# Concerned Member State Comments on Day 180 Assessment Report to be sent at Day 195 at the latest

## 1. This document is sent by:

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| CMS | FR |
| Contact point, project team leader (name)<br>phone<br>email | [redacted] |
| Assessors, if applicable (name e-mail, phone) | [redacted] |
| Date/Day of procedure | |

## 2. This document concerns:

| | |
|---|---|
| Name of the product in the RMS | Teriparatide |
| Name of the active substance | Teriparatide |
| Applicant | Welding GmbH & Co.KG |
| Procedure number | DE/H/6160/001/DC – DE/H/6629/001/DC |
| Deadline for comments | |

## 3. Comments, general

3.1 Assessment of the RMS

We fully endorse the RMS assessment, and have no further comments ☐

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 ☐

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

Quality ☐

Non-Clinical ☐

Clinical ☐

SmPC ☐

PL ☐

Labelling ☐

We have additional points for clarification on the following part of the assessment report

Quality ☐

Non-Clinical ☐

Clinical ☐

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 |
|---|
| Rationale |

**Non-clinical**

| |
|---|
| Potential serious risk to public health not already raised by the RMS |
| Rationale |

**Clinical**

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| Potential serious risk to public health not already raised by the RMS |
| Rationale |

**SmPC**

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|---|
| Potential serious risk to public health not already raised by the RMS |
| Rationale |

**PL**

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|---|
| Potential serious risk to public health not already raised by the RMS |
| Rationale |

**Labelling**

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|---|
| Potential serious risk to public health not already raised by the RMS |
| Rationale |

## 5. Additional points for clarification

**Quality**

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| Points for clarification not already raised by the RMS |
| Rationale |

**Non-clinical**

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|---|
| Points for clarification not already raised by the RMS |

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|---|
| Rationale |

**Clinical**

| Points for clarification not already raised by the RMS |
|---|
| Rationale |

**SmPC**

| Points for clarification not already raised by the RMS |
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| Rationale |

**PL**

| Points for clarification not already raised by the RMS |
|---|
| Rationale |

**Labelling**

| Points for clarification not already raised by the RMS<br>**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**<br>**OUTER CARTON TEXT**<br>**2. STATEMENT OF ACTIVE SUBSTANCE(S)**<br>Each ml contains 250 micrograms of teriparatide. One pre-filled pen of 2.4 mL contains 600 micrograms of teriparatide (corresponding to 250 micrograms per ml).<br>Each dose of 80 microliters contains 20 micrograms of teriparatide |
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| Rationale |

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

| Points for clarification not already raised by the RMS<br><br>For DE/H/6160/001/DC, the proposed product name "**TERIPARATIDE BIOGARAN 20 microgrammes / 80 microlitres, solution injectable en stylo prérempli**" is acceptable in France.<br><br>For DE/H/6629/001/DC, the proposed product name "**TERIPARATIDE TRENE 20 microgrammes/80 microlitres, solution injectable en stylo prérempli**" is not acceptable in France because of the absence of the proof of registered trade mark for "TRENE".<br>The product name "**TERIPARATIDE WELDING 20 microgrammes/80 microlitres, solution injectable en stylo prérempli**" could be acceptable in France. |
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[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.

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| Rationale |
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## Practical information to the applicant

*Response document:*

Please note that any response document submitted by email should be sent to the following email addresses:

*To be added in case of paper submission:*
*4 hard copies should also be sent to the following address:*
*ANSM, 143/147 boulevard Anatole France, 93285 Saint-Denis Cedex, FRANCE*

*National translation*

We kindly remind the MAH that, in case of positive outcome, the **adequate French translation** of the approved SPC, package leaflet and labelling should be sent not later than 5 days after the finalisation of the procedure.

In order to optimise national notifications, please follow A**NSM recommendations**
http://ansm.sante.fr/Activites/Autorisations-de-Mise-sur-le-Marche-AMM/Demande-initiale-d-AMM/(offset)/1

**If any, the letter of commitments should also be translated and provided.**

In order to optimise national notifications, both French and English electronic versions of the final approved SPC, package leaflet and labelling in Word format / Template 10 should be sent to ueurop@ansm.sante.fr