March 2022

Public assessment summary report

Name of the Finished Pharmaceutical Product	Hemlibra 30 mg/mL solution for injection Hemlibra 150 mg/mL solution for injection Hemlibra 60 mg/0.4mL solution for injection Hemlibra 105 mg/0.7mL solution for injection
Manufacturer of the Finished Product	Chugai Pharma Manufacturing Co., Ltd. (CPMC), 16-3, KiyoharaKogyodanchi Utsunomiya City, Tochigi, 321-3231 Japan
License holder	F. Hoffman-La Roche Ltd, Grenzacherstrasse 124, CH-4070, Basel Switzerland
Active Pharmaceutical Ingredient (API)	Emicizumab

1. Introduction

Based on review of quality, safety and efficacy data through the Abbreviated approval procedure, the authority granted a marketing authorization for Hemlibra150 mg/mL solution for injection, Hemlibra 60 mg/0.4mL solution for injection, Hemlibra 105 mg/0.7mL solution for injection and Hemlibra 30 mg/mL solution for injection, manufactured by Chugai Pharma Manufacturing Co., Ltd. (CPMC), Japan.

The active ingredient of Hemlibra is Emicizumab. Emicizumab is in a class of medications called antihemorrhagics, other systemic hemostatics (ATC code: B02BX06).

The product is indicated for: routine prophylaxis of bleeding episodes in patients with Haemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors.
A compressive description of the indications and posology is given in the SmPC.

2. Assessment of quality

GMP compliance of the API manufacture was demonstrated by document review. The necessary waiver for cGMP of the finished pharmaceutical product has been carried out. Marketing

authorization was granted by the stringent regulatory authority (SRA) and appropriate verification of marketing authorization was performed.

Stability testing:
It is confirmed that the finished product stability studies were conducted in the container closure system proposed for the marketing of the product in accordance with the current medicine registration guideline of Ethiopia.

Based on the stability study results, a shelf-life of 30 months with storage conditions "*Store in a refrigerator (2 to 8°C), unopened vials can be kept at room temperature (below 30°C) for up to 7 days"*was proposed. The product stability testing data support the current shelf life and storage conditions of the product.

3. Conclusion

Based on assessment of administrative and technical document, it is considered that the benefit–risk profile of Hemlibra150 mg/mL solution for injection, Hemlibra 60 mg/0.4mL solution for injection, Hemlibra 105 mg/0.7mL solution for injection and Hemlibra 30 mg/mL solution for injection manufactured by Chugai Pharma Manufacturing Co., Ltd. (CPMC), Japan are acceptable for the following indications: forroutine prophylaxis of bleeding episodes in patients with Haemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors.