29 July 2024
EMA/CHMP/350070/2024
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Agenda for the extraordinary meeting

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

29 July 2024, 10:00 -12:00 virtual meeting

Disclaimers

Some of the information contained in this agenda is considered commercially confidential or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. Additional details on some of these procedures will be published in the CHMP meeting highlights once the procedures are finalised and start of referrals will also be available.

Of note, this agenda is a working document primarily designed for CHMP members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the agenda cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which, a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

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1. Introduction

1.1. Welcome and declarations of interest of members, alternates and experts

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CHMP extraordinary meeting to be held on 29 July 2024.

1.2. Adoption of agenda

CHMP agenda for extraordinary CHMP meeting to be held on 29 July 2024.

2. Referral procedures

2.1. Procedure for Centrally Authorised products under Article 20 of Regulation (EC) No 726/2004

2.1.1. Oxbryta - Voxelotor - EMEA/H/A-20/1538/C/004869/0014

Pfizer Europé Ma EEIG

Referral Rapporteur: TBC, Referral Co- Rapporteur: TBC

Scope: Appointment of Rapporteurs, Timetable, Questions to the MAH

Action: For adoption

The EC initiated a procedure under Article 20 of Regulation (EC) No 726/2004 to assess the benefit-risk balance of Oxbryta in its authorised indication. The initiation of the review follows an imbalance of deaths between voxelotor and placebo observed in clinical trials. The findings from these emerging safety data need to be further reviewed, taking into account all available data, to determine whether there is an impact on the benefit-risk balance of Oxbryta in its authorised indication.
In addition, the EC requests the Agency to give its opinion, as soon as possible, as to whether temporary measures are necessary to ensure the safe and effective use of this medicinal product.

2.1.2. Ocaliva - obeticholic acid - EMEA/H/A-20/1531

Advanz Pharma Limited

Referral Rapporteur: Carolina Prieto Fernandez, Referral Co-Rapporteur: Paolo Gasparini

Scope: Update on the procedure

Action: For discussion

The European Commission (EC) initiated a procedure under Article 20 of Regulation (EC) No 726/2004 and requested the Agency/CHMP to assess the benefit-risk balance of Ocaliva (obeticholic acid). The review was prompted by final study results raising concerns of a potential lack of efficacy and worsened safety profile. These findings need to be reviewed in

the context of all available data and their potential impact on the benefit-risk of Ocaliva assessed.

Negative opinion adopted on 27.06.2024. List of outstanding issues adopted on 25.01.2024. List of Questions adopted on 12.10.2023.

3. Any other business

3.1. AOB topic

No items