Safety Alert

The World Health Organization (WHO) has released medicine safety alert with Medical Product Alert No. 6/2023 on 7 August 2023 regarding substandard (contaminated) syrup medicines identified in WHO Region of the Eastern Mediterranean (Annex I). The Alert refers to one batch of substandard (contaminated) COLD OUT syrup (Paracetamol and Chlorpheniramine Maleate) identified in the Republic of Iraq and reported to the World Health Organization (WHO) on 10 July 2023 by a third party.

According to WHO, a sample of the COLD OUT Syrup (stated manufacturer, FOURRTS (INDIA) LABORATORIES PVT. LTD, stated marketer,DABILIFE PHARMA PVT. LTD. - INDIA, Batch No, SF001A02, Expiry date Dec2024) obtained from one location in Iraq and submitted for laboratory analysis was found to contain unacceptable amounts of diethylene glycol (0.25%) and ethylene glycol (2.1%) as contaminants. The acceptable safety limit for both ethylene glycol and diethylene glycol are not more than 0.10%. The stated manufacturer of the affected batch of the product is FOURRTS (INDIA) LABORATORIES PVT. LTD, and the product is stated to be manufactured for DABILIFE PHARMA PVT. LTD. - INDIA.

Based on the WHO's Alert, the Pharmacovigilance and Clinical Trial Lead Executive Office of the Ethiopian Food and Drug Authority (EFDA) conducted a systematic analysis of available information, consulted Medicine Registration and Market Authorization Lead Executive Office, and Medicine Manufacturers Inspection and Enforcement Lead Executive Office of the EFDA to get official information on the registration status and availability of the product on Ethiopian market. Medicine Registration and Market Authorization Lead Executive Office through a letter numbered መ/ተ/ኢ/ዳ/ /2016 (Annex II) informed that the product is not registered in Ethiopia.

Similarly, Southeast Addis Ababa Branch office through a letter numbered ማ/ኢ/ቅ/ጽ/ቤት/06/2016 ዓ.ም (Annex III) updated us that the product didn't get into Ethiopia through Southeast Addis Ababa port office.

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ETHIOPIAN FOOD & DRUG AUTHORITY

Even if the product is not officially registered in Ethiopia, as the product may get into market through different routes, the Pharmacovigilance and Clinical Trial Lead Executive Office of the EFDA recommends the following:

What should patients/clients/consumers do?

Patients/clients/consumers should carefully read the label of any syrup preparation and report to their pharmacist/health care professional if they find COLD OUT syrup (Paracetamol and Chlorpheniramine Maleate) manufactured by FOURRTS (INDIA) LABORATORIES PVT. LTD on the market. They can also report to EFDA through 8482 a free toll number.

What should health care professionals do?

Health care professionals should advise their patients/clients about the risks and benefits of medicines in the context of other available treatments in general. They should advise patients/clients to report if they get COLD OUT syrup (Paracetamol and Chlorpheniramine Maleate) manufactured FOURRTS (INDIA) LABORATORIES PVT. LTD on the market because of the possible increased risk of death and higher risk of serious adverse events.

What should the public do?

The public should be aware of substandard and/or counterfeit products and should get their medicine only from pharmacies/drug shops.

Safety Alert

Proper use of medicine is essential to achieve the desired effect, but misuse can result in unintended harm. Prescription drugs, in particular, require close supervision by healthcare professionals.

Recently, trends on social media have emerged promoting inappropriate drug use, including the misuse of Prednisolone. Prednisolone is a medication intended to treat conditions such as inflammation, allergies, asthma, and other diseases. However, misleading information is being circulated claiming that it is effective for reducing hip and general obesity, which is entirely false.

The Ethiopian Food and Drug Authority (EFDA) is committed to safeguarding public health under the authority granted by Proclamation No. 1112/2019. The EFDA monitors and regulates the quality, safety, and efficacy of medicines and takes corrective action when defects are identified. Additionally, it issues public warnings about improper drug use to protect the community.

Misusing Prednisolone without a doctor's prescription and supervision can lead to serious health complications or even death. These risks are well-documented and scientifically proven. We strongly urge everyone to exercise caution and adhere to the proper use of this medication.

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ETHIOPIAN FOOD & DRUG AUTHORITY

Safety Alert

Ranitidine is an H2 receptors blocker antihistamine, first developed by Sir James Black in the early 1990s. Ranitidine is used for reducing stomach acid in patients with conditions such as heartburn and stomach ulcers. The recent global concern revealed that Ranitidine contains an impurity called N-nitrosodimethylamine (NDMA) which is classified as a probable human carcinogen, based on animal studies.

The source of NDMA is not clear, there is some evidence that NDMA may form from the degradation of ranitidine itself with increasing levels seen over its shelf life. Though there are some studies that suggest NDMA can be formed from ranitidine inside the body. there are others that state otherwise. With the desktop review many countries both from the developed and developing world took measures on the product that include: banning, suspension, recall, withdrawal and related measures due to the associated safety concern.

One of the mandates of the Ethiopian Food and Drug Authority (EFDA) is monitoring the safety of medicines, and EFDA organized system, process and structure for monitoring the safety of medicines. In this connection the responsible wing in EFDA conducted series of activities including desk top review, conducting test on the tablet and API. The lab result confirmed the level of NDMA impurity from all randomly selected test samples were above the limit (about 12 times above the limit). With the evidence from other regulatory authorities, our lab results and consultation with professionals in the field, it has become imperative to issue this safety alert.

Accordingly, EFDA's advise for health professionals consider:

·Prescribers not to prescribe Ranitidine and use other alternative H2 receptor blocker or other related class of medicines.

·Dispensers should refrain from dispensing prescribed Ranitidine and inform the prescriber about the alert and patients should contact their healthcare professionals for advice about which medicine to take.

·All health professionals advise their colleagues and patients not use Ranitidine.

Finally, the EFDA kindly request health institutions (Public and private) and all health professional to discharge their responsibilities in implementing this regulatory decision to protect the public from preventable Adverse Drug Event.

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ETHIOPIAN FOOD & DRUG AUTHORITY

Safety Alert

The Ethiopian Food and Drug Authority (EFDA) is responsible for ensuring the quality, safety, and efficacy of medicines before they are used, as well as conducting regular inspections of medicines available on the market.

During a recent market survey, the EFDA identified a product—Artemether 80 mg/ml injection (Batch No. 231104SPF, manufactured in November 2023 by Shinepharm, China)—that was not registered with the authority. Laboratory analysis of a sample taken from the market revealed that the product did not contain the active ingredient, Artemether.

In response, the EFDA has advised health professionals to avoid using this medicine. The authority has also instructed regional inspectors at all levels to take appropriate measures by implementing strict monitoring in their respective areas.

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ETHIOPIAN FOOD & DRUG AUTHORITY

Safety Alert

Novartis Pharma Schweiz AG, the market authorization holder/manufacturer, has notified the Ethiopian Food and Drug Authority (EFDA) that Tegretol® (carbamazepine) 100 mg/5ml Oral Suspension (OS), a product usually used for the management of generalized tonic-clonic and partial seizures, is no longer recommended for neonates (below 4 weeks of age for term babies or 44 weeks post-menstrual age for pre-term babies) due to the amount of propylene glycol (PG) in this formulation. Propylene glycol, one of the excipients in this product, is generally recognized as safe by the US Food and Drug Administration (FDA) for uses in food and tobacco products, pharmaceuticals, and cosmetics. However, the amount in this product is beyond the safety limit for neonates mentioned in this alert letter. Therefore, the Authority (EFDA) requests all health professionals to avoid prescribing and dispensing the medicine for neonates since the risk of using this medicine in neonates outweigh its benefits.

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ETHIOPIAN FOOD & DRUG AUTHORITY

Safety Alert

The Ethiopian Food and Drug Authority (EFDA) is alerting the public regarding the circulation of an illegal drug, marketed under the name "RELIEF," which has been detected in the Ethiopian market. This product, suspected to contain a mixture of diclofenac, paracetamol, chlorpheniramine, and magnesium trisilicate, is not legally registered with EFDA. Consequently, its quality, safety, and efficacy are unverified, making its use potentially harmful.

Reports suggest that use of this product may result in side effects, including loss of appetite, diarrhea, stomach pain, nausea, vomiting, insomnia, fatigue, visual disturbances, dizziness, headache, skin rash, increased liver enzymes, and, with prolonged use, potential liver and kidney damage. Studies further indicate that extended usage of RELIEF may elevate the risk of severe complications, including liver and kidney damage, heart attack, or stroke.

The EFDA strongly urges the public to avoid purchasing or using this unauthorized drug. Additionally, we request that any individuals or businesses encountering this product promptly report its presence. Reports can be made by calling the EFDA's toll-free line at 8482 or by contacting regional health control authorities.

The EFDA remains committed to protecting public health and enforcing strict drug safety standards. We thank the public for their cooperation in ensuring the safety and well-being of our communities.

Ethiopian Food and Drug Authority

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Alert

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The list of Medicines that have failed Quality Control Testing

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The list of Medicines that have failed Quality Control Testing

S/N	Name of Medicine		Batch no.	manufacturer	Product Registration Status in Ethiopia	Remark
	Generic Name	Brand Name				
1.	Artesunate 60mg/2ml powder for injection	Balsunate 60 mg	E22DP136	Bal pharma limited	Not Registered ያልተመዘገበ	The product did not comply with the parameter uniformity of dosage unit (Waight variation)
2.	Primaquine Phosphate IP 15 mg tablet	Primaquine Phosphate IP 15 mg tablet	PCQ-18	Askon Health Care India	Not Registered ያልተመዘገበ	The product did not comply with the parameter Assay by HPLC
3.	Artesunate 120 mg injection	ZIFF ART-120	D0172313A	Unknown	Not Registered ያልተመዘገበ	The product did not comply labeling information with the manufacturer is not clearly described on the label
4.	Chloroquine phosphate 250 mg tablet	MALARIA-BEN	AMB-13	Askon Health Care India	Not Registered ያልተመዘገበ	The product did not comply with the parameter dissolution by UV
5.	Artesunate 60 mg powder for injection	ARNATE 60mg/vial	T and G DI12232068	T&G Medicare India	Not Registered ያልተመዘገበ	The product did not comply with the parameter uniformity of dosage unit (Waight variation)
6.	Chloroquine phosphate tablets 250mg	MALARIA-BEN	AMB-16	Askon Health Care India	Not Registered ያልተመዘገበ	The product did not comply with the parameter Assay by HPLC
7.	primaquine Phosphate Tablets IP 15mg	Primaquine Phosphate Tablets IP 15mg	PCQ-16	Askon Health Care India	Not Registered ያልተመዘገበ	The product did not comply with the parameter Assay by HPLC
8.	Artesunate 60 mg/mL	Malarbeat 60mg	MRE-01	Hanano India	Not Registered ያልተመዘገበ	The product did not comply with the parameter uniformity of dosage unit (Waight variation)

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ETHIOPIAN FOOD & DRUG AUTHORITY

Safety Alert

The Ethiopian Food and Drug Authority (EFDA) is responsible for ensuringthe quality, safety, and efficacy of medicines before they are used, as wellas conducting regular inspections of medicines available on the market.

The Ethiopia Food and Drug Authority has accepted a market complaint of Illegal Medicine from Addis Ababa City Administration of Food and Drug Authority on Inmunoglobulina Humana Anti-D (Rho) for 5% solution for Intravenous injection Batch No: 11369c Manufacture Date: 10/2023 Expiry Date: 11/2026 11/2026, manufactured by Pare Medicbai a Hanan, Cuba.
In light of this, the Authority assessed compliance, conducted an investigation, and did laboratory testing. Microbiological tests (sample condition, labeling information, and sterility test) and physicochemical testing (glucose identification test and sample condition) do not meet the standards during laboratory examination, indicating that the product is falsified and substandard or out of specification.

The Authority intends to alert health care providers about the need to monitor the distribution, sales, or administration or use of falsified and substandard /out of specification (OOS) medicinal products.

Advice to the Public.
The Authority also intends to alert the public if they have this falsified and substandard or out of specification product, please do not use it. If you, or any one you know have used this product or suffered any adverse reaction/event after use you are advised to seek immediate medical advice from a qualified health care professional.

The EFDA encourage members of the public and health care provider to report all suspicious, substandard and falsified medicinal products to the Ethiopia Food and Drug Authority through, ADE reporting form, Med safety mobile apps available at play store for androids and app store for iPhone, E-reporting available on EFDA website (www.efda.gov.et), through email pharmacovigilance@efda.gov.et andToll-free number 8482.

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