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پیوست: دارد

سرمایه گذاری برای تولید

معاونین محترم غذا و دارو دانشگاه/دانشکده های علوم پزشکی، خدمات بهداشتی و درمانی سراسر کشور

موضوع: هشدار سازمان جهانی بهداشت در خصوص شناسایی فرآورده تقلبی دوروالومب با نام برند Imfinzi

با سلام و احترام؛

به پیوست متن ایمیل دریافتی از گروه حوادث و محصولات پزشکی غیر استاندارد/تقلبی (ISF)، واحد مقررات و ایمنی سازمان جهانی بهداشت در خصوص هشدار دارویی شماره N°5/2024 پیرامون داروی **IMFINZI (Durvalumab) تزریقی 500mg /10ml** تقلبی شناسایی شده در ارمنستان، لبنان و ترکیه، جهت استحضار و اقدام مقتضی ایفاد می گردد.

هشدار فوق مربوط به شماره سری ساخت BAVX بوده است. همچنین شماره سری ساخت BAZR موجود در بازار دارویی هند دارای مندرجات به زبان هندی و شماره سری ساخت BBEG موجود در بازار دارویی مصر دارای مندرجات به زبان عربی، با مشاهده مغایرت های ظاهری با داروی اصلی مشخص می باشند. اطلاعات تکمیلی از طریق لینک زیر در دسترس می باشد.

<https://www.who.int/news/item/23-12-2024-medical-product-alert-n-5-2024>

با عنایت به احتمال وجود فرآورده های تقلبی مذکور در بازار دارویی کشور، مراتب جهت استحضار و دستور اقدام لازم خدمتتان ارسال می شود.

دکتر ناز یلایوسفی

سرپرست دفتر نظارت و پایش مصرف فرآورده های سلامت

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Medical Product Alert N°5/2024

Falsified IMFINZI (durvalumab) injection 500mg /10ml identified in the WHO Eastern Mediterranean and European Regions

Alert Summary

This WHO Medical Product Alert refers to one batch of falsified IMFINZI (durvalumab) injection 500mg/10ml. The falsified products have been detected in the unregulated supply chain in Armenia, Lebanon and Türkiye, and were reported to WHO in November 2024.

IMFINZI is a sterile concentrate for infusion. It contains the active pharmaceutical ingredient durvalumab which is a monoclonal antibody. As monotherapy, it is indicated for the treatment of Non-Small Cell Lung Cancer (NSCLC) in adults.

Information provided to WHO by AstraZeneca, the genuine manufacturer of IMFINZI, has confirmed that the products identified in this Alert are falsified. Laboratory analysis of samples of the falsified IMFINZI have been carried out by AstraZeneca. The analysis confirmed that the vials of the falsified product contained no active pharmaceutical ingredient.

How to identify this falsified product

These products are falsified because they deliberately misrepresent their identity, composition, and source.

To identify these falsified products, check for the following:

- Genuine IMFINZI lot BAVX, is associated with the manufacturing date of 10-2021 and an expiry date of 09-2024.
- A combination of any other dates or lot number should be considered suspicious.
- The 2D data matrix is displayed in the middle instead of the upper-right of the box.
- The face where the 2D data matrix, lot number, manufacturing and expiry dates are displayed should be in black and white, not totally black.
- The rectangle, displaying the strength of the medicine, should be in a paler green colour rather than dark green.
- The metal crimp of the closure around the neck of the vial should not be creased.

Risks

These falsified products should be considered unsafe, and their use may be life threatening in some circumstances. The use of these falsified IMFINZI products may lead to ineffective or delayed treatment. It is important to detect and remove any falsified IMFINZI (durvalumab) injections from circulation so as to prevent harm to patients.

Advice to healthcare professionals, regulatory authorities and the public

Healthcare professionals should report any incident of adverse effects, lack of expected effects or suspected falsification to the National Regulatory Authorities/National Pharmacovigilance Centre.

WHO advises increased surveillance and diligence within the supply chains of countries and regions likely to be affected by these falsified products. Increased surveillance of the informal/unregulated market is also advised. National regulatory authorities/health authorities/law enforcement are advised to immediately notify WHO if the falsified product is detected in their country. If you are in possession of any of these products, WHO recommends that you do not use them. If

you, or someone you know, has, or may have used these products, or suffered an adverse event or unexpected side-effect after use, seek immediate medical advice from a healthcare professional or contact a poisons control centre.

All medical products must be obtained from authorized/licensed suppliers. If you have any information about the manufacture or supply of these falsified products, please contact WHO via rapidalert@who.int.

Annex: Products subject of WHO Medical Product Alert N°5 /2024

Product Name	IMFINZI (durvalumab) injection 500mg/10ml		
Stated manufacturer	AstraZeneca		
Identified in	Armenia	Lebanon	Türkiye
Lot	BAVX	BAVX	BAVX
Manufacturing date	10-2023	10-2021	10-2021
Expiry date	09-2026	09-2024	09-2024
Available photos	    		

WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products
Please visit: <https://www.who.int/health-topics/substandard-and-falsified-medical-products>, or e-mail: rapidalert@who.int

