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## **URGENT FIELD SAFETY NOTICE**

- Commercial name of the affected product: **Relactagel**
- Date: – **06 October 2010**
- Ref number: Internal case number: **MDKHIE2010001**
- Type of action. **RECALL**

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**Dear Customer**

### **Details on affected devices:**

Product: Relactagel  
Lot number: 10102  
Expiry Date: December 2011

### **Description of the problem:**

Kora Healthcare market Relactagel in Ireland.

Kora Healthcare has become aware that Relactagel product destined for the German market has been placed onto to the Irish Market. The affected product is contained in a German Language Carton that includes a German Language Instructions for use.

Our record traceability has shown that you have received some of the affected products.

Please note that only products of the above batch (Lot No 10102) are affected.

This recall does not apply to any other products from Kora Healthcare.

Our distribution process is to be revised to correct this problem and to avoid this occurring in the future.

### **Advise on action to be taken by the user:**

- Check your inventory and sort out all unused products that are affected
- You are kindly advised to quarantine the available stock and to return all products to the contact person identified below.
- Complete and return the Field Safety Notice Response page enclosed.
- If any of the affected batch has been further distributed/sold, identify those customers and inform them of this Field Safety Notice. A copy of this Field Safety Notice may be given to the consignee. Document this action on the Field Safety Notice Response.

**Transmission of this Field Safety Notice:**

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected device has been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

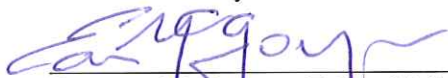
**Contact reference person:**

Eamonn McGowran  
Regulatory Affairs Officer  
KoRa Healthcare  
Swords Business Park, Swords Co. Dublin  
Ireland  
TEL: +353 1 8903011  
FAX: +353 1 8903016  
email emg@newport-pharma.com

Please excuse any inconvenience you may have encountered by this incident. We hope for your kind understanding by performing this recall, in order to prevent any unpleasant incidents with your customers. Our aim is to provide you with product of well-known quality.

The undersigned confirms that this notice has been notified to the Irish Medicines Board

Yours Sincerely



Eamonn McGowran B.Sc., M.Sc.  
Regulatory Affairs Officer, Kora Healthcare

Date: 06-October 2010

**CONFIRMATION OF RECEIPT OF  
URGENT FIELD SAFETY NOTICE**

**Commercial name of the affected product:** Relactagel

**FSCA-identifier:**      Date: – 06 October 2010  
                                 Ref number:- Internal case number MDKHIE2010001

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**Date:**

**Attention:** Regulatory Affairs Officer, KORA HEALTHCARE

This is to confirm that the undersigned has received the above referenced Field Safety Notice

I have reviewed our inventory and the results for below referenced product are as follows:

<b>Product Name</b>	<b>Batch</b>
Relactagel	10102

Number of Cartons in our inventory: \_\_\_\_\_

Number of Cartons sold to customers: \_\_\_\_\_

I have notified my customers of this Field Safety Notice   Y    N

Number of customers notified: \_\_\_\_\_

**Contact reference person:**

Name (Please enter in Blocks)

Organisation \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_