Pacific
Pharmaceuticals Ltd

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11th November 2002

To General Practitioners, Specialists and Physicians

Medicine Recall
Product: Felo ER Tablets 2.5mg, 5mg and 10mg - All Batches

Pacific Pharmaceuticals Ltd in consultation with Medsafe* is recalling all batches and all strengths of its calcium channel blocking agent Felo ER tablets from the market. This recall is to patient level and will remove Felo ER - manufactured in Europe for Swiss generic company Siegfried Ltd - from wholesalers, pharmacies and instruct patients to return to their medical practitioners for advice and prescription of an alternative agent to treat their hypertension or angina.

The decision to institute a patient recall follows Medsafe's assessment of new information. It is now not currently possible to determine the quality, accuracy and validity of the testing methods used in the Swiss bioequivalence studies supplied to demonstrate the effectiveness of Felo ER. Medsafe believes information provided by the German regulatory authority indicates that the quality systems utilised by the Swiss company that performed the bioequivalence studies for Felo ER, failed to control aspects of the studies used to demonstrate the effectiveness of Felo ER. These quality system failures occurred in clinically crucial areas and are of such a nature that the Felo ER bioequivalence studies cannot be regarded as accurate and must be discarded. Without these studies there is no compelling evidence for the effectiveness of Felo ER, and Medsafe can no longer be satisfied as to whether Felo ER offers the same degree of protection from the complications of hypertension and angina as other brands of felodipine.

Pacific Pharmaceuticals Ltd will be advertising this recall in major newspapers on Thursday 14th November 2002. Please note that:

- Pacific Pharmaceuticals Ltd will reimburse doctors for one GP visit for each patient (at your standard charge rate for the patient concerned) relating to this recall of Felo ER. All claims must be received within 30 days from the date of this letter. Enclosed please find a patient disclosure sheet that you need to fill out with your name and address. Photocopy this sheet and then complete for the first consultation of each patient who visits you due to the recall of Felo ER. Collate the information on the Invoice that is provided and send the Invoice plus patient sheets to:

  Pacific Pharmaceuticals Ltd, Private Bag 11914, Ellerslie, Auckland.

- PHARMAC confirms that Plendil ER will be fully subsidised as of 11th November 2002.

- Medsafe advises that pharmacies have access to adequate supplies of alternative treatments for angina and hypertension, (including an alternative brand of felodipine).

- Patient Q & A sheets have been provided for you to give to your patients and Pacific Pharmaceuticals Ltd has set up a free-phone patient information hot-line on telephone number 0800 18 18 16.

*Medsafe (New Zealand Medicines and Medical Devices Safety Authority) is a unit of the Ministry of Health

Patient Management Advice

To minimise the risk to patients who are currently taking Felo ER, the key patient messages are:

1. **Patients should not suddenly stop taking their Felo ER medication, as prolonged periods off all treatment represents a higher health risk to patients than continuing on Felo ER despite the uncertainty about its efficacy;**
2. **Patients should see their GP as soon as is practical and certainly before their current pack of Felo ER runs out;**
3. **Patients will have to pick up a new prescription from their GP to transfer to either another calcium channel blocking agent or some other treatment appropriate for their underlying medical condition(s).**

Medsafe advises that care is necessary where a patient has had their dose of Felo ER changed to control their hypertension or angina and a decision is made to transfer the patient to the alternative brand of felodipine. In these situations it may be necessary to monitor the dose of felodipine prescribed to limit the occurrence of adverse effects such as hypotension. Irrespective of what medication is prescribed, monitoring of the patient's blood pressure to determine the most appropriate dose of medication is recommended.

Medsafe has asked that we encourage you to report any adverse effects you have seen with Felo ER, including cases of lack of effect to the Centre for Adverse Reactions Monitoring in Dunedin. It should be noted however, that the rate of adverse reactions relating to Felo ER reported since its introduction to New Zealand in October 2001 has been well within acceptable levels.

As the distributor of Felo ER, Pacific Pharmaceuticals Ltd is working closely with Medsafe in this recall. Enclosed, please find 10 Q & A sheets that you can use as a basis for discussion or as a hand out to your patients.

Yours sincerely,

Jenny Roodt

Jenny Roodt
Recall Co-ordinator
Pacific Pharmaceuticals Ltd

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Pacific Pharmaceuticals Ltd

FELO ER TABLETS

Patient Disclosure Sheet for Reimbursement of Doctor's Fee

Doctor's Name: _____

Address: _____

_____

_____

Patient Name: _____

Address: _____

_____

_____

I hereby agree to a free doctor's consultation regarding Felo ER Tablets, and confirm that the above information may be forwarded to Pacific Pharmaceuticals Ltd, who will reimburse the doctor.

_____ _____

Patient Signature Date

_____ _____

Doctors Signature Date

Tax Invoice For Reimbursement of Medical Fees

Felo ER Tablets

Doctors Name: _____ GST No.: _____

Address: _____ Date: _____

_____

_____

Payee Name to appear on cheque: _____

Patients Name	Fee
Total:	
GST:	
Total Payable:	

Mail to: Pacific Pharmaceuticals Ltd
Private Bag 11914
Ellerslie
AUCKLAND