NHS England South West

All Chief Executives

All Medical Directors

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Dear Colleagues,

RE: Oxbryta (voxelotor): Withdrawal from UK market

I am writing to advise you regarding the withdrawal of the sickle cell treatment, Oxbryta (voxelotor), from the UK market.

Pfizer Limited, in agreement with the Medicines Healthcare products Regulatory Agency (MHRA), has withdrawn the product, while a review of the benefits and risks is carried out.

The withdrawal follows emerging clinical data from clinical trials and registry-based studies suggesting an unfavourable imbalance in the number of vaso-occlusive crises and fatal events in patients treated with voxelotor.

Pfizer Limited, in a letter to healthcare professionals, has stated that:

- ***New patients should not start treatment with Oxbryta.***
- ***Physicians should contact patients currently on treatment with Oxbryta to discontinue treatment, and where appropriate to discuss alternative treatment options with them. Physicians should instruct their patients to return the product to the hospital pharmacy or homecare company that dispensed it.***
- ***Physicians should continue to monitor patients for adverse events after their treatment with Oxbryta is discontinued and ensure appropriate follow-up as needed.***

As a result of the withdrawal, the MHRA has issued a Class 2 Medicines Recall. The recall asks that treatment teams stop supplying the above product immediately. Remaining stock should be quarantined and returned to the supplier using the supplier's approved processes.

Physicians, specialist prescribers, homecare company providers or any other healthcare professional responsible for prescribing voxelotor should contact all patients undergoing treatment and advise them to discontinue treatment and, where appropriate, discuss alternative treatment options. Patients should be instructed to return the product to the

hospital pharmacy or homecare company that dispensed it.

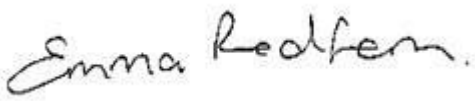
Any enquiries related to the recall should be directed to Pfizer Limited at: https://www.pfizermedicalinformation.co.uk/ or telephone 01304 616161.

Clinicians are advised to follow the instructions in the recall notice and healthcare professional letter. Prescribers will be required to discuss alternative management options with existing patients.

Further updates on the Marketing Authorisation of voxelotor will be provided by the MHRA in due course and any changes to NICE guidance will follow MHRA's decision.

I would be grateful if you could cascade this information to relevant clinical teams within your organisation to support the consistent adoption of the above nationally.

With best wishes,



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