গণপ্রজাতন্ত্রী বাংলাদেশ সরকার ঔষধ প্রশাসন অধিদপ্তর ঔষধ ভবন , মহাখালী , ঢাকা www.dgda.gov.bd

ু চিঞ্জিডিএ/ এলার্ট-নোটিশ/এমসি-১৬/২০১৯ / ১১ ১ ৫ 6

তারিখঃ.. 2... १... ।২০২৩ খ্রীঃ

Director General, Directorate General of Health Services (Attention: Director, Hospital and Clinical Service) 1.

Director, CMSD, Tejgaon, Dhaka

- 3. Director, National Institution of Neuroscience Hospital, Dhaka
- 4. Secretary General, Bangladesh Association of Pharmaceutical Industry (BAPI)
- 5. President, Bangladesh Importers Association
- 6. President, Bangladesh Chemist and Druggist Somity (BCDS)

বিশ্ব স্বাস্থ্য সংস্থা (WHO) সম্প্রতি মেডিক্যাল প্রোডাক্ট এলার্ট 4/2023 এ এই মর্মে সতর্ক করেছে যে, QP PHARMACHEM LTD (Punjab, India) কর্তৃক উৎপাদিত এবং TRILLIUM PHARMA (Haryana, India) কর্তৃক বাজারজাতকৃত GUAIFENESIN SYRUP TG SYRUP এর একটি নকল ব্যাচ মার্শাল আইল্যান্ড ও মাইক্রোনেশিয়ার বাজারে পাওয়া যাচ্ছে। GUAIFENESIN SYRUP TG SYRUP টি Therapeutic Goods Administration (TGA) এর কোয়ালিটি কন্ট্রোল ল্যাবরেটরীতে পরীক্ষা হলে দেখা যায় এতে Di-Ethylene Glycol ও Ethylene Glycol অগ্রহণযোগ্য মাত্রায় কন্টামিনেন্ট বা ভেজাল হিসেবে পাওয়া গিয়েছে। Di-Ethylene Glycol ও Ethylene Glycol মানব শরীরের জন্য ক্ষতিকর ও অনেক ক্ষেত্রে প্রাণঘাতি।

Falsified মেডিক্যাল প্রোডাক্টের বর্ণনাঃ

Product name	GUAIFENESIN SYRUP TG SYRUP	
Stated manufacturer	QP PHARMACHEM LTD, (Punjab, India)	
Stated marketer	TRILLIUM PHARMA (Haryana, India)	
Batch	SL-429	
Expiry date	10/2023	
Identified in	Marshall Islands, Micronesia (Federated States of)	
Available photos	Companier Cash bill Cortinae Gardinen Sin Syrup TESYRUP TESYRUP TO SYRUP TO SYR	

এমতাবস্থায় উল্লেখিত GUAIFENESIN SYRUP TG SYRUP টি ব্যবহার থেকে বিরত থাকার জন্য এবং এতদসংক্রান্ত বিষয়ে সতর্ক থাকার জন্য

অনুরোধ করা হল।

মোঃ আসরাফ হোসেন

পরিচালক

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হেড অব মার্কেট সার্ভিল্যান্স এন্ড কন্ট্রোল ঔষধ প্রশাসন অধিদপ্তর, ঢাকা। ফোনঃ ০২২২২-৮০৮০৩

💪 মোবাইলঃ ০১৮১৯-১৪০৪২১ Email: dgda.gov@gmail.com

১. সংযুক্তিঃ ০২ (দুই) পাতা



World Health Organization

MA ment

25 April 2023

Medical Product Alert No. 4/2023 Substandard (contaminated) syrup medicines identified in WHO Region of the Western Pacific

This WHO Medical Product Alert refers to a batch of substandard (contaminated) GUAIFENESIN SYRUP TG SYRUP identified in the Marshall Islands and Micronesia (Federated States of) and reported to WHO on 6 April 2023.

Guaifenesin is an expectorant used to relieve chest congestion and the symptoms of cough.

Samples of the GUAIFENESIN SYRUP TG SYRUP from the Marshall Islands were analysed by quality control laboratories of the Therapeutic Goods Administration (TGA) of Australia. The analysis found that the product contained unacceptable amounts of diethylene glycol and ethylene glycol as contaminants.

The stated manufacturer of the affected product is QP PHARMACHEM LTD (Punjab, India). The stated marketer of the product is TRILLIUM PHARMA (Haryana, India). To date, neither the stated manufacturer nor the marketer have provided guarantees to WHO on the safety and quality of these products.

The product referenced in this Alert may have marketing authorizations in other countries in the Western Pacific region. It may have also been distributed, through informal markets, to other countries or regions.

Please refer to the Annex of this Alert for full details of the affected products.

WHO has previously published three Alerts on other contaminated liquid dosage medicines. Please see Medical Product Alert N°6/2022, Medical Product Alert N°7/2022 and Medical Product Alert N°1/2023.

Diethylene glycol and ethylene glycol are toxic to humans when consumed and can prove fatal.

The substandard product referenced in this Alert is unsafe and its use, especially in children, may result in serious injury or death. Toxic effects can include abdominal pain, vomiting, diarrhoea, inability to pass urine, headache, altered mental state and acute kidney injury which may lead to death.

If you have the affected product, WHO recommends that you do not use it. If you, or someone you know, has, or may have Advice to regulatory authorities and the public used the affected product, or suffered an adverse reaction or unexpected side-effect after use, you are advised to seek immediate medical advice from a healthcare professional.

WHO requests increased surveillance and diligence within the supply chains of countries and regions likely to be affected by these products. Increased surveillance of the informal/unregulated market is also advised. National regulatory authorities/health authorities are advised to immediately notify WHO if these substandard products are discovered in their respective country.

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

Ref. RPQ/REG/ISF/Alert N°4/2023 |

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cturers of liquid dosage forms, especially syrups that contain excipients including propylene glycol, polyethylene sorbitol, and/or glycerin/glycerol, are urged to test for the presence of contaminants such as ethylene glycol and lane glycol before use in medicines. ene glycol before use in medicines.

incare professionals should report any suspicious cases of adverse events linked to the use of these contaminated redicines to the National Regulatory Authorities/National Pharmacovigilance Centre.

If you have any information about the manufacture or supply of these products, please contact WHO via rapidalert@who.int.

	of WHO Medical Product Alert No. 4/2	023	
Product name	GUAIFENESIN SYRUP TG SYRUP		
Stated manufacturer	QP PHARMACHEM LTD, (Punjab, India)		
Stated marketer	TRILLIUM PHARMA (Haryana, India)		
Batch	SL-429		
Expiry date	10/2023		
Identified in	Marshall Islands, Micronesia (Federated States of)		
Available photos	Guaifenesin Syrup TGSTRUP	Composition: Each Sml Contains: Guarlenesin USP 180mg Excipients q.s. Approved colour used in a flavoured syrupy base Dosage: As directed by the Physician Storage: Store in a cool, dry & dark place away from direct sunlight & moisture and at a temperature below 30°C. Keep the medicine out of reach of children. SNAKE WELL BEFORE USE Causion: it is dangerous to take this preparation except under Medical Supervision Read enclosed pack insert carefully before using this medication. For earl administration only. Mich incha byto pharmachem hd PS, Focal Point, Deta Sess, SAS Nager (Pulyab). 18500 about [GME Carried Company) Neutral Code PB/Drugs*1e19-OSP PB/Drugs*1633-B EC 2217500601 Batch No. SL-429 Mig.Dase. 11/2020 Exp.Date: 10/2023 For Export Only TRILLUM M Michael by TRILENACE TICALS Pis No. 151, bahasani Ass., Page 11. Packlots Pis. 1-MILS Haryan, Lafe.	

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