Dear Ms Persaud,

Thank you for your letter dated 19/10/21 highlighting further concerns about the use of incorrect filters. We acknowledge the concerns raised by the consultant anaesthetists in your findings and will continue to monitor the situation through our regular safety signal and surveillance activities. This includes reviewing multiple data sources, including our own database of reported incidents, reports in journals and other media, as well as routine stakeholder engagement. Where necessary we will issue safety messages to health care organisations, patients, and the public.

As discussed in our letter dated 31st August 2021, we contacted eight of the largest manufacturers of this device type that sell devices in the UK. We asked these manufacturers to conduct a search of their own databases for any similar incidents that had been reported to them in the past five years. As well as identifying if a patient was injured, or if there was the possibility of a patient being injured. We asked the manufacturers to include incidents that were outside of the jurisdiction of the MHRA, such as incidents that had occurred in the wider European Union. All of the manufacturers responded, a total of four incidents were identified. Two of the reported incidents occurred outside of the UK. This data should be considered in context that in this same 5-year period millions of filters were used in the UK

This lack of reported incidents could indicate that this type of issue does not occur as frequently as believed. It is also possible that for the reasons discussed in our previous letter this type of incident may be under reported. To attempt to address this and encourage reporting the MHRA will engage with the medical device safety officers (MDSO) network at the next scheduled meeting in February 2022, to raise awareness of possible incidents involving filters and encourage reporting of such incidents to the MHRA.

We acknowledge your concerns with the lack of clarity of labelling of these devices. Annex 1 (Essential Requirements) of the UK Medical Device Regulations 2002 sets out the labelling requirements for all medical devices. Manufacturers are required to label devices with a range of identifier information which includes in section 13.3.b *the details strictly necessary to identify the device and the contents of the packaging especially for the users;* and 13.4 If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use.

MHRA will write to known manufacturers of filters registered with MHRA and the Association of British HealthTech Industries (ABHI) and UK Approved Bodies, to ask them to conduct a review of the labelling of filter devices against the regulatory requirements, taking into consideration the findings of the inquest, and making improvements where identified

The MHRA fully encourages users to be trained on the use of any medical device before using it, as detailed in our published guidance Managing Medical Devices, however it is not within MHRA's remit to provide training or to enforce it. There are a number of national organisations that carry out medical device training, for example Health Education England and The National Association of Medical Device Educators and Trainers (NAMDET). Training resources may also be available via the Royal Colleges' and other professional organisations/societies.

It is worth noting that existing evidence suggests colour coding to distinguish devices can have little or no impact. This issue should be explored further by HSIB.

We will contact HSIB and pass on your recommendation that an investigation into the possible confusion over filter types is carried out. In this communication we will suggest that they involve both the Royal College of Anaesthetists and The Faculty of Intensive Care Medicine in their investigation. We will also support the HSIB in any investigation that they undertake into this matter

I hope this information has been helpful, if you have any further questions please feel free to contact me.

Yours sincerely,

Chief Safety Officer

Directorate - Directorate Division