FOI 23/255 - tests/trials and results submitted to MHRA for marketing approval by all manufacturers and suppliers of Mirtazepine (Remeron)

REQUEST
6 April 2023

I would like to see copies of all reports of tests/trials and results submitted to MHRA for marketing approval by all manufacturers and suppliers of medication called Mirtazepine (Remeron), including tests/trials and results that were not officially published or released to the general public, and all details concerned.
I am particularly interested in all reports of test results that produced adverse effects or side effects from the medication, with more specific interest in side-effects/adverse effects that may include cochlear hair cell damage in the ear, tinnitus, hearing loss, balance problems or symptoms related to ototoxicity, particularly in the ear.

I would like to have specific reports related to the tests that produced above side effects provided if possible too.

MHRA RESPONSE
15 June 2023

Dear

Thank you for your email.

Please review the Public Assessment Reports (PARs) published for product licences containing mirtazapine, a link to our website page to these is provided below:
https://products.mhra.gov.uk/search/?search=mirtazapine&page=1

The brand leader products are Zispin/Mirtazapine (known as Remeron in the Reference Member State [RMS] Country). These were authorised via a decentralised procedure with the Netherlands as the RMS (NL/H/0132/001-7). As these products were authorised via a decentralised procedure with the Netherlands as the RMS, we refuse to release any information on the initial marketing authorisation application documents under Section 27 (international relations) of the FOI Act.

Please find below details and we suggest you contact the RMS regulator, the Netherlands, for them to consider under their FOI legislation.

Medicines Evaluation Board
Graadt van Roggenweg 500
NL - 3531 AH Utrecht
Netherlands

Phone +31 88 224 80 00
Fax+31 88 224 80 01
Website: www.cbg-meb.nl

Information about possible adverse reactions identified during clinical trials are reflected in the product information. The side effects section of the product information includes details of possible side effects and the frequencies are based on the results from clinical studies. In addition, the MHRA collects and reviews reports of suspected adverse drug reactions to all medicines via the Yellow Card scheme. A complete listing of the reports which we have received for mirtazapine can be found in the interactive Drug Analysis Profile (iDAP): Mirtazapine iDAP.

Since 1997 and up to 30th April 2023 we have received the following numbers of reports of suspected Adverse Drug Reactions for mirtazapine relating to the types of adverse events which you mention in your request:

Deafness: 2
Bilateral deafness: 2
Neurosensory deafness: 2
Unilateral deafness: 1
Hypoacusis: 5
Sudden hearing loss: 1
Hyperacusis: 19
Meniere's disease: 1
Tinnitus: 57
Vertigo: 26
Balance disorder: 45

Please note that reported adverse reactions have not been proven to be related to the drug, and should not be interpreted as a list of known side effects.

The product information can be updated throughout the lifecycle of the product to reflect new safety concerns or updates to existing warnings. However, when safety issues are identified via reporting schemes such as the Yellow Card scheme it is not possible to establish a frequency for the side effect and these are listed in the product information under the frequency category 'not known'.

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk
Please remember to quote the reference number above in any future communications.

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
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU