carries out post-market surveillance of the flu vaccine, through the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS). The CAEFISS includes a voluntary reporting system where local, provincial and territorial public health and health care providers can report adverse events they feel are associated with an immunization. Additionally there is an active paediatric hospital based surveillance network (Immunization Monitoring Program Active, or “IMPACT”) that identifies selected serious adverse events that follow immunization.

Manufacturers are required to report to the BGTD all serious vaccination failures.

**For more information on post-market surveillance for the flu vaccine, refer to the following website**

*[http://www.phac-aspc.gc.ca/im/vs-sv/caefiss\\_e.html](http://www.phac-aspc.gc.ca/im/vs-sv/caefiss_e.html)*

# Conclusion

**Step 1: Identifying the Virus**

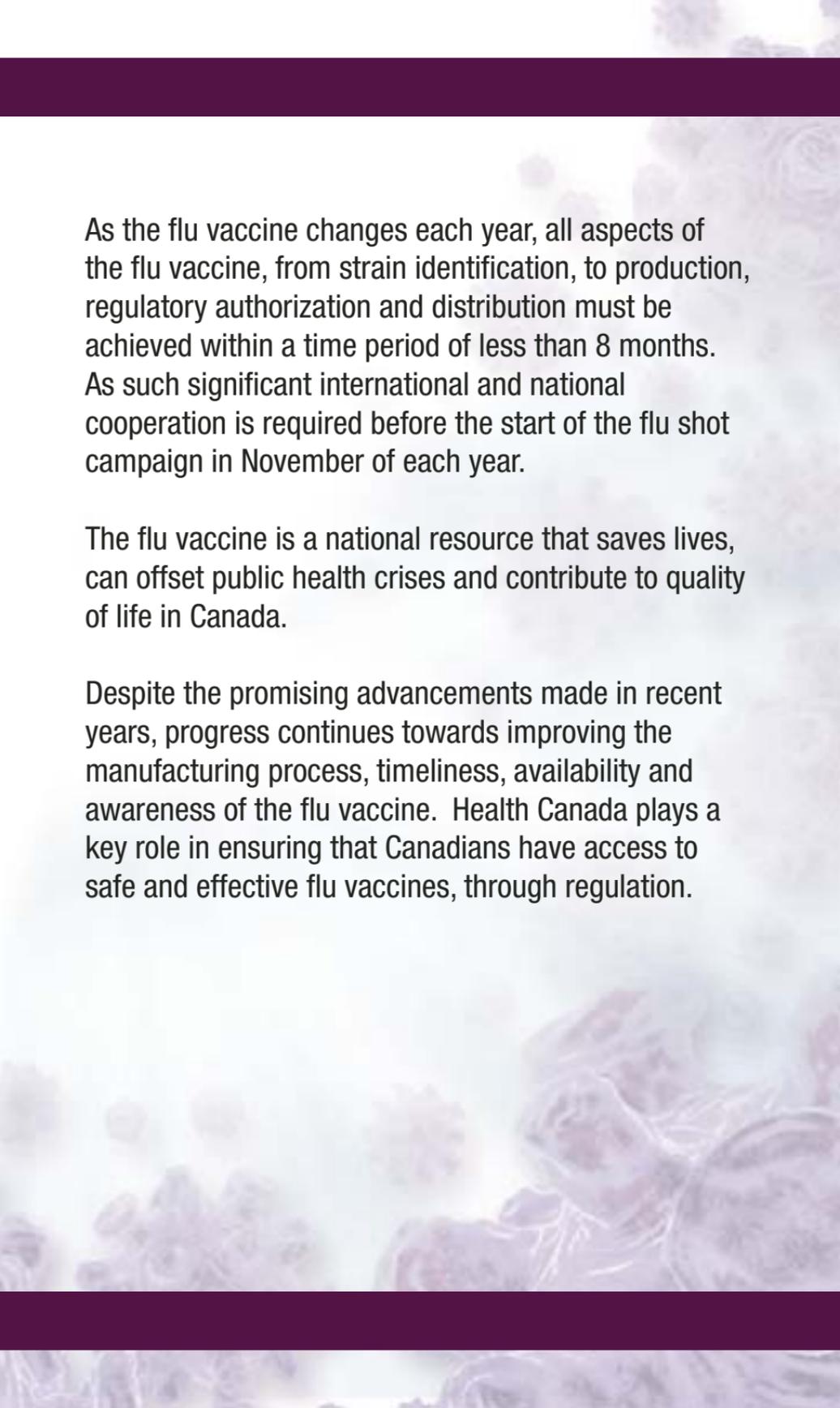
**Step 2: Constructing the Strain and Reagents**

**Step 3: Production of Flu Vaccine**

**Step 4: Market Authorization**

**Step 5: Supply and Distribution of Flu Vaccine in Canada**

**Step 6: Post-Market Surveillance**

A background image showing a microscopic view of virus particles, likely influenza, with a purple and white color scheme. The particles are spherical and have a textured surface. The background is a gradient of light purple and white, with a dark purple horizontal bar at the top and bottom.

As the flu vaccine changes each year, all aspects of the flu vaccine, from strain identification, to production, regulatory authorization and distribution must be achieved within a time period of less than 8 months. As such significant international and national cooperation is required before the start of the flu shot campaign in November of each year.

The flu vaccine is a national resource that saves lives, can offset public health crises and contribute to quality of life in Canada.

Despite the promising advancements made in recent years, progress continues towards improving the manufacturing process, timeliness, availability and awareness of the flu vaccine. Health Canada plays a key role in ensuring that Canadians have access to safe and effective flu vaccines, through regulation.

