World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Ref. RPQ/REG/ISF/Alert N°4/2022 19 August 2022

Medical Product Alert N°4/2022

Falsified DYSPORT (Clostridium botulinum type A toxin-haemagglutinin complex) identified in the WHO Regions of Europe and Eastern Mediterranean

Alert Summary

This WHO Medical Product Alert refers to five falsified batches of DYSPORT detected in five countries - Jordan (May 2022), Türkiye (May 2022), Kuwait (June 2022), United Kingdom (June 2022) and Poland (July 2022).

DYSPORT is indicated to treat symptoms of cervical dystonia, glabellar lines (wrinkles) and spasticity.

The genuine manufacturer of DYSPORT is IPSEN.

The genuine manufacturer has confirmed that all of the products referenced in this Alert are falsified on the basis that they deliberately/fraudulently misrepresent their identity and source.

The variable data (batch numbers and manufacturing-expiry dates) are falsified, there are discrepancies in the packaging languages, printing errors on the cartons and discrepancies of vial types.

Risks

The safety, sterility and quality of the products referenced in this alert are unknown.

DYSPORT is injected intramuscularly. These falsified products may pose a particular high risk to patients.

It is important to detect and remove these falsified products from circulation to prevent harm to patients.

Advice to regulatory authorities and the public

WHO requests increased surveillance and diligence within the supply chains of countries and regions likely to be affected by these falsified products.

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

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

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

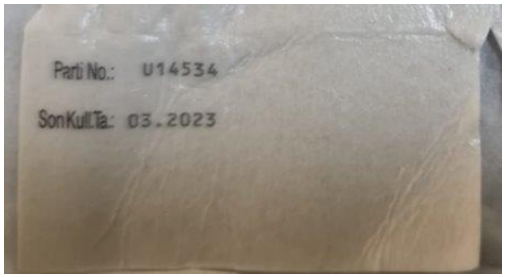
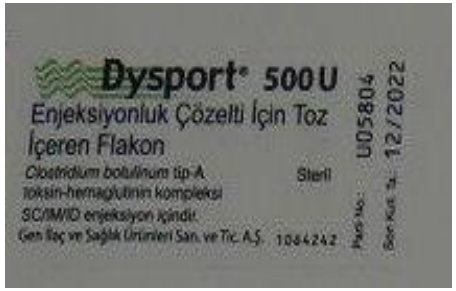
National regulatory/health authorities are advised to immediately notify WHO if these falsified products are discovered in their country.

If you have any information concerning the manufacture and/or distribution of these products, please inform WHO via rapidalert@who.int

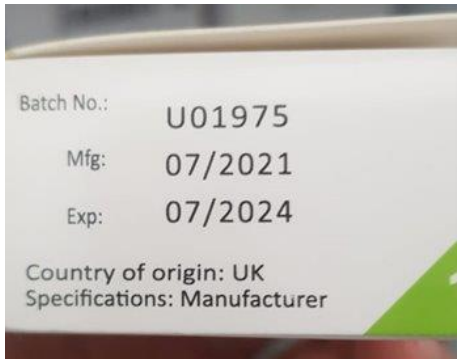
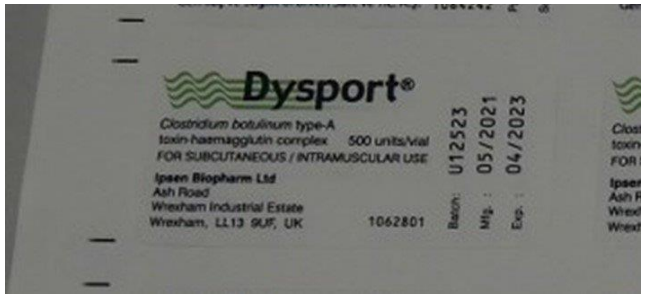
Please see pages 2-3 for details and photos of the five falsified products referenced in Alert N°4 of 2022.

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Ref. RPQ/REG/ISF/Alert N°4/2022

Product Name	Dysport 500U		
Stated manufacturer	IPSEN		
Batch	U14534	U14534	U05804
Exp. date	11/2023	03/2023	12/2022
Packaging language	English	Turkish	Turkish
Identified in	Jordan, Poland, United Kingdom	Türkiye, Kuwait	Jordan, Poland
Available photo		 	

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Product Name	Dysport 500U	
Stated manufacturer	IPSEN	
Batch	U01975	U12523
Exp. date	07/2024	04/2023
Packaging language	English	English
Identified in	Kuwait	Poland
Available photo		

WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products

For more information, please visit our website. Email: rapidalert@who.int