

Public Health Link

from the Chief Medical Officer for Wales

Distribution:	As Appendix 2
From:	Chief Pharmaceutical Officer, Andrew Evans
Date:	26 July 2019
Reference:	CEM/CPhA/2019/19
Category:	Class 2 - Action within 48 hours
Title:	FMD Alert Class 2, Action Within 48 Hours, Kosei Pharma Uk Ltd, Mpt Pharma Ltd, Doncaster Pharmaceuticals Group Ltd And Drugsrus Ltd / P.I.E. Pharma Ltd
For Action by:	<p>Dispensing General Practitioners – please ensure this message is seen by all working in your dispensary and retain a copy in your 'locum information pack'</p> <p>Community Pharmacists</p> <p>Hospital pharmacies</p> <p>Chief Pharmacists</p>
For Information:	See Annex 2 – Distribution List
What is this about:	Full details are set out below.
Why has it been sent:	For your information, action and to pass on to colleagues.

Issue:

Recall of medicines that have been taken out of the regulated medicines supply chain during distribution and later re-introduced. The products were parallel imported into the UK from Italy and re-labelled in Kosei Pharma UK Ltd, MPT Pharma Ltd, Doncaster Pharmaceuticals Group Ltd and Drugsrus Ltd / P.I.E. Pharma Ltd. The products are believed to be legitimate medicines.

Full details of the FMD Alert* are included in the attached PDF file. Please forward to listed recipients. This information is also published on the MHRA website <https://www.gov.uk/drug-device-alerts>.

*Falsified Medicines Directive Alert

Falsified Medicines Directive (FMD) 2011/62/EU introduced new requirements to enhance the security of the European supply chain. Where the MHRA has identified risks to the security of the supply chain, FMD Alerts will be issued.

For further information about FMD and safety features, please see this [link on GOV.UK](#).

Appendix 1

- To: Chief Executives of Health Boards and NHS Trusts
- To: Medical Directors of Health Boards
- To: Nurse Directors Health Boards
- To: Directors of Public Health
- To: Hospital Principals and Chief Pharmacists to action as per alert

To: **NHS Wales Shared Services Partnership to forward to:**

All General Practitioners

Dispensing General

Community Pharmacists

Deputising services

HB Prescribing Advisers

Independent/Private clinics and Hospitals and Hospices throughout Wales



Medicines & Healthcare products
Regulatory Agency

FMD ALERT*

**Class 2 Alert
Action Within 48 hours**

Pharmacy and Patient Level Recall

Date: 25 July 2019

EL (19)A/19

Our Ref: MDR 123-05/19

Dear Healthcare Professional,

Kosei Pharma UK Ltd

Please see Appendix 1 for list of products and batch numbers

MPT Pharma Ltd

Please see Appendix 2 for list of products and batch numbers.

Doncaster Pharmaceuticals Group Ltd

Please see Appendix 3 for list of products and batch numbers.

Drugrus Ltd / P.I.E. Pharma Ltd

Please see Appendix 4 for list of products and batch numbers.

Brief details of issue:

It has come to our attention that these medicines have been taken out of the regulated medicines' supply chain during distribution and later re-introduced. This means that the correct transport and storage conditions cannot be guaranteed during this period and, whilst unlikely, could impact their effectiveness. The products are believed to be legitimate. There is no evidence that they have been tampered with and these medicines are stable at room temperature.

Following the issue of [FMD Alert EL \(19\)A/15](#) on 27 June 2019, we have become aware that Kosei Pharma UK Ltd, CST Pharma Ltd and Ordinant Medical Solutions Ltd have also parallel imported some affected products into the UK from Italy and they have been re-labelled in Kosei Pharma UK Ltd, MPT Pharma Ltd, Drugrus Ltd / P.I.E. Pharma Ltd and Doncaster Pharmaceuticals Group Ltd livery.



Advice for healthcare professionals:

- Please check your stock of all listed products for the relevant products in Kosei Pharma UK Ltd, MPT Pharma Ltd, Drugsrus Ltd / P.I.E. Pharma Ltd and Doncaster Pharmaceuticals Group Ltd livery. If any relevant packs are identified, please quarantine and return to your supplier using your supplier's approved process.
- The MHRA has undertaken a medical assessment to determine whether there is any risk to patients. As a precautionary measure, two medicines are being recalled to patient level because in the very unlikely event that these medicines are not fully effective there is a potential risk to patient safety. For these two particular medicines, whilst the likelihood of their effectiveness being compromised is low (because they are stable legitimate medicines), the consequences of a lack of effectiveness could be serious which is why we are treating them differently. If patients have either of these affected products, you should advise that they continue taking their medicines and contact their GP practice to arrange a new prescription. Once they have a new prescription, patients should return the affected batches to their pharmacist.
- The products being recalled to **patient level** are **Neupro 4mg/24hr patches** and **Vimpat 100mg tablets**. We will use media, social media and will contact patient groups and charities to help draw the attention of patients to the affected batches of these products.
- As a precaution, all other affected medicines are being recalled at **pharmacy level**. Again, you should advise patients to continue taking their medicines. If they have any of these affected medicines, they do not need to arrange a new prescription but if they have any questions, they should speak to their GP or healthcare professional. The products being recalled at **pharmacy level** are: **Dovobet Gel, DuoResp Spiromax 160mcg / 4.5mcg Inhaler, Incrusse Ellipta 55mcg Inhaler, Seretide Evohaler 250mcg and Spiriva 18mcg Inhalation Powder Capsules**.

Contacts for further information:

Kosei Pharma UK Ltd:

For general enquiries, please contact Mr. Saket Jadhav Tel: 01753515054,

Email: saket.j@koseipharma.com

For medical information enquiries, please contact Mr. Kalpesh Patel Tel: 01753515050

Email: Kalpeshkumar.p@koseipharma.com

MPT Pharma Ltd:

For all enquiries please email productrecalls@mptpharma.co.uk

Doncaster Pharmaceuticals Group Ltd:

For all enquiries, please contact:

Rachael Hill, Email: rachael.hill@doncaster-pharm.com Tel 01302 554804

or

Richard Gore, Email: richard.gore@doncaster-pharm.com Tel: 01302 554805

Drugsrus Ltd / P.I.E. Pharma Ltd:

For all enquiries, please contact:

Drugsrus Customer Services, Email: recall@drugsrus.co.uk Tel: 020 8423 3800



Recipients of this Alert should bring it to the attention of relevant contacts by copy of this letter. NHS Regional teams are asked to forward this to relevant clinics, general practitioners and community pharmacists.

Yours faithfully

**Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU
Telephone +44 (0)20 3080 6574**

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Falsified Medicines Directive (FMD) 2011/62/EU introduced new requirements to enhance the security of the European supply chain. Where the MHRA has identified risks to the security of the supply chain, FMD Alerts will be issued.

For further information about FMD and safety features, please see this [link on GOV.UK](#).



Appendix 1: Table of Products / Batches Kosei Pharma UK Ltd

Products and Pack Size	Italian Batch Number	Kosei Batch Number	Expiry Date	Date of First Distribution
DOVOBET GEL 2 X 30G	A54603	A54603/1	Jul-19	07/12/2017
DOVOBET GEL 2 X 30G	A54603	A54603/4	Jul-19	11/01/2018
DOVOBET GEL 2 X 30G	A57133	A57133/3	Aug-19	11/01/2018
DOVOBET GEL 2 X 30G	A57134	A57134/4	Aug-19	11/01/2018
DOVOBET GEL 2 X 30G	A58906	A58906/1	Sep-19	11/01/2018
DOVOBET GEL 2 X 30G	A74927	A74927/2	Apr-20	22/08/2018
DOVOBET GEL 2 X 30G	A77417	A77417/6	May-20	15/11/2018
DOVOBET GEL 2 X 30G	A78018	A78018/2	May-20	15/11/2018
DOVOBET GEL 2 X 30G	A79684	A79684/1	Jun-20	14/11/2018
DOVOBET GEL 2 X 30G	A79729	A79729/2	Jun-20	15/11/2018
DOVOBET GEL 2 X 30G	A83364	A83364/2	Aug-20	31/01/2019
DOVOBET GEL 2 X 30G	A85747	A85747/2	Oct-20	31/01/2019
DOVOBET GEL 2 X 30G	A85936	A85936/1	Oct-20	31/01/2019
INCRUSE ELLIPTA 55MCG INHALER 1 X 30 DOSES	R834141	R834141/1	Sep-19	22/08/2018
INCRUSE ELLIPTA 55MCG INHALER 1 X 30 DOSES	R838744	R838744/1	Oct-19	17/05/2018
INCRUSE ELLIPTA 55MCG INHALER 1 X 30 DOSES	R838744	R838744/2	Oct-19	15/10/2018
INCRUSE ELLIPTA 55MCG INHALER 1 X 30 DOSES	R839098	R839098/1	Oct-19	18/07/2018
INCRUSE ELLIPTA 55MCG INHALER 1 X 30 DOSES	R842742	R842742/1	Jan-20	17/05/2018
INCRUSE ELLIPTA 55MCG INHALER 1 X 30 DOSES	R842742	R842742/2	Jan-20	06/06/2018
INCRUSE ELLIPTA 55MCG INHALER 1 X 30 DOSES	R842742	R842742/3	Jan-20	22/08/2018
INCRUSE ELLIPTA 55MCG INHALER 1 X 30 DOSES	R842742	R842742/4	Jan-20	15/10/2018
INCRUSE ELLIPTA 55MCG INHALER 1 X 30 DOSES	R842742	R842742/5	Jan-20	01/02/2019
INCRUSE ELLIPTA 55MCG INHALER 1 X 30 DOSES	R844186	R844186/1	Dec-19	17/05/2018
INCRUSE ELLIPTA 55MCG INHALER 1 X 30 DOSES	R844186	R844186/2	Dec-19	06/06/2018
INCRUSE ELLIPTA 55MCG INHALER 1 X 30 DOSES	R844186	R844186/3	Dec-19	22/08/2018
INCRUSE ELLIPTA 55MCG INHALER 1 X 30 DOSES	R844186	R844186/4	Dec-19	26/10/2018



INCRUSE ELLIPTA 55MCG INHALER 1 X 30 DOSES	R846745	R846745/2	Jan-20	22/08/2018
INCRUSE ELLIPTA 55MCG INHALER 1 X 30 DOSES	R846745	R846745/3	Jan-20	26/10/2018
INCRUSE ELLIPTA 55MCG INHALER 1 X 30 DOSES	R848815	R848815/2	Feb-20	22/08/2018
INCRUSE ELLIPTA 55MCG INHALER 1 X 30 DOSES	R848815	R848815/3	Feb-20	15/10/2018
INCRUSE ELLIPTA 55MCG INHALER 1 X 30 DOSES	R848815	R848815/4	Feb-20	26/10/2018
INCRUSE ELLIPTA 55MCG INHALER 1 X 30 DOSES	R849465	R849465/2	Feb-20	22/08/2018
INCRUSE ELLIPTA 55MCG INHALER 1 X 30 DOSES	R849465	R849465/3	Feb-20	15/10/2018
INCRUSE ELLIPTA 55MCG INHALER 1 X 30 DOSES	R849465	R849465/4	Feb-20	26/10/2018
INCRUSE ELLIPTA 55MCG INHALER 1 X 30 DOSES	R851918	R851918/2	Mar-20	09/10/2018
INCRUSE ELLIPTA 55MCG INHALER 1 X 30 DOSES	R851918	R851918/3	Mar-20	26/10/2018
INCRUSE ELLIPTA 55MCG INHALER 1 X 30 DOSES	R853231	R853231/1	Mar-20	15/10/2018
INCRUSE ELLIPTA 55MCG INHALER 1 X 30 DOSES	R853231	R853231/2	Mar-20	26/10/2018
INCRUSE ELLIPTA 55MCG INHALER 1 X 30 DOSES	R856773	R856773/1	Jul-20	01/02/2019
INCRUSE ELLIPTA 55MCG INHALER 1 X 30 DOSES	R858970	R858970/1	Aug-20	05/02/2019
INCRUSE ELLIPTA 55MCG INHALER 1 X 30 DOSES	R860226	R860226/1	Aug-20	01/02/2019
NEUPRO 4MG/24HR TRANSDERMAL PATCHES 1 X 28	56659401	56659401/7	Oct-19	28/02/2019
NEUPRO 4MG/24HR TRANSDERMAL PATCHES 1 X 28	56659403	56659403/5	Oct-19	23/05/2018
NEUPRO 4MG/24HR TRANSDERMAL PATCHES 1 X 28	56666402	56666402/9	Nov-19	09/03/2018
NEUPRO 4MG/24HR TRANSDERMAL PATCHES 1 X 28	56666402	56666402/12	Nov-19	23/05/2018
NEUPRO 4MG/24HR TRANSDERMAL PATCHES 1 X 28	56666403	56666403/1	Nov-19	09/03/2018
NEUPRO 4MG/24HR TRANSDERMAL PATCHES 1 X 28	56670401	56670401/2	Dec-19	01/03/2018
NEUPRO 4MG/24HR TRANSDERMAL PATCHES 1 X 28	56670401	56670401/8	Dec-19	23/05/2018
NEUPRO 4MG/24HR TRANSDERMAL PATCHES 1 X 28	56670401	56670401/9	Dec-19	14/06/2018
NEUPRO 4MG/24HR TRANSDERMAL PATCHES 1 X 28	56670401	56670401/11	Dec-19	26/09/2018
NEUPRO 4MG/24HR TRANSDERMAL PATCHES 1 X 28	56679402	56679402/1	Jan-20	14/03/2018



NEUPRO 4MG/24HR TRANDERMAL PATCHES 1 X 28	56679402	56679402/9	Jan-20	13/07/2018
NEUPRO 4MG/24HR TRANDERMAL PATCHES 1 X 28	56679402	56679402/11	Jan-20	22/01/2019
NEUPRO 4MG/24HR TRANDERMAL PATCHES 1 X 28	56688403	56688403/4	Feb-20	23/05/2018
NEUPRO 4MG/24HR TRANDERMAL PATCHES 1 X 28	56688403	56688403/7	Feb-20	28/08/2018
NEUPRO 4MG/24HR TRANDERMAL PATCHES 1 X 28	56688403	56688403/11	Feb-20	22/10/2018
NEUPRO 4MG/24HR TRANDERMAL PATCHES 1 X 28	56688403	56688403/15	Feb-20	22/10/2018
NEUPRO 4MG/24HR TRANDERMAL PATCHES 1 X 28	56695404	56695404/1	Mar-20	24/05/2018
NEUPRO 4MG/24HR TRANDERMAL PATCHES 1 X 28	56695404	56695404/3	Mar-20	11/06/2018
NEUPRO 4MG/24HR TRANDERMAL PATCHES 1 X 28	56695404	56695404/5	Mar-20	12/06/2018
NEUPRO 4MG/24HR TRANDERMAL PATCHES 1 X 28	56695404	56695404/8	Mar-20	22/10/2018
NEUPRO 4MG/24HR TRANDERMAL PATCHES 1 X 28	56695404	56695404/13	Mar-20	22/10/2018
NEUPRO 4MG/24HR TRANDERMAL PATCHES 1 X 28	56699404	56699404/1	Apr-20	14/06/2018
NEUPRO 4MG/24HR TRANDERMAL PATCHES 1 X 28	56699404	56699404/2	Apr-20	22/10/2018
NEUPRO 4MG/24HR TRANDERMAL PATCHES 1 X 28	56699404	56699404/5	Apr-20	21/11/2018
NEUPRO 4MG/24HR TRANDERMAL PATCHES 1 X 28	56699404	56699404/8	Apr-20	31/12/2018
NEUPRO 4MG/24HR TRANDERMAL PATCHES 1 X 28	56699404	56699404/15	Apr-20	31/12/2018
NEUPRO 4MG/24HR TRANDERMAL PATCHES 1 X 28	56699404	56699404/16	Apr-20	31/12/2018
NEUPRO 4MG/24HR TRANDERMAL PATCHES 1 X 28	56712403	56712403/1	Jun-20	31/12/2018
NEUPRO 4MG/24HR TRANDERMAL PATCHES 1 X 28	56712403	56712403/2	Jun-20	21/01/2019
NEUPRO 4MG/24HR TRANDERMAL PATCHES 1 X 28	56712403	56712403/4	Jun-20	18/02/2019
NEUPRO 4MG/24HR TRANDERMAL PATCHES 1 X 28	56712404	56712404/1	Jun-20	10/01/2019
NEUPRO 4MG/24HR TRANDERMAL PATCHES 1 X 28	56712404	56712404/2	Jun-20	24/01/2019
NEUPRO 4MG/24HR TRANDERMAL PATCHES 1 X 28	56712404	56712404/4	Jun-20	18/02/2019
NEUPRO 4MG/24HR TRANDERMAL PATCHES 1 X 28	56722401	56722401/1	Jul-20	18/02/2019
NEUPRO 4MG/24HR TRANDERMAL PATCHES 1 X 28	56728403	56728403/1	Aug-20	18/02/2019



NEUPRO 4MG/24HR TRANSDERMAL PATCHES 1 X 28	56728403	56728403/4	Aug-20	18/02/2019
NEUPRO 4MG/24HR TRANSDERMAL PATCHES 1 X 28	56737110	56737110/1	Sep-20	25/02/2019
NEUPRO 4MG/24HR TRANSDERMAL PATCHES 1 X 28	56742401	56742401/2	Nov-20	28/02/2019
SERETIDE EVOHALER 250MCG 1 X 120 DOSES	K62W	K62W/3	Aug-19	09/02/2018
SPIRIVA 18MCG INHALATION POWDER CAPSULES 1 X30	705605	705605/11	Jul-19	05/06/2018
SPIRIVA 18MCG INHALATION POWDER CAPSULES 1 X30	706803	706803/5	Sep-19	29/05/2018
SPIRIVA 18MCG INHALATION POWDER CAPSULES 1 X30	706803	706803/7	Sep-19	07/06/2018
SPIRIVA 18MCG INHALATION POWDER CAPSULES 1 X30	706803	706803/13	Sep-19	19/07/2018
SPIRIVA 18MCG INHALATION POWDER CAPSULES 1 X30	801497	801497/2	Jan-20	13/07/2018
SPIRIVA 18MCG INHALATION POWDER CAPSULES 1 X30	801497	801497/5	Jan-20	13/08/2018
SPIRIVA 18MCG INHALATION POWDER CAPSULES 1 X30	801497	801497/6	Jan-20	13/08/2018
SPIRIVA 18MCG INHALATION POWDER CAPSULES 1 X30	801500	801500/2	Jan-20	08/08/2018
SPIRIVA 18MCG INHALATION POWDER CAPSULES 1 X30	801932	801932/2	Feb-20	14/06/2018
SPIRIVA 18MCG INHALATION POWDER CAPSULES 1 X30	801932	801932/6	Feb-20	17/07/2018
SPIRIVA 18MCG INHALATION POWDER CAPSULES 1 X30	801932	801932/11	Feb-20	13/08/2018
VIMPAT 100 MG TABLETS 1 X 56	248884	248884/11	Dec-22	05/02/2019
VIMPAT 100 MG TABLETS 1 X 56	252026	252026/5	Jan-23	05/02/2019
VIMPAT 100 MG TABLETS 1 X 56	254265	254265/4	Apr-23	20/02/2019
VIMPAT 100 MG TABLETS 1 X 56	255279	255279/1	Apr-23	20/02/2019

Appendix 2: Table of Products / Batches MPT Pharma Ltd

Products and Pack size	Italian Batch Number	MPT Batch Number	Expiry date	Date of first distribution
NEUPRO 4MG/24H TRANSDERMAL PATCH 1 x 28	56666402	136496	01/11/2019	12/04/2018
NEUPRO 4MG/24H TRANSDERMAL PATCH 1 x 28	56666403	134565	01/11/2019	12/04/2018



NEUPRO 4MG/24H TRANSDERMAL PATCH 1 x 28	56670401	134568	01/12/2019	13/04/2018
NEUPRO 4MG/24H TRANSDERMAL PATCH 1 x 28	56679402	134567	01/01/2020	19/03/2018
DUORESP SPIROMAX 160MCG/4.5MCG 1 x 120	AFB75A	135975	01/04/2020	13/04/2018
INCRUSE ELLIPTA 55mcg INHALER 1 x 30 DOSES	R834141	134561	01/09/2019	21/05/2018

Appendix 3: Table of Products / Batches Doncaster Pharmaceuticals Group Ltd

Neupro 4mg/24 hr Transdermal Patch 1 x 28

EU/1/05/331/005

Italian Batch Number	Doncaster Batch Number	Expiry Date	First Distributed
56688403	56688403/0079	Feb 2020	06/08/2018
56679402	56679402/0079	Jan 2020	17/08/2018
56649401	56649401/0079	Aug 2019	22/08/2018
56695404	56695404/0079	Mar 2020	10/09/2018

Appendix 4: Table of Products / Batches Drugsrus Ltd / P.I.E. Pharma Ltd

Neupro 4mg/24 hr Transdermal Patch 1 x 28

EU/1/05/331/005

Italian Batch Number	Drugsrus Batch Number	Expiry Date	First Distributed
56695404	C23275	Mar 2020	08/04/2019