দৰ এ ভারিই দ্বারা প্রভিন্ধানন কল

গণপ্রজাতন্ত্রী বাংলাদেশ সরকার

द्धेयथ প্रশाসন অधिদপ্তর **खेष४ छत्न, মহाখानी, ঢाका-১২১২**।

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নং-ডিজিডিএ/এলার্ট-নোটিশ/এমসি-১৬/২০১৯/১ ৪৭ 😈 🕝

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বরাবর

- 1. Director General, Directorate General of Health Services (Attention: Director, Hospital & Clinical Service)
- 2. Director, CMSD, Tejgaon, Dhaka
- 3. Director, National Institute of Neuroscience Hospital, Dhaka
- 4. Secretary General, Bangladesh Association of Pharmaceutical Industry (BAPI).
- 5. President, Bangladesh Importers Association.
- 6. President, Bangladesh Chemist & Drugist Somity (BCDS)

বিশ্ব স্বাস্থ্য সংস্থা (WHO) সম্প্রতি মেডিক্যাল প্রোডাক্ট এলার্ট Nº4/2022- এ এই মর্মে সতর্ক করেছে যে, IPSEN কর্তৃক উৎপাদিত DYSPORT এর পাঁচটি নকল ব্যাচ জর্ডান, তুরঙ্ক,কুয়েত, ইউ কে এবং পোল্যান্ডর বাজারে পাওয়া যাচ্ছে। DYSPORT এর আসল উৎপাদনকারী প্রতিষ্ঠান IPSEN জ্ঞানিয়েছে যে, উল্লিখিত DYSPORT এর Vial এ লেবেলে প্রদর্শিত ব্যাচ নং , মেয়াদ উত্তীর্নের তারিখ আলাদা। লেবেলে প্রদর্শিত প্যাকিং এর লেখায় বিভিন্ন ধরনের বৈসাদৃশ্য ও মুদ্রণে বিভিন্ন ধরনের ভুল রয়েছে।

মেডিক্যাল প্রোডাক্টের বর্ণনা :

	1	Dysport 500U			
Product Name	iPSEN .				
Stated manufacturer		014534	U05804		
Batch	U14534	03/2023	12/2022		
Exp. date	11/2023	Turkish	Turkish		
Packaging language	English	TGRøye.	Jordan.		
identified in	Jordan, Poland, United Kingdom	Kuwait	Poland		
Available photo	4734:03582184008207 24:87877CXR840387 25.9 11/2023 107 914554	Appel to 197357 See State of 197357 See State of 197357 See State of 197357	Englishment County for Tax 2 Co. County making the Co. County of the Co.		

	Dyso	ort 500U
Product Name	15	PSEN
Stated manufacturer	U01975	U12523
Batch	07/2024	04/2023
Exp. date		English
Packaging language	English	Poland
Identified in	Kuwat	
Available photo	the 07/2021 the 07/2024 Country of origin: UK Specifications: Manufacturer	Dysport 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1

এমতাবছায়, উপরোল্লিখিত DYSPORT vial টি ব্যবহার থেকে বিরত থাকার জন্য এবং এতদ্বসংক্রান্ত বিষয়ে সতর্ক থাকার জন্য অনুরোধ

সংযুক্তি ঃ ০৩(তিন) পাতা।

মোঃ আসরাফ হোসেন পরিচালক (চঃদাঃ)

ঔষধ প্রশাসন অধিদগুর ঢাকা। ফোনঃ ০২২২২২-৮০৮০৩

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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.

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Dysport 500U IPSEN U14534 03/2023 Turkish Türkiye,	Forth. U14534 Forth. U14534 Soft Kull. To.: 0312033
U14534 11/2023 English Jordan, Poland, United Kingdom	GTIN: 03582186006207 SN: DYN7PCXH84UNBF EXP 11/2023 LOT U14534
Product Name Stated manufacturer Batch Exp. date Packaging language	Available photo

Organisation mondiale de la Santé • Всемирная организация здравоохранения • Organización Mundial de la Salud これの でっしょう かいかい・世界工生组织

Organisation mondiale de la sante • பண்டிப்பட

U01975	07/2021	07/2024	Country of origin: UK Specifications: Manufacturer	
Batch No.	Mfg.	Exp:	Country of Specification	

04/5053

U12523 04/2023 English Poland

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Dysport 500U

IPSEN

English

Packaging language

Exp. date

Batch

Identified in

Kuwait

U01975 07/2024

Stated manufacturer

Product Name

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