<Date>

Oxbryta ▼ (voxelotor): Suspension of EU marketing authorisation

Dear Healthcare Professional,

Pfizer Europe MA EEIG in agreement with the European Medicines Agency and <National competent authority> would like to inform you of the following while a European review of the benefits and risks of Oxbryta is carried out:

Summary

- **The marketing authorisation for Oxbryta is suspended in the European Union as a precautionary measure while the review of the benefits and risks of Oxbryta is ongoing.**

- **All batches of Oxbryta are being recalled in the European Union.**

- **The use of Oxbryta in clinical trials and in early access programs is also being discontinued by the marketing authorisation holder.**

- **The suspension follows emerging clinical data from 2 registry-based studies suggesting an imbalance in the number of vaso-occlusive crises before and after initiation of the treatment with voxelotor, and fatal events on voxelotor in clinical trials.**

- **No new patients should start treatment with Oxbryta.**

- **Physicians should contact patients currently on treatment with Oxbryta to discontinue treatment and discuss alternative treatment options with them.**

- **Physicians should continue to monitor patients for adverse events after their treatment with Oxbryta is discontinued and ensure appropriate follow-up as needed as possible complications when treatment is interrupted abruptly cannot be excluded, but neither efficacy nor a dose for gradual discontinuation have been established.**

Background Information

Oxbryta is authorized in the EU for the treatment of haemolytic anaemia due to sickle cell disease (SCD) in adults and paediatric patients 12 years of age and older as monotherapy or in combination with hydroxycarbamide.

In July 2024, EMA started an EU-wide review of Oxbryta. This was triggered by data from ongoing clinical trials which showed that a higher number of deaths occurred with Oxbryta than with placebo in one trial and the total number of deaths was higher than anticipated in another trial.

Emerging data from two registry-based studies in the United States show an increase in vaso-occlusive crises (VOC) in patients who started treatment with the medicine. Studies data collection and analysis is continuing.

In view of these newly emerging data the marketing authorisation for Oxbryta is suspended in the European Union, until these data are assessed in detail in the ongoing review. EMA is further investigating the implication of these findings for the currently authorised use of Oxbryta.

In the meantime the product is being withdrawn from the market at this time. All ongoing clinical trials and early access programs are also being discontinued.

Patients should no longer be prescribed Oxbryta. Physicians should contact patients currently on treatment with Oxbryta to stop treatment and discuss alternative treatment options.

Physicians should continue to monitor patients for adverse events after their treatment with Oxbryta is discontinued and ensure appropriate follow-up as needed as possible complications when treatment is interrupted abruptly cannot be excluded, but neither efficacy nor a dose for gradual discontinuation have been established.

Other healthcare professionals who receive any questions from patients currently prescribed Oxbryta should direct these patients to their prescriber.

Further advice will be communicated as appropriate at the end of the review.

Call for reporting

[Insert reminder of the need and how to report adverse reactions, including post discontinuation, in accordance with the national spontaneous reporting system, including the details (e.g. name, postal address, fax number, website address) on how to access the national spontaneous reporting system. For biological medicinal products, also include a reminder to report the product name and batch details. Mention if product is subject to additional monitoring and the reasons why]

Company contact point

[Insert contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address]

DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Oxbryta (voxelotor)
Marketing authorisation holder(s)	Pfizer Europe MA EEIG
Safety concern and purpose of the communication	Oxbryta (voxelotor): suspension of the marketing authorisation in the EU
DHPC recipients	Haematologists. Additional healthcare professionals such as specialized primary care physicians, community and hospital pharmacists, emergency units, may also be notified in individual Member States during national implementation depending on health care systems.
Member States where the DHPC will be distributed	European Union Member States where Oxbryta is commercially available or available through Early Access Programs (France, Germany, Italy, Netherlands, Denmark, Finland, Greece, Spain, Sweden, Austria, Cyprus)

Timetable	Date
DHPC and communication plan (in English) agreed by CHMP	**26 September 2024**
Submission of translated DHPCs to the national competent authorities for review	**30 September 2024**
Agreement of translations by national competent authorities	**01 October 2024**
Dissemination of DHPC	**07 October 2024**