Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

# Australian Public Assessment Report for Teriparatide Lupin/ Teriparatide LAPL/ Teriparatide GH

## Active ingredient/s: Teriparatide

## Sponsor: Generic Health Pty Ltd

October 2023

# About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and Aged Care and is responsible for regulating therapeutic goods, including medicines, medical devices, and biologicals.
- The TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety, and efficacy.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to the Australian public outweigh any risks associated with the use of therapeutic goods.
- The TGA relies on the public, healthcare professionals and industry to report problems with therapeutic goods. The TGA investigates reports received to determine any necessary regulatory action.
- To report a problem with a therapeutic good, please see the information on the TGA website.

# About AusPARs

- The Australian Public Assessment Report (AusPAR) provides information about the evaluation of a prescription medicine and the considerations that led the TGA to approve or not approve a prescription medicine submission. Further information can be found in Australian Public Assessment Report (AusPAR) guidance.
- AusPARs are prepared and published by the TGA.
- AusPARs are static documents that provide information that relates to a submission at a particular point in time. The publication of an AusPAR is an important part of the transparency of the TGA's decision-making process.
- A new AusPAR may be provided to reflect changes to indications or major variations to a prescription medicine subject to evaluation by the TGA.

# Contents

# List of abbreviations

| Abbreviation | Meaning |
|---|---|
| ACM | Advisory Committee on Medicines |
| ANDA | Abbreviated new drug application |
| ARTG | Australian Register of Therapeutic Goods |
| ASA | Australia specific annex |
| CMI | Consumer Medicines Information |
| COR | Comparable Overseas Regulator |
| DLP | Data lock point |
| DNA | Deoxyribonucleic acid |
| EMA | European Medicines Agency |
| EU | European Union |
| FDA | Food and Drug Administration (United States of America) |
| IFU | Instruction for use |
| Ph Eur | European Pharmacopoeia |
| PI | Product Information |
| PSUR | Periodic safety update report |
| PTH | Parathyroid hormone |
| rDNA | Recombinant deoxyribonucleic acid |
| RMP | Risk management plan |
| TGA | Therapeutic Goods Administration |
| US(A) | United States (of America) |
| USP | United States Pharmacopoeia |

# Product submission

## Submission details

| | |
|---|---|
| *Type of submission:* | New chemical entity |
| *Product names:* | Teriparatide Lupin/ Teriparatide LAPL/ Teriparatide GH |
| *Active ingredient:* | Teriparatide |
| *Decision:* | Approved |
| *Date of decision:* | 20 March 2023 |
| *Date of entry onto ARTG:* | 6 April 2023 |
| *ARTG numbers:* | 373602, 373603 and 373604 |
| , *Black Triangle Scheme* | Yes |
| *for the current submission:* | This product will remain in the scheme for 5 years, starting on the date the product is first supplied in Australia |
| *Sponsor's name and address:* | Generic Health Pty Ltd<br>Suite 2, Level 2<br>19-23 Prospect Street<br>Box Hill, VIC, 3128 |
| *Dose form:* | solution for injection |
| *Strength:* | 250 µg/mL |
| *Container:* | Pre-filled cartridge |
| *Pack sizes:* | 1 and 3 |
| *Approved therapeutic use for the current submission:* | *Teriparatide Lupin/Teriparatide LAPL/Teriparatide GH is indicated for the treatment of osteoporosis in postmenopausal women and the treatment of primary osteoporosis in men when other agents are considered unsuitable and when there is a high risk of fractures.*<br>*Teriparatide Lupin/Teriparatide LAPL/Teriparatide GH is indicated for the treatment of osteoporosis associated with sustained systemic glucocorticoid therapy in women and men at high risk for fracture.* |
| *Route of administration:* | Subcutaneous injection |
| *Dosage:* | Each dose of 80 µl contains 20 µg of teriparatide.<br>The recommended dose of Teriparatide Lupin/ Teriparatide LAPL/ Teriparatide GH is 20 µg administered once daily by subcutaneous injection in the thigh or abdomen.<br>Based on clinical experience, treatment with Teriparatide Lupin/ Teriparatide LAPL/ Teriparatide GH is recommended for a lifetime duration of 24 months treatment (for post-treatment efficacy, see Section 5.1 Pharmacodynamic |

| | |
|---|---|
| | Properties Clinical Trials). Teriparatide Lupin/ Teriparatide LAPL/ Teriparatide GH should be prescribed to patients with a full explanation and their informed consent on the lifetime duration of 24 months treatment.<br><br>Calcium and vitamin D supplements are advised in patients with a low dietary intake of these nutrients.<br><br>Use in Males – Primary or secondary hypogonadism should first be excluded and, if relevant, be treated (see Section 5.1 Pharmacodynamic Properties - Clinical Trials)<br><br>For further information regarding dosage, refer to the Product Information. |
| *Pregnancy category:* | B3<br><br>Drugs which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human fetus having been observed.<br><br>Studies in animals have shown evidence of an increased occurrence of fetal damage, the significance of which is considered uncertain in humans.<br><br>The use of any medicine during pregnancy requires careful consideration of both risks and benefits by the treating health professional. This must not be used as the sole basis of decision making in the use of medicines during pregnancy. The TGA does not provide advice on the use of medicines in pregnancy for specific cases. More information is available from obstetric drug information services in your State or Territory. |

# Product background

This AusPAR describes the submission by Generic Health Pty Ltd (the sponsor) to register Teriparatide Lupin/Teriparatide LAPL/Teriparatide GH (teriparatide) 250µg/mL, solution for injection, pre-filled cartridge for the following proposed indication:[1]

> *Teriparatide Lupin/Teriparatide LAPL/Teriparatide GH is indicated for the treatment of osteoporosis in postmenopausal women and the treatment of primary osteoporosis in men when other agents are considered unsuitable and when there is a high risk of fractures.*
>
> *Teriparatide Lupin/Teriparatide LAPL/Teriparatide GH is indicated for the treatment of osteoporosis associated with sustained systemic glucocorticoid therapy in women and men at high risk for fracture.*

Teriparatide Lupin has been developed as a generic of Forteo by Eli Lilly. Teriparatide, is a form of parathyroid hormone (PTH) consisting of the first (N-terminus) 34 amino acids, which is the bioactive portion of the hormone. Forteo is a biological product in which the active ingredient is

[1] This is the original indication proposed by the sponsor when the TGA commenced the evaluation of this submission. It may differ to the final indication approved by the TGA and registered on the Australian Register of Therapeutic Goods.

produced by recombinant deoxyribonucleic acid (DNA) technology in *Escherichia coli*. Teriparatide lupin, as presented in this submission, is of synthetic origin.

The active ingredient and product formulation are the same as for the reference product.

The proposed indication, patient groups and dosing regimen are identical to that of the reference product, that is daily 20 µg subcutaneous injections for up to 24 months for the treatment of:

- osteoporosis in postmenopausal women and the treatment of primary osteoporosis in men when other agents are considered unsuitable and when there is a high risk of fractures.
- osteoporosis associated with sustained systemic glucocorticoid therapy in women and men at high risk for fracture.

As Teriparatide Lupin/Teriparatide LAPL/Teriparatide GH does not fulfill the requirements for consideration as a biosimilar or a generic medicine it is being considered as a new chemical entity.

The following United States (US) Food and Drug Administration (FDA) guidance is relevant to this application:[2]

> 'This guidance is intended to assist potential applicants in determining when an application for a synthetic peptide drug product (synthetic peptide) that refers to a previously approved peptide drug product of recombinant deoxyribonucleic acid (rDNA) origin (peptide of rDNA origin) should be submitted as an abbreviated new drug application (ANDA) under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) rather than as a new drug application (NDA) under section 505(b) of the FD&C Act.2 Specifically, this guidance provides recommendations for evaluating whether an ANDA submission is appropriate for a synthetic peptide that references any of the following five previously approved peptide drug products of rDNA origin: glucagon, liraglutide, nesiritide, teriparatide, and teduglutide.
>
> Given the current state of technology for peptide synthesis and characterisation, FDA believes it is now possible for an ANDA applicant to demonstrate that the active ingredient in a proposed generic synthetic peptide drug product (proposed generic synthetic peptide) is the 'same' as the active ingredient in a previously approved peptide of rDNA origin. For a synthetic peptide that is intended to be a 'duplicate' of a previously approved peptide of rDNA origin, a determination of whether an application for the synthetic peptide should be submitted as an ANDA depends largely on its impurity profile as compared to the impurity profile for the peptide of rDNA origin. Differences in impurities, particularly peptide-related impurities, may affect the safety or effectiveness of a peptide drug product as compared to the RLD.'

This submission was submitted through the TGA's Comparable Overseas Regulator B (COR-B) process, using evaluation reports from European Medicine Agency (EMA). The full dossier was submitted to the TGA.

## Regulatory status

This product is considered a new chemical entity medicine for Australian regulatory purposes.

[2] FDA guidance: ANDAs for Certain Highly Purified Synthetic Peptide Drug Products That Refer to Listed Drugs of rDNA Origin Guidance for Industry, May 2021.

At the time the TGA considered this submission, a similar submission had been approved in European Union (EU) on 11 August 2020, New Zealand on 9 December 2021, United Kingdom on 26 May 2022 and Switzerland on 9 June 2022.

## Product Information

The Product Information (PI) approved with the submission which is described in this AusPAR can be found as Attachment 1. For the most recent PI and Consumer Medicines Information (CMI), please refer to the TGA PI/CMI search facility.

# Registration timeline

The following table captures the key steps and dates for this submission.

This submission was evaluated under the standard prescription medicines registration process.

**Table 1: Timeline for Submission PM-2021-03753-1-5**

| Description | Date |
|---|---|
| Submission dossier accepted and first round evaluation commenced | 2 May 2022 |
| First round evaluation completed | 26 July 2022 |
| Sponsor provides responses on questions raised in first round evaluation | 14 November 2022 |
| Second round evaluation completed | 16 December 2022 |
| Delegate's Overall benefit-risk assessment | 10 February 2023 |
| Sponsor's pre-Advisory Committee response | Not applicable |
| Advisory Committee meeting | Not applicable |
| Registration decision (Outcome) | 20 March 2023 |
| Administrative activities and registration on the ARTG completed | 6 April 2023 |
| Number of working days from submission dossier acceptance to registration decision* | 171 |

* The COR-B process has a 175 working day evaluation and decision timeframe.

# Submission overview and risk/benefit assessment

This section is a TGA summary of wording used in TGA's evaluation report, which discussed numerous aspects of overseas evaluation reports and included some information that was commercial-in-confidence.

The following guideline was referred to by the Delegate as being relevant to this submission:

- Food and Drug Administration (FDA) guidance: ANDAs for Certain Highly Purified Synthetic Peptide Drug Products That Refer to Listed Drugs of rDNA Origin Guidance for Industry, May 2021;[2]

# Quality

Generic Health Pty Ltd has applied to register 250 µg/mL teriparatide solution for injection under the trade name Teriparatide Lupin, Teriparatide LAPL and Teriparatide GH. The trade names are acceptable.

This product has been developed as a generic of Forteo by Eli Lilly. There is one other registered generic by Gedeon. Teriparatide, is a form of PTH consisting of the first (N-terminus) 34 amino acids, which is the bioactive portion of the hormone. The innovator product as well as the other generic is a biological product of recombinant origin. Teriparatide as presented in this submission is of synthetic origin.

Each pen contains 28 doses of 20 µg teriparatide (per 80 microlitres). To prevent the possible transmission of disease, each pen must be used by one patient only, even if the needle is changed.

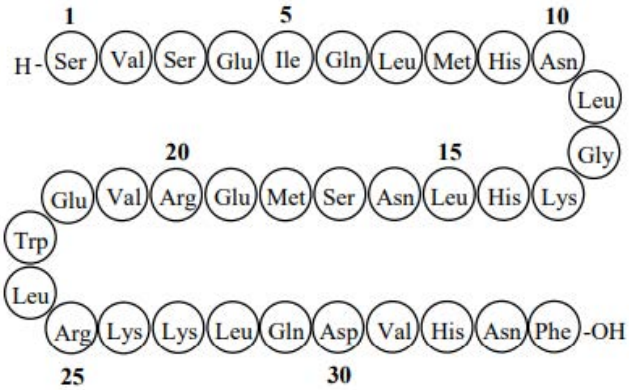
The recommended dose of Teriparatide Lupin is 20 µg administered once daily by subcutaneous injection in the thigh or abdomen. Based on clinical experience, treatment with teriparatide is recommended for a lifetime duration of 24 months treatment.

There are British Pharmacopoeia (BP)/European Pharmacopoeia (Ph Eur) and United States Pharmacopoeia (USP) monographs for Teriparatide and there is a USP monograph for Teriparatide injection. These monographs refer to teriparatide being of recombinant origin.

## Drug substance

Teriparatide, is a form of PTH consisting of the first (N-terminus) 34 amino acids, which is the bioactive portion of the hormone.

**Figure 1: Amino acid sequence for teriparatide**




The only and most important difference between the reference product and generic product is the manufacturing process of the active substance. While the originator Forteo contains recombinantly produced teriparatide, the active substance in the proposed product is of synthetic origin.

The drug substance synthesis involves assembly onto a resin with subsequent amino acid derivatives added to lengthen the peptide by repetition of the deblocking, coupling, and acetylation reactions. Repetition of these three steps results in a protected teriparatide, peptide-

on-resin. The crude peptide is cleaved from the resin, purified by high performance liquid chromatography and isolated by lyophilisation as teriparatide acetate salt.

The drug substance specifications include appropriate tests and acceptable limits for appearance, solubility, identity, peptide content (95 to 105%), related substances, water content, acetic acid content, trifluoroacetic acid content and microbial organisms.

## Medicinal product

The proposed product is a clear, colourless solution, free from visible particles, packaged in a glass cartridge (2.4 mL extractable volume in 3 mL cartridge) closed with a plunger at one end and with a rubber disc and aluminium cap (combiseal) at the other end. The filled cartridge is assembled into a pen injector intended for multiple injections.

The manufacturing process used involves dissolving teriparatide and all excipients in water for injections and adjusting the pH. The solution is sterilised and assembled into the pen device.

The formulation contains m-Cresol as an antimicrobial preservative.

The finished product is appropriately controlled with tests for appearance, particulate contamination, identity, pH, extractable volume, assay, degradation impurities, dose accuracy, m-Cresol content and microbial limits.

Degradation products are controlled according to the Ph Eur identification and qualification thresholds for the proposed product (peptide obtained by chemical synthesis) of 0.5% and 1.0%, respectively

## Biopharmaceutics

The proposed product is intended for subcutaneous injection. It is of the same type of solution (aqueous) and contains the same concentration of the same active substance and the same excipients in similar amounts as the reference product.

Approval for registration of the proposed product is recommended from a pharmaceutical chemistry perspective.

The only and most important difference between reference product and generic product is the manufacturing process of the active substance. While the originator Forteo contains recombinantly produced teriparatide, the active substance in the proposed product is of synthetic origin. The sponsor performed an analytical comparability study on the level of structural comparison and comparison of the impurity profile. This *in vitro* comparison indicates that the products are equivalent.

Data was provided to support a shelf life of 24 months when stored at 2°C to 8°C.

## Recommendation

Approval for registration of the proposed product is recommended from a pharmaceutical chemistry perspective.

# Nonclinical

The oversea evaluator nonclinical assessment noted that the pharmacodynamic, pharmacokinetic and toxicological properties of teriparatide are well known. As teriparatide is a

widely used, well known active substance, the applicant has not provided additional studies and further studies are not required. An overview based on literature review is, thus, appropriate.

The TGA nonclinical evaluator concurred.

The oversea evaluator nonclinical assessment states that '*The non-clinical overview on the pre-clinical pharmacology, pharmacokinetics and toxicology is adequate*.'

The TGA nonclinical evaluator agreed.

## Recommendation

There are no nonclinical objections to registration.

# Clinical

There were no bioequivalence or clinical data for the proposed product submitted. The application is reliant on quality data. The oversea evaluator stated the following in the final assessment report:

> 'The Applicant has not provided results of a bioequivalence study based on the parenteral route of administration and claiming that the clinical performance of teriparatide is irrespective of the mode of synthesis. Furthermore, the Applicant considers the current medicinal product bioequivalent to the originator Forsteo based on full comparative analytical characterisation. Efficacy and safety of the current medicinal product are addressed by an overview considering scientific publications on teriparatide and teriparatide containing medicinal products up to July 2018. Thus, the bioequivalence of the applied medicinal product is solely based on the data provided in the quality part of the dossier, while the clinical part of the dossier is limited to a general overview of the biopharmaceutics, efficacy, and safety of teriparatide.'

## Pharmacology

Not applicable. There were no pharmacokinetic, pharmacodynamic, efficacy or safety data for the proposed product submitted. The sponsor provided a review of the literature regarding the clinical pharmacology, efficacy and safety of teriparatide and teriparatide containing products in the sponsor submitted clinical overview.

The oversea evaluator stated the application contained an adequate review of published clinical data. In Day 70 clinical report, there were two '*major objections*' (relating to lack of a bioequivalence study or other relevant clinical data, and submission of results of the human factor study), and one '*other concern*' (relating to the layout of the product label and device used).

These issues were addressed in the Day 120 clinical report and considered resolved.

- The oversea evaluator considered the major objection relating to the lack of bioequivalence study or other clinical data resolved based on data provided in the quality part of the dossier.
- In response to the major objection relating to the human factor study, the oversea evaluator noted the sponsor performed a formative human factor study to assess the usability of the instruction for use (IFU), with the IFU updated based on the outcomes of this study and subsequently passing validation testing. The issue was considered resolved.

- The other concern relating to the product label layout and device was addressed in part with the response provided regarding the human factor study as discussed and considered resolved.

## Efficacy

No data provided.

## Safety

No data provided.

# Risk management plan

The sponsor has applied to register a new chemical entity, teriparatide (as acetate) (Teriparatide Lupin, Teriparatide GH and Teriparatide LAPL), hereafter referred to as Teriparatide Lupin. Teriparatide Lupin is of synthetic origin, whereas the innovator product, Forteo, (Teriparatide (rbe)), is manufactured by recombinant technology. Hence Teriparatide Lupin is considered a new chemical entity and not a biosimilar or generic medicine.

The sponsor has submitted EU-risk management plan (RMP) version 3.0 (dated 19 June 2020; data lock point (DLP) 16 July 2018) and Australia specific annex (ASA) version 0.2 (dated August 2021) in support of this application. In its Section 31 response, the sponsor has submitted an updated ASA (version 0.3 dated 14 November 2022) in support of this application.

The summary of safety concerns and their associated risk monitoring and mitigation strategies are summarised in Table 2. The TGA may request an updated RMP at any stage of a product's life-cycle, during both the pre-approval and post-approval phases.

**Table 2: Summary of safety concerns**

| Summary of safety concerns | | Pharmacovigilance | | Risk Minimisation | |
|---|---|---|---|---|---|
| | | Routine | Additional | Routine | Additional |
| **Important identified risks** | None | – | – | – | – |
| **Important potential risks** | Osteosarcoma | ü† | – | ü | ü* |
| **Missing information** | None | – | – | – | – |

* Patient Consent Form ASA only.

† Follow-up questionnaire for osteosarcoma

The nonclinical and clinical evaluators did not identify any new safety concerns. The summary of safety concerns is identical to those of recombinant teriparatide products and is acceptable.

Routine pharmacovigilance activities only are proposed. This includes a follow up questionnaire for osteosarcoma. This is consistent with other teriparatide products.

Routine and additional risk minimisation activities are proposed. The additional risk minimisation activity is a patient consent form with a full explanation of the risk of treatment with teriparatide and the patients' informed consent on the lifetime duration of 24 months' treatment. This is consistent with other teriparatide products.

## Proposed wording for condition/s of registration

The implementation of the Patient Consent form and how information on the distribution of patient consent form will be collected, have not been finalised and are still under development. When known, the ASA should be updated with this detail.

However, the sponsor has stated that once finalised, this information will be submitted to TGA along with the final patient consent form for approval at least 6 weeks prior to it being uploaded to company's website.

The document/s to be included in the packaging should also be submitted to the TGA for review when finalised. The sponsor should allow at least 6 weeks for review and acceptance by the TGA. The sponsor should note that it is acceptable to include the CMI in the packaging (plus a user manual) instead of a different package leaflet which contains similar information to the CMI.

### *Wording for conditions of registration*

Any changes to which the sponsor has agreed should be included in a revised RMP and ASA. However, irrespective of whether or not they are included in the currently available version of the RMP document, the agreed changes become part of the risk management system.

The suggested wording is:

> 'The Teriparatide Lupin, Teriparatide GH and Teriparatide LAPL EU-RMP (version 3.0, dated 19 June 2020, DLP 16 July 2018), with ASA (version 0.3, dated 14 November 2022), included with submission PM-2021-03753-1-5, and any subsequent revisions, as agreed with the TGA will be implemented in Australia.'

The following wording is recommended for the PSUR requirement:

> 'An obligatory component of risk management plans is routine pharmacovigilance. Routine pharmacovigilance includes the submission of periodic safety update reports (PSURs).
>
> Reports are to be provided in line with the current published list of EU reference dates and frequency of submission of PSURs until the period covered by such reports is not less than three years from the date of the approval letter.
>
> The reports are to at least meet the requirements for PSURs as described in the European Medicines Agency's Guideline on good pharmacovigilance practices (GVP) Module VII-periodic safety update report (Rev 1), Part VII.B Structures and processes. Note that submission of a PSUR does not constitute an application to vary the registration.'

As Teriparatide Lupin, Teriparatide GH and Teriparatide LAPL are new chemical entities they should be included in the Black Triangle Scheme as a condition of registration. The following wording is recommended for the condition of registration:

> 'Teriparatide Lupin, Teriparatide GH and Teriparatide LAPL (teriparatide acetate) are to be included in the Black Triangle Scheme. The PI and CMI for Teriparatide Lupin, Teriparatide GH and Teriparatide LAPL must include the black triangle symbol and mandatory accompanying text for five years, which starts from the date that the sponsor notifies the TGA of supply of the product.'

### *Recommendation*

The RMP evaluator did not recommend referral to ACM for RMP issues.

# Risk-benefit analysis

## Delegate's considerations

The sponsor has submitted a new chemical entity application to register Teriparatide Lupin (and additional trade names) teriparatide 250 µg solution for injection cartridge for the following indication:

> *Teriparatide Lupin is indicated for the treatment of osteoporosis in postmenopausal women and the treatment of primary osteoporosis in men when other agents are considered unsuitable and when there is a high risk of fractures.*
>
> *Teriparatide Lupin is indicated for the treatment of osteoporosis associated with sustained systemic glucocorticoid therapy in women and men at high risk for fracture.*

The recommended dose of Teriparatide Lupin is 20 micrograms administered once daily.

Teriparatide Lupin has been developed as a generic of Forteo by Eli Lilly. Teriparatide, is a form of PTH consisting of the first (N-terminus) 34 amino acids, which is the bioactive portion of the hormone. Forteo is a biological product in which the active ingredient is produced by recombinant DNA technology in *E. coli*. Teriparatide lupin, as presented in this submission, is of synthetic origin. The proposed indication, patient groups and dosing regime are identical to that of the reference product.

The sponsor stated the product in this application is approved in Europe through several parallel decentralised procedures with Germany as the Reference Member State and several EU countries as the Concerned Member States.

### *Manufacturing and quality control data evaluation*

The only and most important difference between the reference product and generic product is the manufacturing process of the active substance. While the originator Forteo contains recombinantly produced teriparatide, the active substance in the proposed product is of synthetic origin.

The drug substance specifications include appropriate tests and acceptable limits for appearance, solubility, identity, peptide content (95 to 105%), related substances, water content, acetic acid content, trifluoroacetic acid content and microbial organisms.

The finished product is appropriately controlled with tests for appearance, particulate contamination, identity, pH, extractable volume, assay, degradation impurities, dose accuracy, m-Cresol content and microbial limits. Degradation products are controlled according to the Ph Eur identification and qualification thresholds for the proposed product.

The only and most important difference between reference product and generic product is the manufacturing process of the active substance. The sponsor performed an analytical comparability study on the level of structural comparison and comparison of the impurity profile. This *in vitro* comparison indicates that the products are equivalent.

Approval for registration of the proposed product is recommended from a pharmaceutical chemistry perspective.

### *Nonclinical data evaluation*

The oversea evaluator noted that the pharmacodynamic, pharmacokinetic and toxicological properties of teriparatide are well known. As teriparatide is a widely used, well known active substance, the applicant has not provided additional studies and further studies are not

required. The oversea evaluator nonclinical assessment states that '*The nonclinical overview on the pre-clinical pharmacology, pharmacokinetics and toxicology is adequate'*. The TGA nonclinical evaluator agreed.

There are no nonclinical objections to registration.

### *Clinical data evaluation*

There were no bioequivalence or clinical data for the proposed product submitted. The application is reliant on quality data.

The RMP evaluator has recommended changes to the CMI and wording for conditions of registration as described previously in this report.

## Proposed action

It is considered that the data presented for evaluation is sufficient to approve the application to register Teriparatide Lupin/Teriparatide LAPL/Teriparatide GH (teriparatide) 250 µg solution for injection cartridge for the following indication:

> *Teriparatide Lupin is indicated for the treatment of osteoporosis in postmenopausal women and the treatment of primary osteoporosis in men when other agents are considered unsuitable and when there is a high risk of fractures.*
>
> *Teriparatide Lupin is indicated for the treatment of osteoporosis associated with sustained systemic glucocorticoid therapy in women and men at high risk for fracture.*

The Delegate propose to approve the registration of Teriparatide Lupin/Teriparatide LAPL/Teriparatide GH.

## Advisory Committee considerations

The Delegate did not refer this submission to the Advisory Committee on Medicines (ACM) for advice.

# Outcome

Based on a review of quality, safety, and efficacy, the TGA approved the registration of Teriparatide Lupin/Teriparatide LAPL/Teriparatide GH (teriparatide) 250µg/mL, solution for injection, pre-filled cartridge indicated:

> *Teriparatide Lupin/Teriparatide LAPL/Teriparatide GH is indicated for the treatment of osteoporosis in postmenopausal women and the treatment of primary osteoporosis in men when other agents are considered unsuitable and when there is a high risk of fractures.*
>
> *Teriparatide Lupin/Teriparatide LAPL/Teriparatide GH is indicated for the treatment of osteoporosis associated with sustained systemic glucocorticoid therapy in women and men at high risk for fracture.*

# Specific conditions of registration applying to these goods

- Teriparatide Lupin, Teriparatide GH and Teriparatide LAPL (teriparatide acetate) are to be included in the Black Triangle Scheme. The PI and CMI for Teriparatide Lupin, Teriparatide

GH and Teriparatide LAPL must include the black triangle symbol and mandatory accompanying text for five years, which starts from the date that the sponsor notifies the TGA of supply of the product.

- The Teriparatide Lupin, Teriparatide GH and Teriparatide LAPL EU-RMP (version 3.0, dated 19 June 2020, DLP 16 July 2018), with ASA (version 0.3, dated 14 November 2022), included with submission PM-2021-03753-1-5, and any subsequent revisions, as agreed with the TGA will be implemented in Australia.
- An obligatory component of risk management plans is routine pharmacovigilance. Routine pharmacovigilance includes the submission of periodic safety update reports (PSURs).
- Reports are to be provided in line with the current published list of EU reference dates and frequency of submission of PSURs until the period covered by such reports is not less than three years from the date of the approval letter.
- The reports are to at least meet the requirements for PSURs as described in the European Medicines Agency's Guideline on good pharmacovigilance practices (GVP) Module VII- periodic safety update report (Rev 1), Part VII.B Structures and processes. Note that submission of a PSUR does not constitute an application to vary the registration.
- Any changes to which the sponsor has agreed should be included in a revised RMP and ASA. However, irrespective of whether or not they are included in the currently available version of the RMP document, the agreed changes become part of the risk management system.

# Attachment 1. Product Information

The PI for Teriparatide Lupin approved with the submission which is described in this AusPAR is at Attachment 1. For the most recent PI, please refer to the TGA PI/CMI search facility.

The PI for Teriparatide GH and Teriparatide LAPL is identical except for the product name.

**Therapeutic Goods Administration**

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**https://www.tga.gov.au**

Reference/Publication #