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## **ADDITIONAL INFORMATION**

## 7+13. DESCRIBE REACTION(S) continued

The patient's relevant medical history and concomitant medications were not reported.

The following information was reported: DEVICE ISSUE (non-serious), outcome "unknown", described as "The pen didn't work and wouldn't let her put in the medication"; WRONG TECHNIQUE IN DEVICE USAGE PROCESS (non-serious), outcome "unknown", described as "improper handling of the device". The action taken for somatropin was unknown.

Causality for "the pen didn't work and wouldn't let her put in the medication" and "improper handling of the device" was determined associated to device constituent of somatropin (malfunction).

The information on the batch/lot number for somatropin will be requested and submitted if and when received.

Additional information: The patient's mother indicates that she began genotropin treatment last week. She comments that yesterday, 14Jul2025, when she changed the medication inside the pen, the pen didn't work and wouldn't let her insert the medication. Further information is not available because communication is lost.

As for 16Jul2025 the nurse indicated that there was improper handling of the device by the patient's mother.

Follow-up (16Jul2025): This is a spontaneous follow-up report received from a nurse.

Updated information included: New reporters, dosage regimen, new event.

The initial case was missing the following minimum criteria: as there is no indication that the consumer experienced an adverse event under GENOTROPIN PEN. Upon receipt of follow-up information on 15Jul2025, this case now contains all required information to be considered valid.

Follow-up (15Jul2025): This is a spontaneous follow-up report received from product quality group. Updated information included: Reportability Determination.