World Health Organization

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Medical Product Alert N°9/2021

Falsified Soliris identified in WHO regions of the Americas, Europe and South East Asia

Alert Summary

This WHO Medical Product Alert refers to several batches of falsified Soliris (eculizumab) identified in Argentina, Estonia, India and Uruguay and reported to WHO between November and December 2021. The genuine manufacturer of Soliris, has confirmed that the products listed in this alert are falsified. The falsified products were reported at patient level and regulated supply chains in the above-mentioned countries.

Genuine Soliris is indicated for the treatment of paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS), generalized Myasthenia Gravis (gMG) in adults, and neuromyelitis optica spectrum disorder (NMOSD).

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

Table 1: Products subject of WHO Medical Product Alert N°9/2021

Product Name	SOLIRIS 300mg			
Stated manufacturer	ALEXION			
Lot	1012401	1013715	1001600	1001701
Expiry date	SEP 22	FEB 22	03/2023	03/2023
Packaging language	Spanish	Spanish	English	Turkish
Identified in	Argentina, Uruguay	Uruguay	Estonia	India
Photographs	WHO currently does not have photographs to share			

Advice to regulatory authorities and the public

WHO requests increased attention within the supply chains of countries and regions likely to be affected by these falsified products. Increased surveillance 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 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 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** **WHO Global Surveillance and Monitoring System for**