Freedom of Information Act 2000 (FOIA)

Decision notice

Date:	**31 January 2024**
Public Authority:	**Medicines and Healthcare products Regulatory Agency**
Address:	**10 South Colonnade** **London** **E14 4PU**

Decision (including any steps ordered)

1. The complainant on behalf of a charity has submitted seven separate requests for information to the Medicines and Healthcare products Regulatory Agency (the MHRA) for information relating to the plant "St. John's Wort". The MHRA has relied on section 14(1) of FOIA to refuse all seven requests, on the basis that they are vexatious.

2. The Commissioner's decision is that the MHRA is entitled to rely on section 14 of FOIA. He is satisfied that the complainant's requests can be characterised as being vexatious. The requests appear to be part of a concerted campaign that has resulted in a number of requests for information from different requesters, culminating in the complainant's requests, which have placed a significant burden on the MHRA.

3. However, the Commissioner has recorded procedural breaches of sections 1, 10 and 17 of FOIA as the MHRA failed to respond to the complainant's requests within the statutory time limits.

4. The Commissioner does not require the MHRA to take any further action in this matter.

Request and response

5. On 13 May 2023, the complainant submitted seven separate requests for information to the MHRA for information relating to the plant St.

John's Wort. The full details of the seven requests can be found in the annex at the end of this decision notice.

6. On the 20 June 2023, the MHRA responded to five of the requests, refusing to comply with them in accordance with section 12(1) of FOIA (cost of compliance would exceed the appropriate limit).

7. The complainant wrote to the MHRA on 21 June 2023, requesting an internal review of its decision to refuse to comply with the five requests under section 12(1) of FOIA.

8. On the 19 July 2023, the MHRA responded to the remaining two requests, also refusing to comply with them in accordance with section 12(1) of FOIA.

9. The MHRA provided the outcome of its internal review for all seven requests on 9 August 2023, in which it revised its position to one of refusing to comply with all seven requests on the basis that they were vexatious under section 14(1) of FOIA.

Scope of the case

10. The complainant contacted the Commissioner on 10 August 2023 to complain about the way their requests for information had been handled.

11. The Commissioner considers that the scope of his investigation is to consider whether the MHRA has correctly applied section 14(1) of FOIA to all seven requests for information.

Reasons for decision

Section 14 – vexatious requests

12. Section 14(1) of FOIA states that a public authority is not obliged to comply with a request for information if the request is vexatious.

13. The term 'vexatious' is not defined within FOIA. However, it has been considered in the case of The Information Commissioner and Devon County Council v Mr Alan Dransfield (GIA/3037/2011).

14. The Upper Tribunal took the view that the ordinary dictionary definition of the word vexatious is only of limited use because the question of whether a request is vexatious ultimately depends upon the circumstances surrounding that request. The Tribunal concluded that

'vexatious' could be defined as the "…manifestly unjustified, inappropriate or improper use of a formal procedure" (paragraph 27). The decision clearly establishes that the concepts of 'proportionality' and 'justification' are central to any consideration of whether a request is vexatious.

15. In the Dransfield case, the Upper Tribunal also found it instructive to assess the question of whether a request is truly vexatious by considering four broad issues:

    - the burden imposed by the request (on the public authority and its staff);
    - the motive of the requester;
    - the value or serious purpose of the request; and
    - harassment or distress of and to staff.

16. The Upper Tribunal did, however, also caution that these considerations were not meant to be exhaustive. Rather, it stressed the "importance of adopting a holistic and broad approach to the determination of whether a request is vexatious or not, emphasising the attributes of manifest unreasonableness, irresponsibility and, especially where there is a previous course of dealings, the lack of proportionality that typically characterise vexatious requests" (paragraph 45).

17. The Commissioner has identified a number of 'indicators' which may be useful in identifying vexatious requests. These are set out in his published guidance[1] on vexatious requests. The fact that a request contains one or more of these indicators will not necessarily mean that it must be vexatious. All the circumstances of a case will need to be considered in reaching a judgement as to whether a request is vexatious.

Detrimental impact on the public authority – campaigns

18. In this case, the MHRA is of the view that the requests are part of a series of related requests and correspondence from the complainant/charity, another individual and a limited company.

19. When determining if a complainant can be seen as acting in concert for the purposes of deciding if the request is vexatious, the Commissioner

[1] Dealing with vexatious requests (section 14) | ICO

has produced guidance[2] on this matter. The guidance states that if a public authority has reason to "believe that several different requesters are acting together as part of a campaign to disrupt the organisation with the sheer weight of FOIA requests being submitted, then it may take this into account when determining whether any of those requests are vexatious."

20. The Commissioner's guidance suggests that there must be sufficient evidence to substantiate the claim of a link between requests, for example that the requests are similar, the requesters copy each other into requests, the pattern of requests is unusual or frequent, or the group has a website which references a campaign against the public authority. The Commissioner has considered this point very carefully, as he is conscious of the fact that accepting that requesters are acting in concert will add much greater validity to the claims that the requests in this case are vexatious.

21. In its submission to the Commissioner, the MHRA explained that in 2023 it received multiple requests from the Trustees (and 'The Team') of the charity (the complainant), from a limited company, and from an individual requester who the MHRA understands is the Chair and one of the three Trustees of the charity. The individual requester is also a reseller of products sold by the limited company. The MHRA stated that the multiple requests must be viewed in the context of an extended engagement between the MHRA, the limited company and the individual requester.

22. It is the MHRA's view that the requests from the complainant, the individual requester and the limited company have been made by a small number of individuals acting together as a direct result of the MHRA's action against the limited company. By way of background, the action in question related to the sale of products containing St. John's Wort, hence the focus on this in the complainant's requests.

23. The MHRA has stated that whilst the requests made by the complainant do not contain the explicit allegations, or focus on individuals named in the requests made by the limited company and the individual requester, they exist within the wider context and the MHRA believes they are part of this one engagement. The MHRA has therefore come to the view that section 14(1) of FOIA applies, based on relevant records in the public domain but most importantly, from the three requesters' own correspondence to the MHRA.

[2] Are requests made as part of a campaign vexatious? | ICO

24. The MHRA has stated that considerable amounts of correspondence, as well as specific requests, all relate to or stem from regulatory action taken by the MHRA against the limited company. The MHRA has explained that the initial requests and correspondence in 2023 ran alongside the MHRA's action against the limited company, and the limited company's introduction of the charity's initiative. The MRHA stated that these led to a further strand of engagement and requests, resulting in a disproportionate level of disruption and distraction for colleagues in several MHRA teams.

25. The MHRA has stated that "the correspondence is characterised by:

- Multiple requests, complaints and correspondence from the three parties being submitted in short periods of time, on certain occasions with all parties contacting the MHRA a number of times on the same day, overwhelming colleagues working to handle these.

- Cross-over in the content between requests and complaints submitted by the three parties, including similarity of subject matter and in some cases, re-use of request wording previously used by the different parties.

- Requests driven by previous engagements with the MHRA and in respect of communications between [the limited company] and the MHRA, with the result that each new stage of the MHRA's action against [the limited company] generates new requests.

- Complaints by [the limited company] and [the individual requester] against individual MHRA staff who have engaged with the parties. Two initial complaints from [the limited company] were investigated, and the outcomes communicated to [the limited company]; this then led to further allegations and complaints about those who had conducted the investigations and further FOI requests made about these colleagues. This has the effect of harassing staff and causing distress.

- Multiple additional allegations of corruption, criminal activity and conflict of interest made against the MHRA throughout the correspondence and requests from [the limited company] and [the individual requester]. Requests are introduced by or linked with frequent claims and allegations (from the time of [the individual requester's] first contacts with the MHRA in December 2021, and the first requests submitted by both [the complainant] and [the individual requester] in March 2022)."

26. The MHRA has provided the Commissioner with copies of the previous correspondence and requests for information to support this position.

27. From the detailed information and evidence provided to the Commissioner, it is clear that the MHRA has received significant correspondence about the St. John's Wort plant and the investigation into the limited company, including that from the complainant.

28. The MHRA considers that the volume and pattern of requests relating to the St. John's Wort plant and the investigation into the limited company points to a concerted campaign mounted by a number of individuals. It appears to the MHRA that a number of persons, including the complainant, are making information requests and these individuals are known to one another.

29. As evidence of this, the MHRA has drawn the Commissioner's attention to a number of information requests submitted via the three requesters.

30. The Commissioner has reviewed the detailed information and evidence and has found it to be sufficiently compelling for him to believe that a number of individuals are acting in the manner of a campaign. He therefore considers that the complainant's request should be considered in the context of that campaign.

31. The Commissioner has decided that the volume and pattern of the requests made by these persons is such that they are placing a significant burden on the MHRA.

32. It is clear to the Commissioner that the volume of requests received by the MHRA is such that its ability to properly deal with other matters raised by the public is significantly impeded.

33. An examination of the requests and correspondence received by the MHRA in connection with the St. John's Wort plant and the investigation into the limited company has led the Commissioner to conclude that this group of people will not let matters lie and that they are pursuing the MHRA to an unreasonable level. In the Commissioner's opinion, the MHRA has now reached the point where it is appropriate for it to say enough is enough and for it to apply section 14 of FOIA to the requests.

34. The Commissioner is mindful of the judgment of the Upper Tribunal in Wise v The Information Commissioner (GIA/1871/2011) which stated that;

> "…there must be an appropriate balance between such matters as the information sought, the purpose of the request and the time and other resources that would be needed to provide it."

35. The Commissioner must have regard to the resources available to public authorities for dealing with requests for information. In this case, the complainant's request is part of a long line of interrelated requests which have placed a significant burden on the MHRA in terms of officer time and resources. He has therefore decided, solely on the issue of proportionality and burden, that the MHRA is entitled to rely on section 14 of FOIA to refuse all seven of the complainant's requests for information.

Procedural matters

Sections 1, 10 and 17 – time for compliance

36. Section 1(1) of FOIA says that an individual who asks for information from a public authority is entitled to (a) be informed whether the authority holds the information and, if so, (b) to have that information communicated to them

37. Section 10(1) of the FOIA states that a public authority shall respond to information requests promptly and, in any event, by no later than 20 working days from receipt.

38. Section 17(1) of FOIA states that where a public authority refuses a request for information, it must provide the applicant with a refusal notice explaining the exemptions relied upon and why they apply (if not apparent), no later than 20 working days after the date on which the request was received.

39. The Commissioner notes that the time taken for the MHRA to respond to all seven requests for information exceeded 20 working days. The MHRA noted this breach in its internal review response. The Commissioner has therefore recorded breaches of sections 1, 10 and 17 of FOIA against the MHRA as a result.

Right of appeal

40. Either party has the right to appeal against this decision notice to the First-tier Tribunal (Information Rights). Information about the appeals process may be obtained from:

    First-tier Tribunal (Information Rights)
    GRC & GRP Tribunals,
    PO Box 9300,
    LEICESTER,
    LE1 8DJ

    Tel: 0203 936 8963
    Fax: 0870 739 5836
    Email: grc@justice.gov.uk
    Website: www.justice.gov.uk/tribunals/general-regulatory-chamber

41. If you wish to appeal against a decision notice, you can obtain information on how to appeal along with the relevant forms from the Information Tribunal website.

42. Any Notice of Appeal should be served on the Tribunal within 28 (calendar) days of the date on which this decision notice is sent.

Signed .....

Pamela Clements
Group Manager
Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Annex

43. The complainant's first request to MHRA on 13 May 2023:

> "Pursuant to the **Freedom of Information Act 2000**, the following information is herein requested:
>
> 1) Can the MHRA confirm or deny whether the sale of products intended for human use, which contain any part of the plant St. John's Wort (Hypericum perforatum), otherwise than as traditional herbal medicinal products licenced either under the Traditional Herbal Registration (THR) Scheme or under any other permitted scheme as set out in the **Human Medicines Regulations 2012**, is prohibited, restricted and/or banned in the UK?
>
> a) If the answer to Question 1 above is in the affirmative, can the MHRA confirm that the restriction, prohibition and/or ban on the sale of such products has been publicly and officially communicated to the public at large, that complete details with respect to the restriction, prohibition and/or ban have been and are currently published and available to the public at large, in the form of official documents, and that such documents may be freely accessed by any person and at any time (thus evidencing that the restriction, prohibition and/or ban is valid, in effect and may be appropriately referenced to by any person at any time)?
>
> b) If the answer(s) to Question 1 and/or Question 1(a) above is/are in the affirmative, please supply copies of the whole of such documents as described at Question 1(a) above together with the location where they are published.
>
> 2) Can the MHRA confirm or deny whether the sale of products classed as food supplements, as defined in **Directive 2002/46/EC ("the Food Supplements Directive")** and **The Food Supplements (England) Regulations 2003**, that contain any part of the plant St. John's Wort (Hypericum perforatum) is prohibited, restricted and/or banned in the UK?
>
> a) If the answer to Question 2 above is in the affirmative, can the MHRA confirm that the restriction, prohibition and/or ban on the sale of such food supplements has been publicly and officially communicated to the public at large, that complete details with respect to the restriction, prohibition

and/or ban have been and are currently published and available to the public at large, in the form of official documents, and that such documents may be freely accessed by any person and at any time (thus evidencing that the restriction, prohibition and/or ban is valid, in effect and may be appropriately referenced to by any person at any time)?

b) If the answer(s) to Question 2 and/or Question 2(a) above is/are in the affirmative, please supply copies of the whole of such documents as described at Question 2(a) above, together with the location where they are published."

44. The complainant's second request to MHRA on 13 May 2023:

"Pursuant to the **Freedom of Information Act 2000**, the following information is herein requested:

1) Please provide complete formulation specifications and/or requirements, in accordance with relevant UK and retained EU legislation, for products containing any part of the plant St. John's Wort (Hypericum perforatum) in order for such products to be classed as food supplements in the UK in accordance with **Directive 2002/46/EC ("the Food Supplements Directive")** and **The Food Supplements (England) Regulations 2003**.

Examples of formulation specifications/requirements must include, inter alia, the following:

a) the part(s) of plant legally permitted in the formulation of such food supplements;

b) for food supplements containing dry, powdered and/or liquid extracts of the plant as active ingredients, the range of Dry Extract Ratio (DER), expressed as a ratio, legally permitted in the formulation of such food supplements;

c) maximum amount of the plant per single serving, expressed as dry herb equivalent in milligrams (mg), that such food supplements may provide;

d) maximum daily amount of the plant, expressed as dry herb equivalent in milligrams (mg), that such food supplements may provide;

e) any limitation as to the dosage form permitted for such food supplements (for example, tablets, capsules, tinctures et cetera), indicating where appropriate the specific dosage forms not permitted for such food supplements;

f) *et alia*.

2) Can the MHRA confirm that these formulation specifications and/or requirements, as per Question 1 above, have been publicly and officially communicated to the public at large, that complete details with respect to each individual specification/requirement have been and are currently published and available to the public at large, in the form of official documents, and that such documents may be freely accessed by any person and at any time (thus evidencing that specifications/requirements valid, in effect and may be appropriately referenced to by any person at any time)?

3) Please provide complete details with respect to any differences in formulation that must exist between (i) products containing any part of the plant St. John's Wort (Hypericum perforatum) and which are classed as food supplements in accordance with **Directive 2002/46/EC ("the Food Supplements Directive")** and **The Food Supplements (England) Regulations 2003**, and (ii) products classed as medicinal products, also containing any part of the plant St. John's Wort (Hypericum perforatum), which may or may not be licensed either under the Traditional Herbal Registration (THR) Scheme or under any other permitted scheme as set out in the **Human Medicines Regulations 2012**.

4) Please indicate whether any thresholds in the maximum amount per single serving and/or maximum daily amount of the plant St. John's Wort (Hypericum perforatum), expressed as dry herb equivalent in milligrams (mg), have been established by the MHRA in order to classify products containing any part of this plant as medicinal products in accordance with the **Human Medicines Regulations 2012**.

5) Please indicate whether the MHRA has established and/or whether there is any statutory provision, legal requirement and/or official guidance pertaining to any age restriction(s) on the use of products containing the plant St. John's Wort (Hypericum perforatum). For example, please indicate whether the MHRA has established and/or whether there is any statutory provision, legal requirement and/or official guidance pertaining

to the minimum age at which the use of such products is considered safe. If so, please specify the age restriction(s), providing complete details for each individual such restriction.

6) Please indicate whether there exists a legal requirement, statutory provision, and/or official information or guidance issued by the MHRA(and/or by any other competent UK public authority)that prescribes the inclusion of specific safety statements on the labels/packaging of products containing the plant St. John's Wort (Hypericum perforatum) which are classed as food supplements in accordance with **Directive 2002/46/EC ("the Food Supplements Directive")** and **The Food Supplements (England) Regulations 2003**. This question pertains to such statements that are in addition to the information legally required to be included on the labels/packaging of food supplements in general, as set out in the two statuses.

7) Please indicate where there exist any official documents, which are published, publicly available and publicly accessible to any person and at any time, containing the information requested at Questions 1 to 6 above. If such documents exist, please supply copies of the whole of such documents together with the location where they are published."

45. The complainant's third request to MHRA on 13 May 2023:

"Pursuant to the **Freedom of Information Act 2000**, the following information is herein 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:

   a) product name;

   b) manufacturer name and/or brand name;

   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);

   d) number of complaints received, between the dates specified at Question 1 above, 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, including the date(s) when they were issued.

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

46. The complainant's fourth request to MHRA on 13 May 2023:

"Pursuant to the **Freedom of Information Act 2000**, the following information is herein requested:

1) 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".

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:

a) product name;

b) manufacturer name and/or brand name;

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);

d) number of complaints received, between the dates specified at Question 1 above, 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, including the date(s) when they were issued.

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

47. The complainant's fifth request to MHRA on 13 May 2023:

"Pursuant to the **Freedom of Information Act 2000**, the following information is herein requested:

1) 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".

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:

a) product name;

b) manufacturer name and/or brand name;

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);

d) number of complaints received, between the dates specified at Question 1 above, 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, including the date(s) when they were issued.

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

48. The complainant's sixth request to MHRA on 13 May 2023:

"Pursuant to the **Freedom of Information Act 2000**, the following information is herein requested:

1) 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".

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:

a) product name;

b) manufacturer name and/or brand name;

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);

d) number of complaints received, between the dates specified at Question 1 above, 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, including the date(s) when they were issued.

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

49. The complainant's seventh request to MHRA on 13 May 2023:

"Pursuant to the **Freedom of Information Act 2000**, the following information is herein requested:

1) 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".

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:

   a) product name;

   b) manufacturer name and/or brand name;

   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);

   d) number of complaints received, between the dates specified at Question 1 above, grouped by calendar month; 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, including the date(s) when they were issued.

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