

To the reference member state and all concerned member states of the below mentioned procedure

DE, FR

Dr. Christian Wilde

Tel:
Fax:
E-Mail:
Seiten:

Datum
31.01.2019

Subject: Submission of Application Dossier(s) for Marketing Authorisation of Teriparatide 20 µg/80 µl, solution for injection in pre-filled pen in the MS where the application is submitted

**Procedure Number: DE/H/6160/001/DC
ENR: 2203632**

Dear Sir or Madam,

We are pleased to submit our Application Dossier(s) for a Decentralised Procedure which details are as follows:

Name of the medicinal product(s) (in the RMS): Teriparatide 20 µg/ 80 µl Injektionslösung in einem vorgefüllten Injektor

Pharmaceutical form(s) and strength(s): solution for injection in pre-filled pen; 20 µg/ 80 µl

INN/active substance(s): Teriparatide

ATC Code(s): H05AA02

Legal Basis of the Application(s): Article 10(1) generic application

You will find enclosed the submission dossier as specified hereafter:

eCTD format NeeS format

Sequence number: 0000

- We confirm that all future submissions for this specific product will be submitted in this same format
- The eCTD has passed the applicant's internal technical validation (all P/F criteria passed and all BP criteria have been fulfilled up to our best knowledge) using Extedo eCTD Manager Version 5.1-HF6 (5.1.0.038).
- We confirm that the electronic submission has been checked with an up-to-date and state-of-the-art virus checker.
- We hereby certify that the dossier submitted to the RMS and CMS(s) are fully identical.

Please be informed that the dossier is submitted through the Common European Submission Platform (CESP).

Yours sincerely,

i.V. Dr. Christian Wilde

WELDING GMBH & CO. KG
Regulatory Affairs