Ministero della Salute

DIREZIONE GENERALE DELLA PREVENZIONE SANITARIA
Ufficio 05 – Prevenzione delle malattie trasmissibili e profilassi internazionale
Ufficio 03 – Coordinamento USMAF SASN

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LORO SEDI

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OGGETTO: HARVONI falsificato

L'Organizzazione Mondiale della Sanità (OMS) ha informato della vendita di un lotto contraffatto del farmaco "Harvoni" (Ledipasvir/sofosbuvir), indicato per il trattamento dell'epatite C.

Il lotto contraffatto è stato identificato a maggio 2020 in Brasile e a novembre 2020 in Turchia. L'OMS ha ricevuto informazioni recenti che riferiscono che le confezioni del lotto in questione siano ancora in circolazione, verosimilmente già fornite ai pazienti.

L'azienda produttrice, Gilead, ha confermato di non aver prodotto il farmaco oggetto dell'allerta e che il numero del lotto e la data di scadenza non corrispondono ai lotti prodotti e registrati.

In allegato 1 si riportano le specifiche del prodotto, e in allegato 2 la fotografia del prodotto contraffatto.

Si prega di voler dare la massima diffusione alla presente nota circolare ai servizi ed ai soggetti interessati e di rafforzare la vigilanza.

IL DIRETTORE GENERALE
Dott. Giovanni Rezza

Il Direttore dell'Ufficio 5
Dott. Francesco Maraglino

Il Direttore *ff* dell'Ufficio 3
Dott. Ulrico Angeloni

Referenti/Responsabili del procedimento:
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Ref. RPQ/REG/ISF/Alert N°7.2020 8 December 2020

Medical Product Alert N°7/2020

Falsified HARVONI (Ledipasvir/sofosbuvir) identified in the WHO regions of the Americas and Europe

Alert Summary

This WHO Medical Product Alert relates to one batch of confirmed falsified HARVONI (Ledipasvir/sofosbuvir) identified in Brazil and Turkey.

Falsified Harvoni was identified in Brazil in May 2020 and in Turkey in November 2020. WHO has received recent information that suggests these products are still in circulation. Available information indicates that these falsified medicines were supplied at patient level.

The WHO Global Surveillance and Monitoring System database has prior records of other falsified Harvoni batches. Consistent reporting is essential to determine the scope and scale of such falsified products.

HARVONI is an antiviral medicine indicated for the treatment of chronic Hepatitis C. Please refer to the WHO Fact Sheet here for further information on Hepatitis C.

The falsified products identified in this Alert are confirmed falsified on the basis that they deliberately/ fraudulently misrepresent their identity, composition or source:

- The genuine manufacturer of HARVONI – Gilead Sciences – has confirmed it did not produce the product referenced in this WHO Medical Product Alert n°7/2020;
- AND the variable data (batch number and expiry dates) of these products do not correspond to genuine manufacturing records.

Table 1: Products referenced in WHO Medical Product Alert n°7/2020

Product name	**HARVONI 90 mg/400 mg**
Stated Manufacturer	Gilead Sciences
Batch number	22VMYVA12
Expiry date	12 2022
Packaging language	German
Identified in	Brazil, Turkey

For photographs of the above product, please refer to Table 2 on page 2 of this Alert.

Advice to regulatory authorities and the public

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

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.

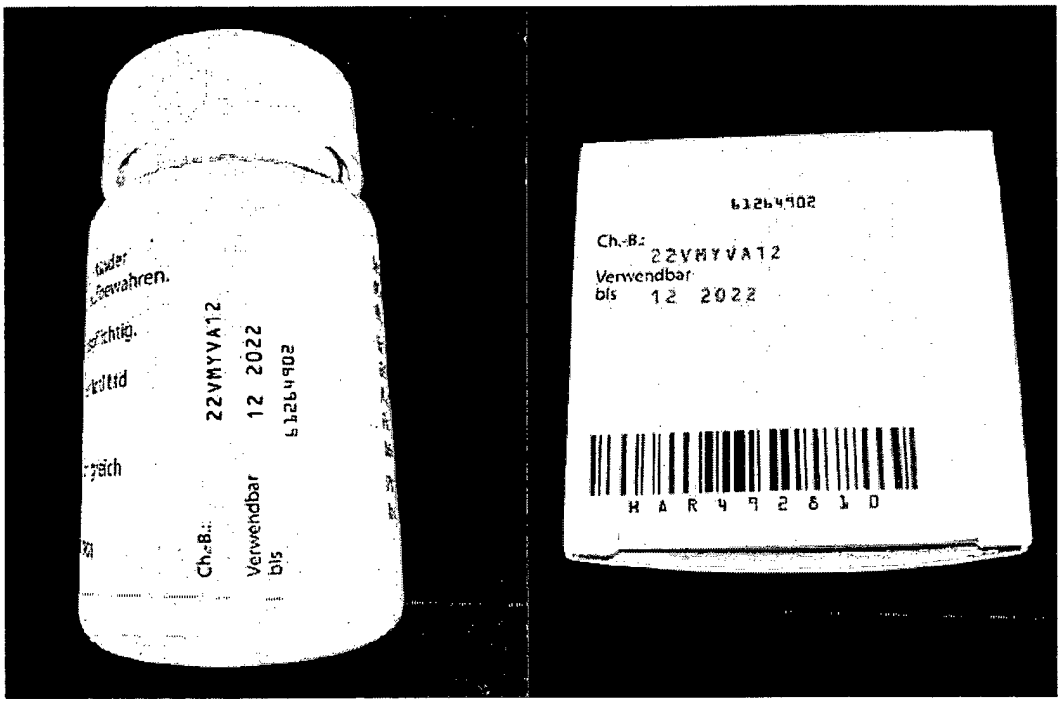
If you have used these falsified products, or you suffered an adverse reaction/event having used these products, you are advised to seek immediate medical advice from a qualified healthcare professional, and to report the incident to the National Regulatory Authorities/National Pharmacovigilance Centre.

National regulatory/health authorities are advised to immediately notify WHO if these falsified products are discovered 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°7/2020

Photographs of falsified HARVONI 90 mg/400 mg, identified in Turkey *(photo shows Lot* 22VMYVA12*)*

Images supplied by Gilead



WHO Global Surveillance and Monitoring System
for Substandard and Falsified Medical Products
For more information, please visit: www.who.int/medicines/regulation/ssffc/en/ Email: rapidalert@who.int