17 December 2015
EMA/32587/2016
Committee for Medicinal Products for Human Use (CHMP)

Assessment report

Caspofungin Accord

International non-proprietary name: caspofungin

Procedure No. EMEA/H/C/004134/0000

Note

Assessment report as adopted by the CHMP with all information of a commercially confidential nature deleted.

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List of abbreviations

ASMF	Active Substance Master File
CHMP	Committee for Medicinal Products for Human use
cfu	Colony Forming Units
CQA	Critical Quality Attribute
EC	European Commission
GC	Gas Chromatography
HPLC	High performance liquid chromatography
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IPC	In-process control
ICP-MS	Inductively coupled plasma mass spectrometry
IR	Infrared
IV	Intra-venous
KF	Karl Fischer titration
LCMS	Liquid chromatography mass spectrometry
MAH	Marketing Authorisation holder
MS	Mass Spectrometry
NMR	Nuclear Magnetic Resonance
NMT	Not more than
Ph. Eur.	European Pharmacopoeia
ppm	parts per million
QTPP	Quality target product profile
RRT	Relative retention time
SmPC	Summary of Product Characteristics
USP	United States Pharmacopoeia
UV	Ultraviolet
WCB	Working Cell Bank

1. Background information on the procedure

1.1. Submission of the dossier

The applicant Accord Healthcare Ltd submitted on 6 March 2015 an application for Marketing Authorisation to the European Medicines Agency (EMA) for Caspofungin Accord, through the centralised procedure under Article 3(3) of Regulation (EC) No. 726/2004– 'Generic of a Centrally authorised product'. The eligibility to the centralised procedure was agreed upon by the EMA/CHMP on 18 December 2014.

The application concerns a generic medicinal product as defined in Article 10(2)(b) of Directive 2001/83/EC and refers to a reference product for which a Marketing Authorisation is or has been granted in in the Union on the basis of a complete dossier in accordance with Article 8(3) of Directive 2001/83/EC.

The applicant applied for the following indications:

- Treatment of invasive candidiasis in adult patients;
- Treatment of invasive aspergillosis in adult patients who are refractory to or intolerant of amphotericin B, lipid formulations of amphotericin B and/or itraconazole. Refractoriness is defined as progression of infection or failure to improve after a minimum of 7 days of prior therapeutic doses of effective antifungal therapy;
- Empirical therapy for presumed fungal infections (such as Candida or Aspergillus) in febrile, neutropaenic adult patients.

The legal basis for this application refers to:

Generic application (Article 10(1) of Directive No 2001/83/EC).

The chosen reference product is:

- Medicinal product which is or has been authorised in accordance with Community provisions in accordance with Community provisions in force for not less than 6/10 years in the EEA:
  - Product name, strength, pharmaceutical form: CANCIDAS, 50 mg and 70 mg, powder for concentrate for solution for infusion
  - Marketing authorisation holder: Merck Sharp & Dohme Ltd, United Kingdom
  - Date of authorisation: 24-10-2001
  - Marketing authorisation granted by:
    - Community
      Community Marketing authorisation number: EU/1/01/196/001 (50 mg); EU/1/01/196/003 (70 mg)

- Medicinal product authorised in the Community/Members State where the application is made or European reference medicinal product:
  - Product name, strength, pharmaceutical form: CANCIDAS, 50 mg and 70 mg, powder for concentrate for solution for infusion
  - Marketing authorisation holder: Merck Sharp & Dohme Ltd, United Kingdom
  - Date of authorisation: 24-10-2001
  - Marketing authorisation granted by:
    - Community
      Community Marketing authorisation number: EU/1/01/196/001 (50 mg); EU/1/01/196/003 (70 mg)

- Medicinal product which is or has been authorised in accordance with Community provisions in force and to which bioequivalence has been demonstrated by appropriate bioavailability studies:

N/A (this medicinal product is a parenteral preparation. Therefore a bioequivalence study is not applicable according to CPMP/EWP/QWP/1401/98 Rev.1)

Information on paediatric requirements

Not applicable

Licensing status

The product was not licensed in any country at the time of submission of the application.

1.2. Steps taken for the assessment of the product

The Rapporteur appointed by the CHMP was:

Rapporteur: Karsten Bruins Slot

- The application was received by the EMA on 6 March 2015.
- The procedure started on 26 March 2015.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 12 June 2015.
- PRAC RMP Advice and assessment overview, adopted by PRAC on 9 July 2015.
- During the meeting on 23 July 2015, the CHMP agreed on the consolidated List of Questions to be sent to the applicant. The final consolidated List of Questions was sent to the applicant on 27 July 2015.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 21 August 2015.
- The Rapporteur circulated the Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 25 September 2015.
- PRAC RMP Advice and assessment overview, adopted by PRAC on 8 October 2015.
- During the CHMP meeting on 22 October 2015, the CHMP agreed on a list of outstanding issues to be addressed in writing by the applicant.
- The applicant submitted the responses to the CHMP consolidated List of Outstanding Issues on 17 November 2015.
- Rapporteur assessment report on the responses provided by the applicant, dated 1 December 2015.
- PRAC RMP Advice and assessment overview, adopted by PRAC on 3 December 2015.
- During the meeting on 17 December 2015, the CHMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive opinion for granting a Marketing Authorisation to Caspofungin Accord.

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