ສາທາລະນະລັດ ປະຊາທິປະໄຕ ປະຊາຊົນລາວ
ສັນຕິພາບ ເອກະລາດ ປະຊາທິປະໄຕ ເອກະພາບ ວັດທະນະຖາວອນ

ກະຊວງສາທາລະນະສຸກ
ກົມອາຫານ ແລະ ຢາ
ໂທ: 021 214 013-14

12634
ເລກທີ /ກອຢ
ນະຄອນຫຼວງວຽງຈັນ, ວັນທີ 23 NOV 2022

ໜັງສືແຈ້ງການ

ຮຽນ: ທ່ານຫົວໜ້າພະແນກສາທາລະນະສຸກນະຄອນຫຼວງ ແລະ ບັນດາແຂວງໃນຂອບເຂດທົ່ວປະເທດ.
ເລື່ອງ: ການແຈ້ງເຕືອນຂອງອົງການອະນາໄມໂລກກ່ຽວກັບຢາແກ້ໄອເດັກນ້ອຍ ທີ່ຕົກມາດຕະຖານ.

- ອີງຕາມ ກົດໝາຍວ່າດ້ວຍຢາ ແລະ ຜະລິດຕະພັນການແພດ ສະບັບເລກທີ 07/ສພຊ, ລົງວັນທີ 21 ທັນວາ 2011;
- ອີງຕາມ ການແຈ້ງເຕືອນຂອງອົງການອະນາໄມໂລກ ເລກທີ N°6/2022 ລົງວັນທີ 5 ຕຸລາ 2022;
- ອີງຕາມ ການຄົ້ນຄວ້າຂອງກົມອາຫານ ແລະ ຢາ.

ກົມອາຫານ ແລະ ຢາ, ກະຊວງສາທາລະນະສຸກ ຂໍແຈ້ງມາຍັງທ່ານຊາບວ່າ: ໃນວັນທີ 5 ຕຸລາ 2022 ອົງການອະນາໄມໂລກ ໄດ້ແຈ້ງເຕືອນກ່ຽວກັບຢາແກ້ໄອສຳລັບເດັກນ້ອຍ ທີ່ຕົກມາດຕະຖານ ຈຳນວນ 4 ລາຍການດັ່ງນີ້:

1) Promethazine Oral Solution
2) Kofexmalin Baby Cough Syrup
3) Makoff Baby Cough Syrup
4) Magrip N Cold Syrup

ຜະລິດຕະພັນຢາທັງ 4 ລາຍການຂ້າງເທິງແມ່ນຜະລິດໂດຍໂຮງງານ Maiden Pharmaceuticals Limited (Haryana, India) ເຊິ່ງມີການປົນເປື້ອນຂອງ diethylene glycol ແລະ ethylene glycol, ໃນເບື້ອງຕົ້ນພົບຜະລິດຕະພັນຢາຕົກມາດຕະຖານດັ່ງກ່າວໃນປະເທດແກມເບຍ (Gambia). ການຊົມໃຊ້ຢາທີ່ມີສານປົນເປື້ອນສານ diethylene glycol ແລະ ethylene glycol ຈະເຮັດໃຫ້ມີອາການເຈັບທ້ອງ, ຮາກ, ຖອກທ້ອງ, ປັດສະວະຍາກ, ໝາກໄຂ່ຫຼັງໄດ້ຮັບຜົນສະທ້ອນ ທີ່ອາດຈະຮຸນແຮງເຖິງຂັ້ນເສຍຊີວິດ.

ຜ່ານການຄົ້ນຄວ້າດ້ານວິຊາການຂອງກົມອາຫານ ແລະ ຢາເຫັນວ່າ: ຜະລິດຕະພັນ 4 ລາຍການດັ່ງກ່າວຍັງບໍ່ມີການຂຶ້ນທະບຽນໃນ ສປປ ລາວ, ແລະ ຍັງບໍ່ມີຜະລິດຕະພັນໃດໆ ທີ່ຜະລິດໂດຍໂຮງງານ Maiden Pharmaceuticals Limited (Haryana, India) ໄດ້ຮັບການຂຶ້ນທະບຽນໃນ ສປປ ລາວ. ແຕ່ເຖິງຢ່າງໃດກໍ່ຕາມ, ເພື່ອປ້ອງກັນການຈໍລະຈອນແຈກຢາຍ ແລະ ຈຳໜ່າຍທີ່ຜິດລະບຽບໃນ ສປປ ລາວ ຈຶ່ງແຈ້ງມາຍັງທ່ານຈົ່ງຊີ້ນຳຕໍ່ຂະແໜງອາຫານ ແລະ ຢານະຄອນຫຼວງ-ແຂວງ ແລະ ໜ່ວຍງານອາຫານ ແລະ ຢາເມືອງຢູ່ໃນຂອບເຂດຄວາມຮັບຜິດຊອບຂອງຕົນດັ່ງລຸ່ມນີ້:

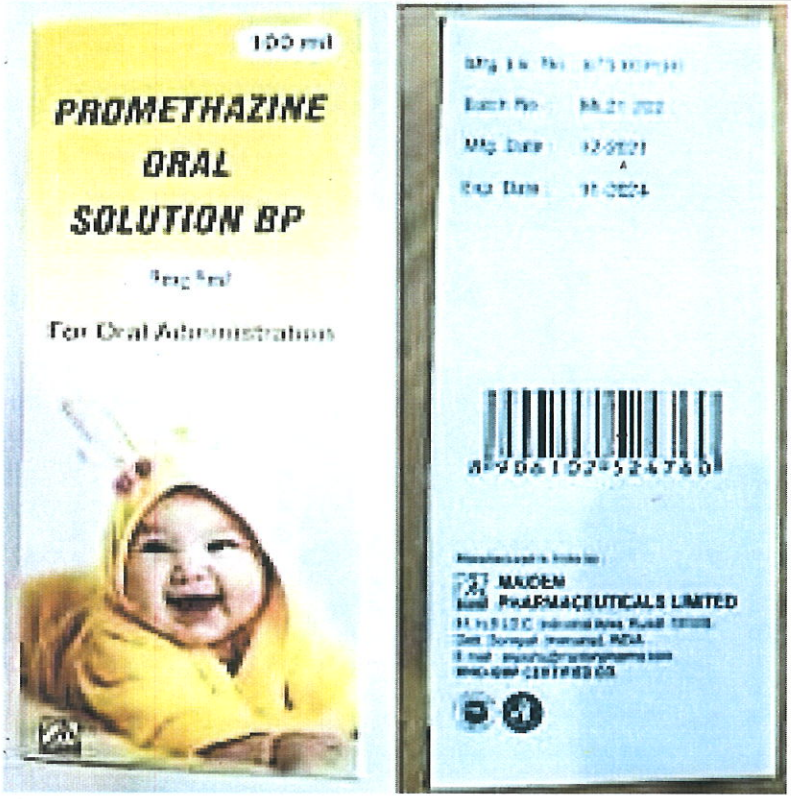
1) ເພີ້ມທະວີການຕິດຕາມກວດກາບັນດາຮ້ານຂາຍຍ່ອຍຢາ ແລະ ການຢາໂຮງໝໍ ເພື່ອແກ້ໄຂໃຫ້ທ່ວງທັນໃນກໍລະນີມີການຈໍລະຈອນແຈກຢາຍ ແລະ ຈຳໜ່າຍທີ່ຜິດລະບຽບການ;
2) ຖ້າພົບເຫັນການຈໍລະຈອນແຈກຢາຍ ແລະ ຈຳໜ່າຍຜະລິດຕະພັນ 4 ລາຍການດັ່ງກ່າວແມ່ນໃຫ້ຍຶດ ແລະ ເກັບຮັກສາໄວ້ຂະແໜງອາຫານ ແລະ ຢາ ພ້ອມທັງບັນທຶກເກັບກຳຂໍ້ມູນໃນການສະໜອງ ແລະ ແຫຼ່ງທີ່ມາລະອຽດ ແລ້ວລາຍງານມາຍັງກອງກວດກາອາຫານ ແລະ ຢາເພື່ອສັງລວມ, ວາງມາດຕະການຕາມລະບຽບຫຼັກການ ແລະ ລາຍງານຂັ້ນເທິງເພື່ອຂໍທິດຊີ້ນຳ.

(ຮູບພາບ ແລະ ລາຍລະອຽດຂອງຜະລິດຕະພັນໄດ້ຄັດຕິດມາພ້ອມນີ້)

ດັ່ງນັ້ນ ຈຶ່ງແຈ້ງມາຍັງທ່ານເພື່ອຊາບ ແລະ ຈັດຕັ້ງປະຕິບັດຕາມແຈ້ງການສະບັບນີ້ດ້ວຍ.

ເຊັນແທນ
ຫົວໜ້າກົມ

ປອ. ດຣ. ສຸຣິສັກ ສູນວໍລະວົງ

ຊື່ຜະລິດຕະພັນ	PROMETHAZINE ORAL SOLUTION BP
ສ່ວນປະສົມທີ່ໃຊ້	Promethazine
ຜູ້ຜະລິດ	MAIDEN PHARMACEUTICALS LIMITED (Haryana, India)
ເລກທີຊຸດ ຜະລິດ	ML21-525
ວັນເດືອນປີ ຜະລິດ	Dec-21
ວັນເດືອນປີ ໝົດອາຍຸ	Nov-24
ພາສາໃນສະຫຼາກ	English
ຮູບພາບ	

2 3 NOV 2022

ກະຊວງສາທາລະນະສຸກ
ກົມອະນາໄມ ແລະ ຢາ

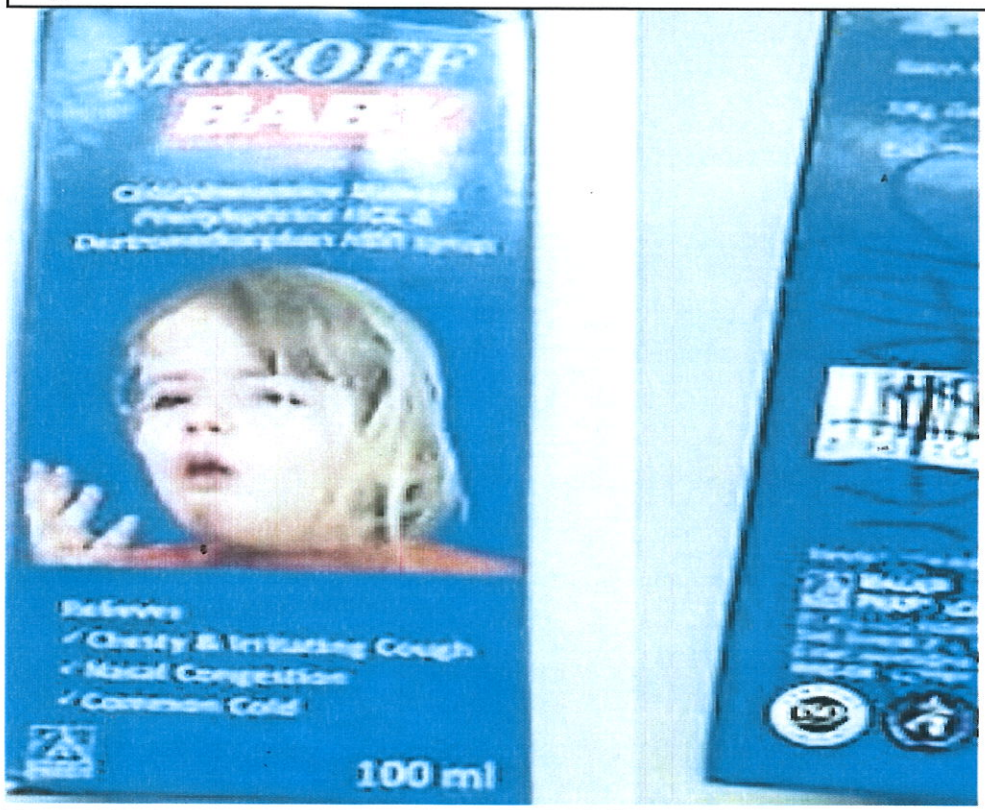
ປອ. ດຣ. ສຸຣິສັກ ສູນວໍລະວົງ

KOFEXMALIN BABY COUGH
Pheniramine Maleate, Ammonium chloride, Menthol
MAIDEN PHARMACEUTICAL LIMITED (Haryana, India)
ML21-199
Dec-21
Nov-24
English

2 3 NOV 2022

ປອ. ດຣ. ສຸຣິສັກ ສູນວໍລະວົງ

MAKOFF BABY COUGH SYRUP
Chlorphenamine Maleate, Phenylephrine HBR, Dextromethorphan syrup
MAIDEN PHARMACEUTICAL LIMITED (Haryana, India)
ML21-199
Dec-21
Nov-24
English



23 NOV 2022

ປອ. ດຣ. ສຸຣິສັກ ສູນວໍລະວົງ

MAGRIP N COLD SYRUP
Paracetamol Phenylephrine HCL, Chlorphenamine Maleate
MAIDEN PHARMACEUTICAL LIMITED (Haryana, India)
ML21-199
Dec-21
Nov-24
English

23 NOV 2022

ປອ. ດຣ. ສຸຣິສັກ ສູນວໍລະວົງ

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°6/2022 5 October 2022

Medical Product Alert N°6/2022

Substandard (contaminated) paediatric medicines identified in WHO region of Africa

Alert Summary

This WHO Medical Product Alert refers to four substandard products, identified in The Gambia and reported to WHO in September 2022. Substandard medical products are products that fail to meet either their quality standards or specifications and are therefore "out of specification"[1].

The four products are *Promethazine Oral Solution, Kofexmalin Baby Cough Syrup*, *Makoff Baby Cough Syrup* and *Magrip N Cold Syrup*. The stated manufacturer of these products is Maiden Pharmaceuticals Limited (Haryana, India). To date, the stated manufacturer has not provided guarantees to WHO on the safety and quality of these products.

Laboratory analysis of samples of each of the four products confirm that they contain unacceptable amounts of diethylene glycol and ethylene glycol as contaminants. To date, these four products have been identified in The Gambia, but may have been distributed, through informal markets, to other countries or regions.

Risks

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

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.

All batches of these products should be considered unsafe until they can be analyzed by the relevant National Regulatory Authorities.

The substandard products referenced in this alert are unsafe and their use, especially in children, may result in serious injury or death.

Advice to regulatory authorities and the public

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

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.

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 have these substandard products, **please DO NOT use them**. If you, or someone you know, have used these products, or suffered any 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 substandard products are discovered in their respective country. If you have any information concerning the manufacture or supply of these products, please contact WHO via **rapidalert@who.int.**

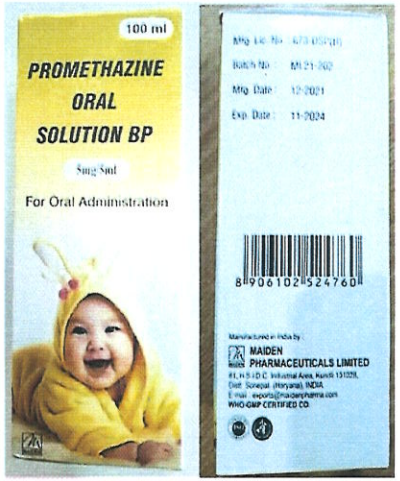
Please see annex for details of the substandard products referenced in Alert N°6/2022.
Alert n°6/2022 may be updated at a later stage as and when necessary.

[1] WHO definitions : https://www.who.int/teams/regulation-prequalification/incidents-and-SF/background/definitions

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°6/2022: PRODUCTS CONTAMINATED WITH DIETHYLENE GLYCOL AND ETHYLENE GLYCOL
The products listed below are manufactured by MAIDEN PHARMACEUTICALS LIMITED (Haryana, India) and were identified to date in The Gambia

Product Name	PROMETHAZINE ORAL SOLUTION BP	KOFEXMALIN BABY COUGH SYRUP	MAKOFF BABY COUGH SYRUP	MAGRIP N COLD SYRUP
Reported active ingredients	Promethazine	Pheniramine Maleate, Ammonium chloride, Menthol	Chlorphenamine Maleate, Phenylephrine HBR, Dextromethorphan syrup	Paracetamol Phenylephrine HCL, Chlorphenamine Maleate
Stated manufacturer	MAIDEN PHARMACEUTICALS LIMITED (Haryana, India)	MAIDEN PHARMACEUTICALS LIMITED (Haryana, India)	MAIDEN PHARMACEUTICALS LIMITED (Haryana, India)	MAIDEN PHARMACEUTICALS LIMITED (Haryana, India)
Lot number	ML21-202	ML21-199	ML21-203	ML21-198
Mfg. date	Dec-21	Dec-21	Dec-21	Dec-21
Exp. date	Nov-24	Nov-24	Nov-24	Nov-24
Packaging language	English	English	English	English
Available photograph				

WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products
For more information, please visit our website. Email: rapidalert@who.int