FORM A

ASEAN POST–MARKETING ALERT SYSTEM

Instructions:

1. Complete the form by entering all the details required.
2. Please tick ☑ where applicable.
3. Indicate **NA** whenever the field is not applicable.
4. Please provide photograph of the product and press statement, if any.

SECTION 1 - ALERT INFORMATION

1.1 Level of confidentiality:

☑ Internal / Restricted circulation

☐ On public domain, specify website: _____

Note: Appreciate that Member State can share the alert via ASEAN PMAS as soon as the information is made available on public domain e.g. online press release, media report.

1.2 Issue:

☐ Adulteration
☐ Falsified*
☑ Quality defect
***Note:** * Falsified products that deliberately/ fraudulently misrepresent their identity, composition or source. (Ref: WHO]*

☐ Safety aspect
☐ Unregistered / unlicensed
☐ Others, please specify: _____

1.3 Action:

☐ Cancellation of registration
☐ Suspension of registration
☐ Withdrawal of product
☑ Recall of product

☐ Labelling change
☐ Issuance of press release
☐ Others, please specify:_____

1.4 Source of alert / Type of signal:

☐ Local ADR reports
☐ Scientific literature / local studies
☐ Post-marketing testing activities

☑ Decision made by other regulatory authorities
☐ Decision made by industry
☐ Others, please specify: _____

SECTION 2 - PRODUCT INFORMATION

(Whenever possible, please also provide the image of the product and press statement (if any) in Section 7)

2.1 Product type:

☐ Biologic
☐ Cosmetic
☐ Health Supplement

☑ Pharmaceutical
☐ Traditional medicine
☐ Others, please specify: _____

2.2 Forensic classification of pharmaceutical/ biologic / traditional medicine in your country:

☐ General Sales List / Over-the-counter
☐ Pharmacy Only

☑ Prescription Only Medicine
☐ Others, please specify: _____

2.3	**Brand / Product name (or drug class):** Zontrixone	2.4	**Alternative name (*e.g. local language*):** ซอนทริโซน
2.5	**Local Registration no.** *(if applicable)*: 1C 186/54		
2.6	**Active ingredient / Generic name / Full formula:** Ceftriaxone sodium		
2.7	**Dosage form** *(if applicable)*: Sterile powder	2.8	**Strength** *(if applicable)* : 1 g.
2.9	**Pack size / Presentation:** Vials	2.10	**Batch / Lot number:** 1910127

2.11	**Expiry date** *(if applicable)* **:** 10/2022	2.12	**Date manufactured** *(if applicable)* **:** 10/2019
2.13	**Intended use as listed on label:** Antibiotics		
2.14	**Countries which the product is exported to:** -		
SECTION 3 - COMPANY INFORMATION			
3.1	**Name & address of Marketing Authorisation Holder / Product Licence Holder / company responsible for placing the product in the market:** Manufacturer: Great Eastern Drug Co., Ltd. Address: 18th Floor Thai Wah Tower I, 21/52-54 South Sathorn Road, Bangkok 10120, Thailand License No.: 85/2526		
3.2	**Status of the company:** ☐ Manufacturer ☐ MAH/PL Holder/ Product registrant ☐ Exporter ☑ Importer ☐ Wholesaler ☐ Retailer ☐ Others:_____		
3.3	**Name & address (including country) of manufacturer:** Manufacturer: REYOUNG PHARMACEUTICAL CO., LTD. Address: People's Republic of China		
SECTION 4 - DETAILS / ACTION(S) TAKEN			
4.1	**Details of investigations:** Glass particle was found in the product after reconstitution.		
4.2	**Actions / proposed actions to be taken: e.g.** • *Level of recall (e.g. hospital, retail, consumers)* • *Type of recall (e.g. batch specific, temporary suspension, permanent)* • *Date of withdrawal or recall* Actions: Inform other related government sectors about the voluntary recall of Zontrixone Reg.no. 1C 186/54 Lot No. 1910127 in Thailand. Proposed actions: Follow up the recall and investigation reports**.**		
SECTION 5 - REPORTING COUNTRY / AUTHORITY			
5.1	**Name of country / issuing authority:** Thailand	5.2	**Department / Designation of person issuing the alert:** Food and Drug Administration, Ministry of Public Health
5.3	**Report reference no.:** 1009.5/3756 (12 June 2020)	5.4	**Date of report:** 25 Jun 2020
SECTION 6 - CONTACT PERSON			
6.1	**Name :** 1.Mrs. Piyaporn Oncompa 2.Ms.Pattreya Pokhagul	6.2	**Department / Designation :** 1.Medicines Regulation Division, Thai FDA 2.Health Product Vigilance Center (HPVC), Strategy and Planning Division, Thai FDA
6.3	**Email address:** 1.QA@fda.moph.go.th 2.adr@fda.moph.go.th	6.4	**Contact number:** **Telephone no.** : +66 2590 7405, 66 2 590 7261 **Fax no.** : +66 2591 8489, 66 2 591 8457

SECTION 7 - IMAGE OF THE PRODUCT(S) AND PRESS STATEMENT (IF ANY)

Please attach the pictures of products clearly from different sides of packaging that contain information of the product, including primary packaging, secondary packaging, labels, or brochure (if any)