Medicines & Healthcare products Regulatory Agency

MHRA

Miss N Persaud
Her Majesty's Coroner
Walthamstow Coroner's Court,
Queens Road,
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E17 8QP

Medicines & Healthcare products Regulatory Agency

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[redacted]

gov.uk/mhra

Dear Miss Persaud,

Please find a summary below detailing the role of the MHRA Devices Division and an outline of the types of assistance that we can offer.

The Medicines and Healthcare Products Regulatory Agency is an executive agency of the Department of Health. As part of this, the MHRA Devices Division is responsible for protecting the public's health and safeguarding the interests of patients and users by ensuring that medical devices and equipment meet appropriate standards of safety, quality and performance and that they comply with relevant UK medical device directives. Details on all the business areas of the agency can be found on the website Medicines and Healthcare products Regulatory Agency - GOV.UK (www.gov.uk).

One major area of the MHRA Devices Division's responsibilities is the investigation of adverse incidents involving medical devices. An adverse incident is an event involving a medical device that produces, or has the potential to produce, unwanted effects impacting on the safety of patients, users and other persons. These incidents may arise from defects in the device design or manufacture, its operating instructions, user practice or conditions of use.

Where adverse incidents involving medical devices have been reported to other authorities, including the Police, Coroners and the Health and Safety Executive (HSE), we are able to provide the following assistance to that authority:

1. Liaise with the manufacturer of the medical device(s) and request that they investigate and test the device(s). As part of the manufacturer's investigation they may choose to have the device independently tested at a laboratory with specialist equipment. We can then request a report from the manufacturer summarising their findings, including the root causes of any device issues (if established), and provide this to the instructing authority.

2. Witness the above testing/inspection of device(s) by the manufacturer or its representatives in the UK only. Please note, we do not have the resources or specialist equipment to undertake our own testing/inspection of medical devices. Normally the manufacturer will undertake testing at their premises, which may be located overseas.

3. Produce a summary letter with comments on the manufacturer's report (if applicable). The summary letter may also provide details such as the number of similar reported incidents on our database, and any related safety actions that may be relevant to the device in question.

4. Help identify an independent medical device test facility, provided that there is no need for proprietary knowledge of unique design or software. Costs incurred will be at the instructing authority's expense.

5. Attend the coroner's court to give evidence, if instructed.

In addition, we may issue safety information to the health service or advise the manufacturer to make design changes to their product to prevent similar occurrences in the future.

To assist us in an effective investigation, please advise us as soon as possible if you have any specific requirements.

With regards to the regulation 28 report dated 07/08/2021 and the MHRA's response to the request for comment received from the DHSC, to date (16/08/2021) the MHRA has not received incident reports for either of the two incidents mentioned in the Coroner's report. This makes it difficult to carry out a thorough investigation or to comment on specifics. For a complete investigation to take place the MHRA would need to be provided details via the yellow card reporting scheme. It would be helpful if you provide:

- The name of the legal manufacturer and model name of the filters in question.
- Details of the devices with which the filters were used including legal manufacturer and model name.
- As detailed a description of the incident as possible.
- If available, the lot and batch numbers of the filters involved.
- Whether the filters involved were returned to the manufacturer for inspection. We accept that this may not be possible at this point due to the length of time that has passed from the date of the incident.
- Any additional information reported would greatly assist our investigation.

With this information the MHRA could undertake the investigation procedure described above with the help of the manufacturers.

The MHRA has no record of any similar reports being received in the past ten years. It is possible that this is not a common incident and could be the result of the unique conditions of the past 12 months. It is also possible however that this type of incident is not often reported to the MHRA. There are a number of possible reasons for this.

It is a commonly held misconception that the MHRA is not interested in incidents that could be classed as "user error". This is not the case however, as if multiple reports of "use error" with a device or device type were received it could be a signal that, despite the manufacturer's best efforts, the device is not user friendly when placed into practice. In these circumstances the MHRA would work with the manufacturer to determine the root cause of the issue. This root cause can then be addressed either as an iterative design improvement or a field safety corrective action by the manufacturer, depending on circumstance.

Another possible reason for non-reporting of this type of incident is that the healthcare professional may notice the error prior to patient treatment or soon after treatment commencing and correct the issue, resulting in no patient harm. In this situation users may have thought that the incident was "too trivial" to report to the MHRA.

It is also possible that this type of incident has occurred and not been noticed by healthcare professionals as no abnormalities or patient harm has occurred.

It should be noted that health care professionals are under no obligation to report any incidents to the MHRA, or device manufacturers. Device manufacturers are required to report incidents that meet the criteria for vigilance

reporting as described in the Medical Device Directives and MEDDEV 2.12-1 rev 8 to the MHRA. However, manufacturers are only able to report incidents where they are informed of them.

With regards to the introduction of a standard on filter colours. At the current time there is no agreed classification of all the filter types, which means that manufacturers can design and make any filter "type" to suit the design of their devices and perceived clinical need. There are not necessarily filters that fulfil the exact same function and specification between manufacturers. This diversity would make agreeing a standard and universal colour coding extremely difficult.

If an agreement over the classification could be reached manufacturers would be under no obligation to stick to the agreement, leading to continued deviation. This has been shown in other areas of critical care and anaesthesia such as with Guedel airways and anaesthetic drugs.

An attempt to create a standard for filter types and colour coding would require input from multiple organisations both domestically and internationally. This would include the manufacturers of the devices, the International Standards Organisation (ISO), the British Standards Institute (BSI), the MHRA and other international competent authorities. The drafting and implementation of a standard would be a protracted piece of work, possibly taking multiple years, and there is no guarantee that this would take precedence over other priorities across these organisations.

The introduction of an international standard could reduce the confusion surrounding the different types of filter and possibly result in a safer environment for patients in the UK and worldwide. However, due to the time required to implement the introduction of a new standard this would not be an immediate solution to the problem experienced in the report. It is possible that the introduction of interim solutions could improve patient safety until a standard could be introduced. These interim measures could include actions such as:

- A reduction in the number of different filter types used to avoid the possibility of confusion.
- Filters being prepared away from the clinical area reducing the reliance on front line staff needing to know the difference between multiple filters.
- Where multiple filter types are required it would be better for clinical areas to use filters from one manufacturer. This is because manufacturers tend to be consistent to their own internal colour coding
- Where possible an alternative manufacturer, preferably with a similar colour coding, should be identified as a back-up supplier.

We acknowledge there is a concern that confusion over the type of filter used in ventilation could potentially lead to patient harm. However, at the current time there is insufficient evidence to show that a standardised colour scheme would reduce the risk of patient harm. The MHRA will work with manufacturers, other regulators, NHS England and Improvement and other stake holders to fully explore the effects that enacting the kind of actions detailed above would have on patient safety. We will also work with these groups to improve reporting of this type of incident and build our knowledge base surrounding the risks with the use of multiple filter types and any issues surrounding their labelling. Any emerging evidence relating to possible risks associated with these devices will be carefully reviewed and, if appropriate, regulatory action will be taken if any serious risks were confirmed

Thank you in advance for your assistance in this matter.

Yours faithfully,

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Director of Devices
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