Draft Public Assessment Report

Update

Quetiapin ”Hexal”

50 mg, 150 mg, 200 mg, 300 mg and 400 mg prolonged-release tablets

Quetiapine (as quetiapine fumarate)

This module reflects the procedural steps and scientific information after the finalisation of the initial procedure.

Scope	Procedure number	Product Information affected	Date of start of the procedure	Date of end of procedure	Approval/ non approval	Assessment report attached
Repeat use with AT, BE, EL, FI, HR, IE, IS, LU, NL, SE and SI	DK/H/2334/001-005/E/001	N	14 July 2015	12 October 2015	Approval	Y, Annex 1

ANNEX 1 – Repeat use procedure (DK/H/2334/001-005/E/001)

The repeat use procedure started on 14 July 2015. There was no discussion in the CMD(h). Agreement between member states was reached during a written procedure. The concerned member states AT, BE, EL, FI, HR, IE, IS, LU, NL, SE and SI on the basis of the data submitted, considered that essential similarity had been demonstrated for Quetiapin "Hexal" 50 mg, 150 mg, 200 mg, 300 mg, 400 mg prolonged-release tablets with the reference product, and therefore granted a marketing authorisation. The repeat use procedure was finalised on 12 October 2015.

The MAH provided an updated dossier for the repeat use procedure. The only changes introduced since finalisation of the initial procedure were:
DK/H/2334/IB/001/G: Name change and introduction of new PSMF.
DK/H/2334/IA/002/G: Addition of batch releaser and secondary packaging site.

The date for the first renewal will be: 11 November 2019.

According to the List of Union reference dates and frequency of submission of periodic safety update reports (PSURs), no routine PSURs are required for this product.

Commitment made during the repeat use procedure:

- The applicant has made a commitment to submit a variation application to update the RMP within 3 months after the End of Procedure.

Conditions pursuant to Article 21a of Directive 2001/83/EC have been agreed:

- Educational material for healthcare professionals to address the risks of
  - Extrapyramidal symptoms – Educational material on benefit/risk of drug administration
  - Somnolence - Educational material on benefit/risk of drug administration
  - Weight gain - Educational material on metabolic parameters
  - Lipid changes (increased cholesterol (including increased LDLs), increased triglycerides, and decreased HDLs) Educational material on metabolic parameters
  - Hyperglycamia and diabetes mellitus - Educational material on metabolic parameters
  - Metabolic risk factors - Educational material on metabolic parameters
  - Potential for off-label use and misdosing – Educational material on drug indications

  The need for distribution of educational material should be decided at national level during the national phase.