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Influenza Vaccine Manufacturing

Industry Perspective: 2025-2026 and upcoming 2026-2027 Northern Hemisphere Influenza Seasons

Vaccines and Related Biological Products Advisory Committee
12th March 2026
Beverly Taylor, PhD
Head of Global Influenza Scientific Affairs, CSL Seqirus
Informed by consultation with Influenza Vaccine Manufacturers

The FDA CBER requested this annual summary of information from influenza vaccine manufacturers supplying the U.S., for purposes of a general presentation to the VRBPAC. This summary has been prepared from a variety of public sources and was reviewed by AstraZeneca, CSL-Seqirus, GSK, and Sanofi.

Presenter Disclosure Statement

I am an employee of CSL Seqirus and own shares in the company.

Key Messages / Agenda

Transition from QIV to TIV for NH 2024/25-season in US achieved

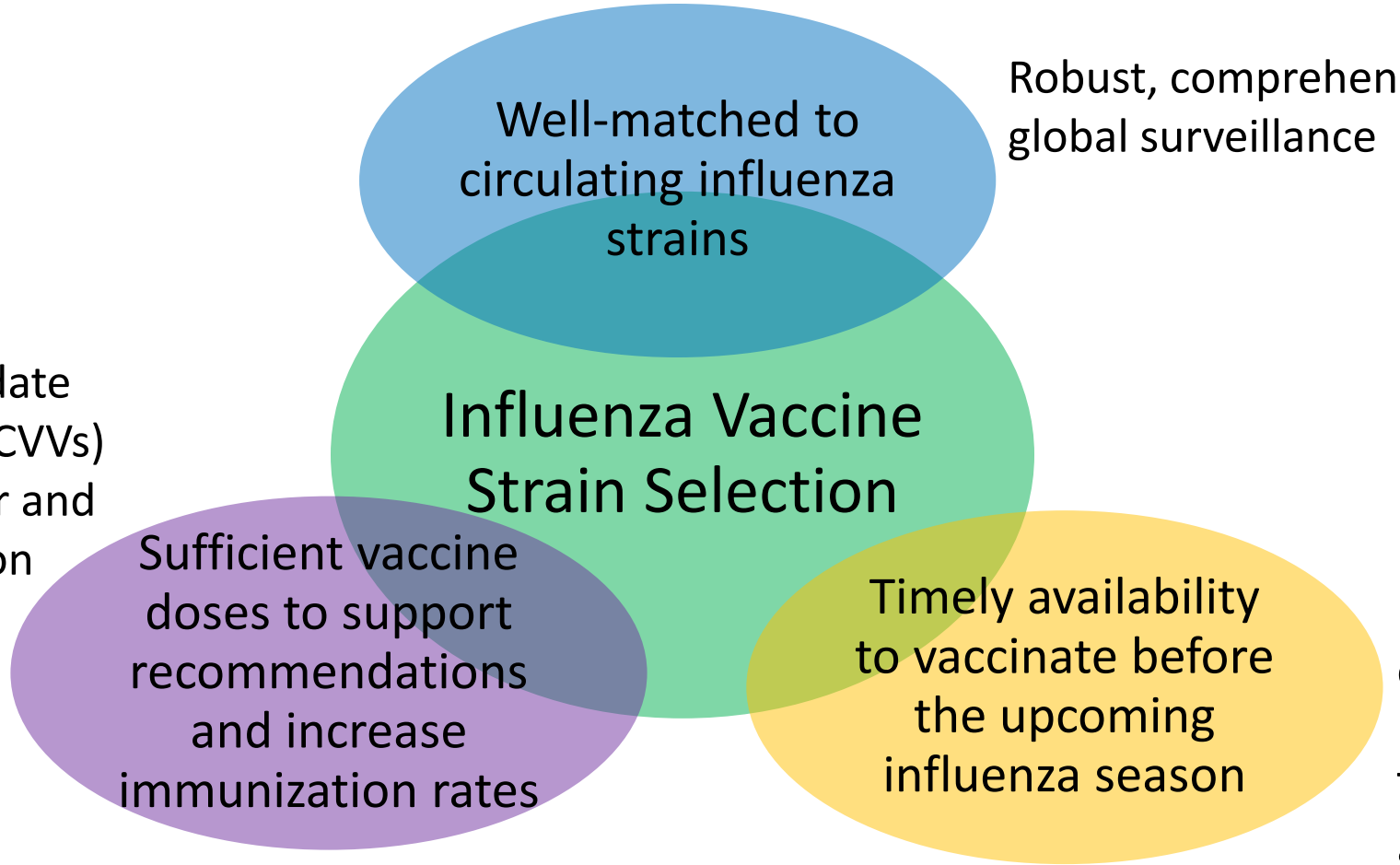
NH 2025/26 campaign successfully delivered

Continued decline of influenza vaccine coverage rates in the US

CBD Nagoya Protocol and compounding Access and Benefit Sharing (ABS) obligations continue to hinder influenza virus supply.

Importance of global scientific collaboration & sharing of surveillance and virus data for public health decision-making.

Successful influenza vaccination campaigns: A balancing act



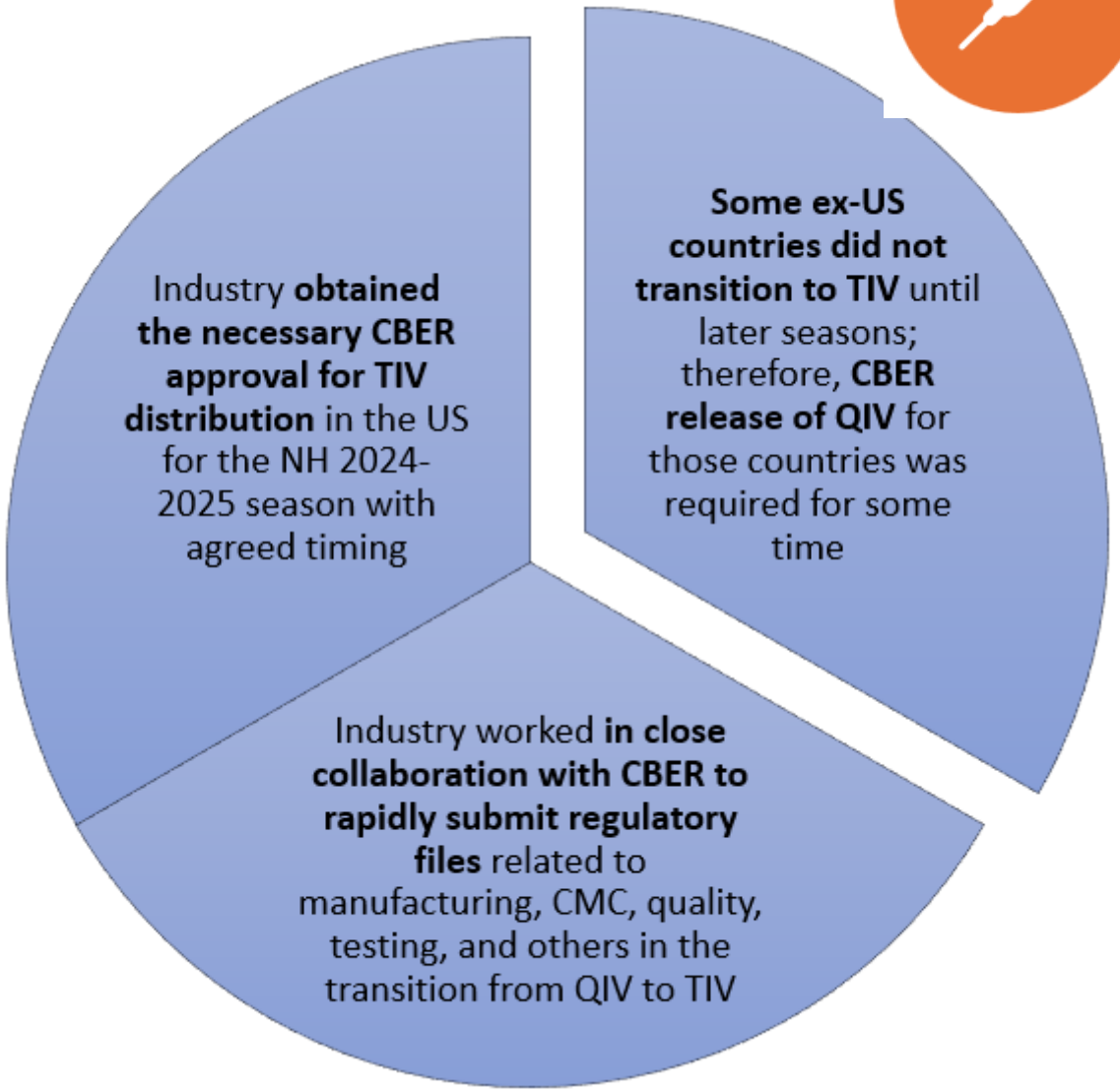
Robust, comprehensive, global surveillance

Choice of candidate vaccine viruses(CVVs) by manufacturer and yield optimization

Maintain current timing of vaccine strain recommendation. Timely supply of CVVs and potency assay reagents

NH 2024/25 Season – Transition to TIV

- For the NH 2024-2025 influenza season, the vaccine for the US transitioned to a trivalent formulation, after removal of the B/Yamagata lineage component.
- The US was the only country to transition in this timeframe - made possible through the agility demonstrated by regulators and manufacturers and strong partnerships across all stakeholders
- There were no delays to the season's vaccine supply.



NH 2025-26 WHO recommendation and FDA CBER decision for US vaccine supply

WHO Influenza Vaccine Composition Recommendations	FDA / CBER Recommendation
The recommendation was that influenza vaccines should contain the following: **For egg-platform vaccines:** an A/Victoria/4897/2022 (H1N1)pdm09-like virus; an A/Croatia/10136RV/2023 (H3N2)-like virus; and a B/Austria/1359417/2021 (B/Victoria lineage)-like virus. **For cell or recombinant-platform vaccines:** an A/Wisconsin/67/2022 (H1N1)pdm09-like virus; an A/District of Columbia/27/2023 (H3N2)-like virus; and a B/Austria/1359417/2021 (B/Victoria lineage)-like virus. **Where quadrivalent egg, cell, or recombinant-platform vaccines are still in use, the following B-Yamagata lineage strain should be included:** ▪ B/Phuket/3073/2013-like virus	On 13th March 2025, The FDA / CBER recommendations for the selection of strains to be included in influenza vaccines for the US NH 2025-2026 influenza season were announced: ✓ inclusion of the same A/H1N1pdm09, A/H3N2, and B/Victoria strains as recommended by WHO. ✓ supply of trivalent formulation egg, cell, and recombinant vaccines in the US (no B/Yamagata component).

Updates from NH 2024/25 season shown in blue. Note: This change had already been made for the SH 2025 season.

CVVs and reagents were available on time and campaign was successfully delivered

WHO, VRBPAC and FDA/CBER Vaccine Strain Recommendations

3 strain changes from NH 2025/26 recommendation and 2 changes from SH 2026 recommendation

Subtype	NH 2025-26	SH 2026	NH 2026-27 (WHO only, VRBPAC TBD)
A(H1N1)pdm09	**Egg:** A/Victoria/4897/2022-like **Cell/recombinant:** A/Wisconsin/67/2022-like	**Egg:** A/Missouri/11/2025-like **Cell/recombinant:** A/Missouri/11/2025-like	**Egg:** A/Missouri/11/2025-like **Cell/recombinant:** A/Missouri/11/2025-like
A(H3N2)	**Egg:** A/Croatia/10136RV/2023-like **Cell/recombinant:** A/District of Colombia/27/202--like	**Egg:** A/Singapore/GP20238/ 2024-like **Cell/recombinant:** A/Sydney/1359/2024-like	**Egg:** A/Darwin/1454/2025-like **Cell/recombinant:** A/Darwin/1415/2025-like
B/Victoria (B strain for TIV)	B/Austria/1359417/2021-like	B/Austria/1359417/2021-like	**Egg:** B/Tokyo/EIS13-175/2025 -like **Cell/recombinant:** B/Pennsylvania/14/2025-like
B/Yamagata (if QIV still supplied)	B/Phuket/3073/2013-like	B/Phuket/3073/2013-like	No recommendation

Updates from previous recommendations in red

Preparations for NH 2026/27

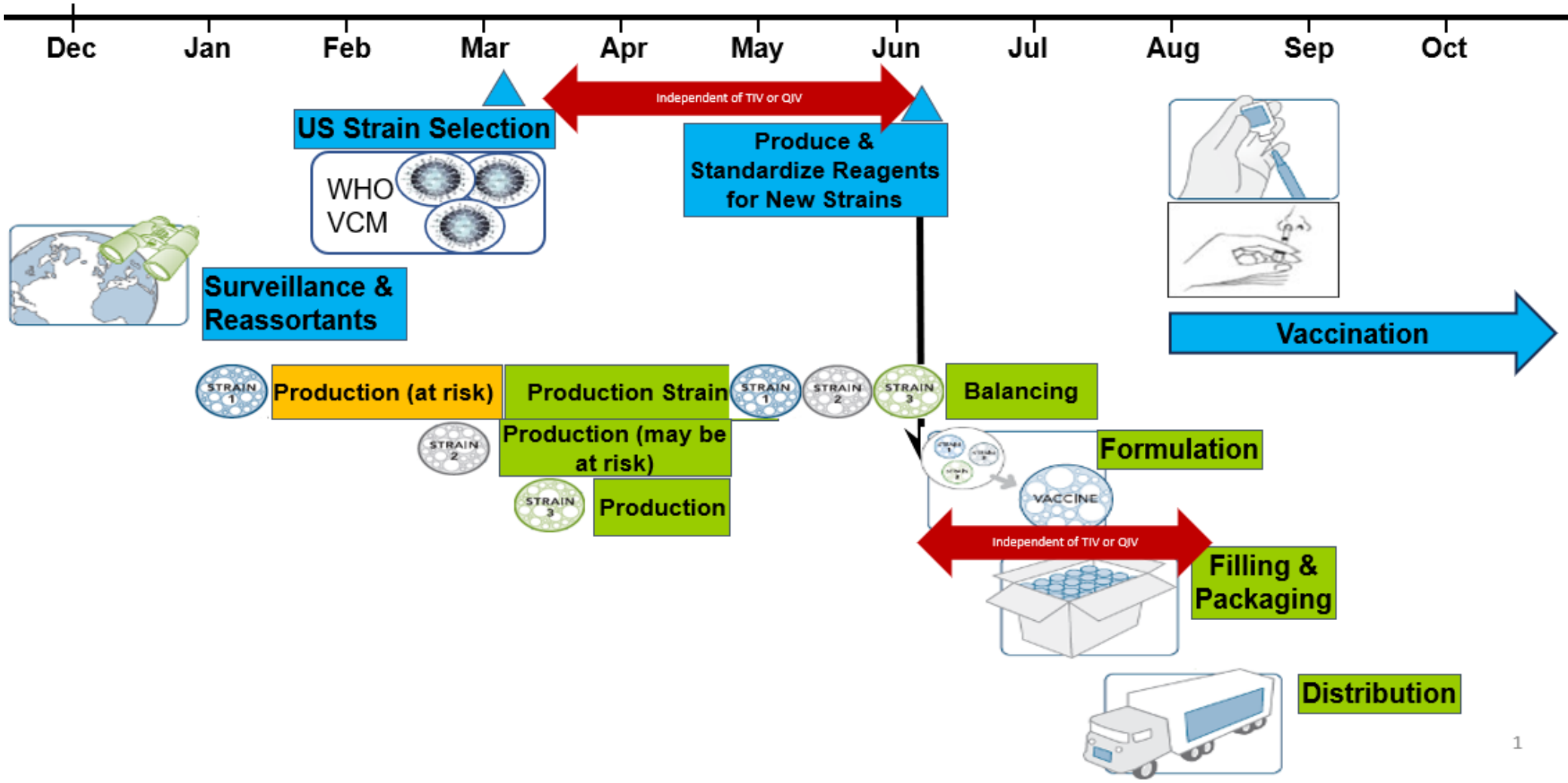
WHO recommended two strain changes

- A(H1N1) pdm – no change recommended, CVVs and Potency Assay reagents are available

- A(H3N2) – strain updated , some CVVs are available and Potency Assay reagents are being prepared

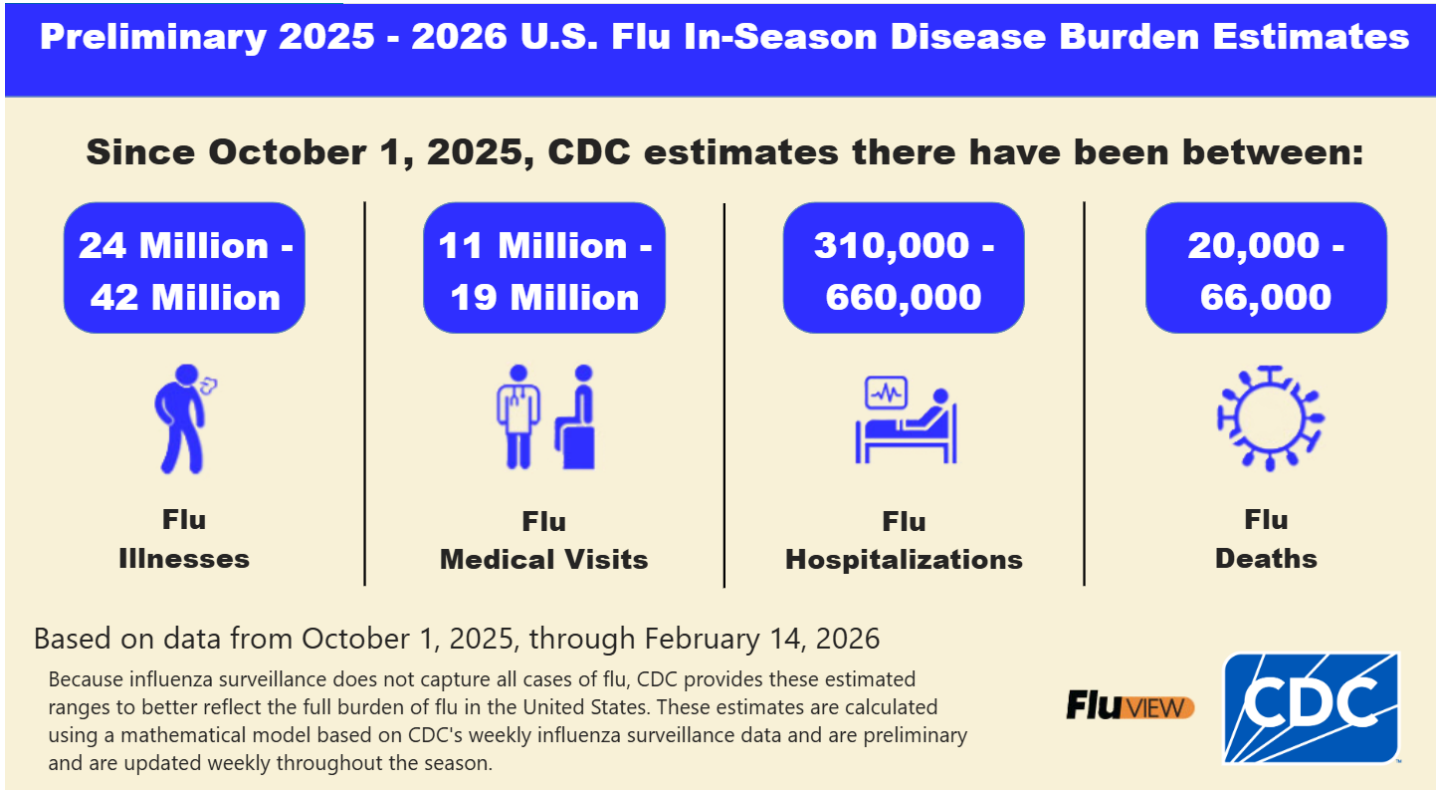
- B/Victoria – strain updated, egg-based CVVs not available until mid March and Potency Assay reagents to be prepared once strain confirmed

Annual TIV Influenza Vaccine Manufacturing Timeline for US NH Supply with Strain Change



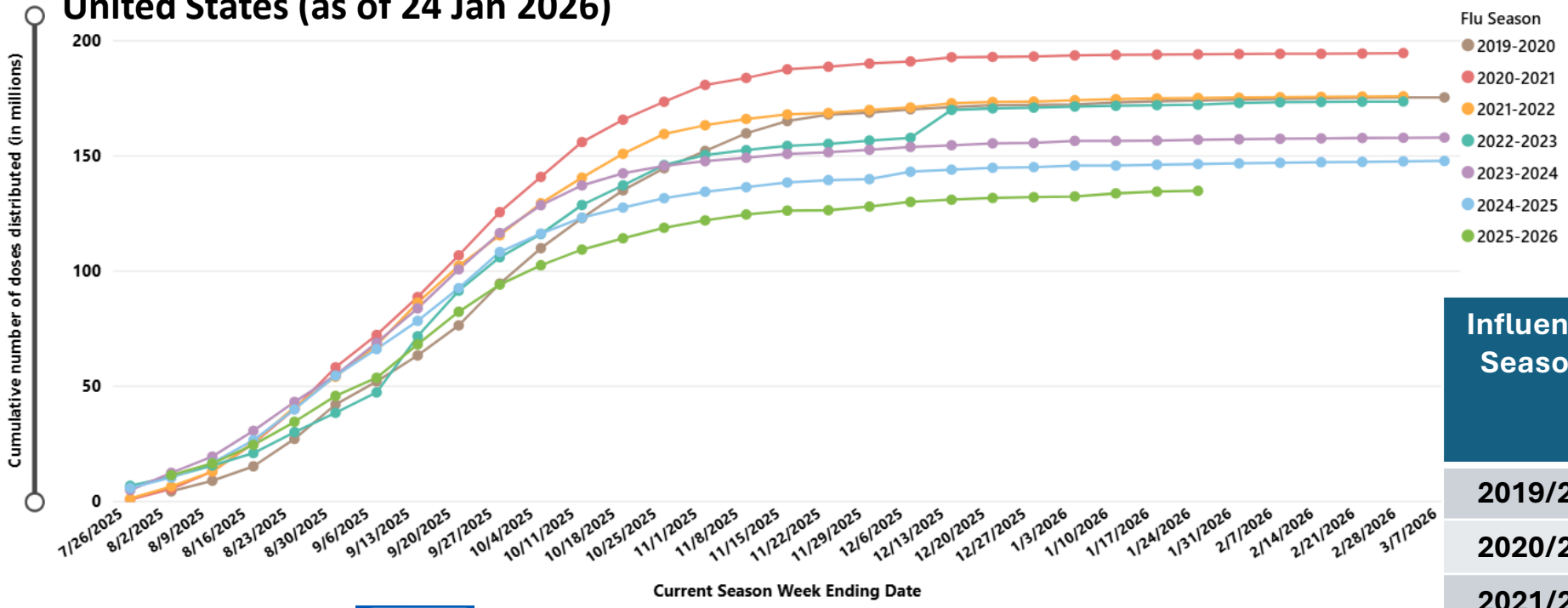
Vaccine Uptake in US Decreasing despite ongoing Disease Burden from Influenza

- The disease burden from seasonal influenza persists, however, since the COVID-19 pandemic, US influenza vaccine uptake and vaccine coverage rates have declined year on year amid vaccine supply surplus.
- The number of vaccines distributed each season has decreased by 23% since the 2019/20 (last pre-covid) season



Reduction in Influenza Vaccine Doses Distributed Year on Year since 2021/22 Season – Approx. 40 million doses

Weekly Cumulative Doses (in Millions) of Influenza Vaccines Distributed by Season in the United States (as of 24 Jan 2026)



Data Source: CDC

Influenza Season	Vaccine doses distributed (millions)	Δ from previous season (millions doses)
2019/20	173.82	-
2020/21	193.86	+20.04
2021/22	174.93	- 18.93
2022/23	171.97	- 2.96
2023/24	156.76	- 15.21
2024/25	146.22	- 10.54
2025/26	134.59	- 11.63

CBD Access and Benefit Sharing (ABS) Obligations for use of “Genetic Resources”

Convention on Biological Diversity

CBD Nagoya Protocol (Physical samples)

- Industry, via the international industry association, IFPMA, must check for any Nagoya obligations for use of seasonal candidate vaccine viruses (CVVs)
- Supply of influenza viruses continues to be impacted - over 40 seasonal viruses have been delayed since 2018
- SH 2026 recommendation for A/Switzerland virus - no delays as process for approval is clear,
- The information regarding the Nagoya status and laws in each country is not kept up to date and many delays are experienced due to lack of resources in some countries

CBD Multilateral mechanism for sharing benefits of the use of DSI (MLM-DSI)

- Companies are expected to contribute either to MLM-DSI or comply with national access and benefit-sharing (ABS) laws.
- Contribution rates depend on company size and business sectors that heavily use DSI, with a suggested rate of 0.1% of total revenue or 1% of total profits, regardless of whether DSI was used for every product

US companies are also impacted

Industry Observations

Rapid and unhindered supply of influenza viruses and their sequence information, both seasonal and pandemic, is critical if vaccines are to be prepared in time

The global access and benefit sharing (ABS) landscape is extremely complex, with Nagoya Protocol, MLM-DSI, WHO Pandemic Agreement and the WHO PIP Framework impacting all manufacturers. This is causing delays in virus sharing

There is some acknowledgement of the need to prevent overlapping requirements between these international “instruments”, as well as with national laws, although it is unclear how this will be achieved in practice

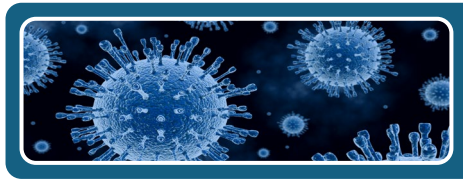
Industry is continuing to provide feedback and engage in discussions

Global Scientific Collaboration

- Viruses have the potential to spread rapidly across the world, making it essential to have a comprehensive overview of emerging viruses, including their origins and transmission patterns.
- International cooperation and the exchange of data and biological materials are vital for vaccine development and distribution, in the US and globally. For example, CDC's continued involvement in the global vaccine composition meetings fosters this collaboration, which is crucial for both seasonal and pandemic readiness.

Key Takeaways

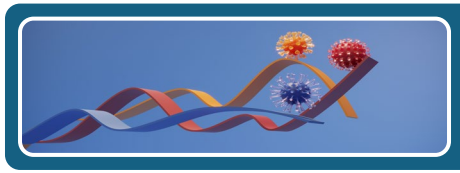
Industry aligned and worked closely with CBER to obtain necessary approvals for the successful transition from QIV to TIV in time for US NH 2024-2025 seasonal vaccine supply.



NH 2025/26 seasonal influenza vaccines contained updated A/H3N2 subtype from NH 2024-2025 – no changes from the SH 2025 vaccines. WHO recommendation for NH 2026/27 seasonal influenza vaccines to update A/H3N2 and B/Vic strains.

Since the COVID-19 pandemic, US influenza vaccine uptake and vaccine coverage rates have declined year on year

Concerns of the Nagoya Protocol, MLM-DSI & Pandemic Agreement, lack of legal clarity & risk of stacking obligations and the impact on seasonal and pandemic influenza vaccine manufacturing.



Global scientific collaboration and transparent sharing of samples and data is critical for public health decision-making.

Thank you for your attention