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Regulatory approval in Europe granted for Synthon's Glatiramer Acetate

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Synthon received regulatory clearance in all 27 EU/EEA member states involved in the procedures

Synthon announced that it has successfully concluded the decentralized procedures for glatiramer acetate 40 mg/ml pre-filled syringe for the treatment of relapsing forms of multiple sclerosis and received regulatory approval in Europe. Synthon's three-times-a-week glatiramer acetate is a therapeutically equivalent version of the originator medicine Copaxone 40mg.

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Synthon's 20 mg/ml glatiramer acetate product has already received marketing authorizations in these European countries. As of the end of 2016, Synthon's partners have introduced glatiramer acetate 20 mg/ml in the majority of these countries.

"We are very pleased with this approval," commented Synthon's chief executive officer Jacques Lemmens. "It allows us to make an affordable version of the 40 mg/ml dosage strength of glatiramer acetate available to MS patients in Europe."