



F.No.13-56/2020-QC
Government of Pakistan
Drug Regulatory Authority of Pakistan
Ministry of National Health Services,
Regulations & Coordination
Islamabad

MOST IMMEDIATE
THROUGH COURRIER

Islamabad, the 11th November, 2020.

[Medical Product Alert]

Subject: **WHO MEDICAL PRODUCT ALERT N° 6/2020-FALSIFIED FLUZONE® QUADRIVALENT INFLUENZA VACCINE.**

I am directed to refer to WHO's Medical Product Alert N°6/2020 dated 29th October, 2020 which relates to three different batches of confirmed falsified Fluzone® Quadrivalent Influenza Vaccine identified in Mexico and reported to WHO on 16th October, 2020. The summary of said Medical Product Alert is as under;

"This WHO medical Product Alert relates to three different batches of confirmed falsified Fluzone® Quadrivalent Influenza Vaccine (See Table 1 Below) identified in Mexico and reported to WHO on 16th October, 2020.

Table 1: Products subject of WHO Medical Product Alert N°6/2020

Product Name	Fluzone® Quadrivalent Influenza Virus Vaccine		
Sated Manufacturer	Sanofi Pasteur		
Batch Number	EUH2174AC	EUH071AB	E0H071AB
Expiry Date	ENE 22	ENE 22	ENE 22

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

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

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- *The genuine manufacturer of Fluzone® Quadrivalent-Sanofi Pasteur has confirmed that 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

WHO requests increased vigilance within the supply chains of countries 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.”

02. If anyone is in possession of the above stated products, please do not use. If anyone has used these falsified products, or if anyone suffer an adverse reaction/event having used these products, it is advised to seek immediate medical advice from a qualified healthcare professional, and to report the incident to Drug Regulatory Authority of Pakistan/ National Pharmacovigilance Centre.

03. All medical products must be obtained from licensed, authentic and reliable sources. Their authenticity and condition should be carefully checked. Seek advice from a healthcare professional in case of doubt.


11.11.2020
(MUHAMMAD ASHFAQ)
Assistant Director QC-I

Copy for information and necessary action – with request to issue necessary directions to points of use/sale (Hospitals Pharmacies, Medical stores, Distributors, Whole sellers, etc) under administrative control/ fall under area of jurisdiction, please.


1. The Secretary (SHC&ME) Health Department (Government of Punjab).
2. The Secretary Primary and Secondary Health Department (Government of Punjab).
3. The Secretary Health Department (Government of Sindh).
4. The Secretary (SHC&ME) Health Department (Government of KPK).
5. The Secretary (SHC&ME) Health Department (Government of Baluchistan).

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6. The Secretary (SHC&ME) Health Department (Government of AJ&K).
7. The Director General Health, M/o NHR&C, Islamabad.
8. The Director General Health, Government of Punjab.
9. The Director General Health, Government of Sindh.
10. The Director General Health, Government of KPK.
11. The Director General Health, Government of Baluchistan.
12. The Director General Health, Government of AJ&K.
13. The Additional Director DRAP, Lahore.
14. The Additional Director DRAP, Karachi.
15. The Additional Director DRAP, Islamabad.
16. The Additional Director DRAP, Peshawar.
17. The Additional Director DRAP, Quetta.
18. The Chief Drug Inspector Baluchistan.
19. The Chief Drug Controller Punjab.
20. The Chief Drug Inspector Sindh.
21. The Chief Drug Inspector KPK.
22. The Chief Drug Inspector G.B.
23. The Chief Drug Inspector AJ&K.
24. Senior Drug Inspector, ICT, Islamabad.

Copy to: -

- i. The Director, QA<, DRAP, Islamabad.
- ✓ii. The Additional Director MIS **with request to upload it on official website in the larger interest of public.**
- iii. PS to CEO, DRAP, Islamabad.
- iv. Office copy.


11.11.2020
Assistant Director (QC-I)

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