Medicines and Healthcare Products Regulatory Agency

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Crispin A Oliver, H M Assistant Coroner for County Durham and Darlington
H.M. Coroners Office
PO Box 282
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15 August 2016

MHRA Ref: 2016/004/012/291/010

RE: Leslie Matthews deceased

Medical Device: oxygen flowmeter
Manufacturer: Oxylitre
Model: F1602
Serial Number: 01729xxx (only a partial number is available due to label damage)

Dear Mr Oliver,

I write with reference to your letter of 1 August 2016.

The Medicines and Healthcare products Regulatory Agency (MHRA) is an Executive Agency of the Department of Health. The aim of the MHRA Devices Division is to take all reasonable steps to protect public health and safeguard the interests of patients and users by ensuring that medical devices meet appropriate standards of safety, quality and performance and that they comply with the relevant Directives of the European Union.

The MHRA liaises with manufacturers to ensure that their products are as safe as reasonably possible, and that all information necessary to allow the device to be used correctly and safely is provided. Where required, we also take appropriate action with manufacturers and issue advice to users as a result of our investigations into adverse incidents.

Synopsis of incident details
Mr Matthews died from an infective exacerbation of Chronic Obstructive Pulmonary Disease on 19 February 2016. He was receiving oxygen at the time of his death, with an Oxylitre flowmeter used to regulate and measure oxygen flowrate. The flowmeter was later found to be damaged.

The forensic post mortem autopsy concluded that the reduced oxygen flow emanating from the damaged flowmeter did not significantly contribute to his death.

On the 1 August 2016, you contacted the MHRA requesting that we look into whether MHRA action could be taken to prevent future deaths. Your main concerns regarded a lack of clarity and completeness of guidance relating to pre-use checks and general maintenance of flowmeters.

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Device Description
The Oxylitre F1602 flowmeter is a device used to measure the flow rate of therapeutic oxygen administered to patients. It is designed to measure oxygen flow rate from 0 – 15 l/min. The device comprises of a chrome-plated brass body with BS (British Standard) probe and an outer tube used to keep the unit "gas tight" (appendix 1).

Manufacturer's investigation
On 12 April 2016 MHRA received an adverse incident report from [redacted] Head of Non-Clinical Risk Management at Darlington Memorial Hospital (Hollyhurst Road, Darlington DL3 6HX). The hospital's report stated "Crack in flowmeter tube causing O_2 leak of indeterminate volume. Device was reported as 'unable to turn off'". Following receipt of the incident report received on 13/04/16, MHRA requested that Oxylitre investigate the event.

On 9 August 2016 MHRA were advised by Oxylitre that they had inspected and tested the F1602 flowmeter to determine whether oxygen flow had been compromised.

Oxylitre noted that a noticeable crack was visible in the outer tube (appendix 2). Upon testing, the manufacturer identified that when plugged into a gas source the flowmeter supplied oxygen at the maximum flow rate (15 l/min). Therefore, the manufacturer's analysis concluded that the device was still capable of supplying sufficient oxygen to the patient. MHRA did not witness the manufacturer's examination of the F1602 flowmeter, but has reviewed the manufacturer's report (appendix 3).

The particular unit in question is approximately 15 years old (exact date of manufacture cannot be established as serial number has been partially removed – appendix 2).The manufacturer has confirmed that the device had exceeded the recommended service life of 10 years. According to your report, a review by the clinical engineering department of Oxylitre flowmeters in use at Darlington Memorial Hospital found that a further 2 devices available for use were cracked.

MHRA analysis of instructions for use (IFU)
Oxylitre provided MHRA with a copy of the IFU for the F1602 flowmeter (appendix 4).

The IFU states "No leaks are permissible on the device", and advises the user to visually check the device for cracks before use. A user who identifies a crack should discard the product prior to patient use.

It would appear that the hospital had not performed pre-use checks in line with the manufacturer's IFU.

The IFU states that, only qualified servicing personnel should perform tests to detect leaks, therefore implying that additional specific instructions referring to pre-use leak tests are unnecessary.

We have undertaken a comparative assessment of various manufacturers' IFUs for similar devices to determine whether there are any insufficiencies in the pre-use checks description for the Oxylitre flowmeter. The information collected indicates that the Oxylitre IFU provides sufficient guidance for the user to perform pre-use checks and is in line with alternative products. Although the IFU appears sufficient, we have forwarded your concerns regarding clarity and completeness of guidance to Oxylitre for their consideration in their next revision.

Additional Guidance
General guidance can be found in the MHRA's publication Managing Medical Devices (appendix 5). The purpose of this document is to outline a systematic approach to the acquisition, deployment, maintenance, repair and disposal of all medical devices. It is intended primarily for people in hospital and community based organisations who are responsible for the management of reusable medical devices to help them promote safe and effective use of medical devices. The document, which can be applied to oxygen flowmeters, states that a healthcare organisation's medical device management policy must cover the provision of maintenance and repair of all

medical devices, including reconditioning and refurbishment. The healthcare organisation is responsible for ensuring their medical devices are maintained appropriately.

Similar reports received by MHRA

Oxylitre have confirmed that no similar incidents or complaints regarding the F1602 flowmeter have been reported to them. A review of the MHRA's adverse incident database has shown that since 2006 we have received no adverse incident reports involving cracked flowmeters.

Conclusion

The MHRA received an adverse incident report concerning a cracked flowmeter which was in use by a patient who subsequently died.

The manufacturer's investigation identified that the cracked flowmeter was still capable of supplying oxygen at the maximum flowrate.

The manufacturer of the oxygen flowmeter is fully compliant with the Medical Device Directive 93/42 EEC, and the device was functional despite exceeding the manufacturer's recommended service life.

The MHRA has not identified a systemic problem with cracks associated to Oxylitre flowmeter. The manufacturer's Instructions for Use appear sufficient including details of pre-use inspection. The MHRA has brought the Coroner's concerns to the attention of the manufacturer. We have also requested that the manufacturer evaluate whether additional clarity in information could be incorporated at the next Instructions for Use review.

The MHRA is continuing to monitor this situation and will investigate any further incidents that we receive.

If the MHRA can be of any further assistance in this matter, please contact us.

Yours sincerely,

Dr Ian Hudson
Chief Executive Officer
[redacted]