

Nijmegen, 20 August 2020

Registration of Clozapine tablets in the European Union

Synthon BV and Genthon BV, an associated company of Synthon, initiated a national and a mutual recognition procedure (MRP) concerning a generic application claiming essential similarity of the Synthon/Genthon Clozapine tablets with the innovator product Leponex / Clozaril from Sandoz (current marketing authorisation holder is Mylan). The innovator product was first registered through a national procedure in Austria in 1969 and 1972 and through a national and mutual recognition procedure in other EU countries. As Synthon's/Genthon's clozapine is a generic product, national and MRP procedures could have been selected for the marketing authorisation application at the time of submission. The selection of the registration procedure was based on target markets. The marketing intention of Synthon was limited to several European countries (our marketing partners are located in specific EU countries). For this reason, the selected registration procedures were both, the national and the MRP.

The first national procedure in the Netherlands was completed successfully on 8 September 1998. From this national registration, a MRP has been started with the Netherlands as the RMS (the ISO 3166 code for the Netherlands is NL). Later, national registrations have been obtained in the Czech Republic and an additional registration in the Netherlands. Below, a summary of the selected countries where the marketing authorisation was granted.

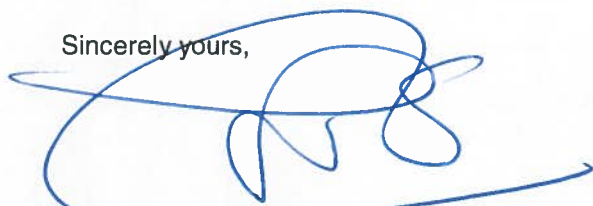
National in DE

NL/H/0175/001-003/MR – the Netherlands (RMS)

CMS: Austria, Belgium (withdrawn), France (deceased), Greece (deceased), Iceland (added through a repeat-use procedure), Italy, Portugal (withdrawn), Spain

There are no public assessment reports available.

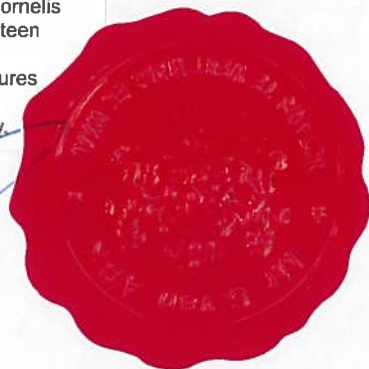
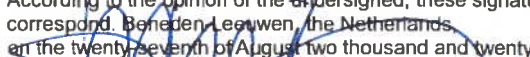
Sincerely yours,



Dr FJC van Strien
Vice President Regulatory Affairs
Synthon B.V

frank.vanstrien@synthon.com

The undersigned, mr. Marijke Bertina Johanna Smits, candidate-notary, a substitute of mr. Cornelis van Ark, residing at the municipal West Maas en Waal, declares that the not in her presence appended signature has been compared to the signature on the copy of the passport of Mr Franciscus Johannes Cornelis van Strien, born at Rucphen on the second of March nineteen hundred sixty-eight, which copy is on file in the office. According to the opinion of the undersigned, these signatures correspond. Beneden Leeuwen, the Netherlands, on the twenty-seventh of August two thousand and twenty.

**Synthon BV**

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APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: THE NETHERLANDS
This public document
2. has been signed by **mr. C. van Ark**
3. acting in the capacity of notary at West Maas en Waal
4. bears the seal/stamp of aforesaid notary

Certified

5. in Arnhem
6. on 02-10-2020
7. by the registrar of the district court of Gelderland
8. no. 20-2143
9. Seal/stamp:
10. Signature:

O. Bkizkaya

