UK Health Security Agency

By email
jamesleighton77@outlook.com

Our ref: 20/10/24/LS/427

23 December 2024

Dear James Leighton,

Re: FOI Request: Pacemakers

Thank you for your request received on 20 October 2024 addressed to the UK Health Security Agency (UKHSA).

Request

I wish to make the following Freedom Of Information Request.

On a recent public letter to Eileen O'Connor, Director of RadiationResearch.org, the UKHSA made the following statement:

"UKHSA advise that interference is unlikely to be a problem in the areas around masts; however, the potential for Electromagnetic Interference (EMI) is device dependent and it falls to the manufacturers to minimise the risk that their device can cause, or be affected by EMI. Where the risk is not eliminated, the manufacturer must include information about the residual risk in the instructions for use. Guidance on this is available from the Medicines & Healthcare products Regulatory Agency" (my emphasis in bold)

Please provide the following information:

1. ***Scientific evidence used by the UKHSA in making the statement that interference around masts is unlikely to be a problem***
2. ***The evidence used by the UKHSA to determine that the risk should be passed on to the manufacturer of the device rather than the mast operator, given that the manufacturer of the device cannot qualify the risk as he does not know the frequencies or power output.***

Response

In accordance with Section 1(1)(a) of the Freedom of Information Act 2000 (the Act), I can confirm that UKHSA does hold the information you have specified in parts one and two of your request. However, as the information held is in the public domain we will, under Section 21 of the Act, (Information accessible to applicant by other means) refer you to the published sources below:

Active Implantable Medical Devices (AIMDs) such as pacemakers are regulated under the UK Medical Device Regulations 2002. Regulating medical devices in the UK: Regulating medical devices in the UK - GOV.UK.

Conformity with the requirements of the Regulations can be demonstrated by applying the relevant designated standards (*THE DEPARTMENT OF HEALTH AND SOCIAL CARE NOTICE OF PUBLICATION: Of references to standards for active implantable medical devices in support of the Medical Devices Regulations 2002* (S.I. 2002/618) 0032/21. 1 January 2021. Available at: Notice of Publication 0032/21: Designated Standards - Active Implantable Medical Devices.

The relevant designated standards for the Medical Device Regulations and Active Implantable Medical Devices (AIMDs) are the British Standards EN 45502. This family of standards specify that the operation of implantable and patient-carried parts of an AIMD should not be influenced by field levels up to the International Commission on Non-Ionizing Radiation Protection (ICNIRP) 1998 General Public Reference Levels, and that any exceptions to this should be declared in the accompanying documentation of the device (EN 45502-1:2015. *Implants for surgery — Active implantable medical devices Part 1: General requirements for safety, marking and for information to be provided by the manufacturer*. Available at: BS EN 45502-1:2015 - TC | 30 Jun 2015 | BSI Knowledge.

Similar requirements can be found in another pertinent designated standard: BS EN ISO 20417:2021. *Medical devices — Information to be supplied by the manufacturer*. Available at: Bibliographic Info :: BSOL British Standards Online.

The mobile phone network operators certify that installations are compliant with the exposure guidelines, when submitting planning applications to local authorities, and they are committed to ensuring compliance through the following Codes of Best Practice: Codes of Practice | Mobile Network Operators | Mobile UK.

Consequently, members of the public who wear AIMDs should be protected if:

- the manufacturer of the AIMD used the designated standard to demonstrate compliance with UK Regulations
- the manufacturer of the AIMD issued no applicable warnings, and
- exclusion zones around mobile phone masts based on the ICNIRP public exposure guidelines are respected by the AIMD wearer

Another pertinent standard is EN50527 which is a family of standards designed for the purpose of determining the risk for workers with implanted pacemakers arising from exposure to electromagnetic fields (EMFs) at the workplace. The EN 50527-1 standard states that EMFs at frequencies above 3 GHz are very unlikely to interfere with pacemakers due to the reflection and absorption of EMFs by body tissue.

The Medicines and Healthcare products Regulatory Agency (MHRA) is the regulatory body for medical devices. For more information, please visit the MHRA guidance webpage: Medical devices: sources of electromagnetic interference - GOV.UK

If you have any queries regarding this response, please refer your query to the Information Rights Team in writing in the first instance. If you remain dissatisfied and would like to request an internal review, then please contact us by emailing InformationRights@UKHSA.gov.uk.

Please note that you have the right to an independent review by the Information Commissioner's Office (ICO) if a query cannot be resolved through the UKHSA internal review procedure. The ICO can be contacted by calling the ICO's helpline on 0303 123 1113, visiting the ICO's website at www.ico.org.uk or writing to the ICO at Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF.

Yours sincerely,
Information Rights Team