1.6.1 NON-GMO (GENETICALLY MODIFIED ORGANISMS)

The Applicant is submitting an application for authorisation of

Teriparatide 20 µg/80 µl, solution for injection in pre-filled pen

according to Article 10.1 of Directive 2001/83/EC, claiming to be generic of the reference medicinal product

Forsteo, 20 µg/80 µl, solution for injection in pre-filled pen

as it has the same quantitative and qualitative composition in active substances and the same pharmaceutical form.

The introduction on the market of this medicinal product will not mean an increase of the number of units sold but it will allow to reduce the pharmaceutical expense. Furthermore, it will give the patient the chance to purchase the medicinal product at a lower price.

In accordance with the *Guideline on the Environmental Risk Assessment for medicinal products for human use* (CPMP/SWP/4447/00), the non-presentation of an Environmental Risk Assessment report is justified when the medicinal product of the application does not increase environmental exposure to the active substance.

The medicinal product in this application -and specifically, its active substance – teriparatide - complies fully with the guideline, as it will take over part of the existing market for this active substance. Next to that the product contains a peptide as active pharmaceutical ingredient, which due to its nature is unlikely to result in a significant risk to the environment. Thus, environmental exposure to teriparatide will not increase and no possible environmental risk should be considered.

The product teriparatide 20 µg/80 µl, solution for injection in pre-filled pen does not contain any component which could lead to additional hazard to the environment during storage, distribution, use and disposal.

Based on the above mentioned, the applicant herewith states that the approval of the product will not lead to an increase of the total quantity of teriparatide released into the environment, and therefore, will not result in an increase of risk to the environment during storage, distribution, use and disposal.
Consequently no new or further information regarding Environmental Risk Assessment is provided.

Dr. Christian Wilde 14.01.2019