Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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MHRA Website

[redacted]

Our Ref: **FOI2026/00331**

21 May 2026

Dea[redacted]

Thank you for your Freedom of Information (FOI) request received on 25 March 2026. You wrote:

> *'In switching from originator to generic dapagliflozin, please can you tell me in which country Teva's dapagliflozin tablets are manufactured as I have concerns over what has been in the press recently in connection with Indian pharmaceutical manufacturers. I understand you cannot disclose the specific site but can you at least tell me the country of manufacture and whether the site is approved. Is the facility approved by the MHRA?'*

MHRA Response

We confirm that we hold the information you have requested and provide it below.

Teva's dapagliflozin tablets are manufactured in India. The MHRA are assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for Teva's dapagliflozin tablets (Dapagliflozin 5 mg Film-coated Tablets PL 00289/2590 & Dapagliflozin 10 mg Film-coated Tablets PL 00289/2591) at all sites responsible for the manufacture, assembly and batch release of these products.

Advice and assistance

We understand that reports of concerns can cause alarm, however, there is a vast pharmaceutical manufacturing sector in India. The above products hold valid marketing authorisations granted by MHRA. MHRA regulatory activities help to ensure that medicines are manufactured to rigorous quality standards to deliver the expected treatment benefits and keep patients safe. We have provided details about some of these regulatory oversight processes below. We would also stress that the country of manufacture should not be a factor when considering whether to take a medicine, as a specific approved medicine in the UK will meet the required standards of manufacturing, regardless of the country of manufacture.

GMP compliance
A site being accepted as GMP compliant follows a site inspection by MHRA inspectors, or inspectors from a trusted partner organisation, such as an EU competent authority.

The marketing authorisations also include sites of Quality Control (QC) Testing whose activities are part of a range of measures which help to ensure a product of consistent quality is manufactured. During QC testing, results must be compared against official specifications and standards.

Patients often switch from an innovator to a generic medicine without any difference in treatment effects, and we expect the experience of switching your medicine proceeds in the same manner. If you have any questions regarding your medicine, please speak to your doctor or pharmacist.

In the rare event that a defective medicine does enter the supply chain, as part of our regulatory duties, the MHRA has a reporting system for defective medicines. Such reports would trigger an investigation, and we would issue appropriate alerts including recall of medicines that are defective. Should this be of interest, please see further information here: Alerts, recalls and safety information: medicines and medical devices - GOV.UK

Some further information about how we regulate medicines to ensure they are safe, effective and produced to quality standards is available at the weblink below:
More information about the MHRA - GOV.UK

While we have released the country of manufacture on this occasion based on the balance of the public interest, each FOI request is handled based on the circumstances at the time of the request. Therefore, this response should not be interpreted as an endorsement that the country of manufacture will be released for other medicinal products. For example, some countries have a very small pharmaceutical manufacturing sector, and in those cases, there is a potential for the information to be used by competitors to undercut business. Further, we wish to make you aware that it is unlikely that we would be able to provide additional information about the site(s) of manufacture above and beyond the country of origin, as revealing the site(s) of manufacture would be of interest to competitors.

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.

Re-use of our information