

Reference Member State

End of Procedure DCP

1. This document is sent by:

RMS	DE
Contact point project team leader (name/E-mail/phone)	Name Tel: Email:
Date of approval / Day of procedure	08.07.2022 (D197)

2. This document concerns:

Name of the product in the RMS	Trientin Waymade 200 mg Hartkapseln
Name of the active substance	Trientine Dihydrochloride
Applicant	Waymade B.V Herikerbergweg 88 1101CM Amsterdam
Procedure number	DE/H/6991/001/DC
CMS involved in the procedure	AT, DK, EL, ES, FI, FR, IT, NL, NO, PT, SE

3. Conclusions

3.1 Conclusion of the RMS

Our conclusion is that the product is
Approvable



Non-approvable



3.2 Agreement/disagreement between Member States

Based on the final positions of the CMS(s) and the discussions thereafter it is concluded that all concerned Member States are in agreement with the RMS



There is disagreement between the conclusions of the RMS and the CMS (s). Therefore, the matter is forwarded to the Co-ordination Group



4. Attached documents

Please find attached:

The approved SmPC



The approved PL



The approved labelling	<input checked="" type="checkbox"/>
The Final Assessment Report	<input checked="" type="checkbox"/>
The approved specifications	<input checked="" type="checkbox"/>

5. Renewal Date/RMP/PSUR-cycle/Conditions to Marketing Authorisation pursuant to Article 21a or 22 of Directive 2001/83/EC/Orphan market exclusivity

Renewal

The common renewal date is 08.07.2027.

Risk management plan (RMP)

The applicant is requested to send the list of safety concerns included in the approved RMP to CMDh secretariat, e-mail address: H-CMDhSecretariat@ema.europa.eu by using the form published by CMDh (<http://www.hma.eu/464.html>)

PSUR

Active substance is currently listed in the published EURD list

- ☒ With regard to PSUR submission, the MAH should take the following into account:
- PSURs shall be submitted in accordance with the requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and published on the European medicines web-portal. Marketing authorisation holders shall continuously check the European medicines web-portal for the DLP and frequency of submission of the next PSUR.
 - For medicinal products authorized under the legal basis of Article 10(1) or Article 10a of Directive 2001/83/EC, no routine PSURs need to be submitted, unless otherwise specified in the EURD list.
 - In case the active substance will be removed in the future from the EURD list because the MAs have been withdrawn in all but one MS, the MAH shall contact that MS and propose DLP and frequency for further PSUR submissions together with a justification.

Active substance is currently not listed in the published EURD list

- ☐ The MAH shall submit the first periodic safety update report for this product with a period of {xx} months/{xx} years (i. e. DLP of {xx} months after authorization) following authorisation. Further, MAHs shall continuously check the European medicines web-portal if the active substance has been included in the list of Union reference dates (EURD list). If yes, after publication in the EURD list the PSURs shall be submitted in accordance with the requirements set out in the EURD list.
- ☐ The medicinal product is authorized under the legal basis of Article 10(1) or Article 10a of Directive 2001/83/EC. No routine PSURs need to be submitted unless it is stated as a condition in the marketing authorisation. Marketing authorisation holders shall continuously check the

European medicines web-portal to see if the active substance has been included in the list of Union reference dates (EURD list). If yes, the PSURs shall be submitted in accordance with the requirements set out in the EURD list.

Conditions to Marketing Authorisation pursuant to Article 21a or 22 of Directive 2001/83/EC

☒ There are no conditions pursuant to Article 21a or 22 of Directive 2001/83/EC (see final overview AR)

☐ Conditions pursuant to Article 21a of Directive 2001/83/EC have been agreed (see final overview AR)

☐ This concerns a marketing authorisation under exceptional circumstances in accordance with Article 22 of Directive 2001/83/EC. For specific obligations agreed upon, see final overview AR

<Information relating to orphan market exclusivity by end of procedure

☐ There <is> <are> positive designation<s> for a condition relating to the indication proposed in this application (see final overview AR). Prior to granting a national MA, MSs should check if an orphan medicinal product has been granted a MA resulting from these designation<s> and check for possible conflict with market exclusivity.>

☒ <N/A>

6. National phase

Applicants are reminded to submit the national translations taking into consideration the recommendations of the Best Practice on the submission of high quality national translations no later than 7 calendar days after the procedure is closed.

7. Compliance statement referred to in Article 28(3) of the Regulation (EC) No 1901/2006

☐ *Where the measures in a PIP contain no study initiated before the entry into force of the Paediatric Regulation (i.e. 26 January 2007)*

The development of this product has complied with all measures in the agreed paediatric investigation plan <reference number>. All studies in the agreed paediatric investigation plan were conducted after the entry into force of Regulation (EC) No. 1901/2006.

☐ *Where the measures in a PIP contain some studies initiated before the entry into force of the Paediatric Regulation*

The development of this product has complied with all measures in the agreed paediatric investigation plan <reference number>. For the purpose of the application of Article 45(3) of Regulation (EC) No. 1901/2006, significant studies in the agreed paediatric investigation plan were completed after the entry into force of that Regulation.

☒ <N/A>

Please note, that translations regarding this procedure only should be submitted to BfArM within 7 calendar days after the end of procedure (*CMDh Best Practise Guide for Decentralised and Mutual Recognition Procedures, May 2018*) using the template "**Bescheidmaske**" as published on our homepage ([German / English](#)). Please submit the completed template to: translations@bfarm.de and translations-fg21@bfarm.de.

Note: All manufacturers should be the same in the RMS's AR, in the latest Application Form and in M3.
Only manufacturers listed in the *Final* AR will be considered for the *national* MA in Germany.