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Eli Lilly's response to hearing on admission to the interchangeable list for Forsteo and Terrosa

Eli Lilly refers to the hearing letter of 04.06.2021, where the Norwegian Medicines Agency recommends that Forsteo and Terrosa be included in the list of interchangeable products (Byttelisten).

We thank you for the opportunity to provide input on the recommended changes to the interchangeable list (Byttelisten).

We acknowledge that there are biosimilars in the market that behave in a *similar* way to Forsteo in terms of effectiveness and safety. However, there are differences between the devices used for Forsteo and the biosimilars like Terrosa.

Forsteo is a disposable pen device, whereas Terrosa is only available in re-usable pens with replaceable cartridges. Training on how to use the device is required for both Forsteo and Terrosa and carried out by a Health Care Provider (HCP) at the hospital where Forsteo is prescribed.

Forsteo was launched in Norway with a re-usable pen, similar to the biosimilar pens available today. After some years in the market, and based of patient and HCP feedback, Eli Lilly decided to introduce a new and improved disposable pen, which is the one available today. The patient's experiences with the disposable pen compared to a re-usable pen show that the disposable pen is easy to use[1].

> *A total of 99% of patients agreed or strongly agreed that the new delivery device was easy to learn to use, and almost all (99.5%) agreed that, overall, the new delivery device was easy to use[1].*

More than 90% of those who used the updated Forsteo pen stated that it reduced their reluctance to take injections [1]. This can help promote adherence, which is a significant challenge in osteoporosis patients.

Unlike Forsteo, Terrosa as a re-usable pen needs to be 'primed' each time a new cartridge is inserted. This is done by half-turning the dial (to the droplet symbol) and pressing the inject button. According to Specialist Pharmacy Service, in their words

> *There is a risk that the patient might forget to prime the pen when a cartridge is changed or could administer the primed 'dose'. This could result in the patient thinking they have received a dose when they have only administered the few drops that are expelled when the pen is primed. When the activation button is pressed the dose is expelled. It is possible to only partially turn the dial and still be able to press the activation button [2].*

We believe that the Forsteo is easier to use for the patients and promotes adherence.

Non-medical switching after treatment start is not supported by Eli Lilly. Additional device training will be required for all patients who are required to switch teriparatide treatment. Device training should be given by trained HCP, with sufficient time to go through the training on how to use their device.

Many patients who use Forsteo likely have no previous experience of administering drugs by injection and they are often quite anxious about self-injection (or injection by a carer) when they first start the treatment. To overcome this Lilly provided extensive support and training to patients and Health care professions. After patients have become comfortable with the Forsteo device they may become anxious about having to change to a different device. As highlighted by Specialist Pharmacy Service, patients may even struggle to correctly operate a different device leading to missed doses or treatment errors[2].

The fact that the majority of patients are over 70 years of age [3], often with physical challenges such as arthritis or visual problems, and may have difficulty following complex instructions and find it challenging to use or get used to a new device for their injections increase our concern for incorrectly used after treatment switch. Further, the recommended maximum total duration of treatment with Forsteo is 24 months [4].

Eli Lilly considers the risk of switching treatment after treatment training and the first dose of Forsteo not worth taking. We are concerned that this may make it more difficult for patients to pursue good self-treatment.

We, therefore, believe that the change of teriparatide should not happen after treatment start, and the choice of teriparatide should take place in consultation with the treating physician and not directly at the pharmacy.

Best Regards,

Eli Lilly Norge

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References:

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2. Specialist Pharmacy Service. *IN USE PRODUCT SAFETY ASSESSMENT REPORT FOR TERIPARATIDE.* 2020 [cited 2021 18 August]; Available from: https://www.sps.nhs.uk/articles/in-use-product-safety-assessment-report-for-teriparatide-2/.
3. Reseptregisteret. *Statistikk fra Reseptregisteret*. 2021 [cited 2021 18 August]; Available from: http://www.reseptregisteret.no/.
4. Forsteo SmPC, section 4.2, 14.10.2020.