

Re: FOI 24/218 ENQUIRY-IMPORTATION (from USA) of Contaminated intrathecal methylprednisolone (MPA) steroid

FOILicensing <FOILicensing@mhra.gov.uk>

Thu 28/03/2024 16:12

To [REDACTED]

Dear [REDACTED]

Regarding your enquiry, we can confirm that no marketing authorisation has been granted in the UK for a product manufactured by New England Compounding Center (NECC). Further to this, we are not aware that any product manufactured by New England Compounding Center (NECC) has been imported into the UK.

If you have a query about the information provided, please reply to this email.

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office

Wycliffe House

Water Lane

Wilmslow

Cheshire

SK9 5AF

Yours sincerely,

The FOI Team, MHRA

From: [REDACTED] >

Sent: Sunday, March 3, 2024 1:41 PM

To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>

Subject: FOI 24/218 ENQUIRY-IMPORTATION (from USA) of Contaminated intrathecal methylprednisolone (MPA) steroid (around 2012) ?.

Dear Sir or Madam

I wonder if you can please help me with my enquiry. See below:

I am trying to ascertain IF ANY products manufactured by the "New England Compounding Center (NECC)" of Framingham, Massachusetts, USA where EVER imported into the United Kingdom say between the years 2010 to 2012 inclusive. In

particular I am interested in the importation of any lots of an injectable steroid-preservative free methylprednisolone acetate

used in interventions to treat back pain.

In September 2012 the Centers for Disease Control and Prevention USA and local Health Departments (USA) and the Food and

Drug Administration (FDA) began investigating a multi state outbreak of Fungal Meningitis and OTHER infections among patients

who had received contaminated steroid injections (manufactured by the above company) in various clinics and hospitals in the USA.

I know that at least 798 patients were sickened and more than 100 people died as a result of the injections received.

Enquiries traced the outbreak to fungal contaminations in three lots of a medication called methylprednisolone used for epidural

steroid injections. Doses from the three lots had been distributed to 75 medical facilities in 23 US States and doses of it had been

administered to about 14,000 patients after May 21 and before September 24, 2012.

Subsequent analysis identified some contamination in other lots and it was alleged that between 2006 and 2012 NECC knowingly

sent out drugs that were mislabeled and unsanitary or contaminated.

Patients developed fungal meningitis symptoms (not contagious) from epidural steroid injections of the contaminated MPA drug

and fungus was found in the cerebrospinal fluid of a number of the patients.

Subsequent Criminal prosecutions and civil litigations followed resulting in the company NECC made bankrupt and its directors

receiving terms of imprisonment in the US.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] me please.

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