Licensed and stockpiled H5 vaccines

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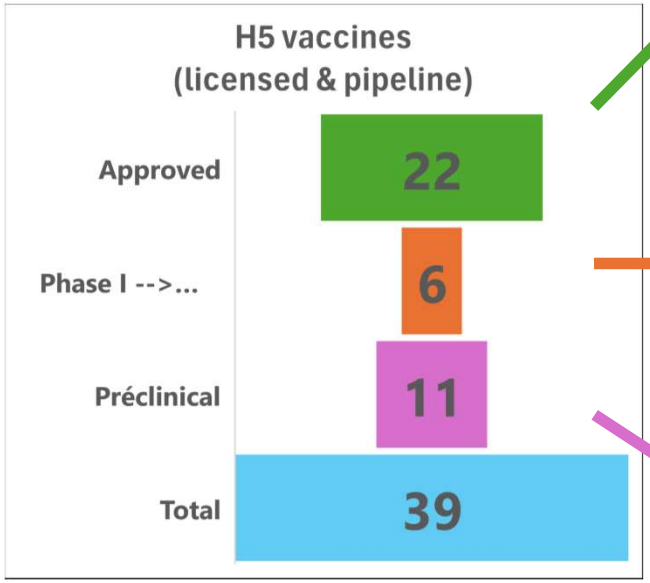
An overview of influenza H5 vaccines

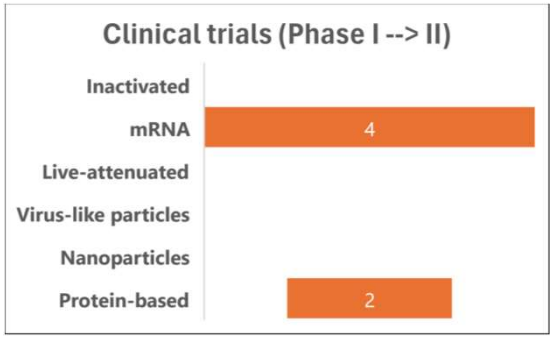
- As of October 2024:

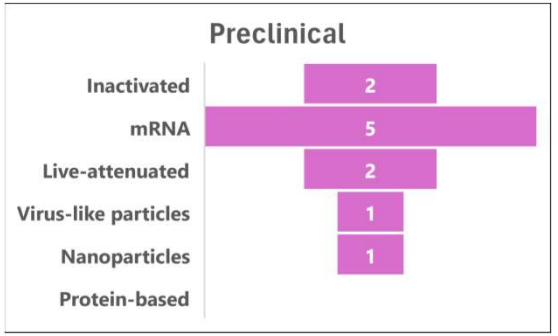
PIV: > 100 pandemic flu vaccines

H5Nx: **39** specifically target HPAI H5

Licensed: **22** are approved (in at least one country)







- **All** approved H5 vaccine **but one** are **inactivated vaccine** (**21/22**)
- Most approved H5 vaccine are A(H5N1)
- A total of **9 mRNA vaccine** (out of 17) under **preclinical (5)** or **clinical trial (4)**

Source: FDA: U.S. Food and Drug Administration; EMA: European Medicines Agency; NMPA: National Medical Products Administration, China; PMDA: Pharmaceuticals and Medical Devices Agency, Japan; TGA: Therapeutic Goods Administration, Australia; GSK: GlaxoSmithKline; BARDA: Biomedical Advanced Research and Development Authority; Data publically available from developpers and Airfinity.

Current influenza A(H5) vaccines licensed

Currently **16 developers** with approved A(H5) vaccines

- Most vaccines follow a **two-dose schedule**
- Most use **inactivated** influenza virus platforms and are **egg-based**
- **10** vaccines indicated for **children** as young as six months and **adults aged ≥65 years**
- **AstraZeneca's** vaccine is the only licensed live attenuated vaccine, with **WHO prequalification,** developed to protect children aged between 12 months and 18 years against influenza during a pandemic
- Only one country (Finland) has implemented an A(H5) vaccination programme for **at-risk groups** (poultry and mink farmers, veterinarians, other exposed individuals)

	Manufacturer location	Vaccine name	Subtype	Vaccine type	Adjuvant	Age group indication*	Licensing authority
AstraZeneca	UK	Pandemic influenza vaccine H5N1 AstraZeneca	H5N1	LAIV, egg based	None	Children†	EMA
Denka Seiken	Japan	Adsorbed influenza vaccine (H5N1) "Seiken"	H5N1	IIV, egg based	Aluminium-based	Information unavailable	PMDA
GC Biopharma	South Korea	GCFLU H5N1	H5N1	IIV, egg based	Aluminium-based	Healthy adults	MFDS
GlaxoSmithKline	UK	Adjupanrix	H5N1	IIV, egg based	AS03	Healthy adults, children, older adults	EMA
GlaxoSmithKline	UK	Q Pan/Influenza A (H5N1) virus monovalent vaccine, adjuvanted	H5N1	IIV, egg based	AS03	Healthy adults, children, older adults	FDA
Daiichi Sankyo	Japan	Adsorbed cell culture-derived influenza vaccine H5N1	H5N1	IIV, cell based	Aluminium-based	Healthy adults, children, older adults	PMDA
Daiichi Sankyo	Japan	Adsorbed influenza vaccine (H5N1) "HOKKEN"	H5N1	IIV, egg based	Aluminium-based	Healthy adults	PMDA
KM Biologics	Japan	Emulsion-adjuvanted cell-culture derived influenza HA vaccine	H5N1	IIV, cell based	AS03	Healthy adults	PMDA
Sanofi Pasteur	France	Influenza virus vaccine, H5N1	H5N1	IIV, egg based	None	Healthy adults	FDA
CSL Seqirus	Australia	Audenz	H5N1	IIV, cell based	MF59	Healthy adults, children, older adults	FDA
CSL Seqirus	Australia	Foclivia	H5N1	IIV, egg based	MF59	Healthy adults, children, older adults	EMA
CSL Seqirus	Australia	Panvax H5N1 influenza vaccine	H5N1	IIV, unknown	Information unavailable	Information unavailable	TGA
CSL Seqirus	Australia	Celldemic	H5N1	IIV, cell based	MF59	Healthy adults, children, older adults	TGA/EMA
CSL Seqirus	Australia	Incellipan	H5N1	IIV, cell based	MF59	Healthy adults, children, older adults	EMA
CSL Seqirus	Australia	Zoonotic influenza vaccine, Seqirus	H5N8	IIV, egg based	MF59	Healthy adults, older adults	EMA
CSL Seqirus	Australia	Panvax H5N8 influenza vaccine	H5N8	IIV, egg based	Aluminium-based	Healthy adults, children, older adults	TGA
CSL Seqirus	Australia	Aflunov	H5N1	IIV, egg based	MF59	Healthy adults, children, older adults	TGA/EMA
Sinovac Biotech	China	Panflu	H5N1	IIV, egg based	Aluminium-based	Healthy adults	SFDA
Takeda Pharmaceutical	Japan	Cell cultured influenza vaccine (H5N1) "TAKEDA"	H5N1	IIV, cell based	None	Information unavailable	PMDA
The Research Foundation for Microbial Diseases for Osaka University	Japan	Adsorbed influenza vaccine (H5N1) "BIKEN"	H5N1	IIV, egg based	Aluminium-based	Healthy adults	PMDA

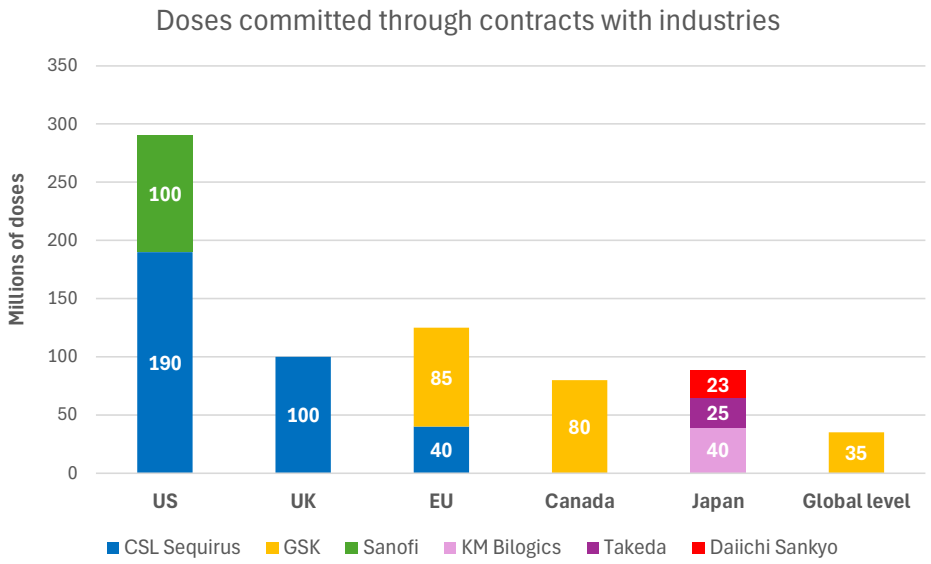
IIV=inactivated influenza virus vaccine. LAIV=live-attenuated influenza virus vaccine. EMA=European Medicines Agency. PMDA=Pharmaceuticals and Medical Devices Agency. MFDS=Ministry of Food and Drug Safety. FDA=US Food and Drug Administration. TGA=Therapeutic Goods Administration. SFDA=State Food and Drug Administration. *Healthy adults generally aged between 18 years and 64 years, with a few exceptions either starting at age 20 years, or ending at age 60 years; infants and children generally aged between 6 months and younger than 18 years, with a few exceptions ending at age 20 years; older adults typically aged 65 years and older, with a few exceptions older than 60 years (depending on the country). †Children aged between 12 months and younger than 18 years.

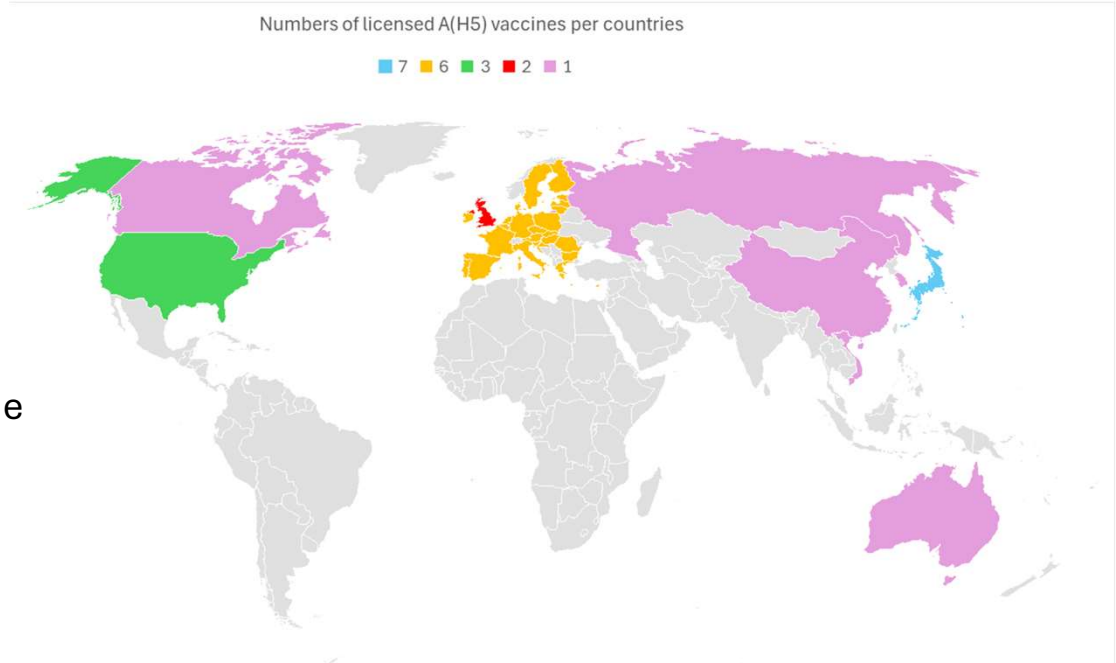
Table: **Key characteristics of licensed influenza A(H5) vaccines**

The Lancet Respiratory Medicine (March 2025)

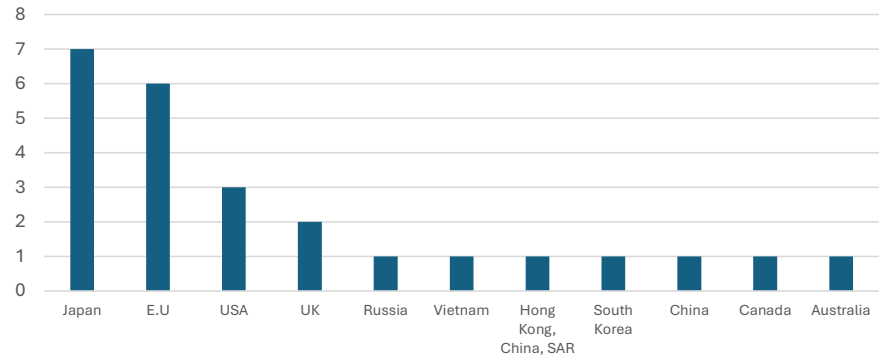
Global licensed H5N1 vaccines

- **36** countries have licensed H5 vaccines
- **Japan** with the highest number of approved vaccine (**7**) followed by **EU (6)** and the **US (3)**
- Since 2019, more than **700 million** pandemic vaccine doses have been committed with various countries





[Japan: Biken, Daiichi Sankyo, Denka Seiken, Kitasato Institute, KM Biologics, Takeda | E.U: AZ, CSL Seqirus (4), GSK | USA: CSL Seqirus, ID Biomedical Corporation of Quebec/GSK, Sanofi | UK: CSL Seqirus, GSK | Australia: CSL Seqirus | Canada: GSK | China: Sinovac | S. Korea: GC Pharma | Hong Kong, China SAR: Sinovac | Vietnam: IVAC | Russia: Microgen



Global production capacity of Seasonal and pandemic influenza vaccines (in 2023)

- Since the last survey in 2019, annual seasonal influenza vaccine production capacity has remained relatively stable at 1.53 billion doses

- Global pandemic vaccine capacity has also remained stable: estimated to be 4.13 billion doses in a moderate-case scenario and 8.26 billion doses in a best-case scenario
  - Does not reflect potential mRNA production capacity (as no influenza mRNA vaccines are licensed yet)

- Several manufacturers are in LMICs (e.g., GAP technology transfer initiative recipients)
  - No production capacity in the African region

- Some manufacturers anticipate challenges to meet pandemic influenza vaccine production capacity potential (e.g. access to eggs and other ancillary supplies)

Number of active influenza vaccine production facilities by WHO region.

WHO Region	Number of production facilities (change from 2019)
African Region	0 (no change)
Region of the Americas	6 (−1)
Eastern Mediterranean Region	1 (no change)
European Region	10 (+1)
South-East Asia Region	3 (no change)
Western Pacific Region	21 (+1)

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Pandemic Vaccines secured under PIP Framework

Global Pandemic Vaccine Production

Total % of Global Pandemic Production Capacity Secured

11.31%

Total Estimated SMTA2 Dose Commitment*

934,292,600

Estimated SMTA2 Dose Donated*

566,913,820

Estimated SMTA2 Dose Reserved*

367,378,780

**Estimates are best case scenario production dose estimates over a 12 month period provided to WHO by manufacturers as part of the WHO Influenza Vaccine Production Capacity Survey*

SMTA2 Vaccine Manufacturers

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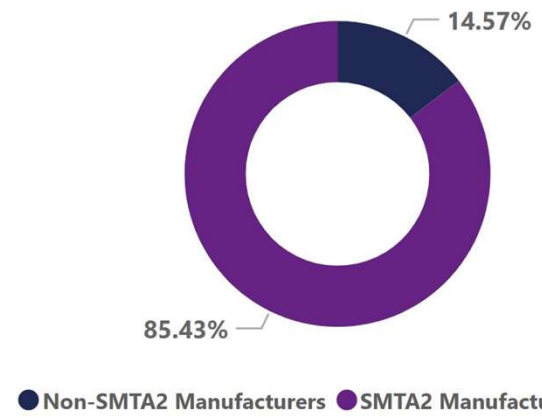
Estimated Global Pandemic Production Capacity*



Source: PIP SMTA2 Products Dashboard

Pandemic Vaccines secured under PIP Framework

Pandemic influenza vaccines

Currently licensed pandemic influenza vaccines produced by SMTA2 manufacturers

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WHO PQ'd Influenza Vaccines

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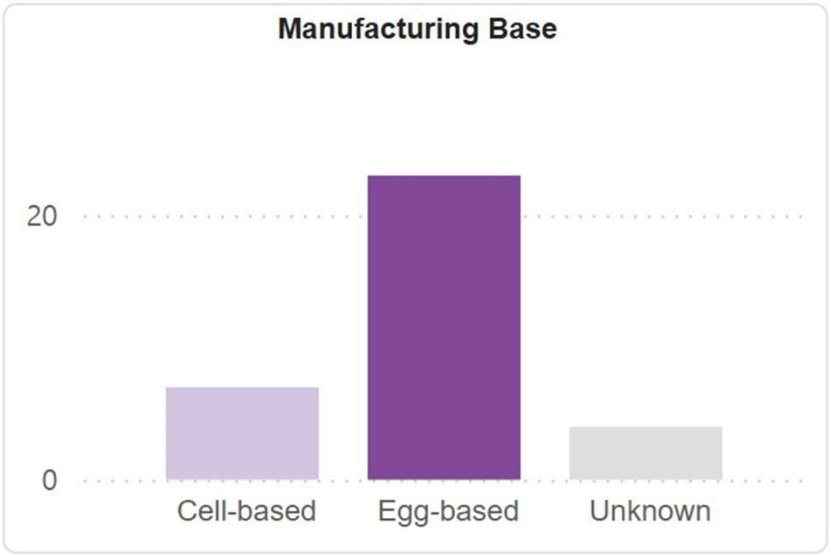
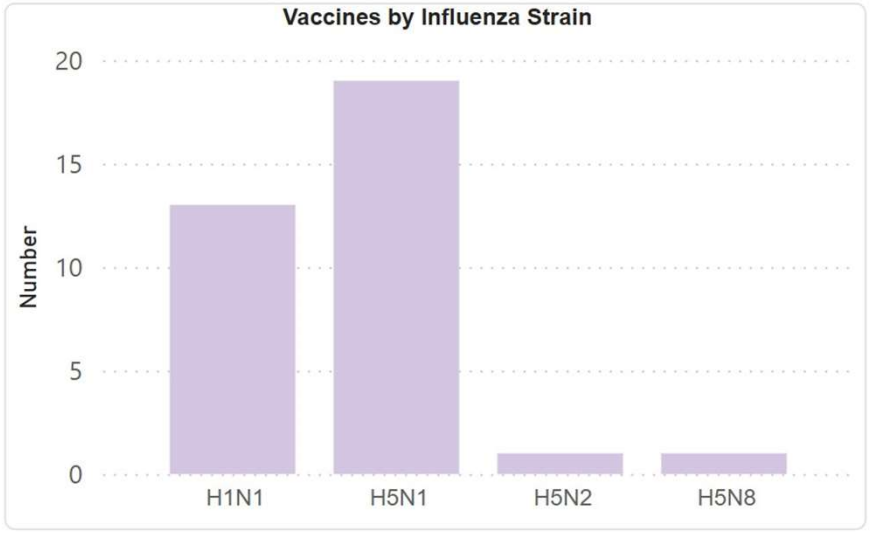
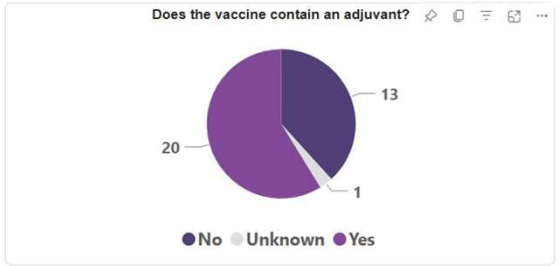






H5 vaccine stockpile

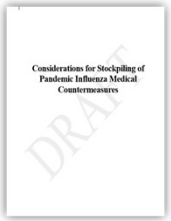
1. Consideration of options for the use of human H5 vaccines during interpandemic period

An update of WHO 2008 scientific document at final WHO clearance stage.

2. H5 vaccine and antiviral stockpiles

WHO is undertaking a series of analysis and outreach efforts to map available H5 relevant stockpiles of vaccines and antivirals.

3. Broad stockpiling for pandemic influenza: considerations brief to aid national decisions

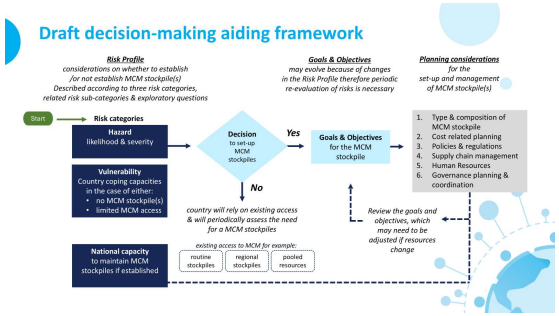


This considerations document aims to support countries in making strategic and operational decisions about MCM by providing a **framework to:**

i) assess the need for stockpiling; and

ii) guide the planning, establishment, and management of stockpiles if a decision to stockpile is made.

The scope of this document specifically addresses MCM for pandemic influenza, as outlined in the WHO Disease Commodity Package, with a primary focus on products intended for human use.



CURRENTELY OPEN FOR PUBLIC INPUT:

Draft document: *Stockpiling of Medical Countermeasures for Pandemic Influenza: considerations brief*.

If you wish to share your feedback, please fill in the online survey **by 4 April 2025**.

Acknowledgement

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