Our ref: FOI 23/373 – questions on complaints about St John's Wort products

MHRA response
20 June 2023

Dear

Thank you for your request of 13 May 2023 in which you requested:

1. *Please provide the total number of complaints received by the MHRA, between 1 January 2017 and 31 December 2018, about products containing any part of the plant St. John's Wort (Hypericum perforatum) that did not, at the time that the complaints were received by the Agency, hold a marketing authorisation, a Traditional Herbal Registration, or that were considered as "unlicenced". Please group the number of complaints by annual quarter. If such information is available, please indicate how many of the complaints were submitted to the Agency by commercial entities (i.e. other companies). Disclosure of the names or other identification data of the commercial entities is not requested or necessary. Please format your response in a table titled "Table 1"*

2. *Please provide a complete list of the products, as per Question 1 above, that the complaints were in relation to. Please note that a complete list of all such products is requested. The following information must be provided for each product: 2(a). product name; 2(b). manufacturer name and/or brand name; 2(c). product specifications, including, inter alia: dosage form (e.g. tablet, capsule, tincture et cetera), serving size, amount of plant per single serving (expressed as dry herb equivalent in milligrams/mg) and maximum daily amount of plant (expressed as dry herb equivalent in milligrams/mg); 2(d). number of complaints received, between the dates specified at Question 1 above, grouped by annual quarter; and 2(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, including 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 1 January 2019 and 31 December 2020, about products containing any part of the plant St. John's Wort (Hypericum perforatum) that did not, at the time that the complaints were received by the Agency, hold a marketing authorisation, a Traditional Herbal Registration, or that were considered as "unlicenced". Please group the number of complaints by annual quarter. If such information is available, please indicate how many of the complaints were submitted to the Agency by commercial entities (i.e. other companies).*

Disclosure of the names or other identification data of the commercial entities is not requested or necessary. Please format your response in a table titled "Table 1"

4. *Please provide a complete list of the products, as per Question 1 above, that the complaints were in relation to. Please note that a complete list of all such products is requested. The following information must be provided for each product: 2(a). product name; 2(b). manufacturer name and/or brand name; 2(c). product specifications, including, inter alia: dosage form (e.g. tablet, capsule, tincture et cetera), serving size, amount of plant per single serving (expressed as dry herb equivalent in milligrams/mg) and maximum daily amount of plant (expressed as dry herb equivalent in milligrams/mg); 2(d). number of complaints received, between the dates specified at Question 1 above, grouped by annual quarter; and 2(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, including the date(s) when they were issued. Please format your response in a table titled "Table 2"*

5. *Please provide the total number of complaints received by the MHRA, between 1 January 2021 and 31 December 2021, about products containing any part of the plant St. John's Wort (Hypericum perforatum) that did not, at the time that the complaints were received by the Agency, hold a marketing authorisation, a Traditional Herbal Registration, or that were considered as "unlicenced". Please group the number of complaints by annual quarter. If such information is available, please indicate how many of the complaints were submitted to the Agency by commercial entities (i.e. other companies). Disclosure of the names or other identification data of the commercial entities is not requested or necessary. Please format your response in a table titled "Table 1".*

6. *Please provide a complete list of the products, as per Question 1 above, that the complaints were in relation to. Please note that a complete list of all such products is requested. The following information must be provided for each product: 2(a). product name; 2(b). manufacturer name and/or brand name; 2(c). product specifications, including, inter alia: dosage form (e.g. tablet, capsule, tincture et cetera), serving size, amount of plant per single serving (expressed as dry herb equivalent in milligrams/mg) and maximum daily amount of plant (expressed as dry herb equivalent in milligrams/mg); 2(d). number of complaints received, between the dates specified at Question 1 above, grouped by annual quarter; and 2(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, including the*

date(s) when they were issued. Please format your response in a table titled "Table 2"

7. *Please provide the total number of complaints received by the MHRA, between 1 January 2022 and 31 December 2022, about products containing any part of the plant St. John's Wort (Hypericum perforatum) that did not, at the time that the complaints were received by the Agency, hold a marketing authorisation, a Traditional Herbal Registration, or that were considered as "unlicenced". Please group the number of complaints by annual quarter. If such information is available, please indicate how many of the complaints were submitted to the Agency by commercial entities (i.e. other companies). Disclosure of the names or other identification data of the commercial entities is not requested or necessary. Please format your response in a table titled "Table 1"*

8. *Please provide a complete list of the products, as per Question 1 above, that the complaints were in relation to. Please note that a complete list of all such products is requested. The following information must be provided for each product: 2(a). product name; 2(b). manufacturer name and/or brand name; 2(c). product specifications, including, inter alia: dosage form (e.g. tablet, capsule, tincture et cetera), serving size, amount of plant per single serving (expressed as dry herb equivalent in milligrams/mg) and maximum daily amount of plant (expressed as dry herb equivalent in milligrams/mg); 2(d). number of complaints received, between the dates specified at Question 1 above, grouped by annual quarter; and 2(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, including the date(s) when they were issued. Please format your response in a table titled "Table 2".*

9. *Please provide the total number of complaints received by the MHRA, between 1 January 2023 and 12 May 2023, about products containing any part of the plant St. John's Wort (Hypericum perforatum) that did not, at the time that the complaints were received by the Agency, hold a marketing authorisation, a Traditional Herbal Registration, or that were considered as "unlicenced". Please group the number of complaints by calendar month. If such information is available, please indicate how many of the complaints were submitted to the Agency by commercial entities (i.e. other companies). Disclosure of the names or other identification data of the commercial entities is not requested or necessary. Please format your response in a table titled "Table 1"*

10. *Please provide a complete list of the products, as per Question 1 above, that the complaints were in relation to. Please note that a complete list of all such products is requested. The following information must be provided for each*

product: 2(a). product name; 2(b). manufacturer name and/or brand name; 2(c). product specifications, including, inter alia: dosage form (e.g. tablet, capsule, tincture et cetera), serving size, amount of plant per single serving (expressed as dry herb equivalent in milligrams/mg) and maximum daily amount of plant (expressed as dry herb equivalent in milligrams/mg); 2(d). number of complaints received, between the dates specified at Question 1 above, grouped by calendar month; and 2(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, including the date(s) when they were issued. Please format your response in a table titled "Table 2".

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
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