Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

By email: [redacted]

14/02/2024

FOI 24/128

Dear [redacted]

Thank you for your information request, dated **23/01/2024** where you asked:

"how much a manufacturer is asked to pay by way of registration fee when they notify their products to the MHRA. How much is it and how much has been received to date and over the last 3 years?"

Please find the requested information below:

- 2020/21 £979k
- 2021/22 £1,155k
- 2022/23 £2,204k
- 2023/24 to Jan £2,115k

As per our webpage: Notification Fees for Great Britain and Northern Ireland - GOV.UK (www.gov.uk) ,please see information provided to manufacturers that relates to your query:

"1. Current costs of notifications
Notification fee: £150 (Per ECID notified in both Great Britain and Northern Ireland)

Annual and Substantial Modification fees will be reviewed in 2024.

The MHRA has given a commitment to review the level of fees in the light of the number of notifications received each year.

2. Payments via MHRA Submissions
From 1st March 2022 submitters are required to pay for notifications using the integrated Gov.Pay system provided as part of MHRA Submissions. Upon validation of a submission you will be able download your invoice and pay for notifications via MHRA Submissions.

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This payment will cover the cost of the notification for Great Britain and Northern Ireland, if the notification has been submitted via MHRA Submissions and EUCEG. Submitters must ensure that product ECIDs are aligned on MHRA Submissions and EUCEG or you will be charged for two product notifications.

If you do not want to submit the notification for assessment or require another company employee to make payments for the submission you will be able to save multiple drafts and complete the submissions and payment at a later time.

Payments for Northern Ireland only notifications must be completed using MHRA Submissions. Upon completing EUCEG and validated MHRA Submissions uploads you will be able to make a payment. If the product is only to be supplied in Northern Ireland, please contact our team to confirm that the payment is to be applied to Northern Ireland only and GB publication is not required. Should you wish to supply to GB in the future no further payment we be required.

Please be aware that our assessment team will not have access to your submissions for review until payment has been completed via MHRA Submissions.

Once the product has been reviewed and published by the MHRA it is legal for supply to the relevant region. Evidence of your product's published status should be made available to distributors, importers, UK enforcement officers and Border Force representatives upon request."

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 E-Cigarette Unit