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Regulatory considerations for the evaluation of a new H5N1 candidate vaccine including mRNA vaccines

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Regulatory process for an influenza pandemic vaccine

As part of pandemic preparedness planning influenza pandemic vaccines have been reviewed in the pre-pandemic phase based on a pre-pandemic strain.

Currently there are 3 pandemic influenza vaccines approved for the Canadian market

Manufacturer	Proprietary Name	Substrate	Adjuvant	Regulatory Status	Strain description
GSK	Arepanrix H5N1	Eggs	AS03	initial authorization	A/Indonesia/5/2005 (H5N1)
				Strain update	A/American wigeon/South Carolina (H5N1)
Seqirus	Foclivia	Eggs	MF59C.1	Initial authorization	A/Vietnam/1194/2004 (H5N1)
Sanofi Pasteur	Panenza	Eggs	None	Initial authorization	A/California/7/2009 (H1N1)

Regulatory requirements for influenza pandemic vaccines

- An influenza pandemic vaccine requires a stand-alone market authorization

- Manufactures have leveraged existing manufacturing process for seasonal influenza products to manufacture a potential influenza pandemic strain.

- Sponsors must provide sufficient evidence of the product's safety, effectiveness and quality for assessment, including
  - Manufacturing details and controls to ensure consistent quality
  - Pre-clinical data to establish safety
  - Clinical data to support safety and immunogenicity of the vaccine
  - Risk management plan to evaluate vaccine effectiveness during a declared pandemic

- For pandemic products, this assessment has been conducted with a pre-pandemic strain either H5N1 or H1N1.

Regulatory requirements for a strain update to an approved influenza pandemic vaccine

- No pre-clinical or clinical data is required to support a change in the pandemic strain included in the approved influenza pandemic vaccine

- CMC quality only package requiring sufficient supportive data
  - CVV sourced from a WHO collaborating center
  - Re-validation of the process which are impacted by the strain (i.e inactivation, splitting)
  - Validation of the SRID assay with the strain specific reagents
  - Characterization assessment to support antigen comparability
  - Accelerated/forced degradation stability data to support product comparability and shelf-life assignment

- Sponsor must maintain the manufacturing process up to date during the interpandemic phase

Regulatory requirements for an mRNA pandemic vaccine

- mRNA or other novel vaccine would have to provide sufficient evidence of the product's safety, effectiveness and quality for assessment,

- Quality data including
  - Quality of the starting materials
  - Consistency of manufacture
  - Potency assessment
  - Stability and storage conditions

- Pre-clinical studies supporting the safety and effectiveness of the vaccine

- Clinical data supporting the safety and effectiveness of the vaccine.

Thank you!