Indian Health Service
National Pharmacy and Therapeutics Committee

Pharmacovigilance Drug Safety Alert

September 1, 2022

JYNNEOS Vaccine Safety: Reporting Adverse Vaccine Events to the Vaccine Adverse Event Reporting System (VAERS)

With the ongoing mpox outbreak and current vaccination strategies involving JYNNEOS, please remember to submit Adverse Vaccine Events (AVEs) from *all* vaccines to the **Vaccine Adverse Event Reporting System (VAERS)** in accordance with the Indian Health Manual[1] and/or your local policies.

Vaccination providers who are administering JYNNEOS under the EUA are **required** to report the following adverse events that occur after JYNNEOS vaccination:

1. Vaccine administration errors whether or not associated with an adverse event
2. Serious adverse events (irrespective of attribution to vaccination)
3. Cases of cardiac events including myocarditis and pericarditis
4. Cases of thromboembolic events and neurovascular events

Instructions for documenting and reporting AVEs and Adverse Drug Events can be found on the IHS Pharmacovigilance website.

1. Visit https://www.ihs.gov/nptc/pharmacovigilance/
2. Click “Learn More” under Adverse Drug Events
3. Click “Learn More” under Reporting Adverse Vaccine Events

Please remember to enter “IHS” in field #26 of the VAERS report (this field is also called the immunization project report number).

References:
1. Indian Health Service (n.d.). Indian Health Manual, Chapter 7, Reporting Adverse Drug Events and Medication Errors
2. Food and Drug Administration (n.d.). Report an Adverse Event to VAERS.
3. Centers for Disease Control and Prevention, JYNNEOS Vaccine, Updated August 31, 2022