

Action plan developed: July 2023

### ICO Practice Recommendation with MHRA actions

This Action Plan was developed and presented to the Information Commissioners Office (ICO) in July 2023. Since then, regular updates have been recorded to log the progress against the ICO’s Practice Recommendation which was issued to the MHRA in August 2023.

Area of FOI Code of Practice	Non-conformity	ICO recommendation	MHRA objectives and action plan	Progress update as of April 2024, including outcomes to date and next steps
<p><b>Part 4 – time limits for responding to requests</b></p> <p><b>Section 4.1 of the Code highlights the “clear” requirement that public authorities respond to requests for information promptly, and within 20 working days of receipt in accordance with section 10(1) of FOIA.</b></p>	<p><b>For the period 1 May to 31 May 2023 MHRA had only met the deadline ‘in time’ in 71% of its information requests. It also received 6 section 10 decision notices between 30 March and 18 May 2023. It had 32 information requests over 6 months old, with the oldest at this time being 6 July 2022.</b></p>	<p><i>Recommendation 1(a)</i></p> <p><i>MHRA should consider using the Commissioner’s FOI self-assessment toolkit to improve its timeliness compliance.</i></p>	<p>Review of processes: use of toolkit to assist with identification of root causes for non-compliance by assessing response rate, handling, training, compliance/assurance, governance structure</p> <p>Take forward and implement improvements to systems and support processes as outlined in the review, building on the existing cross agency network of coordinators and handlers across the new organisational structure.</p> <p>FOI Manager to lead on the training and resources to support this network, working</p>	<p><b>ICO toolkit informed root-cause analysis; objective review using the toolkit in July-August 2023 indicated the following:</b></p> <ul style="list-style-type: none"> <li>• Need for dedicated resource in key areas for FOIA request handling in central monitoring roles and in teams across the devolved system dealing with consistently high numbers of requests</li> <li>• Need for further training and support for central monitoring roles, and access to specialised FOIA expertise to assist teams and colleagues within the MHRA handling volume and complex requests</li> <li>• Need for a shared system to facilitate central monitoring, support oversight of handling, and drive compliance for requests from the centre, and to enable more efficient handling of requests and the preparation of informed, compliant responses by request handlers across the Groups within statutory timeframes</li> </ul> <p><b>Analysis of requests received by each of the MHRA Groups/Functions identified:</b></p>

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			<p>alongside the in-house Learning &amp; Development team to deliver this.</p> <p>Refresh FOI guides and resources on our Intranet platform, including templates and other resources</p>	<ul style="list-style-type: none"> <li>• Compliance rates and Groups/Functions dealing with volume requests in addition to their core duties</li> <li>• Blockages due to volume and limited resource as significant factor in the delays that had occurred</li> </ul> <p><b>Further actions and areas of FOIA knowledge requiring further training identified:</b></p> <ul style="list-style-type: none"> <li>• Identification of FOI Manager role as key contact for specialist advice, initially to facilitate compliant responses for delayed requests to resolve blockages, with training delivered and advice given as required to colleagues of all levels on a case-specific basis</li> <li>• Direct engagement with requesters whose requests were caught in the backlog to advise of delays and provide advice on further requests</li> <li>• Training on general awareness of key points, focusing on recognising a request for recorded information and key considerations in request handling, disseminated to colleagues handling requests as required and delivered via arranged sessions and at Group team meetings</li> <li>• Tailored and case-specific training for key teams and colleagues handling requests, delivered to teams in formal training sessions</li> </ul>
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		<p><i>Recommendation 1(b)</i></p> <p><i>MHRA should also request a consensual audit of its FOIA policies, practices and procedures from the ICO.</i></p>	Discussed with ICO in context of Recommendation 1 actions	This recommendation was discussed with the ICO in meetings in August and September 2023 following a process review begun in June 2023; this had progressed to identify key blockages and areas requiring improvement and process change, for which appropriate actions had been identified. Agreement to hold pending further assessment of compliance during the year and at year end.
		<p><i>Recommendation 2</i></p> <p><i>MHRA should ensure that requests for information are responded to in a timely manner in accordance with section 10(1) of FOIA.</i></p> <p><i>When chased to issue responses by the Commissioner's Case Officers, MHRA should respond in a timely and appropriate manner. This will avoid unnecessary decision notices and subsequent further delays for the requesters.</i></p>	<p>All outstanding late actions from Decision notices to be completed as a priority.</p> <p>Ensuring inflight ICO investigations are completed on time and within deadline.</p> <p>Ensuring any new ICO investigations are completed on time and within deadline.</p> <p>To clear all outstanding initial FOI requests (no backlog and no open</p>	<p>This recommendation concerned two factors:</p> <ul style="list-style-type: none"> <li>• the requirement within the FOIA to meet s10 compliance</li> <li>• the MHRA's failure to respond to the ICO's 10-day interventions in respect of late requests and investigations.</li> </ul> <p>Section 10(1) compliance:</p> <ul style="list-style-type: none"> <li>• Initial review by the FOI Manager and the Customer Experience Centre (CEC) identified outstanding and delayed requests; closure managed by the FOI Manager, CEC and Group Leads alongside handling of newer requests; Request for Executive Committee (ExCo) support for priority completion of delayed requests and future planning; Group Director assistance with handling plans</li> </ul>

			<p>replies that are over 20 working days)</p> <p>Maintain compliance for all incoming and new requests.</p>	<p>for delayed requests and ongoing management of FOIA requests</p> <ul style="list-style-type: none"> <li>• Overall compliance for responses to requests by the MHRA has risen monthly since July 2023 to 91.74% in December 2023</li> <li>• Q4 performance improved to 96.15% in January, 94.55% in February and 96.40% in March 2024</li> <li>• Performance statistics for 2023/2024 are published alongside this paper</li> </ul> <p>Response to ICO interventions:</p> <ul style="list-style-type: none"> <li>• A 'lessons learned' exercise drawing on ICO decision notices recognised that failure to respond to ICO notifications for late requests had led to decision notices requiring response</li> <li>• FOI Manager role assumed responsibility as point of contact for co-ordinating MHRA Group responses in ICO cases and providing further guidance to colleagues on the appeals process and the relevant requirements</li> <li>• Since this time, responses required for ICO live investigations and notifications have been submitted in line with the necessary time frames and any actions required completed</li> <li>• See also recommendation 3(b) below</li> </ul>
		<p><i>Recommendation 3(a)</i></p> <p><i>MHRA should analyse and review its current request</i></p>	<p>Process review alongside toolkit analysis to focus on training/knowledge gaps,</p>	<p>As per Recommendation 1, a process review was undertaken, informing recommendations for dedicated FOIA</p>

		<p><i>handling procedures to ensure that it has adequate long-term resources in the right areas. Its systems and procedures need to be able to cope with sustained increased volumes. For example introduce a case management system or consider a dedicated FOI request handling areas which is separate to general enquiries and other correspondence. It should also consider developing an FOIA policy that enables it to respond to the increased volumes of information requests within the statutory or recommended timeframes.</i></p>	<p>resource and system requirements</p> <p>Build on the existing cross agency network of coordinators and handlers across the new org structure.</p>	<p>resource and the implementation of an FOIA case management system:</p> <ul style="list-style-type: none"> <li>• Analysis of request volumes and compliance rates across MHRA Groups and teams has been undertaken for feedback to Group Heads</li> <li>• Case management system:             <ul style="list-style-type: none"> <li>○ Sept 2023 business case approved</li> <li>○ Oct 2023: FOI CMS Project Team set up to further review processes and inform specifications for an FOIA case management system</li> <li>○ Jan-March 2024; contract signed following procurement process; initial training and user testing</li> <li>○ 18 March 2024: soft launch of system focusing on a select number of requests and teams, with further rollout to all staff dealing with FOIs in April.</li> <li>○ Additional process and FOIA handling guidance to support this change with revisions to FOIA intranet guidance and external landing page to be taken forward for end May to support Agency wide roll-out of system.</li> </ul> </li> <li>• Recruitment for dedicated FOI roles:             <ul style="list-style-type: none"> <li>○ August 2023: FOI Manager fixed-term contract extended, and new Job Descriptions approved for additional dedicated fixed-term central FOI roles at Senior and</li> </ul> </li> </ul>
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				<p>Support Officer level to end March 2024.</p> <ul style="list-style-type: none"> <li>○ Recruitment for 2 x additional FOIA roles approved and advertised in September; Senior FOI Officer took up their role in November 2023. Further recruitment campaign for 2 x FOI Officer with one post taken up end January 2024.</li> <li>○ March 2024: further extension of FOIA fixed-term contracts and recruitment to continue in April.</li> </ul> <p><b>NEXT STEPS:</b></p> <p>The MHRA has recognised that the dedicated FOIA roles have been crucial to improve compliance:</p> <ul style="list-style-type: none"> <li>• Planning in progress to establish an operating model with dedicated resource to be taken to the MHRA Resource Committee.</li> <li>• Further recruitment is taking place for the vacant FTE roles.</li> </ul> <p>For details of training see recommendation 5 below.</p>
		<p><i>Recommendation 3(b)</i></p> <p><i>MHRA should ensure that its processes enable it to comply with the requirements of the Commissioner's decision</i></p>	<p>All outstanding late actions from Decision notices to be completed as a priority.</p> <p>Ensuring inflight ICO investigations are</p>	<p>FOI Manager role from June 2023 as key point of contact for ICO appeals, investigations and complaints. Since this time, all outstanding requirements of the Information Commissioner's decision notices have been actioned:</p>

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		<p><i>notices in the timeframes they specify.</i></p>	<p>completed on time and within deadline.</p> <p>Ensuring any new ICO investigations are completed on time and within deadline.</p>	<ul style="list-style-type: none"> <li>• June 2023: Outstanding actions completed for 1 x adverse decision notice, 1 x decision notice for s10 breach</li> </ul> <p>Actions following the ICO's decision notices in Q2 and Q3 have been met within the stipulated time frames:</p> <ul style="list-style-type: none"> <li>• 1 action to issue delayed response</li> <li>• 1 x action for s16 assistance</li> <li>• 1 x adverse decision notice requiring disclosure</li> <li>• No actions in Q4</li> </ul> <p>Submissions have been provided for all ICO investigations within given timeframes:</p> <ul style="list-style-type: none"> <li>• Timeliness of submissions maintained throughout Q2, Q3 and Q4</li> </ul> <p>At end Q4, there are no outstanding or pending appeals or complaints with the ICO.</p>
		<p><i>Recommendation 4</i></p> <p><i>MHRA should publish its action plan, which incorporates any recovery plan already in development, with appropriate processes put into place to ensure 90% timeliness is achieved by 31st December 2023. This action plan should be supported by a 'lessons learned' exercise, which</i></p>	<p>Action Plan in place; publication to be arranged.</p> <p>Root Cause/lessons learned to be completed as per ICO toolkit</p>	<p>The Action Plan is prepared for publication alongside annual year end stats as a 'transparency collection' after the final publication of 2023 FOIA responses.</p> <p>As per Recommendation 1, 'Lessons learned' were identified through review and root cause analysis including use of ICO toolkit to inform proposals for recruitment and case management; key learning points have also been disseminated to MHRA Groups and teams through awareness raising sessions and tailored training.</p>

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		<p><i>examines the root cause of delays from allocation through to clearance at different stages, with mitigations for any recurring problems addressed specifically in the plan.</i></p>		<p><b>NEXT STEPS</b></p> <p>Teams continuing to receive high volumes of requests have been identified to inform further proposals.</p>
		<p><i>Recommendation 5</i></p> <p><i>MHRA must ensure that its information rights training is sufficient and delivered to all staff to ensure that all information requests are processed within the required timeframes. This should include training on recognising information requests on receipt so that they are transferred to the relevant staff for processing in a timely manner, seeking clarification early if MHRA is uncertain what information is required. It should also identify where training is required for specific exemptions and delivering this to all relevant staff.</i></p>	<p>Key training review to be drawn from root cause analysis.</p> <p>FOI Manager to work with key staff across the agency</p> <p>Case by case advice to be provided as needed.</p> <p>Tailored training packs and guidance to be prepared</p>	<p>As per Recommendation 1, training for key teams and staff has been delivered focussing on the following:</p> <ul style="list-style-type: none"> <li>• General FOIA awareness guidance</li> <li>• Recognising a request for information and necessary actions</li> <li>• Key considerations in request handling and decision-making</li> <li>• Tailored training for relevant staff on specific requirements and exemptions including section 1(1)(a), section 17(1) refusal notices, evidencing prejudice-based exemptions, conducting public interest tests, and applying NCND principles when required</li> <li>• Training for internal reviewers and decision-makers</li> <li>• This training is ongoing and to be further supplemented with external training as required</li> </ul> <p>The FOI Manager role has also provided a key contact for detailed case-specific guidance issued as required; this is to continue with support from FOI Senior and Support Officer roles</p>



		<p><i>Recommendation 6</i></p> <p><i>MHRA's request handling procedures should include provision for when a response is late or is likely to be late at any stage of the internal processes. It must be clear when and to whom the matter will be escalated, who is responsible for taking action, the action they will need to take, and by when.</i></p>	<p>To be agreed with CEC and Group FOI leads</p>	<p>Requests are now monitored throughout their lifecycle by the dedicated FOI roles to identify any handling issues as they occur and to minimise delays. Changes to procedure include:</p> <ul style="list-style-type: none"> <li>• Proactive advice on handling from receipt of request, weekly engagement with all teams to advise of and seek feedback on the status of open requests, and open engagement with FOI points of contact throughout the handling of requests.</li> <li>• If there are concerns that a request will not meet the deadline, this is escalated to the FOI Manager in the first instance</li> <li>• If it is the case that the response cannot be issued and a delay occurs, this is further escalated through the CEC manager to the relevant Group Lead and Group Director.</li> <li>• As noted in Recommendation 1, performance statistics and details of any continuing delays will be notified to Group Directors</li> </ul> <p>This has resolved issues without a section 10 breach occurring, and in a small number of cases, achieved closure within one or two days of the statutory deadline.</p> <p><b>NEXT STEPS:</b></p> <p>Changes to the process have been tailored to lead into and support the introduction of the FOIA case management system in</p>
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				March/April 2024. Further guidance on process and request handling is to be issued with training for request handlers as part of the implementation of this system.
		<p><i>Recommendation 7(a)</i></p> <p><i>In accordance with part 8.5 of the Code MHRA should publish its information access request statistics and make these easily accessible on its website. The statistics should include the number of information access requests that have not been processed and the number of completed requests where the processing took longer than 20 working days.</i></p>	<p>Determine high level FOI compliance data and performance to be published</p> <p>Review required of process for extracting performance statistics</p> <p>Resource to be determined to complete for first publication by 31 December 2023</p>	<p>Review of process for recording FOI requests and appeals, and extracting performance stats undertaken June-July 2023:</p> <ul style="list-style-type: none"> <li>• revised process and use of tracker to improve quality of data entry</li> <li>• proposals for improved recording to be further taken forward in new case management system</li> </ul> <p>Statistics for each quarter of 2023/24 are prepared for publication at year end alongside a monthly breakdown of performance in respect of timeliness compliance for each month within Q3 and Q4. Publication will take place with 2023 requests and outcomes (to allow analysis of disclosure rates and provide an overview of the types of requests received) and updated ICO PR Action Plan.</p> <p><b>NEXT STEPS:</b></p> <p>2024/5 Q1 publication to cover period of eCase launch alongside existing systems. CEC lead to take forward with MHRA webupdates team.</p>

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				From Q2 onwards, performance statistics will be fully generated through eCase; routine publication by CEC via MHRA webupdates team.
		<p><i>Recommendation 7(b)</i></p> <p><i>MHRA should also consider publishing its responses to information requests on its disclosure log and making this information easily accessible on its website. For those FOIA responses issued since this practice was suspended approximately 2 years ago, consider putting a back catalogue together of those responses and making that available on its website.</i></p>	Commitment to publish back catalogue and resume publication by 31 December 2023; resource to be determined to take forward	<p>Publication of 2022 responses resumed prior to year-end 2023; 2022 publications completed 17 January 2024; 2023 publications completed 14 March 2024: <a href="https://www.gov.uk/search/transparency-and-freedom-of-information-releases?organisations[]=medicines-and-healthcare-products-regulatory-agency&amp;parent=medicines-and-healthcare-products-regulatory-agency">https://www.gov.uk/search/transparency-and-freedom-of-information-releases?organisations[]=medicines-and-healthcare-products-regulatory-agency&amp;parent=medicines-and-healthcare-products-regulatory-agency</a></p> <p>While not part of the ICO's recommendations, several further types of information have also been identified for proactive publication from analysis of requests received (for example, Vaccine Benefit-Risk Expert Working Group minutes from inception in 2020, Yellow Card adverse events with a fatal outcome follow-up statistics) as the first stage of wider discussions on future publication strategies.</p> <p><b>NEXT STEPS:</b></p> <p>From Q1 2024/5, the FOI case management system (eCase) will enable</p>

				<p>publication of responses handled on the system on a new platform:</p> <ul style="list-style-type: none"> <li>• April 2024: Links to 'old' and 'new' platforms hosting FOI responses to be included on FOI landing and information pages – CEC lead to confirm with C&amp;E/FOI project team</li> <li>• March-April 2024: FOI Officer to complete retrieval and preparation of Jan-March 2024 responses (pre-eCase) for publication through webupdates team.</li> <li>• April-May 2024: FOI Officer to complete retrieval and preparation of remaining 2024 responses (pre-eCase) for publication through webupdates team.</li> <li>• May 2024: Publication of FOI responses through eCase to commence: CEC Lead to determine frequency of publication</li> </ul>
<p><b>Part 5 – Internal reviews Sections 5.4 and 5.5 of the Code establish that internal reviews should be carried out within 20 working days, or 40 working days where the matter is complex.</b></p>	<p><b>Between 1 May and 31 May 2023 MHRA had 19 open internal reviews, of which 13 were overdue.</b></p>	<p><i>Recommendation 8</i></p> <p><i>MHRA should ensure that internal reviews are carried out and the outcome communicated to the requester in a timely manner. In order to ensure that this happens consistently, MHRA should refresh its procedures for carrying out internal reviews and ensure that these are effective and robust.</i></p>	<p>To clear all outstanding Internal Reviews beyond 40 days</p> <p>To clear all outstanding Internal Reviews within 20-40 days</p> <p>To ensure new internal reviews are recognised and dealt with within timeframes</p>	<p>Lessons learned indicated that early ICO intervention was the result of failing to conduct timely internal reviews on occasion. The importance of internal reviews is recognised and has been a focus since the appointment of the dedicated FOI Manager role:</p> <ul style="list-style-type: none"> <li>• Review of outstanding and delayed internal reviews undertaken</li> <li>• Advice and guidance delivered to CEC and FOI handlers on the appeals process and the importance of the internal review stage in the request lifecycle, to ensure requests for review</li> </ul>

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				<p>are recognised and dealt with within timeframes</p> <ul style="list-style-type: none"><li>• Training delivered for those conducting internal reviews, particular those within S&amp;S</li><li>• Reviews supported by the FOI Manager with case sessions and guidance</li></ul> <p>The backlog of internal reviews was addressed and cleared by end November 2023.</p> <p>The number of internal reviews completed, and completed within time frames, has risen consistently since June 2023, with 100% of reviews completed on time December 2023 – March 2024.</p> <p>The numbers of reviews proceeding to ICO appeal has significantly reduced.</p>
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