

Transparency of the UK Medicines Regulator: auditing freedom of information requests and reasons for refusal

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Introduction

In the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) regulates medicines and medical devices, and monitors them to ensure they continue to meet quality and safety standards.¹ However, recent controversies with both medicines² and devices³⁻⁶ suggest the current system may be failing patients. In the UK, the 2000 Freedom of Information (FOI) Act provides public access to information held by public authorities, and can be used as one method to hold them accountable, and ensure they are promoting adequate patient safety.⁷

Under this Act, the MHRA must disclose information upon request. Requests can come from any member of the public and relate to any process the MHRA is responsible for. These requests are important to facilitate independent assessment of the regulatory process the MHRA undertakes. There are two predominant ways a request can be made. First, it can be submitted by contacting the MHRA directly. Alternatively, it can be sent via the website WhatDoTheyKnow, which forwards requests to the MHRA, and subsequently publishes and archives the response.⁸ Section 10 of the FOI Act dictates that responses should be received within 20 working days.⁷

The FOI Act, however, has 24 provisions and sections that allow the MHRA to refuse particular requests.⁷ Given the importance of transparency and accountability, we set out to audit FOI requests made to the MHRA to determine the proportion of successful requests, evaluate the reasons for refusal, and provide advice for those considering future requests.

What did we do?

A single author (SG) identified all available FOI requests and responses to the MHRA listed on the 'WhatDoTheyKnow' website up until to 31/12/17. We also contacted the MHRA on 21/11/17 and asked them to supply a list of all FOI requests ever made to them, and the subsequent outcomes. We extracted the date of request, date of response, title, category (medicine, vaccine, device, test, or other), and when relevant, the section of the FOI Act used for refusal. We excluded requests classified as 'other', which concerned non-clinical information such as finances, logistics, and administration. When a request came under multiple categories (e.g. medication and device), this was counted and analysed as two requests. Requests for information not held by the MHRA were also excluded from analysis.

In accordance with the system used by the MHRA, we classified each request outcome as 1) successful (if the requested information was provided in full), 2) partially successful (the MHRA provided certain information, but knowingly withheld some, despite having access to it), or 3) refused (where the MHRA knowingly withheld all information, despite having access to it).⁹ We compared the chance of a successful FOI request between categories by calculating the relative risk, with 95% confidence intervals and P-values based on chi-squared statistics. For each partially successful or refused request, we recorded the section/s of the FOI Act used by the MHRA, and subsequently provided illustrative examples of the most common reasons.

What did we find?

We obtained 228 requests from the WhatDoTheyKnow website, dating back to 2008. Our initial request to the MHRA (21/11/17) for all requests ever submitted was refused under section 12 of the FOI Act (cost of compliance exceeds appropriate limits). Instead, after further correspondence, the MHRA agreed to provide all successful, partially successful, or refused requests from January 2015 to December 2017, which totalled to 1,769.

Of the 228 and 1,769 requests accessed from WhatDoTheyKnow and provided by the MHRA respectively, 100 were duplicates, 12 were combined with another request, and 1 request was withdrawn. 658 were subsequently classified as 'other', and 192 requested information not held by the MHRA. Therefore, we included 1,034 eligible requests in our analysis (figure 1).

620 requests had both the date of request and response recorded. The median time to response was 15 working days. 56 (9%) responses occurred beyond 20 working days, and in three instances (0.5%), they had failed to respond completely.

Of the 1,034 requests, 735 (71%) were about medications, 150 (15%) devices, 138 (13%) vaccines, and 11 (1%) tests. The outcomes of requests overall and by category are summarised in table 1. Requests about medications and devices were significantly less likely to be successful than vaccines ([RR: 0.48, 95% CI: 0.43 to 0.56, $p<0.0001$] and [RR 0.41, 95% CI 0.32 to 0.53 $p<0.0001$] respectively). There was no significant difference between medications and devices ($p=0.14$).

Table 1. Outcomes of requests

	Overall (n=1034)	Medication (n=735)	Devices (n=150)	Vaccines (n=138)	Tests (n=11)
Successful	421 (41%)	269 (37%)	46 (31%)	103 (75%)	3 (27%)
Partially successful	291 (28%)	233 (32%)	39 (26%)	14 (10%)	5 (46%)
Refused	320 (31%)	232 (32%)	65 (43%)	20 (15%)	3 (27%)
MHRA not responded yet	2 (0.2%)	1 (0.1%)	0	1 (0.7%)	0

611 (59%) requests were classified as partially successful or refused requests. Fourteen different sections of the FOI Act were quoted 784 times overall to justify these decisions. Often, multiple sections of the FOI Act were referenced per request. Table 2 details the different sections of the FOI Act used for refusal, and Box 1 summarises what each of these sections mean. Section 43 (commercial interests) was the most commonly used section overall, while section 44 (prohibitions on disclosure) was the main reason for device and test request refusal.

Table 2. Sections of FOI Act used for refusal

Grounds	Overall (n=784)	Medication (n=637)	Devices (n=95)	Vaccines (n=41)	Tests (n=11)
Section 1 (More details needed)	15 (2%)	9 (1.4%)	3 (3.2%)	2 (4.9%)	1 (9.1%)
Section 12 (Exceeds cost limits)	74 (9.4%)	62 (9.7%)	3 (3.2%)	7 (17%)	2 (18%)
Section 21 (Accessible elsewhere)	58 (7.4%)	47 (7.4%)	7 (7.4%)	4 (9.8%)	0
Section 22 (For future publication)	28 (3.6%)	27 (4.2%)	0	0	1 (9.1%)
Section 27 (International relations)	31 (4%)	29 (4.6%)	1 (1.1%)	1 (2.4%)	0
Section 30 (Ongoing investigation)	5 (0.6%)	4 (0.6%)	0	1 (2.4%)	0
Section 31 (Law enforcement)	4 (0.5%)	4 (0.6%)	0	0	0
Section 35 (Policy making)	3 (0.4%)	1 (0.2%)	1 (1.1%)	0	1 (9.1%)
Section 38 (Health and safety)	3 (0.4%)	2 (0.3%)	1 (1.1%)	0	0
Section 40 (Personal information)	136 (17%)	116 (18%)	10 (11%)	8 (20%)	2 (18%)
Section 41 (Confidentiality)	145 (18%)	123 (19%)	15 (16%)	7 (17%)	0
Section 42 (Legal privilege)	2 (0.3%)	2 (0.3%)	0	0	0
Section 43 (Commercial interests)	223 (28%)	199 (31%)	13 (14%)	10 (24%)	1 (9.1%)
Section 44 (Prohibited by another act)	57 (7.3%)	12 (1.9%)	41 (43%)	1 (2.4%)	3 (27%)

Box 1. Summary description of sections of FOI Act used for refusal

<p>Section 1 The MHRA requires more information to be able to fulfil the request</p> <p>Section 12: Cost of compliance exceeds appropriate limits (absolute) Allows refusal of 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.</p> <p>Section 21: Accessible by other means (absolute) Information is accessible by other means</p> <p>Section 22: Future publication (qualified) Information is intended for future publication</p> <p>Section 27: International relations (qualified) Information would damage ‘international relations’, or has been obtained confidentially from another State.</p> <p>Section 30: Investigations and proceedings conducted by public authorities (qualified) Information would affect investigations and proceedings conducted by a public authority (e.g. criminal trial)</p> <p>Section 31: Law enforcement (qualified) Pertains to information that may prejudice a wide range of law enforcement interests (e.g. “the prevention or detection of crime”)</p>	<p>Section 35: Formulation of government policy (qualified) Protects information, which may affect the government policy making process, or effective governing.</p> <p>Section 38: Health and safety (qualified) Exempts information that would likely endanger the physical or mental health, or the safety of an individual</p> <p>Section 40: Personal information (N/A) Protects personal information</p> <p>Section 41: Information provided in confidence (absolute) Protects information provided in confidence</p> <p>Section 42: Legal professional privilege (qualified) Information that would be subject to legal professional privilege if litigation were in progress</p> <p>Section 43: Commercial interests (qualified) Disclosure would damage commercial interests, or information is considered a trade secret</p> <p>Section 44: Prohibitions on disclosure (absolute) Prevents release of information that is prohibited under any other enactment, or is incompatible with an EU obligation</p> <p><i>Qualified: subject to ‘public interest test’, where the MHRA must weigh up the arguments for and against releasing information</i></p> <p><i>Absolute: requires no consideration of public interest</i></p>
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What does this mean?

To our knowledge, this is the first public audit of FOI requests to the MHRA. Our findings demonstrated that a low proportion of requests (41%) were successful. In comparison, the most recently available data from the USA Food and Drug Administration shows that of 10,611 FOI requests processed in 2015, 8130 (77%) were fully disclosed.¹⁰ This finding is predominately descriptive, and we did not analyse whether *individual* requests were justifiably or wrongly refused. Nevertheless, we endeavoured to explore an explanation of the low success rate by recording the sections of the FOI Act used for refusal. In our assessment, three main themes emerged.

1. The public should consider certain sections before writing their request.

The public should consider the basic requirements of section 1, 12, and 21 when writing their requests (see box 2). These are exemptions that dictate respectively that the MHRA can refuse a request if it is too broad or if they need more information to guide their response, when the cost and time needed to answer the request exceeds an ‘appropriate limit’, and when the information can be accessed elsewhere. Indeed, we made this mistake ourselves by asking for too much data. However, we consider section 12 of the FOI Act to be ambiguous. The Act does not dictate what an ‘appropriate limit’ is, but rather allows it to vary for different public authorities. For central government, including the MHRA, it is set at the cost of 24 working hours for one person.¹¹ Nevertheless, careful consideration of these sections when formulating requests will minimise time wasted by both the public and the MHRA. This is important as regulatory bodies often have a great burden of work. Whilst it is encouraging that the MHRA is generally responding within the mandated time period, we must endeavour to allow resources to be used more efficiently by reducing unreasonable requests. We believe that an easily accessible document explaining common sections used for refusal, together with associated examples would

help this process.

Box 2. Sections the public should consider before making a request

Section	Example request	Example refusal
1 (More details needed)	The writer asked about delays in updating statin product information referred to in the February 2008 Drug Safety Update (DSU) and specifically for all documents and correspondence relating to this delay	“Under section 1(3) of the FOIA a public authority need not comply with a request unless any further information reasonably required to locate the information is supplied. If a request is too broad or general in nature (for example, seeking information on a topic over many years), public authorities have a duty to provide advice and assistance to the applicant in order to focus the request.”
12 (Exceeds cost limits)	For each vaccine (and brand) in the UK, the writer requested from 2000 – present: total number of adverse drug reaction (ADR) reports, total number of ADR reports categorised as serious and non-serious, total number of doses administered, total number of doses distributed, total number of ADRs by type of reporter (e.g. GP, pharmacist, patient etc.), total number of ADRs by nature of ADR (broadest heading - e.g. neurological conditions etc.), and total number of deaths reported.	“In order to provide the data by vaccine and by brand, this would be in excess of 50 different brands for the vaccines currently on the immunisation schedule. There are also multiple groupings within your request which would stratify the data further, for example for request number 7 you have asked for a breakdown by broadest heading (System Organ Class (SOC)), for which there are 26; this would in turn create very large tables for all 50 brand names which may not be in a form which is useful to you. We estimate that it will take us in excess of 24 working hours to extract the information for all years (2000- current date) with the subsets you reference in your request”
21 (Accessible elsewhere)	Details of all scientific opinions reports under the Early Access Medicine Scheme	“Regarding your request for the details of all SO designations (drug names, company details), we are exempting this information under Section 21 of the FOI Act, as these are available on the MHRA website. Links to the lists of all current and expired SO designations are provided below...”

2. Requests about medical devices are commonly refused under section 44

The success rate for requests about devices was low (31%), with section 44 the most common reason for refusal (43%). Section 44 states that information can be exempt from disclosure if it is incompatible with any European Union obligation, or prohibited by another enactment (see box 3). It is an ‘absolute exemption’, meaning the MHRA does not need to consider public interest. The MHRA often referred to the European Medical Device Directive, which has until recently been the legislation used for regulation in the UK.¹² From this, they frequently note Article 20, which delineates the requirements of confidentiality. It states that all information that becomes available to the MHRA under this Directive cannot be disclosed. However, importantly, as of May 2017, the European Union adopted the new EU Medical Device Regulation act, which will be transitioned in over a three-year period.¹³ This too contains many provisions for confidentiality, which will limit the MHRA in disseminating information publicly. Notably, it is likely the United Kingdom will continue to practice in line with this legislation post-Brexit.^{14 15}

Box 3. Section 44 and medical devices

Section	Example request	Example refusal
44 (Prohibited by another act)	Adverse reactions have been reported following administration of dental fluoride varnish devices since 2006, an annual breakdown of number of patients seen in accident and emergency, and an annual breakdown of the number of patients hospitalised.	“Medical Device incident reporting has to comply with the European Medical Device Regulations. The commercial confidentiality requirements of the Medical Device related regulations prevents us from disclosing information which would make an individual report identifiable or relates to specific products or brands. We are however able to provide general information on reported adverse incidents, providing the information does not breach MHRA regulatory and/or confidentiality obligations. Specifically, it is a requirement that any data received or held by MHRA, or information provided in relation to Medical Device adverse incident regulatory activity will be treated according to: the confidentiality provisions in Article 20 of the Medical Devices Directive (93/42/EEC)”

3. Conflict between public and commercial interest

There are many provisions that serve to protect commercial interests and private business information (see box 4). Section 43 addresses this directly. It is a qualified exemption of information that is commercially harmful to any person, or which is considered a trade secret. In principle, the MHRA must consider whether public interest outweighs any commercial damage. Both of these are very subjective terms, allowing the MHRA much discretion. Despite being the most commonly cited provision in our audit, when the full response was available to analyse, the weight of public interest was never determined to over-rule this exemption. Section 41 prohibits the public accessing information that individuals and companies provide ‘in confidence’ to the MHRA.

Furthermore, section 44 will mean the MHRA will have to abide by any separate legislation that limits access to private sector material. Illustrating this, a request about adverse events of the Essure coil contraceptive implant was refused, as the UK Enterprise Act prohibits disclosing information obtained about specific companies or businesses. In this example, mentioning the brand 'Essure' contributed to the information being withheld. It is clear that there is a conflict between community values about transparency and accountability, and the need to protect sensitive commercial information. Unfortunately, The Independent Commission on Freedom of Information report, published in 2016, did not explicitly address the balance of public and commercial interest in this context.¹⁶ We therefore need to open a dialogue where we debate the merits of the legislation.

Box 4. Sections related to commercial interest

Section	Example request	Example refusal
41 and 43 (Confidentiality, Commercial Interests)	A list of all drugs and vaccines, which have had their licence withdrawn, including the brand name and manufacturer.	"Please find attached a list of medicines which have been withdrawn...Regarding the name of the manufacturer, the MHRA considers this information to be exempt under Section 41 (Information provided in confidence) and Section 43 (Commercial interests). Section 41 is an absolute exemption and requires no consideration of the public interest. Section 43 is a qualified exemption and requires that we consider the public interest. We have considered the public interest and cannot see any public interest in releasing this information that outweighs the commercial harm caused by releasing the names of manufacturers of specific product licences into the public domain"
44 (Prohibited by another act)	Various questions on the Essure implant including how many women have received the implant, the number of reported complications, and removal rates.	"This is a request for adverse events related to a specific named medical device and we are unable to provide the information requested. This information is subject to the exemptions contained in section 44(1) (a) of the Freedom of Information Act (FOIA). In particular Section 237(2) of the Enterprise Act 2002 applies to specified information, which is defined in section 237(1) and section 238 (by reference to Schedule 14 and the regulations made under section 11 of the Consumer Protection Act 1987) to include information held by MHRA and relating to any business of an undertaking. Section 237(2) provides that such information must not be disclosed while the undertaking continues in existence. There are a number of exceptions to this general rule, in Part 9 of the Enterprise Act 2002. The MHRA's position is that none of these exceptions apply to the information that you have requested. As this is an absolute exemption it is not subject to a test of public interest."

There are some limitations to our analysis. As the MHRA did not provide us with their full list, we were only able to analyse a proportion of all requests. However, given the MHRA supplied their most recent requests at the time (2015 – 2017), we believe this sample to be reflective of current practice. Currently, the MHRA and 'Gov.UK' website release a list of titles of all FOI requests that have been answered fully or in part, but not those that have been refused.⁹ We believe transparency can easily be increased by ensuring the entirety of FOI requests and responses are publicly available. Whilst there is a difference in the time period from which the WhatDoTheyKnow requests were drawn, we favoured including both sources to obtain as much data as possible.

Conclusion

Transparency and accountability are critical elements in developing a robust regulatory system. The ability to make a freedom of information request is an integral part of this process. By auditing the MHRA, we hoped to generate a discussion on the effectiveness of this system, and areas for improvement. Future research may use this as a platform to focus on a thematic exploration of specific questions in requests, and how these relate to health policy.

Key messages

- The public should make their requests focused, and consider if the information they want is accessible elsewhere, or if their request can be realistically answered in a reasonable timeframe. A document explaining sections used for refusal with examples would be beneficial.
- Requests about devices are only successful in approximately 1/3 of cases, which is partially as a result of their unique regulation.
- We need to collectively debate the balance of public interest and commercial or sensitive information
- FOI requests to the MHRA should be publicly available.

Conflicts of interest

We have read and understood BMJ policy on declaration of interests and have no relevant interests to declare.

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Contributors and source

Carl Heneghan had the original idea for the analysis piece. All authors were involved in the design of the study, and the interpretation of data. Sam Grigg was responsible for the acquisition of data and the original preparation of the manuscript. All authors contributed to the subsequent drafting and revision, and approved the final version. Data was retrieved from the website WhatDoTheyKnow, and directly from the MHRA.

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Guarantor and transparency statement:

The manuscripts guarantor (SG) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained

Ethical approval

Not required.

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Table 1: Outcomes of requests

Table 2: Sections of FOI Act used for refusal

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Figure 1: Flowchart of FOI requests included in the analysis

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Box 1: Summary description of sections of FOIA used for refusal

Box 2: Sections the public should consider before making a request (examples)

Box 3: Section 44 and medical devices (examples)

Box 4. Sections related to commercial interest (examples)

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