



Llywodraeth Cymru
Welsh Government

Ein cyf/Our ref: ATISN 13455

October 2019

Dear,

ATISN 13455 – MHRA guidelines - Cales UK Limited, Runcorn

Thank you for your email to the Welsh Government requesting information under the Freedom of Information Act (2000), received on 27th October. You requested the following:

In relation to the MHRA strict guidelines for the production and provision of intravenous total parenteral nutrition which applied specifically to production facilities at the Runcorn Factory of Calea UK limited:

- *Disclosure of the MHRA 2015 guidelines*
- *Copies of the 2017 and 2019 audit reports.*

Welsh Government does not hold the information that you have requested and has not had a contract with Fresenius Kabi (Calea). WHSSC commission specialist services for the NHS and you may wish to contact them using the details below:

Welsh Health Specialised Services Committee
Corporate Governance Department
Unit G1, Main Avenue,
Treforest Industrial Estate,
Pontypridd CF37 5YL
Email: WHSSC.GeneralEnquiries@wales.nhs.uk

Any guidelines in relations to production and provision would normally be a matter the manufacturers and Medicines and Healthcare products Regulatory Agency (MHRA) as they are the regulator in this instance. Audits following the issue of these guidelines would be a matter between Fresenius Kabi (Calea) and MHRA.

Should you wish to contact the MHRA, their contact details are below.

Freedom of Information
Customer Services,
10 South Colonnade,
London E14 4PU
Email: info@mhra.gov.uk

If you have any queries about this request, please do not hesitate to contact me at the email address HSSBriefingsandMeeting@gov.wales. You should also quote the ATISN reference number above in any future correspondence.

The request you sent me contains personal information about you - for example, your name and address. The Welsh Government will be the data processor for this information and, in

accordance with the General Data Protection Regulation, it will be processed in order to fulfil our public task and meet our legal obligations under the Act to provide you with a response. We will only use this personal information to deal with your request and any matters which arise as a result of it. We will keep your personal information and all other information relating to your request for three years from the date on which your request is finally closed. Your personal information will then be disposed of securely.

Under data protection legislation, you have the right:

- to be informed of the personal data we hold about you and to access it
- to require us to rectify inaccuracies in that data
- to (in certain circumstances) object to or restrict processing
- for (in certain circumstances) your data to be 'erased'
- to (in certain circumstances) data portability
- to lodge a complaint with the Information Commissioner's Office (ICO) who is our independent regulator for data protection

For further information about the information which the Welsh Government holds and its use, or if you wish to exercise your rights under the GDPR, please see contact details below:

Data Protection Officer
Welsh Government
Cathays Park
Cardiff CF10 3NQ
Email: DataProtectionOfficer@gov.wales

The contact details for the Information Commissioner's Office are:

Wycliffe House
Water Lane
Wilmslow
Cheshire SK9 5AF

Telephone: 01625 545 745 or 0303 123 1113
Website: www.ico.org.uk

Any information released under the Freedom of Information Act 2000 or Environmental Information Regulations 2004 will be listed in the Welsh Government's Disclosure Log (at <https://gov.wales/about/open-government/freedom-of-information/responses/?lang=en>).

Yours sincerely,