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	FR
Contact point, project team leader (name) phone email	[redacted]
Assessors, if applicable (name e-mail, phone)	[redacted]
Date/Day of procedure	09/06/2020

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	**08/06/2020**

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

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

SmPC

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

PL

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

Labelling

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

5. Additional points for clarification

Quality

Points for clarification not already raised by the RMS
Rationale

Non-clinical

Points for clarification not already raised by the RMS

Rationale

Clinical

Points for clarification not already raised by the RMS
Rationale

SmPC

Points for clarification not already raised by the RMS
Rationale

PL

Points for clarification not already raised by the RMS
Rationale

Labelling

Points for clarification not already raised by the RMS
Rationale

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

Points for clarification not already raised by the RMS The product name is under assessment
Rationale

Practical information to the applicant

Response document:

[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.

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