FOI 24/101 - FOIA Request

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

Mon 26/02/2024 20:42

[redacted]

7 attachments (2 MB)

Type1PostInspectionLetter Insp GMPGDP 1790110117-0031_marked for redaction.pdf; Type1PostInspectionLetter Insp GMPIMP 140234574-0017_marked for redaction.pdf; Type5PostInspectionLetter Insp GMP 8828261266-0025);_marked for redaction.pdf; Type5PostInspectionLetter Insp GMPIMP 140234574-0017_marked for redaction.pdf; T5letterMAHCiplaEU-NV Insp GMP 14694-446227-0005.pdf; Type1PostInspectionLetter Insp GMP 14694-446227-0005 - redacted.pdf; Type1PostInspectionLetter Insp GMP 8828261266-0025);_marked for redaction.pdf;

Dear [redacted]

Thank you for you request for information dated Tuesday, January 30, 2024.

I have transferred the site details for the post-inspection letters which you have requested to the table below, and comments which explain if the information is held are provided in this table. Where relevant information (post inspection letters) have been identified these are attached; redactions have been made to these reports have been made under the below Sections of the FOIA.

Section 40

I can confirm that the material we have redacted is that which concerns personal data: this information is withheld as it falls under the exemption in sections 40(2) and 40(3)(a)(i) of the FOIA, which relates to the personal data of which the applicant is not the data subject. Section 40(2) of the FOIA provides that personal data relating to other persons is exempt information if disclosure would breach the Data Protection Act 1998 (DPA). We consider that disclosure of this information is likely to breach the first data protection principle in Schedule 1 to the DPA, which relates to the fair and lawful processing of personal data. Therefore, we have concluded that this information is exempt from disclosure under section 40(2) read in conjunction with section 40(3)(a)(i) of the FOIA.

Section 43(2)

Release of all, or part of, the information would, or would be likely to, cause harm to the third party's commercial interests.

We have considered the balance of the public interest when applying this exemption. The exemption is to safeguard the commercially sensitive information / industrial secrets of a third party / commercial enterprise (which can include a Government Department). As a qualified exemption, this exemption is conditional on the public interest in releasing it not outweighing the company's/commercial enterprise's right to confidentiality and the probable damage that the company/commercial enterprise could suffer as a result of the information being released. In this case we have not identified any issues which would benefit the public as a whole by being brought to their attention (examples of issues would be a major public health risk or a major procedural failure or irregularity) .

Request wording / no.	Comments
Cipla Ltd on August 2, 2017 in Kurkumbh 413 802 Maharashtra, India (Insp GMP 14694/446227-0005);	Please note, the same post-inspection letter (albeit with different PL numbers included in the subject line) was sent to multiple companies, and so only one copy has been provided.

Calea UK Ltd & Fresenius Kabi Ltd on December 14, 2017 in Runcorn, Cheshire, Wa7 1NT, United Kingdom (Insp GMP 8828/261266-0025);	Letters attached.
Strides Shasun Limited on January 11, 2017 in Kudikadu Village Cuddalore 607 005 Tamil Nadu, India (Insp GMP 20003/14392945-0001);	We hold no information that is recorded under this reference number, however, we hold a record related to this certificate UK API 20003 Insp GMP 20003/14223367-0001 | MHRA. If you wish to request the post-inspection report letters for this reference, a new request for information will be required.
- Intas Pharma on March 18, 2016 in Ahemedabad, Gujarat, India (EMA/INS/GMP/300593/2015 (INS/GMP/2015/044 & 055 plus 2016/011));	These appear to be EMA reference numbers. We hold no information that is recorded under these reference numbers.
Catalent Pharma Solutions Ltd. (Zydis facility) on September 15, 2016 in Frankland Road Blagrove SN5 8RU Swindon, United Kingdom (Insp GMP/IMP 14023/4574-0017);	Letters attached.
- Lonza Biologics Tuas Pte Ltd. on February 26, 2016 in 35 Tuas South Avenue 6 - 637377 - Singapore (INS/GMP/2015/031, INS/GMP/2016/010); -	These appear to be EMA reference numbers. We hold no information that is recorded under these reference numbers.
AstraZeneca on December 2, 2015 in Charter Court Macclesfield SK10 2NA Cheshire, United Kingdom (Insp GMP 17901/10117-0031)	Letters attached.

We trust that you will find this information of use. However, if you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask us to review our actions and decisions by writing to: info@mhra.gov.uk, and requesting an internal review.

Please note that your internal review request must be in a recordable format (email, letter, audio tape etc.), and that you have 40 working days upon receipt of this letter to ask for a review. We aim to provide a full response to your review request within 20 working days of its receipt. Please quote the reference number above in any future communications.

If you are not content 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 online via an electronic form: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or in writing to:
Information Commissioner's Office,
Wycliffe House,
Water Lane,
Wilmslow,
Cheshire,
SK9 5AF

Yours sincerely,

HQA FOI Team

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From: [redacted]m>
Sent: Tuesday, January 30, 2024 5:39 PM
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: FOI 24/101 - FOIA Request

Please provide the post inspection letters related to the following inspections:
- Cipla Ltd on August 2, 2017 in Kurkumbh 413 802 Maharashtra, India (Insp GMP 14694/446227-0005)
- Calea UK Ltd & Fresenius Kabi Ltd on December 14, 2017 in Runcorn, Cheshire, Wa7 1NT, United Kingdom (Insp GMP 8828/261266-0025)
- Strides Shasun Limited on January 11, 2017 in Kudikadu Village Cuddalore 607 005 Tamil Nadu, India (Insp. GMP 20003/14392945-0001)
- Intas Pharma on March 18, 2016 in Ahemedabad, Gujarat, India (EMA/INS/GMP/300593/2015 (INS/GMP/2015/044 & 055 plus 2016/011))
- Catalent Pharma Solutions Ltd. (Zydis facility) on September 15, 2016 in Frankland Road Blagrove SN5 8RU Swindon, United Kingdom (Insp GMP/IMP 14023/4574-0017)
- Lonza Biologics Tuas Pte Ltd. on February 26, 2016 in 35 Tuas South Avenue 6 - 637377 - Singapore (INS/GMP/2015/031, INS/GMP/2016/010)
- AstraZeneca on December 2, 2015 in Charter Court Macclesfield SK10 2NA Cheshire, United Kingdom (Insp GMP 17901/10117-0031)

Best,
[redacted]