FOI 22/973 – Thermal screeners

REQUEST

20 September 2022

- All available information on enforcement actions taken by MHRA against those selling thermal cameras and temperature screening products for making COVID-19 diagnosis claims;
- All correspondence with manufacturers and/or vendors of non-contact temperature screeners such as thermal cameras;
- Technical documentation and marketing materials used during investigation and/or received from the manufacturer and/or vendor

MHRA RESPONSE

3 February 2023

Thank you for your information request, dated 20 September 2022. Please accept our apologies for the long delay in response.

Having reviewed your request we can confirm that the MHRA holds the requested information.

By way of background we can confirm that since the start of the COVID-19 pandemic MHRA have opened fifteen investigations for products intended to be used for temperature screening. There have been a variety of differing outcomes including removal from sale, seizure and destruction and bringing a manufacturer into compliance.

However, we have determined that the specific information you have requested is exempt from disclosure under Sections 30 (1) and 43 (2) of the Freedom of Information Act and we cannot process your request any further.

Section 30 (1) states:

> *30 –(1) Information held by a public authority is exempt information if it has at any time been held by the authority for the purpose of –*
> *(a) any investigation which the public authority has a duty to conduct with a view to it being ascertained –*
> *(i) whether a person should be charged with an offence, or*
> *(ii) whether a person charged with an offence is guilty of it,*

Section 43(2) exempts information whose disclosure would, or would be likely to, prejudice the commercial interests of any legal person (an individual, a company, the public authority itself or any other legal entity).

The MHRA is the designated authority that administers and enforces the law on medical devices in the UK, as established in the Medical Device Regulations 2002. Our investigatory and enforcement powers and responsibilities are drawn from multiple pieces of legislation, including the Consumer Protection Act 1987, Consumer Rights Act 2015, the Medicines and Medical Devices Act 2021 as well the Medical Devices Regulations 2002 (as amended) itself.

In the majority of circumstances, where our investigations identify breaches of the regulations, we shall engage with the relevant parties to bring them into compliance and prevent dangerous products being made available to the public. Where parties fail to cooperate or a serious risk to public health is identified, MHRA may exercise its enforcement powers and investigations may lead to prosecution. Further information on how MHRA enforce the Medical Devices Regulations 2002 can be found here.

Sections 30 and 43 are qualified exemptions, which means that we have considered the public interest in releasing the information. We do recognise that there is considerable interest in the work which we undertake to ensure that medical devices placed onto the UK market are compliant with the applicable regulations. That said, we do not consider that the public interest is best served by releasing information which could prejudice any potential legal action taken under the regulations described above that we may pursue. We also consider that providing commercially sensitive documentation (for example technical documentation relating to their product) could prejudice the commercial interests of the organisation or individual that owns that documentation.

If you disagree with how we have interpreted the Freedom of Information Act 2000 with regards to your request, you can ask for the decision to be reviewed. The review will be carried out by a senior member of the Agency who was not involved with the original decision.

If you have a query about the information provided, please reply to this email.

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

If you have a query about the information provided, please reply to this email.

Kind Regards,

MHRA Customer Experience Centre
Medicines and Healthcare products Regulatory Agency
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