FOI 24/135 - Freedom of Information request - Blood Establishments

MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Wed 28/02/2024 14:04
To [redacted]
FOI 24/135

Dear [redacted]

Regarding your email of 08 February 2024, please see below our response to each of your questions:

Could you confirm if you are regulating the use of animal bloods collected and for use in the manufacture of a medicinal product? If not, please could you explain who is regulating the use of animal bloods collected and for use in the manufacture of a medicinal product?
The Medicines and Healthcare products Regulatory Agency (MHRA) regulate biological medicinal products in the UK. This includes the regulation of the ingredients used in biological medicines.

Could you show me the guidance produced to manage the standards, quality and ingredients of a medicinal product where animal bloods are used? Also please could you direct me to the guidance on the use of animal antibodies, animal cell lines that are used in medicinal product by yourselves as the regulator?
UK guidance on biological medicinal products comes from the European Medicines Agency (EMA) guidance on biological medicines. A link to scientific guidelines on biological medicines is provided below:
https://www.ema.europa.eu/en/human-regulatory-overview/research-and-development/scientific-guidelines/biological-guidelines

In addition to the above, although animal blood directly is not used in the manufacture of biological medicinal products, bovine serum may be used in cell culture. Guidance on this can be found in the 'Guideline on the use of bovine serum in the manufacture of human biological medicinal product' (EMA/CHMP/BWP/457920/2012 rev 1), linked below:
https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-use-bovine-serum-manufacture-human-biological-medicinal-products-revision-1_en.pdf

There are also the below International Council on Harmonisation (ICH) Guidelines on the following topics:
- Viral safety evaluation of biotechnology products derived from cell lines of human or animal origin (ICH Q5A(R2) - https://www.ema.europa.eu/en/ich-q5ar2-guideline-viral-safety-evaluation-biotechnology-products-derived-cell-lines-human-or-animal-origin-scientific-guideline
- Derivation and Characterisation of cell substrates used for production of biotechnological/biological products (ICH Q5D) - https://www.ema.europa.eu/en/ich-q5d-derivation-characterisation-cell-substrates-used-production-biotechnological-biological-products-scientific-guideline

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,

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

-----Original Message-----
From: [redacted]
Sent: Thursday, February 8, 2024 9:36 AM
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: FOI 24/135 Freedom of Information request - Blood Establishments

[You don't often get email from request-[redacted] Learn why this is important at [redacted]

Dear Medicines and Healthcare Products Regulatory Agency, Please could you confirm if you are regulating the use of animal bloods collected and for use in the manufacture of a medicinal product?
If not, please could you explain who is regulating the use of animal bloods collected and for use in the manufacture of a medicinal product?
Could you show me the guidance produced to manage the standards, quality and ingredients of a medicinal product where animal bloods are used?
Also please could you direct me to the guidance on the use of animal antibodies, animal cell lines that are used in medicinal product by yourselves as the regulator?

Yours faithfully,

[redacted]

Please use this email address for all replies to this request:
request-[redacted]