Synthon

Nijmegen, 10 September 2020

Registration of Bicalutamide film-coated tablets in EUROPE

Synthon initiated three Mutual Recognition Procedures (MRP) concerning generic applications claiming essential similarity of the Synthon Bicalutamide film-coated tablets with the innovator product Casodex 50 mg and 150 mg film-coated tablets from AstraZeneca. The innovator product was registered in the EU through an MRP in 2000.Synthon based the selection of the registration procedure was based on target markets. The marketing intention of Synthon was limited to several, but not all European countries (our marketing partners are located in specific EU countries) therefore the selected registration procedure was the MRP.

The first two MRP were completed successfully on 14 February 2007, the so-called day 90 of the European MRP. The RMSs are Finland and Slovenia (please read below the number of the procedures that start with the acronym for Finland: FI and Slovenia: SI). Below a summary of the selected countries where the marketing authorisation was granted:

- FI/H/0648/001-002/MR - Finland (AMS)
  - 50 mg CMSs: Austria, Germany, Estonia, Finland, Latvia, Portugal, The Netherlands, Italy, Lithuania
    (retired: Belgium, Czech Republic, Denmark, Greece, Norway, Sweden, Poland, Spain, Hungary, Ireland, Iceland, United Kingdom, Slovenia, Slovakia, Luxembourg)
  - 150 mg CMSs: Austria, Estonia, Finland, Latvia, Portugal,
    (retired: Czech Republic, Denmark, Greece, Norway, Poland, United Kingdom)

- SI/H/0198/001-002/MR - Slovenia (RMS) (before: UK/H/6126/001-002/MR-United Kingdom)
  - 50 mg CMSs: Austria, Czech Republic, Greece, Spain, Iceland, Italy, The Netherlands, Poland, Slovenia, United Kingdom
  - 150 mg CMSs: Austria, Czech Republic, Greece, Slovenia, United Kingdom

The third MRP was completed successfully on 1 July 2008. The RMS was The Netherlands (NL). Below a summary of the selected countries where the marketing authorisation was granted:

- NL/H/2299/001-002/MR - The Netherlands (RMS)
  - 50 mg CMSs: Germany, Portugal, The Netherlands, Italy, Latvia
    (retired: Austria, Bulgaria, Greece, Spain, Romania, Poland, Norway, United Kingdom, Slovakia, Hungary, Finland, France, Lithuania)
  - 150 mg CMSs: Austria, Denmark, Italy, The Netherlands, Portugal, Slovakia, Lithuania
    (retired: Belgium, Bulgaria, Germany, Greece, Spain, Finland, Hungary, Iceland, Norway, Poland, Romania, Sweden, Slovenia, United Kingdom, Finland)

Synthon BV
Microweg 22 | P.O. Box 7071 | 6503 GN Nijmegen | The Netherlands | T +31 (0)24 372 77 00 | F +31 (0)24 372 77 05
info@synthon.com | www.synthon.com | Chamber of Commerce 10036060 | VAT NL.8001.00.517.B01

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More information on the Bicalutamide Synthon procedures is made available by the CMDh and can be found here:
http://mri.medagencies.org/Human/Product/Details/14650
http://mri.medagencies.org/Human/Product/Details/2260
http://mri.medagencies.org/Human/Product/Details/14591
http://mri.medagencies.org/Human/Product/Details/14612
http://mri.cts-mrp.eu/Human/Product/Details/25276
http://mri.cts-mrp.eu/Human/Product/Details/25277

Marjolijn van der Star
Head Regulatory Affairs
Synthon BV

Marjolijn.vanderStar@synthon.com

Signature:

The undersigned, mr. Cornelis van Ark, notary, residing at the municipal West Maas en Waal, declares that the not in his presence appended signature has been compared to the signature on the copy of the passport of Mrs Lijntje Maria van der Star, born at Rotterdam on the fourteenth of October nineteen hundred sixty-six, 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-third of September two thousand and twenty.

de Rechtspraak

Rechtbank Gelderland

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. Ekizkaya