Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
10 South Colonnade
Canary Wharf
London
E14 4PU

foi.request@mhra.gov.uk.

MHRA Website

[redacted]

Our Ref: **FOI2026/00696**

27 July 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 26 June. You wrote:

> *I also request, under the freedom of information acts, to receive all materials related to that application, from filing an application of medical device approval, and up untill receiving an actual medical device approval by MHRA.*
>
> *Should any other documents exists, with regard to Ayla, the new entity Aylacare, or the former owners Brain+, or the former brandname "Your CST Assistant," then this is kindly also asked for being handed over, for me to review this data.*
>
> *I can supplement the request, with a brand name, that was tolled, when Brain+ in september 2023, said it had received protection, where the brand name was, "CST-Therapist Companion", so perhaps MHRA may have provided approval, for that brand name, wich today is known as Ayla.*

MHRA Response

We can confirm that the Agency holds the information you are seeking.

However, we are engaging an exemption from disclosure under Section 41(1) of the FoI Act, which protects information provided in confidence.

The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for ensuring that medicines, medical devices, and blood components for transfusions on the market in the United Kingdom are safe, effective, and manufactured to the highest standards of quality. The Medical Devices Regulations 2002 (MDR 2002) establish the statutory framework that medical devices must meet in order to comply with these standards. The MHRA does not licence or approve medical devices, outside of exceptional circumstances.
For medium and high-risk medical devices, the assessment of the evidence of compliance with the regulations and relevant standards is conducted by an independent Approved Body. For non-sterile, non-measuring Class I medical devices, compliance is demonstrated by a written statement from the manufacturer. The MHRA does not hold the information on assessments or decisions of approved bodies to issue UKCA certificates.

We can confirm that we do not hold any documentation beyond the written statement of conformity. However, we are engaging an exemption from disclosure under Section 41(1) of the FoI Act, which protects information provided in confidence.

The information you have requested was obtained by the Agency from another person and the Agency believes that if this information would be released it would breach the confidence of the person(s) the information pertains to, actionable by them or any other person. Therefore, we are not going to be releasing the requested information.

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
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https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/