Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

FMD ALERT*

CLASS 4 MEDICINES INFORMATION

Caution In Use
Distribute to Wholesaler/Pharmacy Level

Date: 01 September 2020 EL (20)A/42 Our Ref: MDR 101-08/20

Dear Wholesalers and Healthcare Professional,

Kingsley Specials Ltd

Brief description of the problem

The MHRA is currently investigating an incident where several medicines appear to have left the legal supply chain and have then been re-introduced via Kingsley Specials Ltd WDA(H) 49276, who purchased from a company that does not hold a wholesale dealers authorisation and then sold it on to a number of other wholesalers.

The products do appear to be genuine with legitimate batch numbers and safety features. These products are thought to have left the legitimate supply chain and been reintroduced between March and August 2020. This means that the correct transport and storage conditions cannot be guaranteed and while unlikely, could impact their effectiveness.

Only the products mentioned below are within the scope of this alert. Please follow the advice below if you have received any of these products listed in appendix 1, from:

- **WDA(H) 42332 Smartway Pharmaceuticals Limited**
- **WDA(H) 20912 Drugsrus Limited**
- **WDA(H) 48028 Optimal Pharma Limited**

Please note, the above wholesalers did not procure the products listed below directly from Kingsley Specials Ltd. These products were sold onwards by intermediate companies and the companies listed above are not implicated of any wrongdoing and are co-operating with the MHRA to resolve the matter.

Advice for healthcare professionals

Please check your stocks of all the listed products for the relevant batches supplied from the above companies. If any relevant packs are identified, please quarantine and notify the DMRC/MHRA.

The above wholesalers have implemented safety measures by decommissioning the impacted packs, changing the status to STOLEN/INACTIVE in the National Medicines Verification System (NMVS). When scanning the serialised 2D code, the status of packs will report as ‘STOLEN’ and/or ‘INACTIVE.’ These products have been shared with other wholesalers prior to procurement at pharmacy level, therefore please check with your supplier directly for more information of affected packs.

- **Healthcare professionals involved in dispensing these products listed below, should ensure that appropriate scanning takes place at the point of dispensing/good received to highlight packs that may be impacted by this issue. Where they report as being ‘STOLEN’ and/or ‘INACTIVE’, they should not be dispensed. You should quarantine and notify the DMRC/MHRA.**

- **Where there is no ability for scanning, healthcare professionals and wholesalers should consider using the unique serial number (SN) and/or product code (PC)/Global Trade Item Number (GTIN) information available on the outer packaging of the product. This**

information has been provided in Appendix 2 and is available on request from DMRC in other formations, if required.

Advice for wholesalers

The above wholesalers, Smartway Pharmaceuticals Ltd, Drugsrus Ltd and Optimal Pharma Ltd, have traceability for the affected stock which they have supplied and will provide appropriate reimbursement for stock which they have sold in accordance with their own procedures.

- **When contacted by the above wholesalers, regarding the affected products, immediately stop supplying the products; quarantine all remaining stock and hold it pending further instruction from the respective companies.**

The above wholesalers have implemented safety measures by decommissioning the impacted packs, changing the status to STOLEN in the National Medicines Verification System. When scanning the serialised 2D code, the status of packs will report as 'STOLEN' and/or 'INACTIVE.'

Company contacts for further information

Smartway Pharmaceuticals Limited
- Email: regulatory@smartwaypharma.co.uk
- Telephone: 020 8545 7743

Drugsrus Limited
- Email: recall@drugsrus.co.uk
- Telephone: 020 3397 2347

Optimal Pharma Limited
- Email: info@optimalpharma.co.uk
- Telephone: 020 3884 0032

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.

Appendix 1 – Batch data, specific serial numbers/product codes are listed in Appendix 2.

Eliquis 2.5 mg film-coated tablets (apixaban)

EU/1/11/691/003

Wholesaler	Batch Number	Expiry Date	Pack Size	First Distributed
Drugsrus Ltd	ABF5980	31/12/2021	60	22/06/2020
Drugsrus Ltd	ABF6042	31/12/2021	60	22/06/2020
Drugsrus Ltd	ABG1454	31/12/2021	60	22/06/2020
Drugsrus Ltd	ABG1455	31/12/2021	60	22/06/2020
Drugsrus Ltd	ABG1774	31/01/2022	60	22/06/2020
Drugsrus Ltd	ABG1777	31/01/2022	60	22/06/2020
Drugsrus Ltd	ABH0620	31/03/2022	60	22/06/2020
Drugsrus Ltd	ABH0984	31/03/2022	60	22/06/2020
Drugsrus Ltd	ABH4133	30/04/2022	60	22/06/2020
Drugsrus Ltd	ABH4337	31/03/2022	60	22/06/2020
Drugsrus Ltd	ABH4340	28/02/2022	60	22/06/2020
Drugsrus Ltd	ABJ8246	31/05/2022	60	22/06/2020
Drugsrus Ltd	ABJ8737	31/05/2022	60	13/07/2020
Smartway Pharmaceuticals Ltd	ABG1774	31/01/2022	60	15/06/2020
Smartway Pharmaceuticals Ltd	ABG1454	31/12/2021	60	15/06/2020
Smartway Pharmaceuticals Ltd	ABH0620	31/03/2022	60	11/06/2020
Smartway Pharmaceuticals Ltd	ABG1455	31/12/2021	60	26/06/2020

Eliquis 5 mg film-coated tablets (apixaban)

EU/1/11/691/008

Wholesaler	Batch Number	Expiry Date	Pack Size	First Distributed
Drugsrus Ltd	ABH5800	31/05/2022	56	14/08/2020
Drugsrus Ltd	ABK9719	31/08/2022	56	14/08/2020
Drugsrus Ltd	ABL0091	31/08/2022	56	14/08/2020
Drugsrus Ltd	ABL0120	31/08/2022	56	14/08/2020
Smartway Pharmaceuticals Ltd	ABH2809	30/04/2022	56	20/04/2020
Smartway Pharmaceuticals Ltd	ABJ6933	30/06/2022	56	20/04/2020
Smartway Pharmaceuticals Ltd	ABH6037	31/05/2022	56	20/04/2020
Smartway Pharmaceuticals Ltd	ABH4811	30/04/2022	56	20/04/2020
Smartway Pharmaceuticals Ltd	ABJ3373	31/05/2022	56	20/04/2020
Smartway Pharmaceuticals Ltd	ABG0822	28/02/2022	56	20/04/2020

Entyvio 300 mg powder for concentrate for solution for infusion (vedolizumab)

EU/1/14/923/001

Wholesaler	Batch Number	Expiry Date	Pack Size	First Distributed
Optimal Pharma Ltd	11784526	May-22	1	17/07/2020
Optimal Pharma Ltd	11860508	Oct-22	1	17/07/2020
Optimal Pharma Ltd	11815304	Jun-22	1	09/07/2020

Flutiform 250 microgram/10 microgram per actuation pressurised inhalation, suspension
(fluticasone propionate/formoterol fumarate dihydrate)

PL 16950/0169

Wholesaler	Batch Number	Expiry Date	Pack Size	First Distributed
Smartway Pharmaceuticals Ltd	9H162FB	Oct-21	120 doses	05/05/2020

Privigen 20 g - 100 mg/ml solution for infusion
(Human normal immunoglobulin IVIg)

EU/1/08/446/003

Wholesaler	Batch Number	Expiry Date	Pack Size	First Distributed
Optimal Pharma Ltd	P100164906	Oct-22	200ml	10/07/2020
Smartway Pharmaceuticals Ltd	P100164896	Oct-22	200ml	30/05/2020
Smartway Pharmaceuticals Ltd	P100164906	Oct-22	200ml	27/06/2020
Smartway Pharmaceuticals Ltd	P100175026	Nov-22	200ml	37/07/2020

Seretide Evohaler 25 microgram/125 microgram per metered dose pressurised inhalation, suspension
(salmeterol/fluticasone propionate)

PL 10949/0338

Wholesaler	Batch Number	Expiry Date	Pack Size	First Distributed
Drugsrus Ltd	NK3E	28/02/2022	120 doses	15/07/2020
Smartway Pharmaceuticals Ltd	MY8U	30/09/2021	120 doses	04/06/2020
Smartway Pharmaceuticals Ltd	KT5T	30/09/2021	120 doses	04/06/2020
Smartway Pharmaceuticals Ltd	LC5L-1	30/09/2021	120 doses	17/07/2020

Seretide Evohaler 25 microgram/250 microgram per metered dose pressurised inhalation, suspension
(salmeterol/fluticasone propionate)

PL 10949/0339

Wholesaler	Batch Number	Expiry Date	Pack Size	First Distributed
Drugsrus Ltd	KV4U	28/02/2022	120 doses	09/07/2020
Drugsrus Ltd	PE4T	31/03/2022	120 doses	09/07/2020
Drugsrus Ltd	K32A	30/09/2021	120 doses	22/04/2020
Drugsrus Ltd	K32G	30/09/2021	120 doses	25/04/2020

Stelara 45 mg solution for injection in pre-filled syringe
(Ustekinumab)

EU/1/08/494/003

Wholesaler	Batch Number	Expiry Date	Pack Size	First Distributed
Smartway Pharmaceuticals Ltd	JDS0NMW	Mar-22	1 PFS	29/05/2020

Stelara 90 mg solution for injection in pre-filled syringe
(Ustekinumab)

EU/1/08/494/004

Wholesaler	Batch Number	Expiry Date	Pack Size	First Distributed
Smartway Pharmaceuticals Ltd	JIS27MC	Aug-22	1 PFS	30/05/2020

Stelara 130 mg concentrate for solution for infusion **EU/1/08/494/005**
(Ustekinumab)

Wholesaler	Batch Number	Expiry Date	Pack Size	First Distributed
Optimal Pharma Ltd	JKS2D02	Oct-22	1 vial	08/07/2020
Smartway Pharmaceuticals Ltd	JGS2I09	Jun-22	1 vial	30/05/2020
Smartway Pharmaceuticals Ltd	JGS2I02	Jun-22	1 vial	30/05/2020
Smartway Pharmaceuticals Ltd	JKS2D02	Oct-22	1 vial	20/06/2020

Symbicort® Turbohaler® 200 micrograms/6micrograms inhalation, inhalation powder **PL 17901/0092**
(Ustekinumab)

Wholesaler	Batch Number	Expiry Date	Pack Size	First Distributed
Smartway Pharmaceuticals Ltd	SLEE	Dec-21	120 doses	04/06/2020
Smartway Pharmaceuticals Ltd	SLEW	Dec-21	120 doses	04/06/2020
Smartway Pharmaceuticals Ltd	SLED	Dec-21	120 doses	04/06/2020
Smartway Pharmaceuticals Ltd	SLEM	Dec-21	120 doses	04/06/2020
Smartway Pharmaceuticals Ltd	SLFC	Dec-21	120 doses	04/06/2020
Smartway Pharmaceuticals Ltd	SLAN	Oct-21	120 doses	04/06/2020
Smartway Pharmaceuticals Ltd	SLBE	Oct-21	120 doses	04/06/2020
Smartway Pharmaceuticals Ltd	SLAM	Oct-21	120 doses	04/06/2020
Smartway Pharmaceuticals Ltd	SLBF	Oct-21	120 doses	10/06/2020
Smartway Pharmaceuticals Ltd	SLEE	Dec-21	120 doses	04/06/2020
Smartway Pharmaceuticals Ltd	SLEW	Dec-21	120 doses	04/06/2020
Smartway Pharmaceuticals Ltd	SLED	Dec-21	120 doses	04/06/2020

Synagis 100 mg/1 ml solution for injection **EU/1/99/117/004**
(palivizumab)

Wholesaler	Batch Number	Expiry Date	Pack Size	First Distributed
Smartway Pharmaceuticals Ltd	383476	Nov-21	1	31/07/2020

Tysabri 300 mg concentrate for solution for infusion **EU/1/06/346/001**
(natalizumab)

Wholesaler	Batch Number	Expiry Date	Pack Size	First Distributed
Smartway Pharmaceuticals Ltd	1425558	06-2023	1	19/06/2020
Smartway Pharmaceuticals Ltd	1426088	05-2022	1	30/06/2020
Smartway Pharmaceuticals Ltd	1425556	05-2023	1	21/07/2020

Zebinix 800mg tablets **EU/1/09/514/013**
(eslicarbazepine acetate)

Wholesaler	Batch Number	Expiry Date	Pack Size	First Distributed
Smartway Pharmaceuticals Ltd	190329	Jun-24	30	09/04/2020
Smartway Pharmaceuticals Ltd	190142	Apr-24	30	09/04/2020

Appendix 2 – Serial Numbers/Product Codes (PC/GTIN)

Please see attached spreadsheet containing the Serial Numbers/Product Codes (PC/GTIN), which can be used for manual checks to identify affected products.

The attached information is available as a separate document at the bottom of the alert on the website and Central Alerting System (CAS). Please contact DMRC@mhra.gov.uk if you unable to access the document.

This documentation has also been attached/embedded into this PDF document.



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Appendix 2 - Serial N