2.3.R. REGIONAL INFORMATION

Medicinal Products Containing or Using in the Manufacturing Process of Animal and/or Human Origin

No materials of animal and / or human origin are used in the manufacturing process of the drug product. The Declarations of Compliance with the Annex to Directive 75/318/EEC, as amended by Directive 1999/82/EEC relating to TSE are included in Section 3.2.R.

Medical Devices

Teriparatide pen-injector is a drug – device combination product, where the medicinal product provides the primary mode of action, within the meaning of the Directive 2001/83/EC and applicable amendments. The pen-injector represents the device constituent part of the combination product. The cartridge is integrated and non-replaceable.

The complete description of the pen device, covering materials of construction, principles of operation, manufacturer, design considerations, essential performance parameters and results of functional performance testing) can be found in Section 3.2.R-Annex 1.

In Section-3.2.R-Annex 2, the following information about Teriparatide pen-injector can be found:

- General description and suitability according to *Guidance for CCS for Packaging Human Drugs and Biologics*.
- Pen-injector performance according to requirements of *Guidance for Industry and FDA Staff: Technical Considerations for Pen, Jet and Related Injectors Intended for Use with Drugs and Biological Products.*
- Risk Management according to EN ISO 14971: Application of risk management to medical devices.
- Design controls according to ISO 13485 Medical devices quality management systems requirements for regulatory purposes.
- Design development summary (History of changes over the course of teriparatide pen-injector development program).
- Summary of the Design Verification studies conducted, which demonstrate that the pen-injector successfully met all criteria assessed and demonstrated compliance with ISO 11608-1:2014 and ISO 11608-2:2012, Section 11.4.3 Needle hub torque removal.