FYI - FOI 24/047 - Freedom of Information request

MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Thu 25/01/2024 16:32
To [redacted]

Hi all

FYI

Best wishes
[redacted]

From: MHRA Customer Services
Sent: Thursday, January 25, 2024 4:32 PM
To: [redacted]
Subject: RE: FOI 24/047 - Freedom of Information request

FOI 24/047

Dear [redacted]

Thank you for your email.

Please can you clarify your enquiry in terms of the specifics of 'safety data' you require for the listed trials and/or the investigational medicinal product (IMP) VSN16R. From your initial email this term encompasses a broad range of pharmacovigilance within a clinical trial setting.

Unfortunately we cannot provide you with any Development Safety Update Reports (DSURs) for any IMPs as these contain commercially sensitive information and we are bound to abide by the confidentiality posed by the developers of the IMPs.
We can however, provide metrics on the number of suspected unexpected serious adverse drug reactions (SUSARs) or SARs that occurred in those trials that you have referenced, or focus on the number of SUSARs for a specific reaction, reported for VSN16R (in general), or even the number of SUSARs for a specific reaction that has a causal relationship to VSN16R. Would you have a specific reporting period in mind?
Additionally, if you are enquiring on the number of urgent safety measures reported for this IMP or the listed trials, we could provide metrics but may need to liaise with the developers of VDN16R if you want to investigate the nature of the measures taken.

Once you have provided that information on clarification we will log this under a new FOI request and progress your request further.

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

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

MHRA Customer Experience Centre
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

From: [redacted]
Sent: Tuesday, January 16, 2024 9:44 AM
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: FOI 24/047 - Freedom of Information request

You don't often get email from [redacted]

To whom it may concern

I request the drug safety data (DSURs or other data) pertaining to the clinical trials of VSN16R by Canbex Therapeutics Ltd. The specific trials are:

Phase II a Proof of concept study in Multiple Sclerosis (MS) patients with spasticity.
Identifiers.
CBX-001
EudraCT Number: 2014-004412-11
NCT02542787

Phase I Exploratory, Double-blind, Randomised, Placebo-controlled Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of VSN16R Following Single and Multiple Ascending Doses in Healthy Young Male Subjects
Identifiers
IRAS ID: 135674
Eudract number: 2013-002765-18
REC name: HSC REC B
REC reference: 13/NI/0115

With kind regards

[redacted]

[redacted]

[redacted]

[redacted]