Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

Mr Michael Richard Curran
RC ALS Charity
[redacted]

Sent by Special Delivery and email

21 July 2026

INFRINGEMENT NOTICE ("IN")
Served pursuant to regulation 48 of the Medicines for Human Use (Clinical Trials) Regulations 2004 (the "Regulations")

Dear Mr Curran,

The Enforcement Authority is serving this IN on you/RC ALS Charity under regulation 48[1] of the Regulations.

On 14 November 2025 at a meeting at MHRA's Offices at 10 South Colonnade, Canary Wharf, you were informed that the supply of the investigational medicinal product ("IMP"), a peptide, known as RCH4 or Neuralzeta to patients and the subsequent collection of safety and efficacy data is evidence you are conducting an unauthorised clinical trial and that you must immediately cease supply of Neuralzeta/RCH4 and all activities associated with the unauthorised trial. For the avoidance of doubt, data management (e.g. publishing of results) and pharmacovigilance services (collection of safety data) are regarded to be within the scope of a clinical trial.

Carrying out an unauthorised clinical trial is a breach of regulation 12(1) of the Regulations. Regulations 28(1) and 29 of the Regulations also apply and each of these breaches meet the criteria for serving an IN under regulation 48 of the Regulations. These breaches give rise to several other regulatory breaches which, both collectively and individually, provide additional grounds for serving an IN in accordance with regulation 48 of the Regulations. However, the Enforcement Authority has taken the view that this IN will centre on:

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[1] Regulation 48 applies to regulations 3A, 12(1) & (2), 13(1), 22(2) to (5), 25(1) & (2)(a), 27, 28(1) to (3), 29, 29A, 30(2), 31A to 35, 36(1), 36A, 36B, 42, 43(1) & (6), 45A, 46 and 46A of the Medicines for Human Use (Clinical Trials) Regulations 2004.

1) **The breach of regulation 12(1) of the Regulations** (Requirement for authorisation and ethics committee opinion) as the trial was started without first being authorised by the Licensing Authority (MHRA) and without a favourable opinion from an ethics committee.

2) **The breach of regulations 28(1) and (2) of the Regulations** (Good clinical practice and protection of clinical trial subjects) as the trial was not being conducted in accordance with the conditions and principles of good clinical practice (regulation 28(1)). The key principles breached were:

   - Each individual involved in conducting a trial shall be qualified by education, training and experience to perform their respective tasks (schedule 1 part 2 paragraph 1 of the Regulations, read with principle 5.1 of the ICH guidelines[2]).
   - A trial shall be initiated only if an ethics committee and the Licensing Authority comes to the conclusion that the anticipated therapeutic and public health benefits justify the risks (schedule 1 part 2 paragraph 1 of the Regulations read with principles 1.2 and 3.1 of the ICH guidelines).
   - The available non-clinical and clinical information on an investigational medicinal product shall be adequate to support the proposed clinical trial (schedule 1 part 2 paragraph 1 of the Regulations, read with principle 4.1 of the ICH guidelines).
   - The investigator and sponsor shall consider all relevant guidance with respect to commencing and conducting a clinical trial (schedule 1 part 2 paragraph 3 of the Regulations).
   - The medical care given to, and medical decisions made on behalf of, participants shall always be the overall responsibility of an appropriately qualified doctor or, when appropriate, of a qualified dentist (schedule 1 part 2 paragraph 1 of the Regulations, read with principle 1.5 of the ICH guidelines).
   - Provision has been made for insurance or indemnity to cover the liability of the investigator and sponsor which may arise in relation to the clinical trial (schedule 1 part 2 paragraph 4 of the Regulations).

3) **The breach of regulation 29 of the Regulations** (Conduct of trial in accordance with clinical trial authorisation etc.) as the trial was not conducted in accordance with the protocol relating to the trial, and the application documents related to the approvals (authorisation and ethics committee opinion) associated with the trial, as these did not exist.

In addition, importing or exporting an IMP is considered a manufacturing activity and requires a manufacturing licence (an MIA(IMP)). There is no evidence to support that the peptide Neuralzeta/RCH4 was imported into the UK or supplied further by a company holding the required MIA(IMP). These issues are outside the scope of regulation 48 and have been investigated separately.

You must immediately cease supply of Neuralzeta/RCH4 and all activities associated with the unauthorised trial.

Should you wish to be involved in any clinical trial activity in the UK, including the supply of Neuralzeta/RCH4, including import, and supply from the UK to a third party for onward supply to patients who reside elsewhere, you must not commence until you have ensured it is fully compliant with the Regulations. For clarity, this means you must implement effective mechanisms:

- Ensure that a request for approval is made to both the Licensing Authority and ethics committee and that this request is granted prior to the commencement of any future clinical trial conducted in the UK, in accordance with regulation 12 of the Regulations.
- To ensure for any trial conducted in the UK complies with the principles of GCP, in accordance with regulation 28 of the Regulations.

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[2] The "ICH guidelines" are the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guidelines for Good Clinical Practice E6(R3).

- Hold the requisite licence to obtain the IMP (as mentioned above).

Please send a written response to this IN to IAG2Secretariat@mhra.gov.uk by 11 August 2026. The response should confirm that the measures set out above will be implemented.

You are reminded that failing to comply with:

- Regulation 12 is an offence by regulation 49(1) (aa).
- Regulation 28 is an offence by regulation 49(1) (d).
- Regulation 29 is an offence by regulation 49(e).

An offence is punishable by a fine and/or up to 2 years imprisonment (see regulations 49 and 52 of the Regulations). If you do not respond to this IN, further action, including criminal prosecution, will be considered.

Please note this IN and any responses, will be provided to the US Food and Drug Administration and the medicines regulators in Spain. It may also be published on the MHRA website.

This IN is without prejudice to any other action that the Enforcement Authority may take.

Yours sincerely,



Dr Chris Jones
A person authorised to sign on behalf of The Secretary of State for Health and Social Care
IAG2Secretariat@mhra.gov.uk