Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

FMD ALERT*

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy and Wholesaler Level Recall

Date: 16 September 2020 EL (20)A/45 Our Ref: MDR 118-08/20

Dear Healthcare Professional,

Beachcourse Limited

Please see Table 1 for list of products and batch numbers

Orifarm A/S

Please see Table 2 for list of products and batch numbers

OPD Laboratories Limited

Please see Table 3 for list of products and batch numbers

Strathclyde Pharmaceuticals Limited

Please see Table 4 for list of products and batch numbers

Quadrant Pharmaceuticals Limited

Please see Table 5 for list of products and batch numbers

Lexon (UK) Limited

Please see Table 6 for list of products and batch numbers

Brief details of issue:

We have been notified of an issue whereby several affected batches of the products from the above parallel distributors (repackers) have been found to have mismatched unique pack numbers on the bollino label (a security and safety feature on the outer packaging). The unique pack numbers on the bollino label should be identical – see example image below.

Based on the information provided to the MHRA, a wholesaler in Italy has purchased stock from an unauthorised wholesaler. Some of these packs have bollino labels which contain mismatched unique pack numbers.

It is known that a number of parallel distributors have purchased the affected batches and these have been distributed to the UK market. There is no suggestion at this time that any of the UK parallel distributors have knowingly purchased or onward supplied medicines that they knew or believed to be falsified.

However, parallel distributors who have procured the affected batches are recalling these at pharmacy and wholesaler level due to concerns that the supply chain may have been compromised and the origins of the products are unknown.

This case is currently under investigation in collaboration with the Italian authorities – further updates will be published if there are other products which may be impacted.

Advice for healthcare professionals:

Please quarantine all stock from the affected batches which are parallel distributed or repacked by the named companies detailed in the tables below. The name of the parallel distributor/repacker can be found on the product packaging. If you have any affected stock, please return it to your supplier.

Advice for wholesalers:

Please quarantine all stock from the affected batches which are parallel distributed or repacked by the named companies detailed in the tables below, and return the medicines (including those returned from pharmacies) to the named parallel distributor/repacker for further instructions. The name of the parallel distributor/repacker can be found on the product packaging.

Company contacts for further information:

BeachCourse Limited:

For all enquiries please contact Julio Iglesias (Site Manager) at 02088969075 or email julio.bcourse@btconnect.com

Orifarm A/S

For all enquiries please contact:

- Paul Tobin (Responsible Person) at 07583577513 or email paul.tobin@orifarm.com
- Steven Cross (UK Parallel Import Sales Manager) at 07498975920 or email steven.cross@orifarm.com

OPD Laboratories Limited

For all enquiries please contact Vasanth Samson (Quality Assurance Manager /Responsible Person) at 01923332773 or email vasanth@sigmapl.com

Strathclyde Pharmaceuticals Limited

For all enquiries please contact Derek Cochrane (QA Manager) at dcochrane@munro-group.eu

Quadrant Pharmaceuticals Limited

For all enquiries please contact Abdul Butt (Director, Quality & QP) at 07838038063 or email abdul.butt@maxearn.co.uk

Lexon (UK) Limited

For all enquiries please contact Yogesh Patel at yogesh.patel@lexonuk.com

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this notice.

NHS regional teams are asked to forward this alert to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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

*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.

Table 1: Affected products / Beachcourse Limited

Product	EU ref number	Pack Size	Batch Number	Expiry Date
Neupro 4mg/24 hour Transdermal Patches	EU/1/05/331/004 or EU/1/05/331/005	7 or 28	58017123	10/2021

Table 2: Affected products / Orifarm A/S

Product	EU ref number	Pack Size	Batch Number	Expiry Date
Vimpat 100mg Tablets	EU/1/08/470/004 or EU/1/08/470/005	14 or 56	291621	09/2024
Vimpat 100mg Tablets	EU/1/08/470/004 or EU/1/08/470/005	14 or 56	295851	12/2024
Vimpat 100mg Tablets	EU/1/08/470/004 or EU/1/08/470/005	14 or 56	296212	10/2024

Table 3: Affected products / OPD Laboratories Limited

Product	EU ref number	Pack Size	Batch Number	Expiry Date
Vimpat 100mg Tablets	EU/1/08/470/004 or EU/1/08/470/005	14 or 56	258582	06/2023
Vimpat 100mg Tablets	EU/1/08/470/004 or EU/1/08/470/005	14 or 56	259249	06/2023
Vimpat 100mg Tablets	EU/1/08/470/004 or EU/1/08/470/005	14 or 56	267862	08/2023

Table 4: Affected products / Strathclyde Pharmaceuticals Limited (repacked by Munro Wholesale Medical Supplies Limited)

Product	EU ref number	Pack Size	Batch Number	Expiry Date
Vimpat 100mg Tablets	EU/1/08/470/004 or EU/1/08/470/005	14 or 56	267525	10/2023
Vimpat 100mg Tablets	EU/1/08/470/004	14 or 56	267862	08/2023

	or EU/1/08/470/005			
Vimpat 100mg Tablets	EU/1/08/470/004 or EU/1/08/470/005	14 or 56	267863	10/2023
Vimpat 100mg Tablets	EU/1/08/470/004 or EU/1/08/470/005	14 or 56	263100	08/2023
Vimpat 100mg Tablets	EU/1/08/470/004 or EU/1/08/470/005	14 or 56	258582	06/2023
Neupro 4mg/24 hour Transdermal Patches	EU/1/05/331/004 or EU/1/05/331/005	7 or 28	58033101	03/2022

Table 5: Affected products / Quadrant Pharmaceuticals Limited (repacked by Maxearn Limited)

Product	EU ref number	Pack Size	Batch Number	Expiry Date
Neupro 4mg/24 hour Transdermal Patches	EU/1/05/331/004 or EU/1/05/331/005	7 or 28	58033101	03/2022

Table 6: Affected products / Lexon (UK) Limited

Product	EU ref number	Pack Size	Batch Number	Expiry Date
Neupro 4mg/24 hour Transdermal Patches	EU/1/05/331/004 or EU/1/05/331/005	7 or 28	58017123	10/2021
Neupro 4mg/24 hour Transdermal Patches	EU/1/05/331/004 or EU/1/05/331/005	7 or 28	58030102	01/2022
Neupro 4mg/24 hour Transdermal Patches	EU/1/05/331/004 or EU/1/05/331/005	7 or 28	58033103	03/2022
Neupro 4mg/24 hour Transdermal Patches	EU/1/05/331/004 or EU/1/05/331/005	7 or 28	58037101	04/2022