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05.07.2024

Response to Coroner's Regulation 28 Report (Ref: 2024-0256)

Dear Ms Robertson,

Firstly, may I apologise for the late response to your Regulation 28 Report (Ref: 2024-0256) concerning the outcome of the Inquest into the death of Ben Christopher Harrison, on 18 December 2020. Although we are now aware that you sent the report to BOC, our first sight of the document was in an e-mail sent to myself on the 20th of June from the MHRA, whereby a copy of your report was attached to the e-mail correspondence. Having received the e-mail from the MHRA, we checked all the likely recipients of this type of correspondence in BOC but could not find any evidence of its receipt. It would be very helpful if you could indicate to whom you sent your original note so that we can investigate as to why it was not forwarded to the appropriate personnel in BOC.

I appreciate that you are looking for a timely response to the conclusions that you came to during the Inquest, but I felt it was important to provide you with some of the regulatory background concerning the design and supply of the portable CD Medical Oxygen cylinders fitted with an integral valve. It is unfortunate that BOC was not involved in your investigation during the Inquest, as we would have been able to provide you with this additional information at that time.

To provide some history behind the development of the integral valved medical gas cylinder packages, BOC initially raised a variation to their long-standing Marketing Authorisation (PL 0735/5000) back in 2000. The variation covered the supply of Medical Oxygen in a lightweight cylinder, fitted with a GCE CombiLite integral valve (referred to as a Valve with Integral Pressure

Regulator (VIPR)). The variation was submitted to the Medicines and Healthcare products Regulatory Agency (MHRA), who approved the new cylinder package for use.

The new CD cylinder was designed to replace the existing D size Medical Oxygen cylinder, which consisted of a heavy steel cylinder shell fitted with a standard 'pin index' medical cylinder valve. This package required a separate pressure regulator to be fitted to the cylinders to control the flow of gas to the patient. There were a number of benefits with the introduction of the new package, including a significant reduction in the package weight, and the ability to almost double the gas capacity of the cylinder by increasing the filling pressure from 137 bar(g) to 230 bar(g) . But the main benefits were to provide a cylinder which eliminated the user having to make high pressure connections to the valve and not requiring any additional equipment (such as a valve opening key) to enable the cylinder to be used for administration to the patient.

Although there have been several changes to the CD cylinder since its introduction (including further increases to the cylinder pressure to increase capacity and adding the CombiLite integral valve (VIPR) to different cylinder sizes and products), the basic valve design is the same as the original valve fitted to the CD cylinder in 2000.

The CombiLite valve is manufactured and tested by Gas Control Equipment (GCE) and is CE certified by their Notified Body (as a Class IIB medical device) to the Medical Device Regulations (MDR), as being compliant with the requirements set out in the relevant ISO standard (BS ISO 10524-3).

As part of the requirements of the Marketing Authorisation, BOC must provide information to the end user of the cylinder package about how to handle and use the cylinder safely. This includes the agreed wording for the cylinder labelling, information in the Summary of Product Characteristics (SmPC) and the Patient Information Leaflet (PIL), which is designed to provide information to the patient in 'easy to understand' language. These documents are made available to Healthcare Facilities and to Homecare patients to inform them how to safely use the cylinder and to form part of the training requirements for its safe use. Note that the safety refers to both the safety of the person administering the gas to the patient and the patient safety aspects of oxygen therapy.

In addition to the safety information that we are obliged to provide on the cylinder label, in the SmPC and in the PIL, BOC took the decision to prepare an illustrated 'Instructions for Use' (IFU) to provide additional information to make sure that sufficient information is made available to the end user to operate the valve both correctly and safely. The IFU (copy attached) is provided 'on-line' as a suitable training document for both Healthcare Professionals and Homecare patients to access and

for Healthcare Facilities to use as additional training material, when training their staff. In addition to describing the correct method of operating the VIPR, the IFU also covers the cylinder handling requirements to administer oxygen safely.

BOC also provides videos on-line to help show users how to safely use the product, both to ensure that the patient receives the correct gas for therapy and that the risks associated with delivering oxygen safely are met.

It should also be noted that BOC has worked with the relevant UK and European Gas Associations (British Compressed Gases Association (BCGA) and the European Industrial Gases Association (EIGA)) to prepare 'best practice' guidance for both the industry and for end users (via their websites). These Guidance Notes were prepared to harmonise the information that the individual gas companies prepare to accompany their products and have been reviewed prior to publication by the relevant national Regulatory Authorities - the MHRA in the UK and the HPRA in Ireland. Although the GCE valve used in the CD cylinder package is the most common type of VIPR used by BOC in medical gas cylinder packages, it is also commonly used by other gas suppliers in the UK and across Europe.

As part of the certification process when the valve was initially introduced, GCE were required to carry out usability testing, to demonstrate that the user would not be 'confused' by the new design. It should be noted that when the GCE CombiLite valve was first introduced, it was 'standard practice' for all cylinder packages that a 'shut-off' valve would be required to be opened initially, before setting the flowrate to be administered to the patient. The development of the new type of cylinder valve simplified this process, providing a means to operate the valve without any additional equipment, as previously mentioned.

Since the initial introduction of the integral valve, BOC has placed more than 600,000 medical gas cylinder packages fitted with VIPRs onto the UK and Irish markets. To date, BOC has supplied approaching 40 million Medical Oxygen cylinders to Healthcare Facilities throughout the UK and Ireland, as well as to Homecare patients, providing the opportunity for patients with respiratory disease to live a 'normal' life. As the cylinders are not supplied specifically for 'single' patient use, they are usually operated multiple times during each supply, indicating that this type of integral valve has been 'opened' to supply patients upwards of 200 million times over the last 24 years.

Although BOC understands the need for the valve to be operated 'intuitively', especially during emergency situations, it is also important to note that it is imperative that users are appropriately

trained in the use of Medical Oxygen cylinders due to the nature of oxygen and the associated risks related to the potential for ignitions, if the user instructions are not correctly followed.
Within the 40 million cylinders supplied, there have been a couple of serious incidents that have unfortunately led to the patient being killed or seriously injured. During the Coroner's Inquests covering these incidents, the Coroner has praised BOC for the information they have developed to promote the safe use of the product and the relevant mitigation that we now recommend to avoid the outcome of an oxygen ignition when administering the gas. In all cases, BOC feels that it is imperative that anyone who is required to administer Medical Oxygen should be trained in the operation of the cylinder package to ensure that they minimise the risk of an oxygen fire occurring, as well as making sure that gas is flowing to the patient when it is being administered. Although the potential risks are high, providing the simple rules for the handling and setting up of the cylinder are followed, I would stress that Medical Oxygen cylinders have an extremely safe record.

With respect to the incident that occurred at Glan Clwyd Hospital, I can confirm that BOC were not informed of the incident at the time it occurred. In response to the statement made in your Regulations 28 Report, where it is mentioned:
BCUHB also reported to the Medicines and Healthcare products Regulatory Agency (MHRA) on 6 October 2022 under The Yellow Card Scheme. No response was formally received.
I can confirm that BOC did receive two separate Yellow Card reports from the MHRA in October 2022. Both Yellow Card reports were anonymous, in that the reporter ticked "no" on the report to the question "Can we send your personal contact details to the manufacturer", meaning that BOC were not aware as to who had submitted the Yellow Card reports to the MHRA, so we were unable to formally respond to the reporter of either report. BOC did however respond to the MHRA's Defective Medicines Report Centre (DMRC) in response to both Yellow Card reports.
Some details stated in one of the received Yellow Card reports were, however, identical to information that had been reported to BOC by Betsi Cadwaladr University Health Board (BCUHB) via email communications in September 2022. This led BOC to suspect that one of the Yellow Card reports had been submitted by someone from BCUHB but as no reporter details were submitted on the Yellow Card report, we were unable to confirm this, or report back to the reporter.
Around the time of the two Yellow Card reports, BOC had been in discussion with the MHRA about the actions we had already taken, to emphasise the need to open the cylinder valve handwheel prior to

selecting the prescribed flow for the patient. This included a change to the cylinder valve handwheel tamper evident cover (which is fitted as a regulatory requirement over the cylinder valve handwheel as a tamper evident seal). The raised letters on the cover were pad printing in black to make it more obvious that the cover should be removed before use, making it more obvious that the cylinder valve handwheel should be opened to administer the gas. When BOC supplies medical oxygen to Homecare patients, part of the procedure we have to follow is to ensure that either the patient or their 'carer' are fully trained and assessed to make sure they understand the correct procedure to be used. With Healthcare Facilities, this is a little more difficult to organise (as we have no indications / records of the staff that may be required to use the cylinders). However, BOC does regularly offer a variety of training programmes for different aspects of handling Medical Oxygen, as well as offering 'free' training for nursing staff to make sure that they are familiar with the correct procedures. With the cylinder package now having been in service for almost 25 years, the responsibility of ensuring that all staff are appropriately trained is down to the Healthcare Facility, as they are aware of the changes in the staffing levels and their need for retraining.

From the discussions BOC has had with the staff at Glan Clwyd Hospital, I can confirm that BOC has provided them with some training, but this has been related to the management of the Medical Gas Pipeline System (MGPS). The training BOC provided was intended for 'Training the Trainer', aimed primarily at the engineering and portering staff responsible for operating the MGPS. Although it did cover some aspects of handling cylinders, this was related to cylinders used to supply the pipeline, rather than cylinders used at the patient's bedside or when transferring patients between departments. BOC has offered to provide awareness training for nurses in their 'mess room', (avoiding any issues of taking nurses away from the wards), but this offer was declined by the hospital.

It is noted in your Regulation 28 Report that the nurses have undergone ALS / ILS training with respect to administering Medical Oxygen in emergency situations. It is disconcerting that you also indicated that, despite being retrained, nurses are still making the mistake of not turning on the cylinder valve handwheel prior to administering the gas. It would be useful if you could provide the scope of the Life Support training to see whether it correctly covers the operation of the cylinder valve as well as the precautions to be taken when administering Medical Oxygen. BOC's understanding of this training is that an essential part of any procedure involving the administration

of Medical Oxygen is that there is a requirement to ensure that a flow of gas has been established for the patient.

As part of the range of cylinders BOC offers to customers, we now have available to Healthcare Facilities the IQD Medial Oxygen cylinder, based on the same lightweight cylinder, but fitted with a VIPR that has an electronic gauge. The gauge has a number of functions, including visual and audible alarms to warn the user when the cylinder has not been set up correctly. One of the alarms provides an indication as to when a flow has been selected without first opening the cylinder valve handwheel. I understand that BOC has offered this cylinder package to Glan Clwyd Hospital, but they have decided not to purchase it. I have attached for your information, a copy of the IFU for the IQD cylinder package so that you can see the functionality of the electronic gauge, but you will note that the instructions still cover the safe use and handling of Medical Oxygen cylinders.

I can also confirm that BOC is currently in the process of working with two medical gas valve manufacturers who are developing a single operation Medical Gas VIPR, where the cylinder valve handwheel and flow selector functionality is incorporated into the same knob/valve. This work is in its final stages, with BOC due to conduct testing on the valves to ensure they operate in compliance with the relevant ISO standard. However, it should be noted that from a usability point of view, the introduction of this valve will need to be carefully controlled as it will require the user to follow 'different' procedures compared to those for the existing valve design.

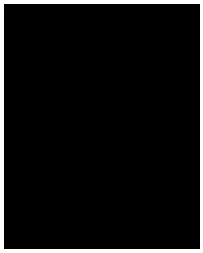
As you can see from the information I have provided, BOC attaches great importance to constant product evaluation as part of our continuous improvement programme., In this regard, BOC has a number of projects currently under way to improve both the safe operation of the valve, as well as reviewing and improving patient safety. One issue we have with many users is that incidents with valves are not always reported to BOC, and with the MHRA's Yellow Card procedure, it is not always possible to understand the full circumstances related to each incident. The 22 incidents at Glan Clwyd Hospital were only reported to BOC verbally, long after the event, and we have received no indications of the two cases that you have referenced in your Report has having occurred this year.

As it appears that the appropriate personnel in BOC did not receive your Regulation 28 Report until late June, via the e-mail from the MHRA (which will require a separate investigation to see why your official Report was not received), we would request an extension to your time frame before providing the exact information you have requested. Although we have provided you with a description of the

plans that BOC has in place to address the issues raised in your Regulation 28 report, we would need more time to provide timescales for some of the actions, hence the request for an extension. It would be informative were BOC to have a formal meeting with you to go through our responses to the points you have raised in the Regulation 28 Report to clarify our position with respect to this unfortunate incident and to ensure that you are satisfied with our responses.

Please accept my apologies for the lengthy response to your report, but, as you can see, there are many aspects related to the use and operation of our Medical Gas cylinder packages. We would welcome the opportunity to meet with you to go through the points raised and I look forward to your reply to this response.

Yours sincerely



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