Patient Level Batch Recall
NovoMix® 30 Penfill® 100 U/ml (biphasic insulin aspart)
Suspension for injection in cartridge (Penfill®)
EU/1/00/142/004

Batch number	Expiry date
CS6C411	08/2014
CS6C628	09/2014
CS6D422	10/2014

29th October 2013

Dear Wholesaler,

We wish to advise you that all units of batch numbers CS6C411, CS6C628 and CS6D422 of NovoMix® 30 Penfill® (EU/1/00/142/004) are being recalled with immediate effect.

Please note that, in Ireland, **this recall relates to NovoMix® 30 Penfill® only** and that NovoMix® 30 FlexPen® on the Irish Market is unaffected.

This recall is going to patient level.

Please immediately quarantine any units of these batches which you have in your possession and arrange for the return of this stock to Allphar Services by Friday Nov 22nd 2013, for credit. Replacement compliant stock is available to order.

This action has been agreed with the Irish Medicines Board.

The reason for the recall is that some of the units in these batches may not meet the specifications for insulin concentration, which may lead to patients' blood sugar levels becoming higher or lower than expected.

If you have supplied these batches to any other wholesaler, please fax those wholesalers a copy of this recall letter, requesting that they quarantine and return any unsold quantities of these batches to you.

We apologise for any inconvenience this action may cause. If you require further information related to this recall, please contact Novo Nordisk Medical Information on 1850 665 665 or info@novonordisk.ie

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Yours sincerely,

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Clinical, Medical and Regulatory Manager