

FOI 23/267

**MHRA RESPONSE**  
**12 May 2023**

Dear

Thank you for your request of 08 April 2023 in which you requested:

1. *Please provide the number of complaints received by the MHRA, between 2017 and 2022, about products containing the herb St. John's wort (*Hypericum perforatum* L.) that did not, at the time the complaints were received by the Agency, hold a marketing authorisation, a Traditional Herbal Registration or that were considered as "unlicensed".*

*Please group the number of complaints by annual quarter.*

*Please indicate how many of the complaints were submitted to the Agency by commercial entities (i.e. other companies). We are not requesting disclosure of the names or other identification data of the commercial entities.*

*Please format your response in a table titled "Table 1".*

2. *Please provide a complete list of the products, as per Point 1 above, that the complaints were in relation to. We are requesting a complete list of products. For each product, please provide the following:*
  - a. *product name;*
  - b. *manufacturer name;*
  - c. *product specifications, including product type (e.g. tablet, capsule, tincture et cetera), serving size, amount of herb equivalent per serving (in milligrams) and maximum daily serving amount;*
  - d. *number of complaints received, between 2017 and 2022, grouped by annual quarter; and*
  - e. *number of urgent notices, voluntary compliance letters, complaint letters, provisional determination notices, final determination notices or other similar communications issued by the MHRA to the manufacturers/suppliers of the products, with the date(s) when they were issued*

*Please format your response in a table titled "Table 2".*

3. *Please provide the total number of complaints received by the MHRA, between 2017 and 2022, about the following product: Healthy Mood St. John's Wort 500mg Extract *Hypericum Perforate* (supplied since or before February 2022). A copy of the product is produced at the exhibit marked "STJ/1" (page 4).*

*Please group the number of complaints by annual quarter.*

*Please indicate how many of the complaints were submitted to the Agency by commercial entities (i.e. other companies). We are not requesting disclosure of the names or other identification data of the commercial entities.*

*Please also provide the number of urgent notices, voluntary compliance letters, complaint letters, provisional determination notices, final determination notices or other similar communications issued by the MHRA to the manufacturer/supplier in relation to this product, indicating the date(s) when they were issued.*

*Please format your response in a table titled "Table 3"*

Upon review we consider that Section 12 of the Freedom of Information Act (the Act) would apply to your request. Section 12 allows public authorities to refuse requests where the cost of dealing with them would exceed the appropriate limit, which for central government is set at £600. This represents the estimated cost of one person spending 24 working hours in determining whether the department holds the information, locating, retrieving and extracting the information. We estimate that it will take us at least 35 hours to comply with your request.

In order for us to proceed we ask that you refine the date range of your request to reduce the number of years that your request covers.

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](mailto: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

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