RE: CEC-169601 Specification for glucometers

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

Fri 12/01/2024 15:13

[redacted]

Our ref: FOI 24/026

Dear [redacted]

Thank you for your request of 11 December 2023 which we have handled under the Freedom of Information Act. You requested:

1. What specification is used to ensure glucometers are suitable and accurate enough?
2. Who approves the 'recommended meters' in England Scotland & NI?
2. How are glucometers calibrated to ensure they are accurate? Is this performed by manufacturers? What tolerances/uncertainty are permitted?
2. Which organisation performs 'market surveillance' on glucometers, and what acceptance criteria is used?
2. Any other information that would help UAE establish an appropriate regime there.

We have re-produced the questions below and added our responses beneath each.

1. What specification is used to ensure glucometers are suitable and accurate enough?

We do not hold the information you have requested. However, manufacturers of blood glucose meters used for self-testing can demonstrate compliance with ISO 15197, which covers elements of accuracy, as part of their conformity assessment for UKCA marking. For further information on this please see: Medical devices: conformity assessment and the UKCA mark - GOV.UK (www.gov.uk)

2. Who approves the 'recommended meters' in England Scotland & NI?

Powers relating to Health and Social Care are devolved. Any decisions made regarding recommended meters for self-testing are often based on cost, patient demographics etc, but we would always encourage that any recommended meter is CE/UKCA marked.

2. How are glucometers calibrated to ensure they are accurate? Is this performed by manufacturers? What tolerances/uncertainty are permitted?

For a self- test blood glucose meter, the manufacturer will set out in their Instructions For Use (IFU) details relating to calibration and quality control expectations in order that a user can identify any issues related to meter and/or test strip function. These checks should be performed at the points specified by the manufacturer i.e. on opening a new test box, when a result doesn't match a patient's symptoms or at weekly time points.

4. Which organisation performs 'market surveillance' on glucometers, and what acceptance criteria is used?

Manufacturers are obliged to monitor their products' safe performance and report to MHRA any device adverse incidents as stipulated in MEDDEV 2.12-1 rev 8. Any issues identified relating to medical devices can also be reported directly to MHRA via Report a problem with a medicine or medical device - GOV.UK (www.gov.uk)

5. Any other information that would help UAE establish an appropriate regime there.

There are some MHRA webpages below that you may find helpful:

[http://Medical%20devices:%20information%20for%20users%20and%20patients%20-%20GOV.UK%20(www.gov.uk)]Medical devices: information for users and patients -

GOV.UK (www.gov.uk) - Advice relating to Buying medical devices for personal use with specific advice regarding Blood glucose meters.

Point of care testing with blood glucose meters: leaflet - GOV.UK (www.gov.uk) - advice on how to use blood glucose meters safely for point of care testing.

We hope you find this information helpful.

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

Or online via: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Yours sincerely

MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

From: [redacted]
Sent: Monday, December 11, 2023 5:40 PM
To: MHRA Customer Services MHRACustomerServices@mhra.gov.uk
Subject: RE: CEC-169601 Specification for glucometers
Importance: High

You don't often get email [redacted]

Dear [redacted]
All is well thank you, I am not asking for consultancy I am just enquiring as to who decides what glucometer is suitable for NHS to use and what the specification is as far as accuracy. So yes, I would appreciate the the MHRA guidance on the legislation regarding the buying, specifications and use of glucometers.
I could ask a Freedom of information Act question if you prefer as to what advice has been given to the NHS and Health Cre sector on what glucometers are suitable for them to use and what the specifications (accuracy) requirements are, if that helps.
I have already provided the list of approved glucometers for Wales, what lists/guidance exist for the rest of the UK?
Thank you for any assistance you can provide.
Best wishes for an enjoyable Christmas & all the best for the New Year
Howard

[redacted]

From: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Sent: Monday, December 11, 2023 2:55 PM
To: [redacted]
Subject: RE: CEC-169601 Specification for glucometers

Dear [redacted],

I hope all is well. Apologies about the delay in responding. Thank you for your patience.

The MHRA is a regulatory agency and so cannot provide consultancy related to specific devices. The MHRA may provide advisory on the current regulations, and you may take advantage of the Devices Regulatory Advice Meeting (£906 fee).

Best Wishes,

[redacted]
MHRA Customer Experience Centre
Communications and engagement
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU
Telephone 020 3080 6000
gov.uk/mhra
Stay connected

From: [redacted]>
Sent: Monday, November 20, 2023 12:40 PM
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: CEC-169601 Specification for glucometers
Importance: High

You don't often get email from [redacted]

Good afternoon,

I am sharing experiences and information with Inspectors from UAE regarding the equipment used by measuring blood glucose levels (glucometer).

As a 'retired' Trading Standards Officer I am aware of MID (2014/32/EU) and the various instruments controlled and the modules used for other 'trade use' instruments overseen by OPSS, but I am unaware of the controls on glucometers and would greatly appreciate your assistance.

I have found the attached documents but I cannot find information that would help set up a suitable specification for glucometer in UAE.

Could you please provide information (or web links) to the following:

1. What specification is used to ensure glucometers are suitable and accurate enough?
2. Who approves the 'recommended meters' in England Scotland & NI?
2. How are glucometers calibrated to ensure they are accurate? Is this performed by manufacturers? What tolerances/uncertainty are permitted?
2. Which organisation performs 'market surveillance' on glucometers, and what acceptance criteria is used?
2. Any other information that would help UAE establish an appropriate regime there.

Thanks you so much for your help.

Best regards

[redacted]

[redacted]

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