World Health Organization

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Ref. RPQ/REG/ISF/Alert N°6.2020 29 October 2020

Medical Product Alert N°6/2020

Falsified Fluzone® Quadrivalent Influenza Vaccine identified in WHO region of the Americas

Alert Summary

This WHO Medical Product Alert relates to three different batches of confirmed falsified Fluzone® Quadrivalent Influenza Vaccine identified in Mexico and reported to WHO on 16 October 2020.

Fluzone® Quadrivalent is a quadrivalent inactivated vaccine for immunization against influenza A virus (H1N1 and H3N2) and B subtypes.

The products subject of this alert are confirmed falsified because they deliberately/fraudulently misrepresent their identity, composition or source:

- The genuine manufacturer of Fluzone® Quadrivalent - Sanofi Pasteur – has confirmed they did not produce or distribute the products subject of this WHO Medical Product Alert n°6/2020,
- AND the variable data (batch number and expiry dates) of these products do not correspond to their genuine manufacturing records.

Genuine Fluzone® Quadrivalent has not yet been legitimately distributed in Mexico by Sanofi Pasteur and is not expected on the market before November 2020.

This falsified product was identified at patient level.

On 21 September 2020, the WHO Strategic Advisory Group of Experts (SAGE) on immunization highlighted[1] that health workers and older adults are considered as the highest priority risk groups to receive influenza vaccines during the COVID-19 pandemic. It is therefore crucial to identify, as early as possible, any falsified influenza vaccines in circulation.

Table 1: Products subject of WHO Medical product Alert n°6/2020

Product name	**Fluzone Quadrivalent Influenza Virus Vaccine**		
Stated Manufacturer	Sanofi Pasteur		
Batch number	EUH2174AC	EUH071AB	E0H071AB
Expiry date	ENE 22	ENE 22	ENE 22

For photographs of the above products, please see below.

Advice to regulatory authorities and the public

WHO requests increased vigilance within the supply chains in countries and regions likely to be affected by these falsified products. Increased vigilance should include hospitals, clinics, health centers, wholesalers, distributors, pharmacies and any other suppliers of medical products.

[1] Please see https://www.who.int/immunization/policy/sage/en/

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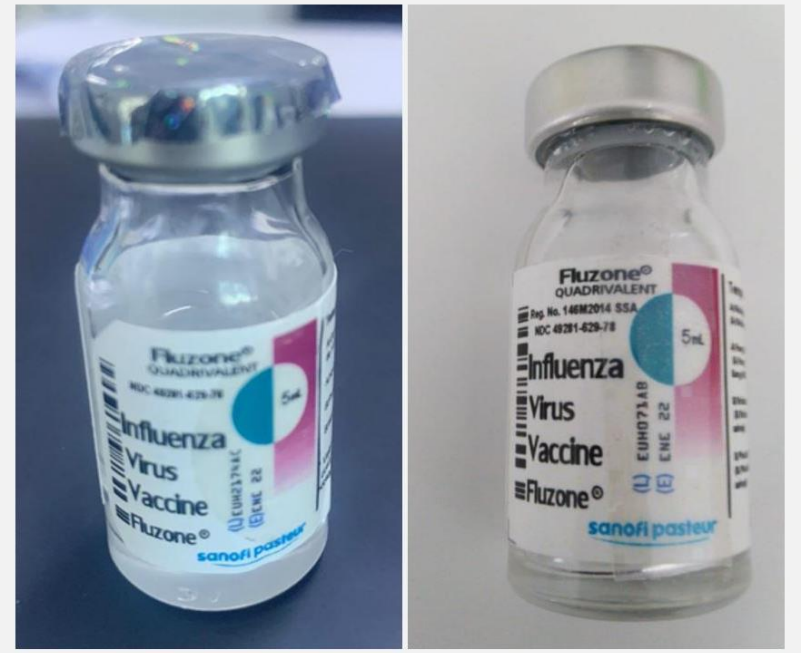
All medical products must be obtained from authorized/licensed and reliable suppliers. The products' authenticity and physical condition should be carefully checked. Seek advice from a healthcare professional in case of doubt.

If you are in possession of the above falsified products, please do not use them.

If you have used these falsified products, or you suffered an adverse reaction/event having used these products, you are advised to seek immediate medical advice from a qualified healthcare professional, and to report the incident to the National Regulatory Authorities/National Pharmacovigilance Centre.

National regulatory/health authorities are advised to immediately notify WHO if these falsified products are identified in their country. If you have any information concerning the manufacture, distribution, or supply of these products, please contact rapidalert@who.int

Table 2: Photographs of products subject of WHO Medical product Alert n°6/2020

Photographs of Falsified Fluzone® Quadrivalent (Influenza Vaccine) identified in Mexico	
Name as stated on falsified product	Fluzone Quadrivalent Influenza Virus Vaccine
	

WHO Global Surveillance and Monitoring System
for Substandard and Falsified Medical Products
For more information, please visit: https://www.who.int/health-topics/substandard-and-falsified-medical-products
Email: rapidalert@who.int