Concerned Member State Comments on Day 120 Assessment Report to be sent at Day 145 at the latest

1. This document is sent by:

CMS	France
Contact point, project team leader (name) phone email	[redacted]
Assessors, if applicable (name e-mail, phone)	**Quality** [redacted] Tel: [redacted] Email : [redacted] **Biokinetics** [redacted] Tel : [redacted] Email : [redacted]
Date/Day of procedure	

2. This document concerns:

Procedure number	DE/H/6991/001/DC
Name of the medicinal product in the RMS	Trientin Waymade
Name of the active substance	Trientine Dihydrochloride
Applicant	Waymade B.V
Deadline for comments	

3. Comments, general

3.1 Assessment of the RMS

We endorse the RMS assessment, but also have additional comments ☒

We do not fully endorse the RMS assessment, and have other comments ☐

3.2 Conclusions on the product
Our conclusion is that the product is:

Approvable, provided that satisfactory responses are given to the list of questions and/or the SmPC/PL/labelling is changed according to the comments ☐

Non-approvable ☐

3.3. List of Questions/Proposed conditions for marketing authorisation
We have grounds of potential serious risks to public health on the following part of the assessment report not already raised by the RMS as major objections

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Quality ☐

Non-Clinical ☐

Clinical ☐

Risk Management Plan ☐

SmPC ☐

PL ☐

Labelling ☐

We have additional other concerns on the following part of the assessment report

Quality ☐

Non-Clinical ☐

Clinical ☐

Risk Management Plan ☐

SmPC ☐

PL ☐

Labelling ☐

Module 1 – Application related comments (including product name) ☐

4. Potential serious risk to public health

Quality

Potential serious risk to public health not already raised by the RMS as major objection
Rationale

Non-clinical

Potential serious risk to public health not already raised by the RMS as major objection
Rationale

Clinical

Potential serious risk to public health not already raised by the RMS as major objection

Potential serious risk to public health not already raised by the RMS as major objection
Rationale
Rationale

Risk management plan

Potential serious risk to public health not already raised by the RMS as major objection
Rationale

SmPC

PL

Potential serious risk to public health not already raised by the RMS as major objection
Rationale

Labelling

Potential serious risk to public health not already raised by the RMS as major objection
Rationale

5. Additional other concerns

Quality

Other concerns not already raised by the RMS
Rationale

Non-clinical

Other concerns not already raised by the RMS
Rationale

Clinical

Other concerns not already raised by the RMS
Rationale

Risk Management Plan

Other concerns not already raised by the RMS
Rationale

SmPC

Other concerns not already raised by the RMS
Rationale

PL

Other concerns not already raised by the RMS
Rationale

Labelling

Other concerns not already raised by the RMS
Rationale

Module I – Application related comments (including product name)[1]

Other concerns not already raised by the RMS - Copy of the license manufacturing of the responsible for placing the product on the French market **MEDIPHA SANTE** (so called "exploitant" in France) should be provided.

[1] Please note that for 10.1 and 10.3 applications with a centrally authorised product as reference product, the product name in RMS and all CMS must be the same. It is therefore important that comments on the product name are sent early in the procedure in order to reach agreement before day 210/90.

Rationale

6. Additional information for the Applicant

Response document:

Please note that any response document submitted by email should be sent to the following email addresses:
[redacted]
Ueurop@ansm.sante.fr

National translation:
In order to optimise national notifications, the French electronic versions of the final approved SPC, package leaflet and labelling in Word format / Template 10 should be sent to Ueurop@ansm.sante.fr
Please read carefully the recommendations, especially concerning the "How to submit" part, in order to know how to word the object of the email. Indeed, if the subject of the email is not conform, the email cannot be forwarded to the correct recipient.
It needs to be stated **"Traduction - AMM initiale - number of procedure - name of the product - spécialité générique / princeps".**
All required documents are listed in the recommendations:
https://ansm.sante.fr/page/modalites-de-soumission-pour-une-amm (see “traduction” part)
You can also use the tutorial on the ANSM site:
https://ansm.sante.fr/page/propositions-dannexes-amm-enregistrements-rcp-notice-etiquetage
and the "feuille de style T10 - Modèle complet" available on the site, and use the proposed sentences when applicable.
There should be only one document per strength, combining SPC/labelling and patient leaflet.
Please note that:
- You should not delete any part of the template, only mention "sans objet" whenever the section does not apply to your case.
- The style "normal" is not conform. All the styles you should use begin with "Amm", for example, AmmCorpsTexte, instead of normal.
- If applicable, section D of the Annexe II should be fullfilled, in accordance with the RMP ;