FOI 23/612

Dear

Thank you for your email.

According to the attached EMA document, the following UK MAs for Seroquel were originally granted to AstraZeneca UK Ltd via NL/H/0156/001-003 & 007):

Seroquel 25 mg film-coated tablets – PL 17901/0038 (via NL/H/0156/001) Seroquel 100 mg film-coated tablets – PL 17901/0039 (via NL/H/0156/002) Seroquel 200 mg film-coated tablets – PL 17901/0040 (via NL/H/0156/003) Seroquel 300 mg film-coated tablets – PL 17901/0088 (via NL/H/0156/007)

Please can you advise if these MAs are still valid or if they have been transferred to another MA Holder via Change of ownership application?

If they have been transferred to a new MAH, please can you advise the new MA numbers, new MAH name & address, and date of change of ownership of the MAs ?

These have been transferred to another MA holder via a change of ownership.

The new MA numbers are PL 50827/0002-5. The new MA holder is Luye Pharma Limited, Surrey Technology Centre, 40 Occam Road, Surrey Research Park, Guildford GU2 7YG.

The date of the change of ownership was 22/9/2020.

If you disagree with how we have interpreted the Freedom of Information Act 2000 with regards to your request, you can ask for the decision to be reviewed. The review will be carried out by a senior member of the Agency who was not involved with the original decision.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office Wycliffe House Water Lane Wilmslow Cheshire SK9 5AF

Yours sincerely

MHRA Customer Experience Centre