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How your approach to compliance can impact your business and your legal defence

Solicitor, Alison Newstead, explains why compliance is crucial to the continued success of your business and how failings can lead to fines and even a prison sentence.

“Is all of this really necessary?” questions a medical device supplier, keen to market a great new medical device, but feeling bogged down with a myriad of pre and post-market compliance activities. The short answer from those advising such companies will always be a resounding: “Yes!” But why is compliance so crucial? Of course, the primary goal of compliance is to ensure the safety of end users, but the way in which your business approaches compliance and the importance that it attaches to both pre- and post-market compliance activities can significantly influence how it fairs in the face of any legal action which may arise.

Achieving compliance is not always a straightforward process. It often takes significant time, effort and cost. However, every second invested and every penny spent will be worthwhile when your business is faced with a regulatory investigation or legal action.

“What’s the worst case scenario?” is a question that is frequently asked when clients are faced with an MHRA investigation. There is no “one-size fits all” answer: there are, in fact, a range of approaches that the MHRA can take and different levels of enforcement action which can be employed. These are likely to depend on the nature and potential seriousness of the issue, but experience shows that how your business responds to MHRA engagement can also have an impact – both positive and negative.

The MHRA’s initial approach is usually to contact a company via email - requesting information, providing guidance and seeking assurances about action that needs to be taken. Failure to give careful consideration to these first responses and, importantly, the implications that answers may have later down the line can be catastrophic. Not responding to an MHRA communication is never a sensible option and ultimately increases the risk of enforcement action. Enforcement action can take many forms: such as a prohibition notice, a notice to warn or a suspension notice. Compliance failures can lead to an unlimited fine, a prison sentence - or a mixture of these.

So how should you respond? Never ignore a regulator. Even if you do not agree with their interpretation of the situation, you must engage with them. It is the only way in which you can put forward your position and hopefully reach an outcome that is satisfactory for all stakeholders. Although prompt action is the order of the day, do not rush in with a hot-headed reaction. Beware of the ease and speed in which emails can be sent and consider how they may be used in later legal proceedings. Seek prompt guidance from your compliance and legal advisors – it’s not just the risk of regulatory action that could be on the horizon, there could also be potential civil claims to consider, as well as brand and future sales to protect.

How best to prepare? Ensure that everyone in the business recognises the value of good – and continuing-compliance practices. Making sure that your products are compliant, your paperwork is in order and that you continue

to comply with regulatory requirements and best practices will put you in the best possible position when the MHRA calls.

When you need to consider the question **“What am I going to say to the MHRA?”** you want to be sure that your compliance activities have equipped you with the tools to respond in the most beneficial way. Your legal team does not want to present a picture of patchy compliance, lax practices and reticence in engagement and rectifying any issues. Taking steps now to ensure your compliance activities are always in order will prove invaluable when you ultimately need to rely on them.



**Alison
Newstead**
Partner/Solicitor
+44 (0)20 7332 4664
anewstead@shb.com

For further guidance on how to respond to an MHRA investigation or legal claim, you can contact Alison Newstead directly on anewstead@shb.com. You can also connect with Alison and follow her legal updates on [Linked-In](#).