14 December 2023
EMA/CHMP/509232/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion

Arpraziquantel

arpraziquantel

On 14 December 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion in accordance with Article 58 of Regulation (EC) No 726/2004[1] for the medicinal product Arpraziquantel, intended for the treatment of schistosomiasis in young children. The applicant for this medicinal product is Merck Europe B.V.

Arpraziquantel will be available as a 150 mg dispersible tablet. The active substance of Arpraziquantel is arpraziquantel, an anthelmintic (ATC code: P02BA03). The active substance is the single active enantiomer of racemic praziquantel and induces muscular spasms and paralysis and tegumental disruption in schistosome worms. This causes the schistosomes to loosen their grip on the wall of mesenteric veins and migrate to the liver, to be eventually destroyed and eliminated.

The benefits of Arpraziquantel are a cure rate for *Schistosoma mansoni* that is at least comparable with that of its racemate and a high cure rate for *S. haematobium*. In addition, arpraziquantel has a taste that is more acceptable for young children compared to racemic praziquantel. The most common side effects are abdominal pain, diarrhoea, somnolence and vomiting.

The full indication is:

> Treatment of schistosomiasis caused by *Schistosoma mansoni* or *Schistosoma haematobium* in children aged 3 months to 6 years.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR).

Arpraziquantel is intended exclusively for markets outside the European Union.

[1] Scientific opinion in accordance with Article 58 of (EC) No Regulation 726/2004 in the context of cooperation with the World Health Organisation (WHO)

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union