29 January 2026
EMADOC-1700519818-2855720

CHMP List of questions

To be addressed by the marketing authorisation holder(s) for Tavneos

Procedure under Article 20 of Regulation (EC) No 726/2004

Procedure number: EMA/REF/0000325221

INN/active substance: avacopan

Marketing authorisation holder(s): Vifor Fresenius Medical Care Renal Pharma France

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The marketing authorisation holder (MAH) is requested to address the following questions:

Question 1

The MAH should provide the marketing status and patient exposure to avacopan dichloride in European Union (EU) Member States (MS), Iceland, and Norway, and worldwide:

a. since the data lock point (DLP) of the latest concluded periodic safety update report single assessment (PSUSA);

b. yearly since Tavneos's first approval.

This should include data from completed and ongoing studies and all post-marketing sources.

Question 2

The MAH is requested to describe in a detailed, clear, and precise manner the handling of the database for the ADVOCATE study prior to the regulatory approval of Tavneos in the EU.

In this context, the MAH should:

a. provide the detailed sequence of events with dates, responsibilities and tasks done, including but not limited to the details of database lock(s) and unblinding process used in the trial, and the quality control process for any changes in the data after the database lock(s). Details of the unblinded sponsor personnel should be also provided (title and role in the clinical trial, when unblinded, what data they had access to and the justification for this). Additionally, details on the generation and content of unblinded initial/summary results should be submitted, together with a description of the information provided to the blinded, independent Adjudication Committee after the database lock(s), including the timing and the personnel involved;

b. describe the consistency of the data handling with the pre-specified protocol and statistical analysis plan provided to the regulatory authorities and provide the MAH's position on whether any deviations from the protocol were transparently disclosed;

c. provide full supporting documentation, including the study results analysis plan (SRAP).

Question 3

The MAH should share any relevant information that was requested by, provided to or received from other regulatory agencies, and details of any completed or ongoing regulatory submission or action, related to the data handling and/or any other considerations pertaining to the ADVOCATE study, and the detailed reasons for said actions.

Question 4

The MAH should provide a critical appraisal of the overall impact of the above information on the benefit-risk balance of Tavneos in the authorised indication.