Press release of the National Agency for Medicines and Medical Devices

on recall of batches no. U299B and no. T737 series of Sutent,

50 mg capsules

The National Agency for Medicines and Medical Devices (NAMMD) has decided to recall of the two batches of Sutent, 50 mg capsules because of information received from the marketing authorisation holder for the original product (Pfizer) and the European Medicines Agency.

The decision concerning the recall is the result of detection of a phial of counterfeit Sutent 50mg, batch no. T737, in the Romanian legal distribution network as well as of a phial of counterfeit Sutent 50mg, batch no. U299B, in Germany.

As a precaution, the marketing authorisation holder for the original product (Pfizer) has initiated recall of the 2 batches of Sutent 50 mg.

The NAMMD has informed all EU competent authorities on the situation via the rapid alert system.

At this time, police authorities in charge together with the marketing authorisation holder (Pfizer) and the NAMMD are conducting an investigation in this respect.