

13 October 2022

NeoRecormon (epoetin beta): Risk of medication error - potential missing labels on NeoRecormon pre-filled syringes in single packs

Dear Healthcare Professional,

F. Hoffmann-La Roche Ltd in agreement with the European Medicines Agency and the Italian Medicines Agency would like to inform you of the following:

Summary

- Missing labels were reported for five individual NeoRecormon pre-filled syringes (PFS) packaged in single-pack folding boxes distributed in France. Other single-pack batches of NeoRecormon PFS produced at the same time were also shipped to Italy, Poland, Romania and Slovenia. Only NeoRecormon batches manufactured before 28 March 2022 were potentially impacted by this defect. A list of the **potentially impacted** NeoRecormon batches can be found in the Annex.
- **NeoRecormon PFS without a label SHOULD NOT be administered to patients**, and the defect should be reported. In addition, contact Roche for further instructions.
- **Healthcare professionals SHOULD CHECK NeoRecormon PFS within single packs prior to dispensing** to ensure no unlabelled PFS are dispensed to the patients.

Background on the defect

Five unlabelled NeoRecormon PFS in single-pack folding boxes have been identified. Three unlabelled syringes of the 3000 IU strength NeoRecormon were reported from a French dialysis center on 20 July 2022, one unlabelled syringe of the 6000 IU strength NeoRecormon was reported via the French Health Authority ANSM on 22 July 2022, and one unlabelled syringe of the 3000 IU strength NeoRecormon was reported from a French hospital on 27 July 2022. The five NeoRecormon PFS were not administered to patients. No additional reports of unlabelled NeoRecormon PFS have been received to date.

The majority (~94%) of the relevant single packs, packaged before 28 March 2022, were manufactured for the French market. All of these batches have been fully distributed to hospitals in France by the end of August 2022. Batches, which maybe affected, have also been distributed to four other EU countries: Italy, Poland, Romania and Slovenia.

A Roche investigation concluded that the probability of other unlabelled syringes is low. Roche continues to release NeoRecormon single-pack batches to the market to ensure uninterrupted patient access to the medication.

Minimal impact on patient safety is expected due to this defect, which may result in missing doses. NeoRecormon is administered over prolonged periods, occasional missed doses are not expected to have a significant effect on patient treatment.