Medicines & Healthcare products Regulatory Agency

MHRA

[redacted]

Medicines and Healthcare products
Regulatory Agency
10 South Colonnade
Canary Wharf
London14 4PU
United Kingdom
Email
FOILicensing@mhra.gov.uk
Mhra.gov.uk

22 May 2023

Dear [redacted]

Ref: FOI 23/282: Public Assessment Report and the Clinical Overview (Module 2.5) for Adaflex (melatonin) tablets marketed by AGB-Pharma AB.

Thank you for your communication dated 13 April 2023, where you requested the above documentation.

The Marketing Authorisations for Adaflex 1 mg, 2 mg, 3 mg, 4 mg and 5 mg tablets (PL 52497/0001-0005; SE/H/2048/0001-005/MR) were granted in the UK via an incoming mutual recognition procedure on 29 May 2020. The Reference Member State (RMS) for the procedure was Sweden.

The Public Assessment Report can be obtained from the Heads of Medicines Agencies (HMA) MRI product index (https://www.hma.eu/human-medicines/mri-product-index.html) or by contacting the RMS at the address below:

Medical Products Agency
Dag Hammarskjölds väg 42 / Box 26
SE – 751 03 UPPSALA
Sweden
Email: registrator@mpa.se

The Marketing Authorisation Holder objected to release of some parts of the Clinical Overview on the grounds that the information is commercially confidential. We, therefore, called a test of the public interest to determine whether to exempt release of sections of the report according to Section 43 (Commercial interests) of the FOI Act. The test of the public interest has been concluded, therefore please find attached a copy of the Clinical Overview.

Please note that Confidential information has been redacted according to Section 40 (Personal information), Section 41 (Information provided in confidence) and Section 43 (Commercial interests) of the FOI Act. Section 40 and 41 are absolute exemptions

and no consideration of the public interest is required. Section 43 is a conditional exemption, conditional on the public interest in releasing it not outweighing the company's/commercial enterprise's right to confidentiality and the probable damage that the company/commercial enterprise could suffer as a result of the information being released. In this case we have not identified any issues which would benefit the public as a whole by being brought to their attention (examples of issues would be a major public health risk or a major procedural failure or irregularity).

We now consider this FOI request closed. If you require any further information, please respond to the FOI Licensing Team at FOILicensing@mhra.gov.uk.

If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option, please email: info@mhra.gov.uk

After that, if you remain dissatisfied, you may write to the Information Commissioner at:
The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

They will make a decision on whether or not we have interpreted the FOIA correctly in handling your request.

Yours sincerely,
FOI Team