Medicines & Healthcare products Regulatory Agency

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[redacted]

Our Ref: **FOI2026/00587**

17 June 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 1 June. You wrote:

> *Any minutes or papers from the Executive Committee or Board that reference objective 2.7 by name or by subject matter (generic medicines regulatory reform)*
> *Any defined criteria or framework developed under objective 2.7 for determining where regulator involvement adds most value in generic medicines regulation'*

*The above was a clarified version of your initial request (*FOI2026/00540*):*

> "Specifically, I request:
> Any internal progress reports, RAG status assessments, or milestone tracking documents relating to objective 2.7 produced between July 2023 and the date of this request
> Any minutes or papers from the Executive Committee or Board that reference objective 2.7 by name or by subject matter (generic medicines regulatory reform)
> Any defined criteria or framework developed under objective 2.7 for determining where regulator involvement adds most value in generic medicines regulation"

MHRA Response

Following a search of our electronic records and confirmation from subject matter experts, we have established that the information you requested is not held by the Agency.

Advice and assistance

Year 3: 2025/26 (to be completed by 31 March 2026)

2.7 Transform the regulation of generic medicines, building on defined criteria to meet evolving goals where regulator involvement adds most value, for example for sustainable medicines including green chemistry and reduction of plastics.

When the Corporate Plan was published, the above objective was in the early stages of development as reflected in the longer-term goals that were set. Based on discussions, it has been established that the specific examples given for the above goal were superseded by

other priorities. In particular, significant attention and resource was devoted to improving performance with respect to processing and assessing marketing authorisation applications, including those for generic medicines, in line with expected timelines.

As reported in the MHRA Annual Report and Accounts 2024-2025 (MHRA_Annual_Report_2024_25.pdf), Business Plan objective 2.1 *Improve and optimise regulatory services via development of new risk-proportionate regulatory pathways including international recognition of other stringent regulators' decisions* was met. To achieve this, risk-proportionate processes were adopted, including utilisation of an International Recognition Procedure. We hold information related to initiatives on risk-proportionate regulation, however, we do not consider this documentation to be within the scope of your request because:

A. The information does not mention objective 2.7 by name or directly by subject matter and
B. The information is broader cross-relating to clinical trials, all types of marketing authorisations, as well as a small mention of generics.
C. The title of this paper is "How is the implementation of risk proportionate new ways of working supporting sustainable improvement in our performance?"

However, should this information be of interest it can be requested.

A similar conclusion was reached related to other recent activities which concern the way we manage and regulate generic medicines, and that has occurred since the publication of the corporate plan (Pub. July 2023), such as the examples below:

UK-wide licensing for human medicines - GOV.UK
Established medicines: marketing authorisation application changes - GOV.UKInternational Recognition Procedure - GOV.UK
RegulatoryConnect - GOV.UK – programme closed

While this recently developed procedural information and guidance can and does apply to generic medicines, it was not specifically developed to fulfil objective 2.7 and therefore, was *not* considered to be within the scope of your request.

Please also note, Red, Amber, Green statuses tend to apply to the Business Plan rather than the Corporate Plan within which Objective 2.7 appeared.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.
Website: ICO FOI and EIR complaints or telephone 0303 123 1113.

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