Vertex Pharmaceuticals (Europe) Ltd
2 Kingdom Street
London W2 6BD
United Kingdom
Tel: +44 (0)203 204 5100

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DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Kaftrio 75mg/50mg/100mg (ivacaftor/tezcaftor/elexacaftor) and Kalydeco 50mg, 75mg and 150mg film coated tablets (ivacaftor):

Temporary Supply of stock to UK(NI) with blue box referencing Ireland only.

Dear Healthcare Professional,

Vertex Pharmaceuticals (Europe) Limited in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA) would like to inform you of the following:

Summary: Vertex Pharmaceuticals (Europe) Limited is supplying Kaftrio and Kalydeco with the the incorrect blue box information. UK(NI) is not referenced on the blue box.

Please note the following:

- This product is considered licensed in the UK (Northern Ireland).
- The product from Ireland has the same formulation as the UK (Northern Ireland) product
- The product from Ireland is manufactured according to the same manufacturing process and quality controls as the UK(Northern Ireland) product.
- The adverse reporting that is stated in the Irish PIL is applicable for Northern Ireland.
- The leaflet in the pack is applicable for Northern Ireland.
- The MHRA has agreed to an exemption according to Article 63(3) of Council Directive 2001/83/EC, from the obligation that certain particulars should appear on the outer and immediate packaging of the products listed in the table below.

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to the patients.

Background

Currently Northern Ireland is supplied with combined packs with Ireland. However, the batches listed in the table below have been released for Northern Ireland but the blue box was not updated to include Northern Ireland. The only difference between the Ireland and the Northern Ireland is in the blue box information, Northern Ireland is not referenced within the blue box, all other details remain the same.

To ensure continuity of supply Vertex has been authorised by the MHRA to temporarily supply Northern Ireland with the stock listed in the table below.

This is only a temporary measure and will only impact orders placed until June 2023 after which the blue box information will be updated to include UK(IE).

Product Name	Batch No	Expiry Date	QP Released
Kalydeco 50mg tablets 56 IE	W060102AR	29.02.2024	22.12.2021
Kalydeco 75mg tablets 56 IE	W060103AR	29.02.2024	06.01.2022
Kaftrio 75/50/100mg tablets 56 IE	W065402E	30.11.2023	30.05.2022
Kalydeco 150mg tablets 56 IE	M002035A	29.02.2024	31.01.2022
Kalydeco 150mg tablets 28 IE	M001562D	31.10.2024	20.01.2022

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website https://yellowcard.mhra.gov.uk/, the free Yellow Card app available from the Apple App Store or Google Play Store, and some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals. Suspected side effects can also be reported by calling 0800 731 6789 for free.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, treatment dates, and product brand name.

Company contact point

If you have any questions about this letter or require more information about Kaftrio or Kalydeco please contact the Vertex Medical Information team at vertexmedicalinfo@vrtx.com or +44 203 871 8772.

Please do not hesitate to contact us if you have any questions regarding this letter.

Yours faithfully,

Sonia Morjaria
Associate Director, UK & Ireland Regulatory Affairs
Vertex Pharmaceuticals (Europe) Ltd.
2, Kingdom Street, London, W2 6BD, UK
Mob: +44 (0) 7568611474
Email: sonia_morjaria@vrtx.com