ZUELLIG PHARMA
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7th April 2020

Direct Healthcare Professional Communication:

Esmya™ (ulipristal acetate 5mg) [TH Reg. no. 1C 15047/61 (NC)]:

Voluntary Product Recall

Dear Healthcare Professional,

The European Medicines Agency (EMA) has recommended that Patients temporarily stop taking 5mg Ulipristal acetate (Esmya™) for symptomatic uterine fibroids while pending a safety review of the product.

As a precautionary measure, Zuellig Pharma is initiating a voluntary recall at Degree/Class B/ Level II: all points of sales (Hospitals & Clinics) for all batches of:

Ulipristal acetate 5 mg (Esmya™), TH Reg. no. 1C 15047/61 (NC)

This voluntary recall covers all undispensed Esmya™ stock in your hospital and clinic as well as unconsumed and partially consumed Esmya™ dispensed to your Patients.

You are requested to immediately examine your inventory and to quarantine the product that is the subject of this voluntary recall. If you have distributed this product, please identify your Patients and notify them at once of this voluntary product recall. Your notification to your Patients may be enhanced by including a copy of this letter

Summary of product recall:

A. Undispensed stocks in your hospital or clinic

- Zuellig Pharma will process all requests for stock returns and refund via credit note for customers with undispensed stock stored at their hospital or clinic. Please record the total inventory of undispensed stocks on the Business Reply Form provided.

B. Unconsumed and partially consumed stocks by patients

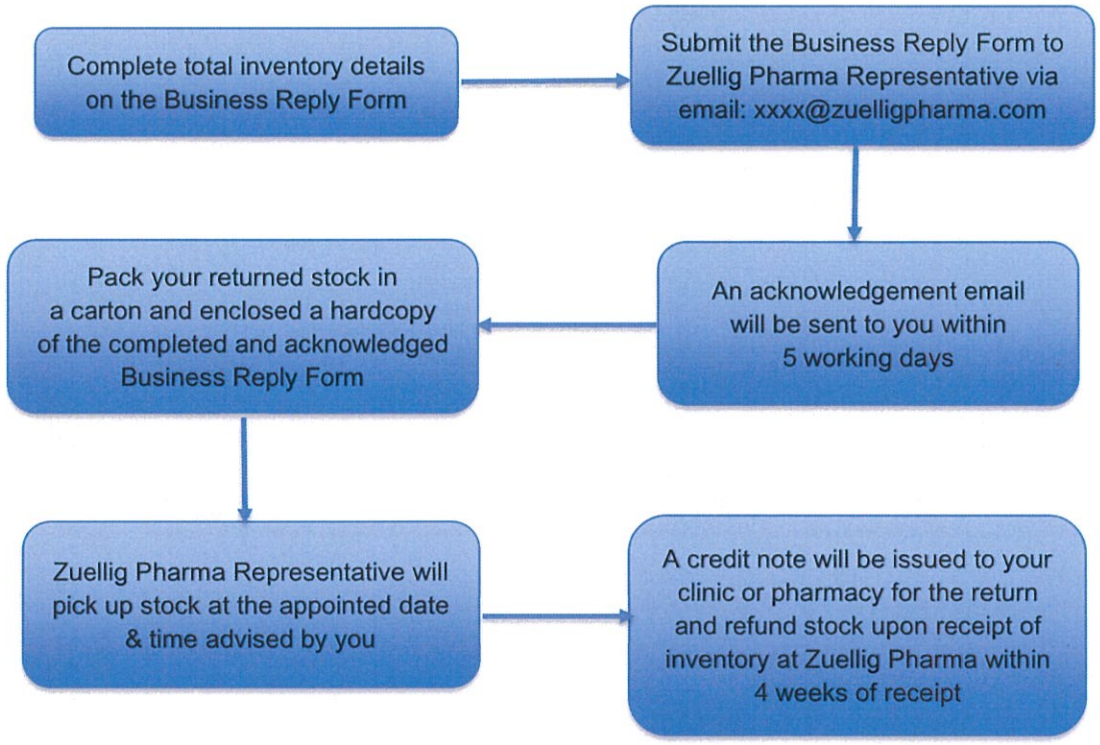
- Existing Patients who are unable to complete the current course of treatment with the product can request for return and refund of unconsumed and partially consumed stock through your hospital or clinic.
- Please note that **refunds will be based on price sold per box to your hospital or clinic**, even for a partially consumed box.
- As one full course of treatment with the product is equivalent to three (3) boxes, a maximum limit of three (3) boxes per Patient can be returned to your hospital or clinic , which will be returned and refunded in credit note by Zuellig Pharma to your hospital or clinic.
- Please record the total inventory of stocks returned by your Patients on the Business Reply Form.

บริษัท ซิลลิค ฟาร์มา จำกัด
ชั้น 8-9 อาคารเพลินจิตเซ็นเตอร์ เลขที่ 2 ถนนสุขุมวิท แขวงคลองเตย เขตคลองเตย กรุงเทพฯ 10110
โทรศัพท์ +66 2656-9800 I โทรสาร +66 2656-9801 I ตู้ ปณ. 409 ปณจ. บางรัก กทม. 10500
www.zuelligpharma.com

- Please refer to **Appendix A** for the different scenarios that Zuellig Pharma can accommodate returns and refunds of the product from an existing Patient through your hospital and clinic:

C. Voluntary product recall and refund in credit note process

- The following steps outline the recall and refund in credit note process for your undispensed stock, as well as unconsumed and partially consumed stock from your existing Patients through your hospital and clinic:



Further information on the safety concern

A 2018 EMA review concluded that there is a risk of rare but serious liver injury with ulipristal acetate medicines for the treatment of uterine fibroids, and measures were implemented to minimise the risk (e.g. update of labelling, patient card, and liver function tests).

However, a new case of serious liver injury leading to transplantation occurred. The current case raises concerns that, in spite of adherence to the implemented risk minimisation measure, a progression in the development of hepatic failure leading to liver transplantation, could not be prevented. The need of further exploring the effectiveness of the risk minimisation measures is warranted.

Status for product information

There are no changes to the current package insert (enclose PI).

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Call for adverse event reporting

Adverse drug reactions should also be reported to our local Pharmacovigilance/Drug safety representative:

- Mr.Kriangsak Teerasaksopon (kriangsakt@zuelligpharma.com)

For further medical information on **Esmya™**, please contact our local medical affairs representative:

- Dr.Puchong Padungsutt (PuchongP@zuelligpharma.com)
- Ms.Valerie Anne Lara Saksopin (ValerieAnneLaraS@zuelligpharma.com).

Please complete and return the enclosed business reply form as soon as possible.
This recall is being made with the knowledge of The Food and Drug Administration, Ministry of Public Health

Your assistance is appreciated.

Yours sincerely,

Dr.Puchong Padungsutt
Vice President – Medical Affairs
Regional Medical Director , ZuelligPharma

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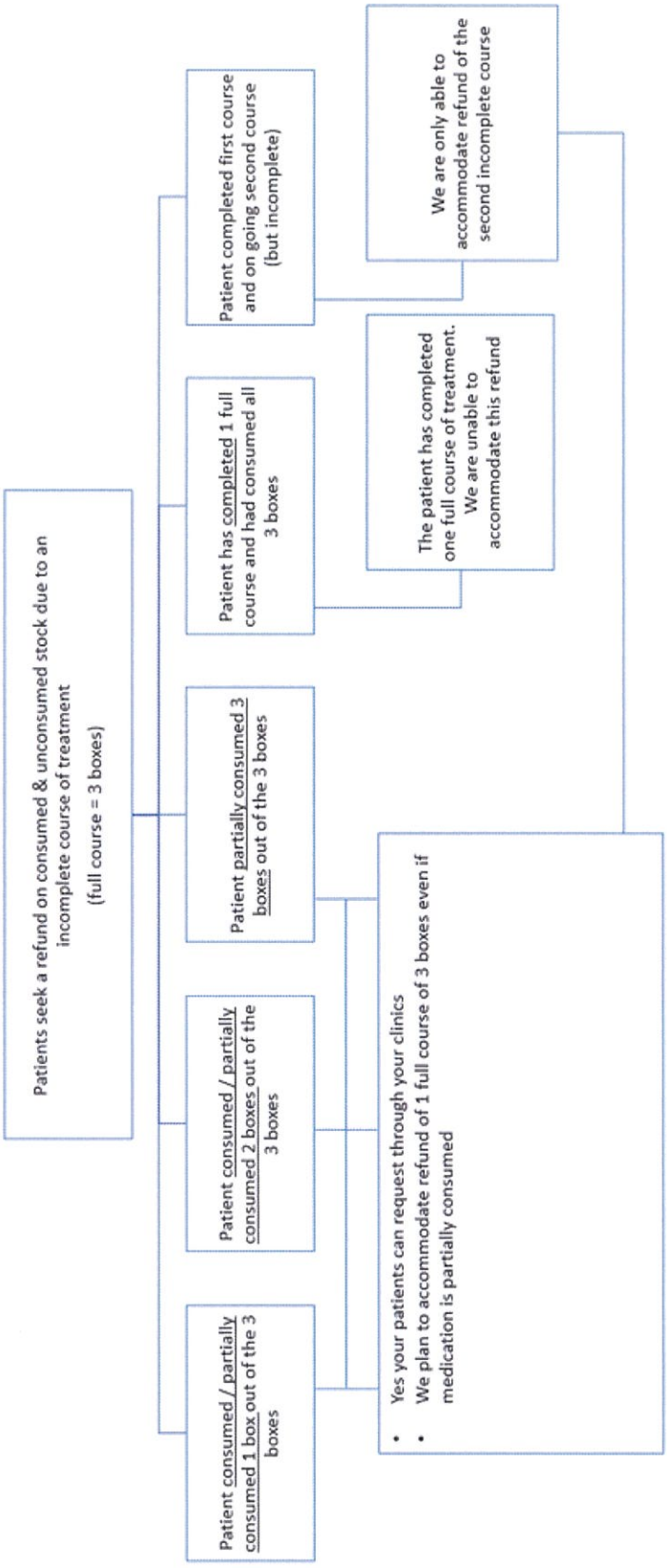
Appendix A



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